2021 National Trade Estimate Report on Foreign Trade Barriers (NTE)

Submitted by

The Pharmaceutical Research and Manufacturers of America

(PhRMA)

(October 2020)

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October 29, 2020

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Mr. Edward Gresser
Chair, Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street NW
Washington, D.C. 20508

PUBLIC DOCUMENT
USTR-2020-0034

Re: Request for Comments to Compile the National Trade Estimate Report on Foreign Trade Barriers, 85 Fed. Reg. 55,925 (September 10, 2020)

Dear Mr. Gresser,

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I am pleased to submit the attached comments identifying significant barriers to the export of goods, services and overseas direct investment for inclusion in the 2021 National Trade Estimate Report (NTE).

America's biopharmaceutical companies are committed to developing solutions to help diagnose and treat those with COVID-19, a disease caused by a novel strain of coronavirus. In addition to applying their scientific expertise to find ways to diagnose, treat and prevent infections from the virus, the biopharmaceutical industry is providing financial support and in-kind donations to organizations and collaborating with U.S. and global health authorities to combat this global public health emergency. More than half of PhRMA members have R&D for potential treatments and vaccines under way or are providing donations of medicines and critical medical supplies as well as providing financial donations to support patients and first responders in addressing this evolving crisis.

As a key component of America's high-tech economy, the research-based biopharmaceutical sector supports over 4 million jobs across the economy, including more than 800,000 direct jobs, and contributes more than $1 trillion in economic output on an annual basis when direct, indirect, and induced effects are considered.[1] In 2019, U.S. biopharmaceutical goods exports exceeded $66 billion, and these exports have grown in recent years, more than tripling between 2002 and 2019.[2] Our sector also continues to be one of the most research-intensive in America. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone.[3]

At the same time, our member companies face enormous challenges. The process of discovering and developing a new medicine is long, complex, and costly. Today, bringing a new

[1] TEConomy Partners; for PhRMA. The Economic Impact of the US Biopharmaceutical Industry 2017: National and State Estimates.
[2] TradeStats Express™: National Trade Data for NAICS Code 3254 Pharmaceuticals and Medicines, available at http://tse.export.gov/TSE/TSEHome.aspx (last accessed Oct. 28, 2020).
[3] Pharmaceutical Research and Manufacturers of America, PhRMA Annual Membership Survey, 2020, available at https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA_Membership_Survey_2020.pdf (last visited Oct. 28, 2020).

medicine from concept to market can take an average of 10-15 years. As a result, the average cost to develop a new medicine has grown from $179 million in the 1970s[4] to an average $2.6 billion today including the cost of failures,[5] with overall development costs more than doubling in the last decade due to growing complexities.[6] The risks involved in developing new drugs are also substantial. For every single medicine approved by the FDA, tens of thousands of compounds have been screened during the research and development process. Even medicines that reach clinical trials have less than a 12 percent chance of being approved,[7] and only two out of ten approved drugs produce revenues that match or exceed average research and development costs.[8] Of the approximately 1,200 biopharmaceutical companies in the United States, more than 90 percent do not earn a profit.[9]

The attached submission outlines the principal trade barriers that our member companies face worldwide and identifies concrete actions that the U.S. Government can take to address these barriers. Per your request, the submission is divided into country-specific files. The challenges are many, especially as America's innovative pharmaceutical industry actively battles COVID-19, but vigilance and perseverance are the only options to maintain the strength of America's biopharmaceutical industry – the world's engine for medical innovation.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 called for the Administration to develop a strategy to address foreign government price controls on pharmaceuticals and related practices through bilateral and multilateral trade negotiations. More recently, multiple agencies within the current Administration, including the Office of the U.S. Trade Representative (USTR), the Department of Health and Human Services, and the Council of Economic Advisors, has continued to highlight the problem of advanced economies undervaluing U.S. innovative medicines.[10]

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[4] J. A. DiMasi, R. W. Hansen, and H. G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, Journal of Health Economics 22 (2003): 151–185.

[5] 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 https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf (last visited Oct. 28, 2020).

[6] Previous research by DiMasi and Grabrowski estimated average R&D costs in the early 2000s at $1.2 billion in constant 2000 dollars (*see* DiMasi JA, Grabowski HG. The cost of biopharmaceutical R&D: is biotech different? Managerial and Decision Economics. 2007;28: 469-479). That estimate was based on the same underlying survey as the author's estimates for the 1990s to early 2000s reported here ($800 million in constant 2000 dollars), but updated for changes in the cost of capital.

[7] *Supra* n. 5.

[8] J. A. Vernon, J. H. Golec, and J. A. DiMasi, *Drug Development Costs When Financial Risk Is Measured Using the Fama-French Three-Factor Model*, Health Economics Letters (2009).

[9] 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 Oct. 28, 2020).

[10] Office of the U.S. Trade Representative, *2020 Special 301 Report*, April 2020, available at https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (last visited Oct. 28, 2020); U.S. Department of Health and Human Services, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, May 2018, available at https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (last visited Oct. 28, 2020); Office of the U.S. Trade Representative, *USTR Engagement on Pharmaceutical and Medical Device Issues*, April 2018, available at https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2018/april/ustr-engagement-pharmaceutical-and (last visited Oct. 28, 2020); The Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad*, February 2018, available at

PhRMA believes that the cornerstone of any such strategy must be a proactive U.S. trade policy focused on addressing government price controls and related practices and highlighting the global benefits for patients from the potential groundbreaking research that could result from a reduction in key trade barriers. Unfortunately, foreign government pricing and reimbursement policies around the globe over the last year have continued to have a deleterious impact on both U.S. innovators and patient access to innovative medicines.

In its *2020 Special 301 Report*, USTR noted that "pricing and reimbursement systems in foreign markets that are not market-based, or that do not otherwise appropriately recognize the value of innovative medicines … present significant concerns … and undermine incentives for innovation in the health care sector."[11] Further, USTR noted that it "has been engaging with trading partners to ensure that U.S. owners of IP have a full and fair opportunity to use and profit from their IP, including by promoting transparent and fair pricing and reimbursement systems."[12]

PhRMA encourages USTR to continue and enhance these efforts, as it is critical that the U.S. Government engage on these issues with its wealthiest trading partners taking advantage of U.S. innovation (*e.g.*, Australia, Canada, Europe, Japan and Korea), and to require immediate and meaningful steps that more fully recognize innovation in government pricing and reimbursement and related market access polices.

PhRMA also is particularly alarmed by the compulsory license recently granted in Malaysia and by similar drastic steps under consideration in Chile and Colombia – all U.S. free trade agreement partners. Such damaging actions have broken or would break patents that protect valuable treatments and cures developed in the United States. In its *2020 Special 301 Report*, USTR raised "serious concerns" about compulsory licensing and pledged to "monitor developments" and to "engage, as appropriate, with trading partners."[13] Such engagement is sorely needed now.

Unfortunately, compulsory licensing often is used to achieve national industrial policy goals. We remain particularly concerned that many World Trade Organization (WTO) Members are implementing industrial policies, including local manufacturing requirements and discriminatory intellectual property regimes, that discriminate in favor of domestic companies and thus inhibit our industry's ability to compete globally. Many of these policies appear to breach obligations under international treaties, *e.g.*, the General Agreement on Tariffs and Trade and the WTO Agreements on Technical Barriers to Trade, Trade-Related Aspects of Intellectual Property Rights (TRIPS), and Trade-Related Investment Measures.

In addition, numerous markets fail to provide adequate protection of our members' intellectual property rights. Consistent with the TRIPS Agreement, each of the markets identified in this submission should establish functional intellectual property protection systems that provide strong patent protection and safeguard test and other data against disclosure and unfair

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https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (last visited Oct. 28, 2020); The Council of Economic Advisors, *Funding the Global Benefits of Biopharmaceutical Innovation*, February 2020, available at https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf?mod=article_inline (last visited Oct. 28, 2020).

[11] *2020 Special 301 Report*, at pp. 14-15 (Apr. 2020), available at https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (last visited Oct. 28, 2020).

[12] *Id.* at 13.

[13] *Id*. at 14.

commercial use. In particular, this data should not be used prematurely to support other applications for marketing approval by competitors. PhRMA urges enhanced U.S. advocacy abroad to promote strong intellectual property rights and effective patent and data protection regimes that are essential to promoting clinical research.

The reduction and elimination of trade barriers is for the benefit of patients, for whom increased trade liberalization by U.S. trading partners will lead to greater access to life-saving and life-enhancing new medicines. PhRMA member companies are actively engaged in helping to solve health problems in both developed and developing countries, and America's research-based biopharmaceutical companies are among the largest funders of the research and development necessary to cure such major diseases as malaria, tuberculosis, sleeping sickness and dengue fever. However, these efforts are seriously threatened by the imposition of market access barriers, the erosion of intellectual property protections, and the undermining of incentives to innovate new medicines.

PhRMA appreciates the opportunity to contribute to the 2021 NTE. We commend the continuing efforts of USTR, the Department of Commerce, the Department of State, and other agencies within the Administration to make progress toward eliminating discriminatory and trade-restrictive barriers to U.S. exports of biopharmaceuticals and strengthening intellectual property protection.

Please do not hesitate to contact me if you have any questions regarding the content of PhRMA's submission.

Sincerely,

/s/ Jay Taylor

Jay T. Taylor

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA)

NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS (NTE) 2021

Table of Contents

PhRMA 2021 NTE OVERVIEW 1
ALGERIA 38
ARGENTINA 45
AUSTRALIA 50
BRAZIL 61
CANADA 67
CHILE 80
THE PEOPLE'S REPUBLIC OF CHINA 86
COLOMBIA 108
EGYPT 116
EUROPEAN UNION 119
INDIA 133
INDONESIA 148
JAPAN 155
KOREA 167
MALAYSIA 173
MEXICO 179
NEW ZEALAND 187
THE PHILIPPINES 192
RUSSIA 198
SINGAPORE 210
SAUDI ARABIA 214
TAIWAN 219
THAILAND 224
TURKEY 228
UKRAINE 237
UNITED ARAB EMIRATES 240
UNITED KINGDOM 242
VIETNAM 247

PhRMA 2021 NTE OVERVIEW

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide this submission for the *2021 National Trade Estimate Report*. The COVID-19 pandemic has rattled health systems around the world, but the biopharmaceutical industry is working around the clock to find ways to diagnose, treat and prevent infections from the virus and other conditions. Recognizing the unprecedented scale of this pandemic and the significant impact that it is having on global health and economies, it is essential that governments and industry continue working together to provide access to safe and effective COVID-19 treatments and vaccines once approved. To this end, governments around the world should adopt mechanisms to compensate individuals in the unlikely event that they experience a significant adverse event as a result of a COVID-19 vaccine and to ensure all parties involved in the development through to delivery of vaccines are provided appropriate liability protection. Additionally, in order to continue innovating and delivering innovative medicines to patients globally, USTR must address the many significant trade barriers that foreign governments impose against pharmaceuticals innovated and manufactured in the United States.

America leads the world in the research and development of valuable new medicines and vaccines. However, foreign governments' trade barriers, discriminatory measures, and failure to comply with international obligations significantly threaten the ability of our member companies to develop and export life-saving treatments and cures. The National Trade Estimate Report provides the Administration with an important opportunity to confirm its strong commitment to defend American inventions in overseas markets and a critical tool to address damaging market access and intellectual property barriers abroad that harm America's innovative and creative industries.

Urgent action is required to address serious market access and intellectual property barriers in the countries named in this submission. As explained further below, biopharmaceutical innovators in the United States face a wide array of damaging 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 damaging pricing policies in several markets, including **Australia**, **Canada**, **Europe**, **Japan**, and **Korea**. Government price controls imposed in many markets are non-tariff barriers to trade that substantially eliminate incentives to invest in the development of new medicines for patients. They deny American inventors and workers the ability to compete on fair and equitable terms in foreign markets, undermine the expected benefit of intellectual property protections, and inappropriately and artificially exacerbate the U.S. trade imbalance.

Ending damaging pricing policies in these markets and others could add billions of dollars to research and development for new medicines and lower overall health care costs around the world.[14]

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.[15] Innovators in this critical sector depend on strong intellectual property protection and enforcement, and on fair and equitable access to overseas markets. With the right policies and incentives in place at home and abroad, they can continue to bring valuable new medicines to patients 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.[16] They work in partnership with universities, clinical researchers, patient organizations, health care providers and others to bring new treatments and cures to patients who need them at home and abroad – introducing nearly 650 new therapies since 2000[17] and investing in many of the over 8,000 new drugs currently in development worldwide,[18] with about three quarters having the potential to be first-in-class treatments.[19]

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[14] *See* Council of Economic Advisors, "Reforming Biopharmaceutical Pricing at Home and Abroad," February 2018, available at https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (last visited Oct. 28, 2020); 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), available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf (last visited Oct. 28, 2020).

[15] 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://phrma-docs.phrma.org/sites/default/files/pdf/phrma_growthplatformforeconomiesaroundtheworld_20120508.pdf (last visited Oct. 28, 2020).

[16] TEConomy Partners, *The Economic Impact of the U.S. Biopharmaceutical Industry*, Oct. 2017, available at http://phrma-docs.phrma.org/files/dmfile/PhRMA_GoBoldly_Economic_Impact.pdf (last visited Oct 28, 2020).

[17] U.S. Food and Drug Administration, "New Drugs at FDA: CDER's new molecular entities and new therapeutic biological products," available at https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products (last visited Oct. 28, 2020); and U.S. Food and Drug Administration, "Biological approvals by year," available at https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biological-approvals-year (last visited Oct. 28, 2020).

[18] *Adis R&D Insight database*, last accessed Jan. 4, 2019.

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

Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports good-paying jobs in all 50 states. In 2017, biopharmaceutical research and development activity added more than $1.3 trillion to the U.S. economy and supported more than four million American jobs, including indirect and induced jobs.[20] 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.[21] In 2019, U.S. biopharmaceutical goods exports totaled over $66 billion.[22] The biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2019 – which in addition to biopharmaceuticals included navigational/measuring/medical/control instruments, semiconductors and other electronic components, medical equipment and supplies, and communications equipment.[23]

Even more important than the biopharmaceutical sector's role in the U.S. economy is its contribution to global patient health. Biopharmaceutical innovation extends lives, improves worker productivity and cuts health care costs. Between 1950 and 2016, life expectancy for women and men in the United States increased by more than a decade[24] – adding trillions of dollars to the U.S. economy.[25] 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.[26]

For example, the AIDS death rate has dropped nearly 87 percent since the approval of antiretroviral treatments in 1995.[27] Today, a 20-year old diagnosed with HIV can expect to live another 50 years.[28] New medicines have cut heart disease deaths by 38 percent,

[20] TEConomy Partners; for PhRMA. The Economic Impact of the US Biopharmaceutical Industry 2017: National and State Estimates.
[21] *Id.*
[22] TradeStats Express™: National Trade Data for NAICS Code 3254 Pharmaceuticals and Medicines, available at http://tse.export.gov/TSE/TSEHome.aspx (last accessed Oct. 28, 2020).
[23] U.S. Census. USA Trade: Foreign Trade Data, 2019; National Science Foundation Business Research and Development Survey (BRDIS), 2020; Siwek, Stephen E. Copyright Industries in the U.S. Economy, 2016 and 2014 reports. International Intellectual Property Alliance, available at https://iipa.org/files/uploads/2018/01/2016CpyrtRptFull-1.pdf and https://iipa.org/files/uploads/2018/01/2014CpyrtRptFull.pdf (last visited Oct. 28, 2020); ndp | analytics.
[24] U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2017*, Table 15, May 2018, available at https://www.cdc.gov/nchs/data/hus/2017/015.pdf (last visited Oct. 28, 2020).
[25] 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 Oct. 28, 2020).
[26] 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 Oct. 28, 2020).
[27] 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/hus/hus14.pdf (last visited Oct. 28, 2020).
[28] *Id.*

according to the Centers for Disease Control and Prevention.[29] More than 80 percent of the increase in life expectancy of cancer patients since 1980 is attributable to new treatments.[30] New hepatitis C therapies approved since 2013 cure over 90 percent of patients – a more than two-fold increase from previously available treatment options.[31]

PhRMA member companies are building on these achievements and pioneering new treatments and cures for some of the world's most devastating diseases. Researchers are developing more than 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.[32] 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.[33]

New medicines can lower the overall cost of treating these and other devastating diseases by reducing medical complications, hospitalizations and emergency room visits. For example, the use of cholesterol-lowering statin drugs has cut hospitalizations and saved the U.S. health care system at least $5 billion.[34] Every $24 spent on new medicines for cardiovascular diseases in OECD countries saves $89 in hospitalization costs.[35] Treating high blood pressure according to clinical guidelines would result in annual health

[29] 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 Oct. 28, 2020); 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 Oct. 28, 2020).

[30] 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 Oct. 28, 2020); 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 Oct. 28, 2020).

[31] *See, e.g.*, "FDA approves Viekira Pak to treat hepatitis C," Dec. 19, 2014, available at https://www.formularywatch.com/fda/fda-approves-viekira-pak-treat-hepatitis-c (last visited Oct. 28, 2020).

[32] PhRMA, 2013 Medicines in Development – Infectious Diseases Report, Pharmaceutical Research and Manufacturers of America, Dec. 2013, available at https://www.phrma.org/en/Report/Medicines-in-Development-for-Infectious-Diseases-2013-Report (last visited Oct. 28, 2019).

[33] *Id.*

[34] 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 Oct. 28, 2020).

[35] 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 Oct. 28, 2020).

system savings of about $15.6 billion.[36] In addition to lowering overall health care costs, appropriate use of medicines can increase worker productivity by reducing rates of absenteeism and short-term disability.[37] A 2012 study demonstrated that appropriate use of diabetes medicines saved 15 percent and 20 percent per month in medical spending after one year of initiating treatment[38] and an estimated reduction of more than one million emergency department visits and hospitalizations annually, for an annual savings of up to $8.3 billion.[39]

PhRMA members are working to overcome significant systemic challenges that can prevent the poorest patients from accessing medicines. Together with governments, academia and others, they are leading more than 300 initiatives with more than 1,000 partners to help shape sustainable solutions that improve the health of all people.[40] In 2017, more than 20 biopharmaceutical companies joined the World Bank and the Union for International Cancer Control to launch Access Accelerated – a first-of-its-kind global initiative to address cancer and other non-communicable diseases that cause more than 28 million deaths per year in low and lower-middle income countries.[41]

Between 2000 and 2011, biopharmaceutical innovators contributed an estimated $98.4 billion dollars toward achieving health-related Millennium Development Goals.[42] Despite a three percent drop in public funding for neglected disease (excluding Ebola) research and development in 2014, biopharmaceutical industry funding increased by 28 percent during the same period.[43]

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[36] 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 Oct. 28, 2020).

[37] 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 Oct. 28, 2020).

[38] Jha A.K., Aubert R.E., Yao J., Teagarden J.R., Epstein R.S., "Greater adherence to diabetes drugs is linked to less hospital use and could save nearly $5 billion annually," *Health Affairs*, Aug. 2012, available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2011.1198 (last visited Oct. 28, 2020).

[39] Slejko J.F., Ho M., Anderson H.D., Nair K.V., Sullivan P.W., Campbell J.D., "Adherence to statins in primary prevention: yearly adherence changes and outcomes," *J Manag. Care Pharm*., Jan. 2014, available at https://www.jmcp.org/doi/10.18553/jmcp.2014.20.1.51 (last visited Oct. 28, 2020).

[40] *See* Global Health Progress, available at http://www.globalhealthprogress.org (last visited Oct. 28, 2020).

[41] Access Accelerated, "22 Biopharma Companies Partner and Launch Access Accelerated," Jan. 2017, available at https://accessaccelerated.org/news-and-events/test-post-f/ (last visited Oct. 28, 2020).

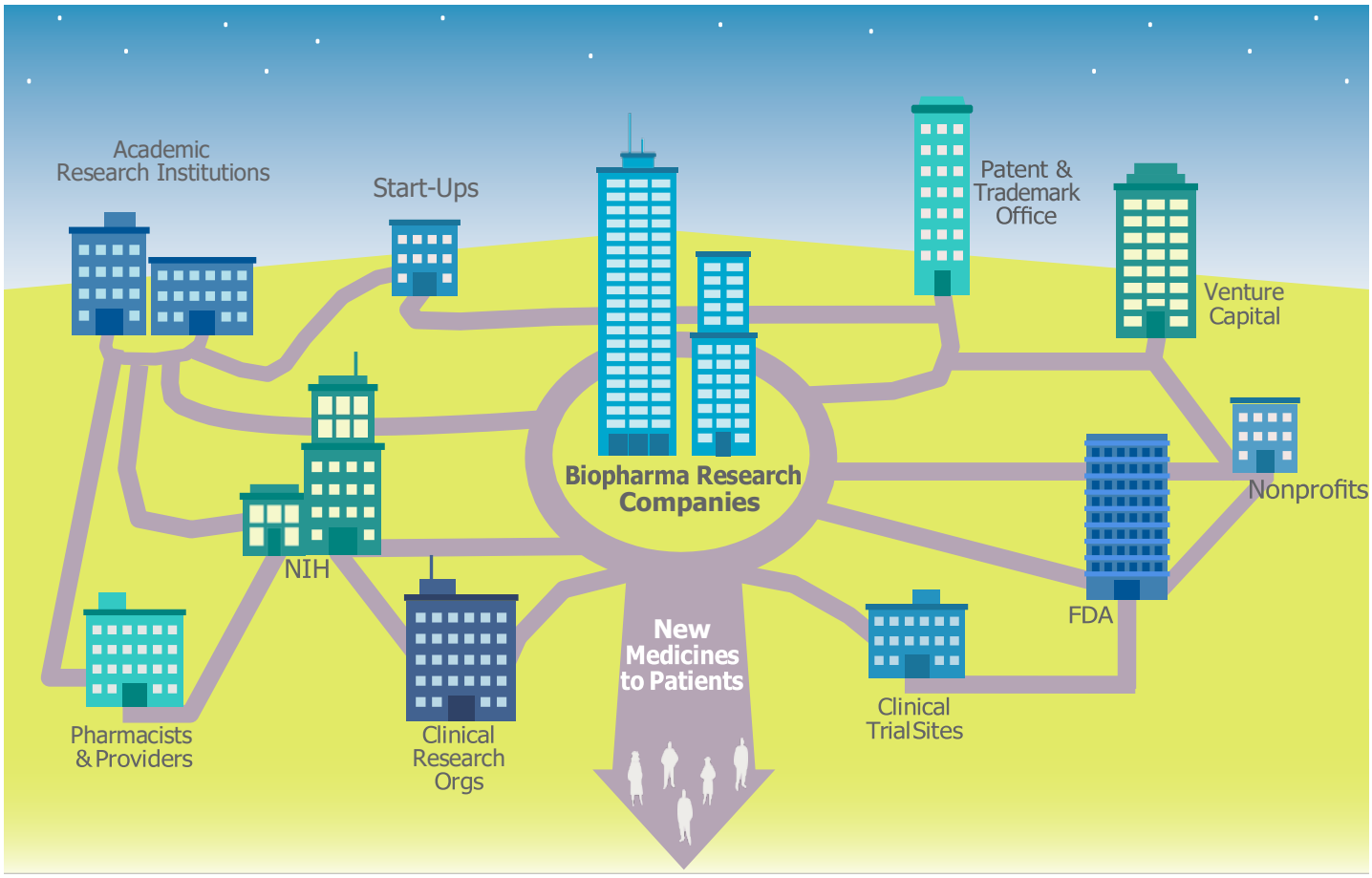
[42] Morris, Jeremiah et al., *The Pharmaceutical Industry's Contributions to the United Nations Millennium Development Goals*, Hudson Institute, May 2013, available at http://www.hudson.org/content/researchattachments/attachment/1260/the_pharmaceutical_industry_s_contibutions_to_the_un_millennium_development_goals.pdf (last visited Oct. 28, 2020).

[43] Global Funding of Innovation for Neglected Diseases: G-Finder, available at https://gfinder.policycuresresearch.org/ (last visited Oct. 28, 2020).

B. Policies that power prevention, treatments and cures

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

Figure 1: Collaboration and the biopharmaceutical R&D process



As highlighted in Figure 1 above, research, development and distribution of innovative medicines increasingly involves collaboration and the exchange of commercially sensitive information 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 close to $591 billion to the U.S. economy and supporting more than four million American jobs between 1996 and 2015.[44] Such collaboration is delivering similar benefits in other countries. Recent research in the United Kingdom found that public expenditure on biomedical and health research leveraged even greater private sector investment, delivering a total rate of return to public biomedical and health research of up to 28 percent.[45]

Patents and market-based pricing policies promote competition and greater treatment options. In exchange for the limited period of protection that patents provide, innovators must fully disclose their inventions to the world. That disclosure accelerates innovation and empowers potential competitors to build on those inventions. Competition means more medicines in the same therapeutic class, more options for patients and even lower prices.[46] For example, less than a year after market entry of the first in a new class of hepatitis C treatments, there were multiple suppliers that competed both on price and clinical benefits. Indeed, competition was so fierce that the largest U.S. pharmacy benefit manager claimed hepatitis C treatment is less expensive in America than in other western countries.[47] European countries have seen similar gains from competition.[48]

Today, biopharmaceutical innovators face competition faster – both from other innovators and from generic drug companies. In the 1970s, a new medicine might remain the only innovative treatment available in its therapeutic class for ten years or more. By the 2000s, that period had declined to about two years.[49] Generic competitors now challenge patents earlier and more frequently – even as early as four years after the

[44] *See* Association of University Technology Managers, Statistics Access for Technology Transfer (STATT) database, available at https://autm.net/surveys-and-tools/databases/statt (last visited Oct. 28, 2020); and 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 Oct. 28, 2020).
[45] 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://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-016-0564-z (last visited Oct. 28, 2020).
[46] 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 Oct. 28, 2020).
[47] LaMattina, J., "For Hepatitis C Drugs, U.S. Prices are Cheaper Than in Europe," *Forbes*, Dec. 2015, available at http://www.forbes.com/sites/johnlamattina/2015/12/04/for-hepatitis-c-drugs-u-s-prices-are-cheaper-than-in-europe/#1483772d64bb (last visited Oct. 28, 2020).
[48] Berdud, M. et al., "R&D, Competition and Diffusion of Innovation in the EU: The Case of Hepatitis C," Office of Health Economics, July 2018, available at https://www.ohe.org/publications/rd-competition-and-diffusion-innovation-eu-case-hepatitis-c (last visited Oct. 28, 2020).
[49] 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 https://csdd.tufts.edu/impact-reports/ (last visited Oct. 28, 2020).

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

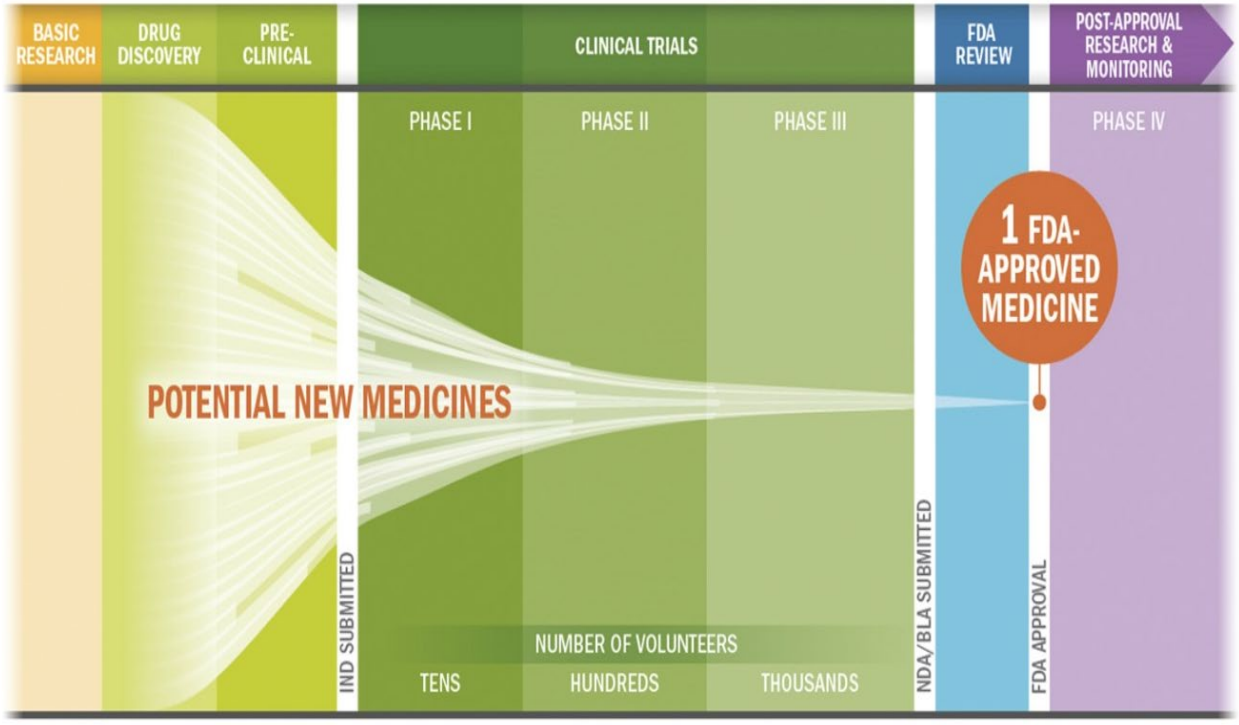
Patents promote faster access to new medicines. A major 2014 study found firms launch innovative medicines sooner in countries where there is effective patent protection and enforcement. The study looked at data from the launch of more than 600 drugs in almost 80 countries between 1983 and 2002. It showed that strong patent protection accelerates new product launches in higher and lower income countries alike.[53] Launching a medicine in a particular country also has important effects on the whole health care system. For instance, when a new medicine is introduced, biopharmaceutical companies invest in educating health care providers on the science and appropriate use of that medicine.[54] This investment later enables accelerated acceptance of generic versions once relevant patents expire.

Strong intellectual property protection and enforcement has long been a critical goal of America's trade policy agenda. Strong intellectual property protection and enforcement at home and abroad, and the efficient market conditions necessary to enjoy those rights, provide essential incentives for investment in the biopharmaceutical sector and in all of the innovative industries that today account for nearly 40 percent of U.S. gross domestic product.[55] For each of these industries, developing and bringing new products and processes to market is a risky endeavor; it requires time and substantial resources. In most cases, new products will fail to deliver returns that meet or exceed investment. Some three-quarters of all venture capital-backed internet startups fail.[56] And even those that succeed often fail to make a profit. Biopharmaceutical firms face similar challenges. Just two of every ten marketed medicines achieve returns that match or exceed average research and development costs.[57] Of the approximately 1,200

[50] 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 Oct. 28, 2020).
[51] *Id.*
[52] *See*, *e.g.*, Sagonowsky, E., "As competition heats up, U.S. prices for Remicade and biosims slip: analyst," FiercePharma, Dec. 2018, available at https://www.fiercepharma.com/pharma/amid-biosim-competition-remicade-prices-gradually-slipping-analyst (last visited Oct. 28, 2020).
[53] 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 Oct. 28, 2020).
[54] 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.
[55] 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 Oct. 28, 2020).
[56] 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 Oct. 28, 2020).
[57] 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 Oct. 28, 2020).

biopharmaceutical companies in the United States, more than 90 percent do not earn a profit.[58]

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.[59] Unlike products made by other innovative industries, new medicines are not market-ready at the time they are developed. As highlighted in Figure 2 above, biopharmaceutical firms rigorously test and evaluate potential therapies through a series of clinical trials to demonstrate they are safe and effective for treatment of a particular disease or condition.[60] In 2017, biopharmaceutical companies sponsored more

[58] 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 Oct. 28, 2020).
[59] 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 Oct. 28, 2020).
[60] 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 https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf (last visited Oct. 28, 2020); U.S. Food and Drug Administration, *Development & Approval Process | Drugs*, available at https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (last visited Oct. 28, 2020).

than 4,500 clinical trials in the United States alone, with trials in all 50 states, the District of Columbia and Puerto Rico. These trials involved close to one million participants and accounted for nearly $43 billion in economic activity.[61] Test data generated through those trials is then submitted to national regulatory agencies for marketing approval.

For these reasons and others, research and development is more capital intensive in the innovative biopharmaceutical sector than in other industries. Firms in this sector invest twelve times more in research and development per employee than the average of all other manufacturing industries.[62] In 2017 alone, American biopharmaceutical companies invested approximately $97 billion in research and development.[63] Clinical trials can account for more than 60 percent of the total cost of bringing a new medicine to market, and there is no guarantee promising molecules and proteins that enter clinical trials will result in a new treatment or cure.[64] The process of evaluating potential new therapies is so exacting that less than 12 percent of all potential new drugs entering clinical trials result in an approved medicine.[65]

Advances in the treatment of diseases typically are not driven by large, dramatic developments, but more commonly build on a series of continuous improvements over time. The best clinical role and full value of a particular therapy typically emerges years after initial approval as further research is conducted and physicians and other health care providers gain real-world experience. These improvements and the further development of therapeutic classes of medicines often lead researchers to explore new treatments in related areas – restarting the research and development cycle. Indeed, nearly a quarter of existing therapeutic indications are treated by medicines initially developed to address a different concern.[66] And more than 60 percent of therapies on the World Health Organization's (WHO's) Essential Medicines List relate to improvements

[61] TEConomy Partners; for PhRMA. Biopharmaceutical Industry-Sponsored Clinical Trials. April 2019.
[62] 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 Oct. 28, 2020).
[63] Research!America, U.S. Investments in Medical and Health Research and Development, 2013-2016, Arlington, VA, Fall 2017, available at https://www.researchamerica.org/sites/default/files/RA-2017_InvestmentReport.pdf (last visited Oct. 28, 2020).
[64] *Id.*
[65] 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 https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf (last visited Oct. 28, 2020).
[66] 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 Oct. 28, 2020).

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

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 percent 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,[69] would create the policy and legal framework necessary for innovation-based economic development of WTO Members by rewarding innovation with reliable rights-based systems and permitting the flow of its attendant commercial benefits. Because it concerns both the definition and enforcement of rights, TRIPS is one of the single most important steps toward effective protection of intellectual property globally. WTO Members, including the United States, have an important role to play in fully and effectively implementing, reiterating and enforcing TRIPS minimum standards.

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[67] *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 Oct. 28, 2020).

[68] Goss, T.F., E.H. Picard, and A. Tarab, *Recognizing the Value in Oncology Innovation*, Boston Healthcare Associates, June 2012, available at http://phrma-docs.phrma.org/sites/default/files/flash/phrma_innovation_oncology.pdf (last visited Oct. 28, 2020).

[69] 164 members as of July 29, 2016.

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 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), Unitaid 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.[70]

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 2021 National Trade Estimate Report and to use all available tools to address and resolve them.

A. Practices that deny fair and equitable market access

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

In recent years, America's biopharmaceutical sector has witnessed a surge in the number and severity of arbitrary and discriminatory government price controls abroad that threaten U.S. exports and jobs. Such measures cause serious damage in the countries that maintain them by rationing patient access to health care. They also can have

[70] Hudson Institute, "The Patent Truth about Health, Innovation and Access," June 2016, available at https://s3.amazonaws.com/media.hudson.org/files/publications/20160706ThePatentTruthAboutHealthInnovationandAccess.pdf (last visited Oct. 28, 2020).

significant ripple effects across other markets. For example, government price controls implemented in one country can spill over to many other countries through international reference pricing. These policies can restrict competition and artificially depress prices below market value, ultimately delaying and denying patient access to new medicines.[71]

A 2004 Commerce Department study[72] found that international reference pricing and other such measures that "rely heavily on government fiat to set prices rather than competition in the marketplace" put short-term government objectives ahead of long-term strategies that would ensure continued R&D into medicines that patients need most. The report showed that moving to market-based systems would add billions to research and development for new medicines and lower overall health care costs around the world by promoting greater efficiencies in off-patent markets. A 2020 report from the Council of Economic Advisors[73] found that foreign government price controls have worsened over the past 15 years, causing innovative products to be sold "below fair market value," leading to a "slower pace of innovation" and "fewer potential new life-saving therapies for patients in all countries." Urgent action is needed to address and resolve the following government price control regulations, policies and practices that are limiting market access for medicines researched and developed in the United States:

- *Government price controls*. In many countries, governments are the primary payer of medicines and in effect dictate prices. This dominant position often results in U.S. trading partners failing to appropriately recognize the value of innovation in their pricing and reimbursement policies, instead engaging in actions that distort markets and artificially depress prices below what a competitive market would provide. Foreign governments are increasingly employing a range of regulatory measures, including international reference pricing, therapeutic reference pricing, mandatory price cuts, clawback taxes, and flawed health technology assessments. These measures are often layered to exert maximum pressure. **Korea** employs several price control measures – including health technology assessments that require unreasonable thresholds for "cost-effectiveness," international reference pricing of inappropriate off-patent and generic comparators, and *ad hoc* measures – to systematically cut prices. In recent years, **Japan** approved sweeping changes to pricing policies that significantly undermine efforts to carry a fair share of the costs of global research and development. In particular, the eligibility criteria for the new Price Maintenance Premium (PMP) program as well as other price-cutting

[71] Danzon, P., Y. Wang et al., "The Impact of Price Regulation on the Launch Delay of New Drugs – Evidence from Twenty-Five Major Markets in the 1990s," Health Economics, March 2005, available at https://onlinelibrary.wiley.com/doi/abs/10.1002/hec.931 (lasted visited Oct. 28, 2020).
[72] 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) available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf (last visited Oct. 28, 2020).
[73] The Council of Economic Advisors, *Funding the Global Benefits of Biopharmaceutical Innovation*, February 2020, available at https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf?mod=article_inline (last visited Oct. 28, 2020).

measures such as newly proposed health technology assessments will mean that some of America's most innovative medicines will be significantly undervalued. In **Canada**, the Patented Medicine Prices Review Board regulates the maximum allowable price that a manufacturer can charge for a patented medicine to public or private payers. This year, the Board announced draconian changes intended to set prices at levels paid by less wealthy countries. Examples of other highly-developed markets that undervalue innovative medicines include **Australia**, **Europe** and **New Zealand**.

- *Discriminatory pricing policies*. In some countries, governments have policies that further benefit domestic drug companies and wholesalers at the expense of innovators in the United States. For example, in 2018, **Japan** revised its PMP program based on company criteria that appear to be inherently biased towards domestic companies (*e.g.*, number of local clinical trials and whether the product was launched first in Japan), and in 2019 implemented new health technology assessments that will subject imported products to greater scrutiny and price cuts than domestic products. These new company and country-of-origin criteria call into question Japan's commitment to fair and non-discriminatory policies, including that of national treatment.

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

- *Import barriers.* High tariffs and taxes can limit U.S. biopharmaceutical exports and prevent access to new treatments in overseas markets.[74] 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.[75] However, biopharmaceutical innovators in the United States do not benefit from the same access to China, India and other emerging economies that, despite being major producers and exporters of drugs and active pharmaceutical ingredients, are not parties to the WTO Pharmaceutical Agreement. Between 2006 and 2013, the value of worldwide biopharmaceutical trade in countries that are not parties to that Agreement increased at a compound annual growth rate of more than 20 percent. This means that a larger proportion of medicines distributed

[74] Bate, R. et al., "Still Taxed to Death: An Analysis of Taxes and Tariffs on Medicines, Vaccines and Medical Devices," AEI-Brookings Joint Center for Regulatory Studies, Feb. 2006, available at https://www.researchgate.net/publication/46454258_Still_Taxed_to_Death_An_Analysis_of_Taxes_and_Tariffs_on_Medicines_Vaccines_and_Medical_Devices (last visited Oct. 28, 2020).
[75] General Agreement on Tariffs and Trade, "Trade in Pharmaceutical Products" (L/7430), Mar. 1994, available at https://ustr.gov/sites/default/files/WTO%20Pharmaceutical%20Agreement%20March%201994.pdf (last visited Oct. 28, 2020).

around the world are potentially subject to tariffs.[76] For example, **India**'s basic import duties on biopharmaceutical products and active ingredients average about ten percent.[77] Additional duties and assessments can raise India's effective import duty to as high as 20 percent or more.[78] Combined federal and state taxes add about 31 percent to the cost of medicines in Brazil, one of the highest tax burdens on medicines in the world compared to the global average of 6%.[79] Examples of other countries that maintain high tariffs and taxes on imported medicines include **Argentina**, **Russia** and **Thailand**.

- *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 China than other major markets. In other words, a "drug lag" remains in China. Examples of other markets with complex and lengthy regulatory approval processes include **Mexico**, **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 that have received regulatory approval. These processes vary by country with the result that government reimbursement decisions can be almost immediate in some countries to several years in others. For example, prior to 2017, **China** had only undertaken two substantive updates (2004 and 2009) to the National Reimbursement Drug List which delayed reimbursement by up to seven years. In **Mexico**, delays can stretch as long as 1,500 days or more, on average, compared to 230 days in other countries.[80] PhRMA is encouraged by efforts that China has made to accelerate updates to its reimbursement list. However, patients would be better served by a model that allows all new drugs to be reviewed for reimbursement on a more regular, or rolling, basis.

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[76] 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 Oct. 28, 2020).
[77] *Id.*
[78] 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 Oct. 28, 2020).
[79] Brazilian Institute of Tax Planning, 2018.
[80] 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 Oct. 28, 2020). *See also* Salieri, G. and F. Fuentes, "Biopharmaceutical Innovation in Mexico: At the Crossroads," Fundacion IDEA, 2016, available at http://geneva-network.com/article/biopharmaceutical-innovation-mexico-crossroads/ (last visited Oct. 28, 2020).

- *Lack of transparency and due process.* Lack of transparency, due process, and delayed reimbursement decisions are widespread across the world. In **Canada**, **Japan** and **Korea**, the governments continue to make significant pricing policy reforms without adequate consultation with the industry. In **Mexico**, excessive regulatory approval delays are compounded by new 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.

PhRMA members recognize the efforts undertaken by the U.S. Government to address these barriers, including eliminating tariffs and promoting fair, reasonable and non-discriminatory pricing and reimbursement policies in trade agreements and addressing regulatory approval delays and other market access challenges in bilateral forums. PhRMA also welcomes the Administration's continued focus on the problem of advanced economies undervaluing U.S. innovative medicines.[81] As more countries enact price controls, the burden for financing medical advances will be borne increasingly by U.S. patients and biopharmaceutical innovators, while patients abroad will suffer decreased access to improved therapies over the long term. It remains critical that the U.S. Government engage on these issues with its trading partners, effectively enforce U.S. trade agreements, and require immediate and meaningful steps by foreign governments to resolve existing barriers and to ensure that patients have faster access to new treatments and cures.

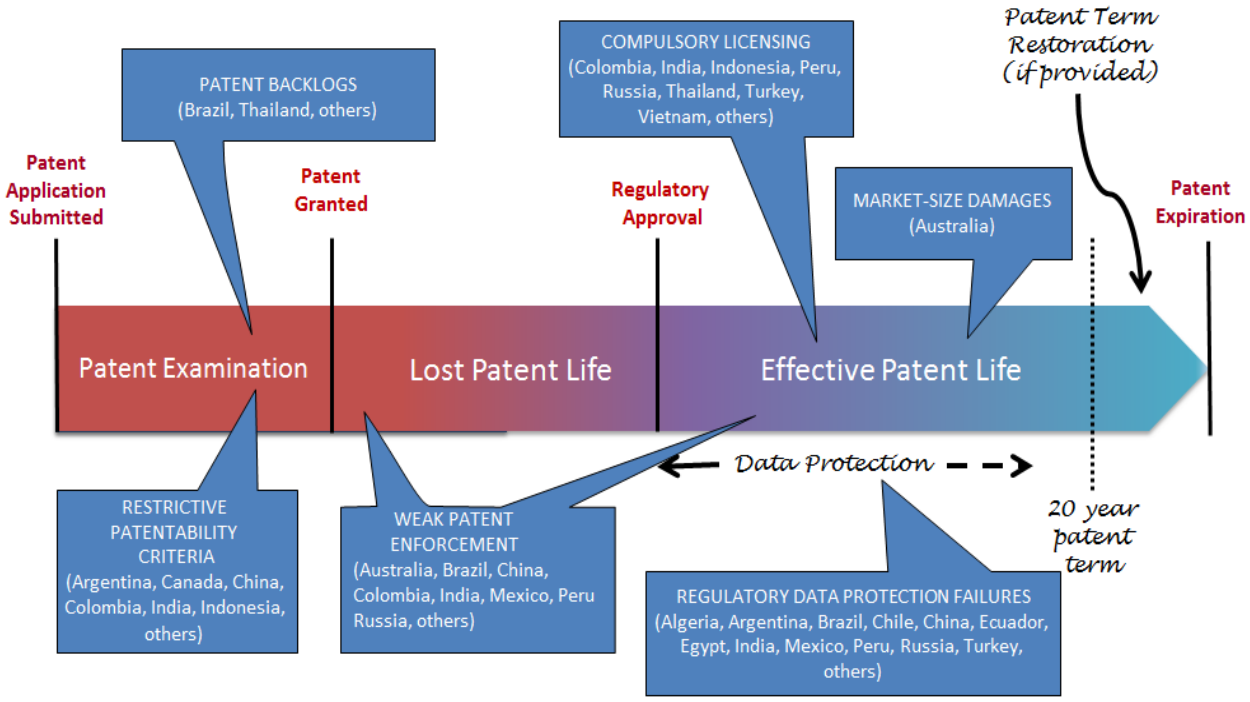
B. Practices that undermine biopharmaceutical innovation

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

[81] *See, e.g.*, 2020 Special 301 Report, at pp. 13-16 (April 2020), available at https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (last visited Oct. 28, 2020); The Council of Economic Advisors, *Funding the Global Benefits of Biopharmaceutical Innovation*, February 2020, available at https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf?mod=article_inline (last visited Oct. 28, 2020); U.S. Department of Health and Human Services, *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*, May 2018, available at https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (last visited Oct. 28, 2020); Office of the U.S. Trade Representative, *USTR Engagement on Pharmaceutical and Medical Device Issues*, Apr. 2018, available at https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2018/april/ustr-engagement-pharmaceutical-and (last visited Oct. 28, 2020); The Council of Economic Advisors, *Reforming Biopharmaceutical Pricing at Home and Abroad*, Feb. 2018, available at https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf (last visited Oct. 28, 2020).

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.[82] 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

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

treatments that can improve health outcomes[83] and reduce costs[84] 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[85] – 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 news forms and new uses of existing medicines. **India**'s Patent Law harms its own domestic

[83] 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 Oct. 28, 2020).

[84] Encouraging patients to take their medicines consistently and as prescribed can lower overall health care costs. The cost of non-adherence has been estimated at $100 billion to $300 billion annually, including the costs of avoidable hospitalizations, nursing home admissions and premature deaths. Making patents available for improvements and new indications can also drive price competition for medicines by encouraging the development of alternative treatments – leading to multiple drugs in a single therapeutic class and increasing the range of options for patients and health care providers. *See* Osterberg, Lars and Terrence Blaschke, "Adherence to Medication," *New England Journal of Medicine*, Aug. 2005, available at http://www.nejm.org/doi/full/10.1056/NEJMra050100 (last visited Oct. 28, 2020); 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 Oct. 28, 2020); 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 Oct. 28, 2020).

[85] Examples of improvements include enantiomers and combination treatments. *See* Stevens, P. and J. Ellis, "Enantiomer Patents," Geneva Network, June 2017, available at https://geneva-network.com/wp-content/uploads/2017/07/enantiomer-patents.pdf (last visited Oct. 28, 2020); and Stevens, P. and J. Ellis, "The Power of Combination Drugs," Geneva Network, June 2017, available at https://geneva-network.com/wp-content/uploads/2017/07/Combination-drugs-patentability.pdf (last visited Oct. 28, 2020).

drug companies[86] by prohibiting patents on new forms and new uses of known substances, unless applicants can demonstrate they meet an additional "enhanced therapeutic efficacy" test. **Ukraine** adopted recently legislation that restricts the patentability of new forms and uses.

In addition, multilateral organizations such as **UNDP** and **Unitaid** advocate actively for patentability restrictions and additional patentability requirements that are inconsistent with international practice. For example, although UNDP does not appear to have specialized expertise on intellectual property matters, it issued patent examination guidelines in 2016 that, if followed, would prevent innovators from securing patents on many kinds of biopharmaceutical inventions.[87] Similarly, Unitaid partnered with various non-governmental organizations in 2018 to launch a campaign to erode intellectual property policies and laws globally.

- *Restrictions on post-filing submissions.* Unlike patent offices in the United States, Europe, Japan, Korea and other major markets, **China**'s National Intellectual Property Administration (CNIPA) does not consistently accept data generated after a patent is filed during patent prosecution to describe inventions or satisfy inventive step requirements. This practice, contrary to China's 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, 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. PhRMA and its members look forward to addressing these concerns through implementation of Article 1.10 of the Economic and Trade Agreement between the United States and China (Phase One Trade Agreement).

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.[88] 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.

[86] Geneva Network, "Copy or Compete: How India's patent law harms its own drug industry's ability to innovate," December 2018, available at https://geneva-network.com/research/copy-or-compete-how-indias-patent-law-harms-its-own-drug-industrys-ability-to-innovate/ (last visited Oct. 28, 2020).
[87] 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 Oct. 28, 2020).
[88] Hollman, C.M. et al., "Patentability Standards for Follow-On Pharmaceutical Innovation," *Biotechnology Law Report*, June 2018, available at https://www.liebertpub.com/doi/pdf/10.1089/blr.2018.29073.cmh (last visited Oct. 28, 2020).

PhRMA members appreciate steps that 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.[89] Because the term of a patent begins on the date an application is filed, unreasonable delays can directly reduce the value of granted patents and undermine investment in future research. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines.[90] 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.[91] In Brazil, the patent backlog challenge is compounded by an unnecessary dual examination process for biopharmaceutical patent applications. The Brazilian Health Surveillance Agency (ANVISA) may review all patent applications for new medicines, in addition to the formal patent examination process conducted by the Brazilian Patent Office.[92] 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,[93] and yet in 2015, India granted one patent based on an application filed 19 years earlier.[94]

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[89] 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 Oct. 28, 2020).
[90] 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 Oct. 28, 2020).
[91] 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 Oct. 28, 2020).
[92] Cipriano, M., "Biodiversity Law Reform Spurs Innovation, But Patent Backlog Remains," Oct. 2016, available at https://pink.pharmaintelligence.informa.com/PS119423/Biodiversity-Law-Reform-Spurs-Innovation-But-Patent-Backlog-Remains (last visited Oct. 28, 2020).
[93] *Id.*
[94] 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 Oct. 28, 2020).

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.[95] Patent backlogs are a particular challenge for small start-up firms that are playing an increasingly important role in biopharmaceutical innovation. According to a U.S. Patent and Trademark Office (PTO) Economic Working Paper, for every year an ultimately-approved patent application is delayed, a start-up firm's employment growth decreases by 21 percent and its sales growth decreases by 28 percent on average over the following five years.[96] Each year a patent application is delayed, the average number of subsequent patents granted decreases by 14 percent, and the probability that a startup will go public is cut in half.[97]

PhRMA members support patent term adjustment 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, damaging legislation in the **European Union** has weakened patent term restoration mechanisms in Europe by reducing the patent protections restored through Supplementary Protection Certificates. 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[98] – particularly when governments and the private sector partner to improve health outcomes.

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[95] 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 Oct. 28, 2020).

[96] Farre-Mensa, J., D. Hegde, and A. Ljungqvist, "What Is a Patent Worth? Evidence from the U.S. Patent 'Lottery'," USPTO Economic Working paper No. 2015-5, Dec. 17, 2015, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2704028 (last visited Oct. 28, 2020).

[97] *Id.*

[98] *See, e.g.*, Attaran, A. and L. Gillespie-White, "Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatments in Africa?" *Journal of the American Medical Association*, Oct. 2001, available at https://jamanetwork.com/journals/jama/fullarticle/194301 (last visited Oct. 28, 2020); Attaran, A. "How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries," *Health Affairs*, May 2004, available at https://www.healthaffairs.org/doi/full/10.1377/hlthaff.23.3.155 (last visited Oct. 28, 2020).

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

Experience and recent research demonstrates that compulsory licensing is not an effective way to improve access or achieve other public health objectives. It does not necessarily lower prices[99] or speed access[100] in the short-term, or provide sustainable or comprehensive solutions to longer-term challenges. It does not address systemic barriers to access[101] – from weak health care delivery systems to low national health care funding and high taxes and tariffs on medicines. Compulsory licensing is particularly ineffective relative to the many alternatives available. Biopharmaceutical innovators support different tools and programs that make medicines available to patients who could not otherwise afford them, including drug donation and differential pricing programs, voluntary licensing and non-assert declarations.[102] In sub-Saharan Africa, for example, the majority of antiretrovirals are manufactured under voluntary licenses to local generic drug companies.[103]

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.[104] For example, **Malaysia** issued a CL in 2017 in a move that appears

[99] 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 Oct. 28, 2020).
[100] 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 Oct. 28, 2020).
[101] Vesper, I., "Cheap drugs not enough to fight hepatitis C in Asia," SciDevNet, July 2018, available at https://www.scidev.net/global/disease/news/drugs-fight-hepatitis-asia.html?utm_source=link&utm_medium=rss&utm_campaign=/global/global_rss.xml& (last visited Oct. 28, 2020).
[102] 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 Oct. 28, 2020).
[103] 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 Oct. 28, 2020).
[104] 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

designed to facilitate the local development and marketing 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.[105]

In its 2020 Special 301 Report, USTR rightly highlighted concerning actions by "trading partners to unfairly issue, threaten to issue, or encourage others to issue compulsory licenses" and committed to "engage, as appropriate, with trading partners".[106] PhRMA members welcomed these statements and urge USTR and other federal agencies to engage to address serious and growing compulsory licensing threats across Latin America, Southeast Asia and elsewhere.

Weak Patent Enforcement

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

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

PhRMA members welcomed bold proposed intellectual property reforms **China** announced in 2017, including planned implementation of a patent linkage system. While those efforts had stalled, they have been reinvigorated this year by the inclusion of effective patent enforcement commitments in the Phase One Trade Agreement. As a result, China has proposed critical elements of a patent linkage system in both

https://www.dndi.org/2017/media-centre/press-releases/dndi-welcomes-malaysia-move-access-affordable-treatments-hepc/ (last visited Oct. 28, 2020).

[105] 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 Oct. 28, 2020).

[106] *2020 Special 301 Report,* at p. 14 (Apr. 2020), available at https://ustr.gov/sites/default/files/2020_Special_301_Report.pdf (last visited Oct. 28, 2020).

amendments to the Patent Law, as well as draft Measures for the Implementation of Patent Linkage. A well-functioning patent enforcement system is critical in China, particularly in light of the fact that its regulatory authority continues to approve follow-on products while the reference products in each case are still subject to patent protection. As such, PhRMA and its member companies strongly welcome the intellectual property commitments included in the Phase One Trade Agreement and look forward to securing expeditious implementation of Article 1.11 of these commitments in a manner fully consistent with international best practices.

Biopharmaceutical innovators strongly supported passage of patent linkage legislation in **Taiwan** in late 2017. We welcomed regulations issued on January 30, 2019, to implement patent linkage for both biologic and chemically synthesized medicines. In July 2019, Taiwan published the final patent linkage regulation and shortly thereafter the Executive Yuan approved implementation of the patent linkage system effective August 20, 2019. Disappointingly, however, the Taiwan Food and Drug Administration has unilaterally determined that Taiwan's patent linkage system should not include patents that protect new doses, new dosage forms or new unit strengths. If allowed to continue, this action will seriously undermine the value of Taiwan's patent linkage system. We stand ready to work with the Taiwan Government to support appropriate implementation of the regulation and to ensure that patents on all innovative medicines are effectively enforced.

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 are unable to quickly secure effective preliminary injunctions in **Mexico**. Until recently, **Australia** did not require any notice of a third party's intention to obtain marketing approval**,** so as to enable final resolution of patent claims before marketing approval.

Saudi Arabia has knowingly facilitated the infringement of the patent on a medicine formulated and exported from the United States by giving a local company approval to produce a competing product during the patent term. Similarly, in 2017 the **United Arab Emirates (UAE)** approved the sale of patent infringing generics despite the government's pharmaceutical patent commitments in Ministerial Decree No. 404 and reciprocal patent recognition obligations under the Gulf Cooperation Council. Promisingly, recently issued Decree No. 321 suggests that the UAE may be poised to remedy this deficiency. In **Bangladesh**, local companies are taking advantage of the country's least developed country (LDC) status to undermine intellectual property protections in other countries. Specifically, they are reverse engineering and making copies of biopharmaceutical products in Bangladesh that are under patent in other parts of the world. These unlicensed biopharmaceutical products are entering markets abroad, *e.g.* India, where patent protection exists. The quality and safety of these products have not been reviewed and could pose significant risks. Furthermore, local companies are adopting product names for biopharmaceutical products that are nearly identical to well-known product names of U.S. biopharmaceutical companies creating confusion in the

market as to their source and/or association. Under the terms of a waiver adopted in 2001 (and extended in 2015), LDCs are not obligated to comply with WTO intellectual property rules.[107]

Effective early resolution mechanisms are also needed in **India**, **Russia** and other countries, where innovators are not notified of marketing approval applications filed for potentially infringing products and generally are unable to secure provisional enforcement measures.

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.

Excessive and Punitive Damages

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

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

Canada's implementing regulations of the Comprehensive Economic and Trade Agreement (CETA) further expose innovators to excessive liability under Section 8. These regulations enable competitors to claim indefinite future loses and to seek compensation for production "ramp-up" costs that they may have incurred before the stay was granted and after it was lifted. In addition, Canada's courts are now contemplating even more excessive damage awards for generic litigants using obscure legal theories under the "Statute of Monopolies" to seek **treble** damages from innovators that unsuccessfully

[107] WTO Council decision, available at https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm (last visited Oct. 28, 2020).

enforced their patent(s) against a generic litigant. An Ontario trial court decision awarding a generic litigant damage under this statute is currently under appeal.

Australia's Therapeutic Goods Act passed as part of legislation implementing the U.S.-Australia Free Trade Agreement,[108] 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.

In a 2004 letter[109] 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

[108] *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 Oct. 28, 2020).
[109] 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 Oct. 28, 2020).

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.[110] In exchange, innovators received a period of protection for test data gained through substantial investments in clinical trials over many years. As a result of this and other provisions of Hatch-Waxman, the percentage of prescription drugs filled by generics soared from 19 percent in 1984 to 74 percent in 2009. Today, generics account for approximately 90 percent of all prescriptions filled in the United States.[111]

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.[112]

Unfortunately, many U.S. trading partners do not provide RDP. Examples, some of which are described further in the country profiles below, include **Algeria**, **Argentina**, **Brazil**, **China**, **Egypt**, **India** and **Turkey**. Others, like **Saudi Arabia**, provide RDP but have allowed local companies to rely on data submitted by American innovators during the period of protection. This is contrary to WTO rules, which require parties to protect regulatory test data submitted as a condition of obtaining marketing approval against both disclosure and unfair commercial use. U.S. trade agreements generally require parties to provide RDP for a specified period of time, but some partner countries have not fully honored their commitments. For example, **Mexico** and **Peru** provide RDP for small-molecule treatments, but not for biologics. **Israel** enacted legislation affording limited RDP to small molecule drugs, but it fails to provide such protection for biologics. Israel established an inter-governmental committee in 2018 to consider providing RDP for biologics, although the process has not yet yielded a policy recommendation for providing adequate protection. We urge Israel to complete the regulatory impact assessment process and provide a period of RDP for biologic drugs that reflects the highest international standards. Meanwhile, **Canada** passed legislation in 2014 that gives the Health Minister broad discretion to share undisclosed test data without safeguards to

[110] 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).
[111] PhRMA analysis based on IQVIA National Sales Perspective and Quintiles, IMS Institute MIDAS™ audited data, 2017.
[112] *See, e.g.*, Grabowski, H. et al., "Data exclusivity for biologics," *Nature Reviews – Drug Discovery*, Jan. 2011, available at https://fds.duke.edu/db/attachment/1592 (last visited Oct. 28, 2020).

protect against unfair commercial use. Other countries provide RDP in a manner that discriminates against foreign innovators.

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

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 **Argentina**, **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 entry or other benefits conditioned on local manufacturing.* While many economies provide positive incentives for businesses to conduct research and development and to manufacture in their markets,[113] an alarming number are seeking to grow their economies by discriminating against innovators in the United States and other countries. For example, **Turkey** has removed products from the reimbursement list 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

[113] 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 Oct. 28, 2020).

patented medicines if the patent holder does not begin manufacturing that medicine in Indonesia within three years after the patent is granted.[114]

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

- *De facto bans on imports.* Manufacturing licensing requirements generally are intended to ensure that companies meet globally recognized standards – such as good manufacturing practices (GMP). Some countries exploit these licensing requirements by adopting policies that virtually prevent market entry. For example, **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.

Recent research[115] demonstrates 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.[116]

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[114] 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 Oct. 28, 2020).

[115] *See, e.g.*, 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 Oct. 28, 2020); 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 Oct. 28, 2020); Hufbauer, G.C., J.J. Schott et al., *Local Content Requirements: A Global Problem*, Peterson Institute for International Economics, Sep. 2013, available at https://www.piie.com/bookstore/local-content-requirements-global-problem (last visited Oct. 28, 2020).

[116] Pugatch Consilium, "Separating Fact From Fiction – How Localization Barriers Fail Where Positive Non-Discriminatory Incentives Succeed: A Global Assessment of Localization Policies and Incentivizing

PhRMA members appreciate the attention that 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 2021.

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. Negotiating new trade agreements, modernizing existing trade agreements and strengthening enforcement activity in the months and years ahead will be critical to end discriminatory pricing policies and to address longstanding intellectual property challenges around the world – particularly in countries that are U.S. trade and investment agreement partners, that have made important unfulfilled WTO accession commitments and that benefit from U.S. trade preference programs.

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 to take steps necessary to ensure that countries abide by rules to which they have agreed.

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

Life Science Investment and Innovation," 2016, available at http://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf (last visited Oct. 28, 2020).

products containing a new chemical ingredient.[117] China has never implemented this obligation, despite agreement to do so during the 2012 U.S.-China Joint Commission on Commerce and Trade meeting.[118] In light of these deficiencies, we strongly welcomed the CFDA draft Circular 55 (Relevant Policies on Protecting Innovators' Rights to Encourage New Drug and Medical Device Innovation) and draft "Implementing Provisions on Protection of Drug Trial Data" (April 2018), which propose up to twelve years of RDP for therapeutic biologics, orphan and pediatric medicines and six years of RDP for new small molecule drugs. These proposals represent a strong first step toward reform in this area, but it is now imperative that these proposed policy revisions are transparently and expeditiously implemented in a manner that provides for effective protection for U.S. biopharmaceutical companies and is consistent with international best practices and China's renewed commitment to provide RDP as affirmed in the chapeau to Section C of Chapter One of the Phase One Trade Agreement.

The Generalized System of Preferences (GSP) program provides unilateral duty-free access to the U.S. market for more than 3,500 products.[119] 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."[120] However, GSP beneficiaries like **Argentina**, **Brazil**, and **Indonesia** do not provide adequate and effective protection of intellectual property rights or fair and equitable market access.

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

The Special 301 Report likewise is an important tool. 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.[121] Out-of-cycle reviews announced in the Special 301 Report should be conducted and should involve the participation of relevant stakeholders.

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[117] 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 Oct. 28, 2020).
[118] 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 Oct. 28, 2020).
[119] Office of the United States Trade Representative, *U.S. Generalized System of Preferences Guidebook*, Apr. 2018, available at https://ustr.gov/sites/default/files/files/gsp/GSP%20Guidebook%20April%202018.pdf (last visited Oct. 28, 2020).
[120] *See* Title V of the Trade Act of 1974 (19 U.S.C. § 2461 et seq.), as amended.
[121] *See* Section 182 of the Trade Act of 1974 (19 U.S.C. § 2242), as amended.

USTR should pursue a variety of enforcement initiatives, including – but not limited to – the filing of dispute settlement cases to secure compliance with trade and investment agreement commitments. In addition, USTR should create and fill key positions, such as the Chief Innovation and Intellectual Property Negotiator required by the Trade Facilitation and Trade Enforcement Act of 2015.[122]

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

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

PhRMA supports 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.[123]

C. End discrimination in pricing and reimbursement

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

The biopharmaceutical industry is unique in that most foreign governments, as sole or primary health care providers, impose burdensome and often discriminatory price controls and regulations on the sector. Others have resorted to improperly using national

[122] Public Law 114–125 (Feb. 24, 2016), available at https://www.congress.gov/114/plaws/publ125/PLAW-114publ125.pdf (last visited Oct. 28, 2020).
[123] U.S. Department of Commerce, International Trade Administration, "2016 Top Markets Report: Pharmaceuticals," May 2016, available at https://legacy.trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf (last visited Oct. 28, 2020).

compulsory licensing provisions to threaten or coerce manufacturers to accept pricing agreements on unreasonable commercial terms and conditions. As a result, market access for pharmaceuticals is dependent not only on innovators meeting strict regulatory approval standards and obtaining necessary intellectual property protections, but also on obtaining positive government pricing and reimbursement determinations. It is imperative, 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."[124]

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

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

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. Counterfeit medicines may deprive patients of the medicines they need and contribute to drug-resistant forms of tuberculosis and other serious diseases and contain impurities or toxins that can cause harm or even death.[125] This challenge is exacerbated by the ease with which counterfeiters can offer

[125] Testing reported in *The Lancet* found one-third of anti-malarial medicines in sub-Saharan Africa and South East Asia lacked active ingredients. 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 Oct. 28, 2020). *See also* Testimony of Howard Sklamberg, U.S. Food and Drug Administration Deputy Commissioner for Global Regulatory Operations and Policy, before the House Energy and Commerce Subcommittee on Oversight and Investigations, "Counterfeit Drugs: Fighting Illegal Supply Chains," Feb. 2014, available at https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg88828/pdf/CHRG-113hhrg88828.pdf (last visited Oct. 28, 2020).

fake medicines over the Internet[126] and ship them by mail[127] to patients and consumers worldwide.[128]

Counterfeit medicines are a potential danger to patients everywhere, including in the United States. During fiscal year 2018, U.S. Customs and Border Protection seized more than 2,200 shipments of counterfeit pharmaceuticals at America's borders.[129] Using a broader measure that includes counterfeiting, illegal diversion and theft, the Pharmaceutical Security Institute documented more than 4,400 incidents of pharmaceutical crime in the United States in calendar year 2018 – an all-time high.[130] Across all sectors, the Organization for Economic Cooperation and Development (OECD) found that global counterfeiting and piracy accounts for 2.5 percent of world trade and disproportionately harms innovators in the United States.[131]

China and **India** are leading sources of fake medicines seized at ports of entry in the United States[132] and elsewhere,[133] though many other jurisdictions are involved – particularly in online sales.[134] 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

[126] 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 Oct. 28, 2020).
[127] An OECD study found that more than 60% of counterfeit goods seized around the world between 2011 and 2013 were shipped by mail or express carrier. OECD, "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact," 2016, available at http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#.WHv5mpcraBc#page1 (last visited Oct. 28, 2020).
[128] Institute of Medicine (IOM), *Countering the Problem of Falsified and Substandard Drugs*, Feb. 2013, available at https://www.ncbi.nlm.nih.gov/books/NBK202530/ (last visited Oct. 28, 2020). The IOM notes that "because the internet facilitates easy international sales, online drug stores have spread the problem of falsified and substandard drugs...." *Id.*
[129] Homeland Security, "Intellectual Property Rights: Fiscal Year 2018 Seizure Statistics," Aug. 2019, available at https://www.cbp.gov/sites/default/files/assets/documents/2019-Aug/IPR_Annual-Report-FY-2018.pdf (last visited Oct. 28, 2020).
[130] Pharmaceutical Security Institute, "Incident Trends," available at https://www.psi-inc.org/incident-trends (last visited Oct. 28, 2020).
[131] 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 Oct. 28, 2020).
[132] Homeland Security, "Intellectual Property Rights Seizure Statistics: Fiscal Year 2017," Apr. 2018, available at https://www.cbp.gov/document/stats/fy-2017-ipr-seizure-statistics (last visited Oct. 28, 2020).
[133] *See, e.g.*, "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 Oct. 28, 2020).
[134] 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 Oct. 28, 2020).

the books often are not effectively enforced or do not come with sufficient penalties to deter counterfeiting.[135]

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

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

E. Build and strengthen global cooperation

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

PhRMA members appreciate the steps that USTR and other federal agencies already are 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.

[135] 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 Oct. 28, 2020).

All this provides a valuable foundation on which to build in the coming year and beyond. PhRMA members believe that strengthening such coalitions will be particularly critical in multilateral organizations that advise countries and provide assistance on policies related to global trade, intellectual property, and pharmaceutical markets. Organizations such as the WHO, the World Intellectual Property Organization (WIPO), the WTO, UNDP, and UNCTAD often focus their work inappropriately on limitations and exceptions to intellectual property rights, as well as promote a range of harmful policies that would undermine vital incentives for innovation. For example, WHO's new Roadmap on Access to Medicines envisions providing "technical support" to countries that intend to engage in compulsory licensing,[136] with one regional WHO office openly asserting that compulsory licensing is "important and to be encouraged."[137] The international organization Unitaid has directed millions of dollars to programs that seek to weaken intellectual property laws and lobby governments to reject provisions in international trade agreements that would strengthen innovation incentives.[138] U.S. leadership is essential to preventing such organizations from weakening or even eliminating the intellectual property protections that drive America's innovation economy.

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

[136] WHO, "Road Map for Access to Medicines, Vaccines, and Other Health Products, 2019–2023," p. 18, available at https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_17-en.pdf (last visited Oct. 28, 2020).
[137] WHO South-East Asia Regional Office (SEARO), "Access to medical products in the South-East Asia Region 2019," available at https://apps.who.int/iris/bitstream/handle/10665/326829/9789290227281-eng.pdf (last visited Oct. 28, 2020).
[138] Unitaid, "Unitaid expands its work on access to medicines," Sep. 8, 2018, available at: https://unitaid.org/news-blog/unitaid-expands-its-work-on-access-to-medicines/#en (last visited Oct. 28, 2020).

ALGERIA

Algeria's policies and actions pose significant market access and intellectual property challenges for PhRMA members. PhRMA and its member companies believe, however, that Algeria has the potential to foster investment in pharmaceutical innovation and to address the unmet medical needs of the country. Notably, since the election of a new government in December 2019, a new Ministry of Pharmaceutical Industry (MoPI) has been established with a mandate to energize the sector and improve its contribution to economic growth.

PhRMA noted some success in collaborating with the prior government in place until mid-2012, with that government stating publicly its support for a new strategy that better integrates the innovative pharmaceutical sector into Algeria's economy and health care system. Subsequent Ministers have reaffirmed their commitment to boosting Algeria's competitiveness in the innovative biopharmaceutical sector, but dozens of proposed reforms have not been implemented. Despite deterioration in the overall business and investment environment, PhRMA's member companies are hopeful for a cooperative dialogue with the government to address the key challenges they face in Algeria. Recently, the new MoPI hosted meetings and working sessions with industry which have included the Minister and his team. PhRMA members are contributing to the successful implementation of the national health care law through the local innovative pharmaceutical association.

Key Issues of Concern:

- **Import restrictions and forced localization**: Algeria prohibits imports of most pharmaceutical products that compete with similar products that are manufactured domestically. Pharmaceutical products and active pharmaceutical ingredients (APIs) that are not locally manufactured are subject to annual import quotas.

- **Pricing procedures**: Algeria's pricing and reimbursement mechanisms are cumbersome and delayed. Historically, some patented medicines have been referenced against generic products deemed to be in the same therapeutic class. In addition, the new drug pricing procedure issued in August 2015 has key weaknesses related to its reference pricing system and the frequency of updates. As a result, prices in Algeria do not recognize the value of innovative products, nor do they reward the significant investment involved in developing new medicines or encourage the development of tomorrow's cures. Notably, the new government has expressed interest in revising pricing procedures and it is anticipated that the local association will be invited to contribute through policy proposals.

- **Cumbersome and slow regulatory system**: Despite significant improvements in the Ministry of Health's (MoH's) registration process in 2013, the registration process remains slow and burdensome. As a result, patient access to innovative medicines in Algeria lags significantly behind peer countries. A new National

Agency of Pharmaceutical Products (ANPP) has been created under the supervision of the MoPI and given the challenge of resolving the registration backlog of around 700 products awaiting clearance. The local association is proposing to support solutions to the backlog such as regulatory reliance.

- **Failure to renew representative office licenses**: Many pharmaceutical companies operating in Algeria have established representative offices. Licenses for such offices must be renewed every two years, and yet in 2018 the Ministry of Commerce suspended renewing these licenses until September 2019. (Renewals have been granted for companies in other sectors, but not for the pharmaceutical industry.) In addition to creating significant uncertainty as to the ability of these companies to continue operating in Algeria, it has resulted in local banks blocking access to member accounts and MoH suspending promotional activities as per an October 28, 2019 notice, until their office licenses are renewed. So far, concerned companies have been asked by the Minister of Commerce to submit again some files. Still the renewal would only be for one year.

- **Weak patent enforcement and regulatory data protection failures**: Algeria has inadequate patent protection, ineffective mechanisms to enforce patents, and does not grant regulatory data protection (RDP). Judicial training to handle complex patent disputes would greatly assist in improving the patent enforcement environment in Algeria.

- **Pharmacie Centrale des Hôpitaux procurement**: It is not known when the next tender will be published, creating uncertainty about when innovative medicines registered during the last two to three years will be able to access the market. Demand for these medicines is evident from the hospital sector.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Import Restrictions

On October 21, 2008, the Algerian Government issued a decision[139] stipulating that, effective January 2009, the importation of pharmaceutical products that compete with similar products that are being manufactured locally is prohibited. This decision was essentially a reinstatement of a previous ministerial decree[140] that was suspended as part of the WTO accession process. Subsequently, the MoH published lists of such products comprising hundreds of branded medicines, and this import policy continues to be

[139] The decision was published in November 2008 under the name “Arrêté du 30 novembre 2008 relatif àl’interdiction des produits pharmaceutiques et dispositifs médicaux destinés à la médicine humaine fabriqué en Algérie.”
[140] Instruction #5 for the Generalization of Generics (Sept. 2003).

implemented in a non-transparent and arbitrary manner. Repealing this decision should be a prerequisite before Algeria can join the WTO.

In August 2015, the MoH issued a procedure for the inclusion of products on a list of pharmaceutical products prohibited for import. The innovative pharmaceutical industry is highly concerned about the proposed procedures to ban imports of certain products to promote local manufacturing. This proposal contradicts the government's aspirations to attract more investment by the innovative biopharmaceutical industry and for Algeria to accede to the WTO. As the procedures themselves recognize, such restrictions could have major consequences on patient access to innovative products as well as on the operations and sustainability of our member companies in Algeria.

In 2017, the Algerian Government arbitrarily imposed volume restrictions on imports of pharmaceutical products that compete with similar products produced domestically and/or imported generic products.

Algeria's restrictions on the importation of pharmaceuticals severely restrict patient access to innovative medicines, discriminate unfairly against PhRMA members, and are a significant barrier to trade. They have resulted in shortages of some drugs, further harming Algerian patients. During numerous discussions over the last few years between the Algerian government and industry, officials signaled their intent to reform the system to improve access and minimize stock disruptions. As of today, however, the system remains unchanged.

Investments and Commercial Laws

In December 2008, the Algerian Government declared that any company engaged in foreign trade should have a minimum of 51 percent of local Algerian shareholders. While the 2020 Finance Bill removed this restriction for "non-strategic sectors", complementary legislation enacted in July 2020 identified the pharmaceutical industry as a strategic sector. As yet, however, the government has not defined what activities constitute investment.

Since 2009, importers have been required to secure letters of credit and set aside a percentage of the import value as a deposit on their purchase.

In May 2010, the MoH issued a circular that prohibits local manufacturers from selling products to wholesalers, and requires them to sell such products directly to pharmacies. Therefore, PhRMA members who invested in local manufacturing will now also have to invest in distribution infrastructure. While this circular has never been applied, the uncertainty of the regulation continues to concern PhRMA members.

Volume Control

Algeria continues to impose an annual import quota for medicines and active pharmaceutical ingredients with the requirement that each shipment receives prior clearance from the MoH.

The Government routinely blocks imports as a temporary cost-containment tool. The unintended consequence, however, is that it leads to shortages in the market, to the detriment of Algerian patients. The narrow focus on cost means that it cannot capture the underlying value of promising new medicines for patients or reduce other costs in the health care system, such as avoiding expensive hospitalizations, surgery, rehabilitative or long-term care.

Pricing Procedures

The Algerian Government uses international reference pricing (IRP) to set the prices of medicines. As a general matter, IRP suffers from serious flaws as a mechanism for pharmaceutical pricing. It assumes similarity across all countries in the reference basket and implicitly imports the pricing policies of those countries without accounting for circumstances that justify price differentiation. Importantly, IRP ignores the local value of the product, patient benefits and physician requirements, existing standards of care, placement within the health care system, patterns of disease burden, socioeconomic factors including ability to pay, stage in the pharmaceutical life cycle, etc. IRP also ignores circumstances unrelated to a product's value such as budget overruns that lead to price cuts. In short, IRP as a policy is inconsistent with Algeria's goal of promoting a local innovative biopharmaceutical industry.

In August 2015, the Algerian Government issued a new procedure for determining pharmaceutical prices. Key weaknesses in Algeria's new pricing procedure and the IRP model include:

- The new pricing procedure references a basket of countries including Greece and Turkey, which are inappropriate comparators. Prices in Turkey are based on deflated prices in Europe as a result of a discriminatory fixed Euro-Turkish Lira exchange rate, and prices in Greece have been set based on the ongoing economic crisis in that country. In short, the artificially low prices in both countries do not reflect the value of innovative medicines and certainly are not consistent with a country seeking to encourage local R&D. This measure ignores the damage that such policies have had on the innovative biopharmaceutical industry in those countries, where investment has stagnated and the industry is in a state of contraction. As such, Turkey and Greece should be removed from Algeria's basket of reference countries.

- To ensure greater predictability and fairness, the IRP calculation should be based on the average or median price in the basket of countries, not the lowest price in the basket (or even worse, the lowest European price less 10 percent).

- Re-referencing should be predictable, objective (*i.e.*, following the same procedures for both price increases and decreases in the reference countries) and limited to reasonable intervals, such as every five years during the marketing approval renewal process. While the industry commends Algeria for providing a process for allowing manufacturers to seek adjustments during the marketing approval renewal process to account for changes in the reference countries, it is not reasonable to require manufacturers to continually monitor prices in all of the reference countries (a significant administrative burden) and report on relevant alterations.

- Greater clarity is needed in the procedures around the exchange rates to be used to determine prices in the reference countries and how Algeria defines "the country of origin."

- While the innovative pharmaceutical industry commends the Algerian Government for providing an appeal mechanism, ten days is an insufficient period for a company to prepare the appropriate supporting documents for the appeal, particularly given that this will likely require coordination with regional offices and headquarters in other countries. Instead, we would propose that the appeal deadline should be extended to 30 days after the date of the notification of the price established by the Economic Committee.

Cumbersome and Slow Regulatory System

Despite some improvements in the MoH's registration process since 2013 and recent structural changes to MoH's engagement with the pharmaceutical industry, the registration process remains slow and is now falling further behind regulatory reform trends observed in the region, namely in the largest pharmaceutical markets Egypt and Saudi Arabia. In those countries, new review procedures are expected to significantly reduce the time it takes to register new medicines by 90 percent. This will accelerate marketing authorizations and enable patients to access promising new treatments in as little as 30-60 days after those new medicines are approved for use in Europe or the United States. Algeria should adopt similar review procedures to achieve the same results.

Additional burdensome requirements for obtaining registration to market pharmaceutical products, especially innovative products, have been implemented. As a result, patient access to innovative medicines in Algeria lags significantly behind peer countries.

While the agencies responsible for drug registration processes in Algeria have been reorganized under the MOIP (with the goal of streamlining the drug registration), the agency still lacks sufficient resources and staffing to handle the current backlog in drug registration, price approval and testing on importation (TOI). Furthermore, for new drug applications, no assessment of pre-submissions has taken place since September 2018. Additionally, 700 new applications have been submitted to the Agency which are pending registration due to the Agency's lack of quality testing capabilities

In addition, the innovative industry continues to face significant and growing access challenges within the Reimbursement Committee (CRM) process led by the Ministry of Labor (MoL):

- The MoH via the Price Committee (MoL is a member of this committee) approves a price for the new medicine as part of the marketing approval process. However, this price is rarely accepted during the separate reimbursement process, even though MoH is a member of CRM. As a result, manufacturers are required to enter into separate reimbursement negotiations with the CRM, and the new lower price must then be re-approved by the MoH. These combined procedures are inefficient, redundant, and unfair to innovative pharmaceutical manufacturers.

- There is no clarity or fixed timeline between the first submission to the CRM of the dossier for reimbursement and the application at the pharmacy level. While the intent of the MoL is to reduce the maximum number of products on the list of reimbursable products, this particularly affects imported products so that a new (innovative) product has a very low chance of being reimbursed. And recently even locally produced medicines are affected. Further, even when MoH lists the products, hospitals have not been supplied with those products creating significant uncertainty and operational challenges for PhRMA member companies and lack of access for Algerian patients.

Finally, since June 2010, pharmaceutical companies have noticed lengthy delays of many months in approving variations for imported products already available on the market, albeit that there have been some improvements in recent months.

Industry is hopeful that the newly established Ministry of Pharmaceutical Industry, which has been made responsible for all aspects of regulating the sector, will be better positioned to improve the regulatory environment in Algeria.

Failure to Renew Representative Office Licenses

Many pharmaceutical companies operating in Algeria have established representative offices. Licenses for such offices must be renewed annually, and yet in 2018 the Ministry of Commerce suspended renewing these licenses. In addition to creating significant uncertainty as to the ability of these companies to continue operating in Algeria, it has resulted in local banks blocking access to member accounts and MoH

suspending promotional activities as per an October 28, 2019 notice, until their office licenses are renewed.

Intellectual Property Protection

Weak Patent Enforcement

Marketing approval authorities in Algeria improperly interpret current laws and regulations by granting marketing approval to patent infringing follow-on products while relevant patent(s) are still in effect. Despite patent owners' repeated attempts to alert Algerian authorities, Algeria's marketing approval agency has approved infringing follow-on products many years in advance of the original product patent expiration.

Compounding these actions, effective judicial remedies are not available to prevent infringement of patent rights. Algerian courts do not provide injunctive relief that could prevent irreparable harm prior to the resolution of the patent dispute, thus placing originators in an untenable position with no possibility to defend their rights. Violations of Algerian patents that have occurred in recent years have still not been corrected.

Regulatory Data Protection Failures

Algeria does not protect pharmaceutical test and other data from unfair commercial use and disclosure. Algeria should correct this deficiency through implementation of meaningful RDP.

ARGENTINA

PhRMA and its member companies operating in Argentina continue to face longstanding market access barriers and serious intellectual property (IP) issues. While the previous administration had signaled willingness to address significant IP concerns related to patentability and regulatory data protection (RDP), this willingness did not result in the initiation of reforms and IP issues remain a matter of concern. 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. Although general registration and evaluation regulations for biopharmaceutical products exist, some complementary regulations are missing and the established evaluation deadlines are not being met, thus generating legal and business uncertainty for companies.

Key Issues of Concern:

- **Flawed cost containment measures**: In recent months the Argentine Government has made several statements regarding their plans to establish price controls for "high-cost" medicines through an international reference pricing (IRP) methodology. Because this methodology limits the flexibility and adaptation of prices to local market conditions, among other reasons, the biopharmaceutical industry does not consider this tool appropriate for achieving competitive prices and improving patient access to innovative medicines.

- **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 are 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.

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

- **Compulsory licensing**: On December 21, 2019, the Argentine Congress passed economic emergency legislation that, among other things, raises the risk of compulsory licenses of patents in Argentina. Article 70 of the new law empowers the Ministry of Health to establish a mechanism to monitor the prices of medicines and to utilize measures such as compulsory licensing against "problems of availability or unjustified or irrational price increases."

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Flawed Cost Containment Measures

In recent months the Argentine Government has made several statements regarding their plans to establish price controls for "high-cost" medicines through an international reference pricing methodology. As a general matter, IRP suffers from serious flaws as a mechanism for pharmaceutical pricing. It assumes similarity across all countries in the reference basket and implicitly imports the pricing policies of those countries without accounting for circumstances that justify price differentiation. Importantly, IRP ignores the local value of the product, patient benefits and physician requirements, existing standards of care, placement within the health care system, patterns of disease burden, socioeconomic factors including ability to pay, stage in the pharmaceutical life cycle, *etc*. IRP also ignores circumstances unrelated to a product's value such as budget overruns that lead to price cuts. For these reasons, the biopharmaceutical industry does not consider IRP appropriate for achieving competitive prices and improving patient access to innovative medicines in Argentina.

Discriminatory Reimbursement Policies

On October 1, 2015, the Ministry of Health and the Secretary of Commerce issued Joint Resolutions 1710 and 406, which establish a preferential reimbursement system for national generics and biosimilar products. These resolutions provide that Health Insurance Agents must give preference to Argentine products available in the market that have the same active ingredient or that are biosimilar to those originating abroad. This resolution is subject to the condition that the final selling price of the Argentine products must be significantly lower than the average price of similar products of foreign origin.

Key terms remain undefined, and while these policies have yet to be applied the reimbursement system appears to be inconsistent on its face with international biosimilar guidelines (providing that biosimilars cannot be automatically substituted for the original biologic) and Argentina's national treatment obligations under the WTO General Agreement on Tariffs and Trade.

In addition, provisions of the "Buy Argentine and Development of Suppliers (27.437)" policy further restrict market participation in Argentina for foreign innovators. Foreign companies are required to submit "Productive Cooperation Agreement Proposals" (ACPs) in order to participate in public tenders – including details on their relationships with subcontracting companies, direct investment, technology transfer or other capacity building programs. Argentina's Instituto Nacional de Servicios Sociales para Jubilados y Pensionados (INSSJP), the agency that oversees health insurance for retirees, has recently granted preferential commercial conditions in its pharmaceutical purchasing agreements to local products on the grounds introduced by Law No. 27,437.

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, 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. While the prior Argentine administration recognized that the guidelines and resolution are problematic, it did not take action to reform them, and the current administration has not indicated that their reform is part of its political agenda.[141]

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

Regulatory Data Protection Failures

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[142]

[141] On June 6, 2012, CAEMe, joined by over 40 innovative biopharmaceutical companies, filed an administrative petition seeking to invalidate the Joint Resolution. That administrative review petition was dismissed 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 still pending.

[142] 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,

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 and Decree 150/92 allow Argentine officials to rely on data submitted by innovators in other markets to approve requests by competitors to market similar products in Argentina. The Law provides no period of protection against reliance and does not define key terms including "dishonest" use.

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

available at https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf (last visited Oct. 28, 2020).

Patent application delays can be lengthy in Argentina, where life science innovators wait an average of 6.6 years for patents to be granted.[143] According to some estimates, the overall patent backlog is approximately 21,000 applications. Argentina's patent law does not provide for patent term adjustments to compensate for unwarranted delays in the examination of patent applications. Although the Argentine Patent Office implemented a Patent Prosecution Highway (PPH) mechanism under Regulation P-56/2016 in order to accelerate the examination process, restrictions on the application of this mechanism make it inapplicable to patent applications for pharmaceutical products.

To address this challenge, Argentina should open the PPH mechanism to all invention, including innovative pharmaceutical products. In addition, Argentina should accede to the Patent Cooperation Treaty (PCT), a step that would facilitate the filing and examination of patent applications in Argentina as it does now in more than 152 Contracting Parties. While the Argentinian Congress has long-considered accession to the PCT, no final action has yet been taken. Accession to the PCT could allow Argentina to reduce its current patent application backlog and use the PCT system to lower filing costs and reduce the review period for future patent applications. Indeed, it is noteworthy that there are concrete examples where Argentine national institutions, such as the National Scientific and Research Council (Consejo Nacional de Investigaciones Científicas y Técnicas, or CONICET), have established a mechanism to access PCT in order to pursue the recognition of the Argentine inventions in other countries. It is time, therefore, that Argentina extends the benefit of acceding to the PCT to innovators in other countries.

Compulsory Licensing

Among other things, the economic emergency law passed by the Argentine Congress in December 2019 (Law 27541, "Social Solidarity and Productive Reactivation") empowers the Ministry of Health to establish a compulsory or mandatory licensing mechanism, or to directly import certain medicines, to address potential problems caused by unjustified or unreasonable price increases that affect the population's access to medicines in a way that could put their health at risk.

Empowering the Ministry of Health to establish new mechanisms of compulsory licensing will undermine the incentives for innovators to develop and bring new therapies to Argentine patients, and will lead to greater uncertainty and potential legal challenges. Moreover, such a mechanism appears to encourage additional use of compulsory licensing in a manner that will not only undermine patient access to new medicines but also appears inconsistent with Argentina's international obligations.

[143] Schultz M. and Madigan K, The Long Wait for Innovation: The Global Patent Pendency Problem, CPIP (2016), available at https://sls.gmu.edu/cpip/wp-content/uploads/sites/31/2016/10/Schultz-Madigan-The-Long-Wait-for-Innovation-The-Global-Patent-Pendency-Problem.pdf (last visited Oct. 28, 2020).

AUSTRALIA

PhRMA and its member companies support the U.S.-Australia Free Trade Agreement (AUSFTA) ratified by both countries in 2004. The Agreement has contributed to expanded patient access to new medicines in Australia, a key priority for PhRMA. However, we believe there is much more to do to further improve market access which will also serve to foster innovation in Australia's pharmaceutical and biotechnology sectors domestically and abroad – a key priority of the Australian Government, as well as protect and strengthen Australia's intellectual property (IP) regime for new and innovative medicines.

In the Pharmaceuticals Annex to the AUSFTA, Australia and the United States agreed to provisions for increased transparency and accountability, and enhanced consultation between the United States Government, industry and the Australian Government to improve the operation of Australia's Pharmaceutical Benefits Scheme (PBS). Annex 2-C of the AUSFTA at [1] commits the Parties to four principles to facilitate high quality health care and continued improvements in public health. These principles are: "(a) the important role played by innovative pharmaceutical products in delivering high quality health care; (b) the importance of research and development in the pharmaceutical industry; (c) the need to promote timely and affordable access to innovative pharmaceuticals through transparent, expeditious and accountable procedures; and (d) the need to recognize the value of innovative pharmaceuticals through the operation of competitive markets or by adopting or maintaining procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical." Annex 2-C of the AUSFTA at [3] also establishes a Medicines Working Group (MWG) to promote discussion and mutual understanding of the importance of pharmaceutical research and development to continued improvement of health care outcomes.

While progress has been made in implementing these agreed principles, on-going collaboration is required to ensure that the full potential of the pharmaceutical industry can be realized. We look forward to constructive outcomes from the locally-established, bilateral (Government-Industry) Access to Medicines Working Group (AMWG), first established in 2006 as part of reforms to the PBS. Industry has also welcomed the implementation of a tranche of reforms to the regulations for the registration and market approval of medicines and medical devices in Australia. These reforms are starting to streamline processes and regulations and make some life-saving medicines and medical devices available to Australian patients in a more timely manner.

PhRMA is encouraged by the recent bilateral discussions regarding the reconvening of the MWG. PhRMA recommends that, as set out in the AUSFTA, regular meetings under the MWG (which is distinct from AWMG) resume as a matter of urgency; it has been approximately ten years since this MWG last met. While intervening negotiations and meetings may have provided opportunity for our officials to remain in contact, those contacts have been insufficient to address industry issues.

Key Issues of Concern:

- **Difficulties in listing new medicines on the PBS**: PhRMA and its member companies welcome the recent October 2020 budget announcement from the Australian Government for the establishment of a New Medicines Funding Guarantee for new and amended medicine listings. The announcement will guarantee new funding each year for the listing of new medicines on the PBS. Approximately $2.8 billion in new funding is expected to be committed over the next four years to meet the cost of new and amended medicine listings. Alongside this funding guarantee, the Australian Government has committed to list all new medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) and to no longer require equal offsets for all new medicine listings. These changes should help improve the timely listing of new medicines recommended by the PBAC.

  While these announcements are positive, companies continue to face challenges and uncertainty in securing positive recommendations from the Pharmaceutical Benefits Advisory Committee (PBAC) to list new medicines on the PBS. As one of the only health programs required to demonstrate a particular standard of cost effectiveness, the growing inadequate investment in the PBS compared to other parts of the health system remains a concern. Policies such as the ongoing legislated price reductions and lowest cost comparator selection do not support investment in innovation and ultimately result in delayed access to innovative medicines for Australian patients. For new medicines, navigating the regulatory framework of market authorization and reimbursement remains complex and, particularly for reimbursement, iterative.

- **Biosimilars**: There have been significant developments regarding the introduction of biosimilar medicines into the Australian market. We welcome the commitment and ongoing efforts of the Australian Government, through the Strategic Agreement with Medicines Australia, to ensure appropriate and broad consultation with the sector to help deliver a coordinated and balanced policy. This policy should strike the right balance between broader access to biological medicines, the freedom of physicians to prescribe the right treatment for the right patients and continued access to innovation.

- **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. In addition, the industry believes that any cost-effectiveness reviews should be conducted using the same framework as that of post-market reviews to ensure procedural fairness.

- **Public Summary Document changes**: The PBAC has implemented new requirements for Public Summary Documents in which it will publish all clinical evidence relied upon by the PBAC to inform its decision-making process. The only exception will be for Academic-in-confidence (AiC) information. The PBAC does not consider 'commercial-in-confidence' (CiC) issues should apply to the publishing of clinical data used for deliberations. While there has been ongoing consultation with the industry on this matter, Medicines Australia remains concerned that the clinical data redaction criteria are too narrow and may discourage submission of CiC data in PBAC submissions. To that end, Medicines Australia has stated it will proactively monitor this issue to address any unintended consequence or access barriers that have arisen.

- **Weak patent law enforcement**: Contrary to its obligations under Art. 17.10(4) of the AUSFTA, Australia has not implemented a system by which patent holders, as a matter of practice, receive advance notice of third-party applications for marketing approval of potentially patent-infringing pharmaceutical products. The lack of adequate patent holder notification makes it difficult to resolve patent challenges prior to competitor market entry, creating significant uncertainty for patent right holders. In the rare circumstances where any such advance notice is actually provided, the amount of notice is inadequate to enable the final resolution of any patent infringement claims *before* the relevant third-party product obtains regulatory approval for market entry during the term of the relevant patent/s.

  PhRMA welcomes the Australian Government's response to the 2019 Therapeutic Goods Administration (TGA) consultation on "[w]hether the TGA should publish that a prescription medicine is under evaluation." In response to public demand for increased information on prescription medicines that are under evaluation, the Government has decided to implement enhanced transparency measures for prescription medicines. These will include: publishing a description of major innovator medicine applications that are under evaluation by the TGA from January 2021; and for patent holders to be notified before a first generic or biosimilar medicine application has been accepted for TGA evaluation. We are encouraged by this progress and look forward to seeing the proposals in more detail.

- **Market-size damages**: In cases of patent invalidation by the courts, the Australian Government has taken legal action against innovators for damages attributed to a delay in the PBS price reduction while the patent dispute is being resolved. These so-called "market-sized damages" create significant uncertainty for pharmaceutical patent owners, who need to be able to rely on the rights conferred by granted patents (unless and until they are finally invalidated) to support the large investments needed to develop new medicines. It also undermines the rights of patent holders in Australia by introducing a strong disincentive to exercise their core right to enforce their IP protections and is inconsistent with Australia's international commitments under the AUSFTA and the World Trade Organization

(WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

- **Compulsory licensing**: In 2016, the Australian Government launched a Productivity Commission (Commission) inquiry into Australia's "Intellectual Property Arrangements."[144] The Commission's report was publicly released on December 20, 2016 and contained a number of concerning findings. In its August 2017 and November 2018 responses to the report, the Australian Government indicated that some of the more concerning recommendations would not be accepted. However, in August 2019, the Government passed amendments to the intellectual property legislation which appear inconsistent with AUSFTA and which would unnecessarily broaden the scope of compulsory licensing. These amendments could permit compulsory licensing on grounds that are not related to a judicially or administratively determined remedy for anticompetitive behavior, a national emergency, or other circumstance of extreme urgency.

- **Inadequate regulatory data protection (RDP)**: Australia should strengthen its regulatory data protection (RDP) to align with international best practice, to improve the country's attractiveness as a destination for foreign investment by global pharmaceutical companies, and to encourage companies to bring new medicines to Australia sooner.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access

Beginning with legislative changes implemented in June 2017, significant progress has been made with the implementation of the Medicines and Medical Devices Review; this progress highlights the benefits of regulatory review involving industry consultation. Measures such as the "Priority Review" and "Provisional Approval" pathways that deliver expedited access for some medicines in areas of high unmet need are welcome. However, unlike other jurisdictions, there is currently no corresponding change in the health technology assessment system to accommodate these fast-track approvals, especially in the case of the Provisional Approval pathway. Industry looks forward to working with the Australian Government to implement a fit for purpose reimbursement system to ensure that Australians have timely access to life-saving immuno-oncology medicines.

Difficulties in Listing New Medicines on the PBS

PhRMA and its member companies welcome the recent October 2020 budget announcement from the Australian Government for the establishment of a New Medicines Funding Guarantee for new and amended listings. The announcement will guarantee new

[144] *See* http://www.pc.gov.au/inquiries/completed/intellectual-property#report (last visited Oct. 28, 2020).

funding each year for the listing of new medicines on the PBS. Approximately $2.8 billion in new funding is expected to be committed over the next four years to meet the cost of new and amended listings. Industry also welcomes the Australian Government's commitment to list all medicines recommended by the PBAC and to no longer require equal offsets for all new medicines listings. This should help improve timely listing of new medicines recommended by the PBAC.

Prescription medicines accessed via the PBS constitute the vast majority of prescription medicines dispensed in Australia.[145] Accordingly, the reimbursement process to obtain PBS-listing, as well as PBAC guidelines and decision making, effectively dictate access to the Australian pharmaceutical market. Predictable and equitable 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 aims to resolve 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 older medicines, comparators are increasingly being drawn from very low-cost drugs. Additionally, in therapy areas where has been less recent innovation, the clinical comparator may be off-patent. These medicines are commonly in the F2 formulary, having reached the end of patent life and subject to generic or biosimilar competition. Today's innovative medicines are increasingly targeted and personalized and can provide great value in some of the hardest-to-treat diseases and may offer a more targeted treatment, meaning they may be more effective than other available

[145] *See Australian Statistics on Medicines 2014,* available at http://www.pbs.gov.au/statistics/asm/2014/australian-statistics-on-medicines-2014.pdf (last visited Oct. 28, 2020).

options. Comparing these medicines to older existing medicines that are less complex and developed decades earlier does not represent a fair value for the innovation involved.

Comparator price erosion undermines the intent of Australia's split formulary system – which was designed to recognize the value of innovation by excluding patented products from price reductions applied to off-patent products that are subject to market competition – and is an additional disincentive to bringing innovative medicines to Australia. Recent activities to provide clarity on this issue have not led to widespread selection of the most appropriate comparator. There is ongoing work to be done in this area and we welcome the Australian Government's commitment to consider the issue of comparator selection as part of the AMWG discussions.

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 application of stakeholder-agreed biosimilar uptake drivers 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 Australian Government's policy of allowing decisions regarding substitution (*i.e.*, enabling a patient's medicine to be switched) between biologic and biosimilar products at the pharmacy level, particularly in a system that does not support unique naming conventions for biological medicines, has not yet been assessed. It will be important to ensure that policies seeking 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.

Contrary to Australia's goal of fostering a biotechnology industry, the Government elected in early 2018 not to implement a unique naming convention for biologic medicines. It is regrettable that the Government did not recognize the benefit to clinical confidence that such a system would provide, as its absence has the potential to weaken pharmacovigilance, post-market monitoring, and confidence in the introduction of biosimilar medicines.

We would strongly encourage the Australian Government to consult with Medicines Australia as it seeks to develop evidence-based, consistent and comprehensive biosimilars policies that support 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.[146]

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) most reviews have narrowly focused on cost. Industry hopes that considering the statutory price reductions included in the Agreement, the focus of future post-market reviews will be to improve QUM. Industry would also like to see any cost-effectiveness reviews subject to the same framework as post-market reviews to ensure procedural fairness.

Intellectual Property Protection

Weak Patent Law Enforcement

Mechanisms that provide for the early resolution of patent disputes before a potentially infringing product is allowed to enter the market are critical to ensuring adequate and effective protection of IP rights for the research-based pharmaceutical sector. Such mechanisms prevent marketing of a product potentially covered by a patent until expiration of the patent or until any dispute relating to infringement or validity of such a patent is resolved. An effective early resolution mechanism provides a procedural gate or safeguard. It ensures drug regulatory entities do not enable marketing authorization, PBS listing or the launch of a product which has been asserted to infringe patent rights. In this regard, the Australian Government's approach is highly concerning to PhRMA members because it encourages unnecessary, costly, and lengthy litigation processes. The Australian Government has indicated that it will grant an application to list a competing generic product on the PBS, even when it has received a certificate submitted by the patent holder that:

- patent infringement proceedings in respect of that product have been commenced in good faith;
- the proceedings have reasonable prospects of success;
- the proceedings will be conducted without unreasonable delay; and
- even when a court has granted a preliminary injunction preventing the generic company supplying that generic product.

As indicated above, 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 the patent owner to be notified of such request and the identity of any

[146] *See* http://www.pbs.gov.au/info/browse/reviews (last visited Oct. 28, 2020).

such other person."[147] This should include a database or other mechanism by which a third party may determine whether there are patents that may be infringed by the product or use for which the third party is seeking approval.

However, originator pharmaceutical companies in Australia generally do not receive any notice of a third party's intention to enter the market with a product that may infringe a valid and enforceable patent prior to its listing on the ARTG.

Originator companies are significantly impacted when generic medicines enter the market prior to the expiry of the originator patent, in part through mandatory and irreversible price cuts for innovator products listed on the PBS, and through market share erosion. The only legal option available to the innovator patentee to prevent the generic company from launching is to obtain preliminary injunctive relief (or equivalent relief), which in the case of PBS listing must be obtained in the few months between the time marketing approval of the generic product is published on the ARTG and the next possible PBS listing date, in order to prevent the irreversible price reduction. The preliminary injunction process also comes with risk of market-sized damages as discussed below.

Currently, the lack of effective mandatory notification, the absence of an effective mechanism for the early resolution of patent disputes before an infringing product is launched in Australia, and the unduly prejudicial penalties being sought by the Australian Government from patent holders for seeking to defend their IP (including liability for market-sized damages as discussed in detail above) significantly weakens the level of IP protection for pharmaceutical innovation in Australia, serving to deprive patent holders of expected benefits under international agreements including the AUSFTA.

In light of these shortcomings, PhRMA welcomes the Australian Government's response to the 2019 Therapeutic Goods Administration (TGA) consultation on "whether the TGA should publish that a prescription medicine is under evaluation." In response to public demand for increased information on prescription medicines that are under evaluation, the Government has decided to implement enhanced transparency measures for prescription medicines. This will include two broad measures. The first will be for the TGA to publish a description of major innovator medicine applications that are under evaluation by the TGA from January 2021. The second measure is subject to the Australian parliament passing legislative amendments that are expected to be introduced in late 2020. These amendments will "require" that a patent holder must be notified by the sponsor of a generic or biosimilar medicine when their application has been accepted for evaluation by the TGA, before the TGA commences the evaluation. This obligation will apply to the first generic or biosimilar medicines that would be listed on the ARTG after the innovator's medicine.

We look forward to seeing these measures in greater detail, particularly the legislative amendments relating to earlier patent holder notification. If implemented appropriately, the resulting mechanism will benefit not only innovators, but also

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

generics/biosimilar manufacturers and the Australian government alike, by allowing all parties involved to assess, and hopefully resolve, possible patent infringement issues before generic products and biosimilars are approved.

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" from innovators that pursue unsuccessful patent claims after being granted a preliminary injunction unfairly penalize and discourage the use of provisional enforcement measures as part of well-functioning early resolution mechanisms. These policies undermine legal certainty, predictability and the incentive provided by patents to invest in new treatments and cures.

Australia's Therapeutic Goods Act, as amended by the legislation implementing the AUSFTA, provides for the award of damages in limited specific circumstances, where a court determines that the patent holder has engaged in improper conduct specifically identified in that legislation in commencing proceedings or seeking a preliminary injunction.[148] Damages under this scheme have not been sought since its introduction. However, outside of that scheme, and pursuant to the usual undertaking as to damages provided by patent holders as a requirement for obtaining a preliminary injunction, since around 2012 the Australian Government has stated its intent to seek – and has sought – market-size damages from biopharmaceutical innovators that have legitimately but ultimately unsuccessfully pursued patent claims. It has done so even where the preliminary injunction was granted several years before the Australian Government first stated its intention to seek such damages. Those claims are purported to compensate the PBS for the effect of any delays in price reductions for patented medicine during the period of a preliminary injunction. The PBS imposes automatic price cuts on medicines as soon as competing versions are listed on the PBS, but the policy does not include any corresponding mechanism to automatically compensate innovators for losses if an infringing product is launched prematurely.

By pursuing market-size damages, the Australian Government is unfairly tipping the scales in pharmaceutical patent disputes – and discouraging innovators from enforcing their granted patents. This policy permits the same court that granted a provisional enforcement measure in a patent dispute to allow that measure to be used as the basis for a claim for compensation by the government or another non-party to the dispute. It exposes innovators to significant additional compensation claims that may be difficult to quantify and were not agreed to or contemplated at the time the preliminary injunction was granted. The punitive size of these additional claims effectively equates legitimate patent enforcement, in circumstances where the market effects of infringing generic entry are difficult to quantify, with patent abuse. Allowing governments or other non-parties to a patent dispute to collect market-size damages undermines legal

[148] *See* Schedule 7 of the US Free Trade Agreement Implementation Act 2004, available at https://www.legislation.gov.au/Details/C2004A01355/ (last visited Oct. 28, 2020).

certainty, predictability and the incentives that patents provide for investment in new treatments and cures. Australia's practice appears to be inconsistent with the AUSFTA and with WTO intellectual property rules, including with respect to provisional measures.

Indeed, in the course of claiming market-size damages, representatives of the Australian Government have stated that the Australian Government will grant an application to list a competing generic product on the PBS (the effect of which is an automatic price cut), even when:

- the patentee has lodged a certificate, required as a result of the amendments to the Therapeutic Goods Act as a result of the legislation implementing the AUSFTA as a precondition for commencing patent infringement proceedings, stating that infringement proceedings in respect of that product have been commenced in good faith, have reasonable prospects of success, and will be conducted without unreasonable delay; and/or

- a preliminary injunction has been granted by a court which prohibits the supply of that product by the generic company.

Such comments typify the Australian Government's conflict of interest, as well as the disregard paid by the Australian Government to the legitimate interests of innovators in enforcing their granted patent rights.

PhRMA members urge USTR and other federal agencies to prioritize actions to address Australia's pursuit of market-size damages. The Australian Government should immediately and publicly abandon its policy of seeking market size damages, or any damages, when a patent holder has legitimately sought to enforce its patent rights.

Compulsory Licensing

In 2016, the Australian Government launched a Productivity Commission (Commission) inquiry into Australia's "Intellectual Property Arrangements."[149] The Commission's report was publicly released on December 20, 2016, and contained a number of findings that biopharmaceutical innovators did 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 a patentable inventive step.[150]

[149] *See* http://www.pc.gov.au/inquiries/completed/intellectual-property#report (last visited Oct. 28, 2020).
[150] 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. *See* "Joint Submission to the Consultation on the Issues Paper by the Productivity Commission on Intellectual Property (IP) Arrangements in Australia," available at http://www.pc.gov.au/__data/assets/pdf_file/0010/194770/sub087-intellectual-property.pdf (last visited Oct. 28, 2020).

In its August 2017 and November 2018 responses to the report, the Australian Government indicated that some of the report's most damaging recommendations would not be accepted. However, recent (October 2019) amendments to Australia's intellectual property legislation on compulsory licensing, including Crown use, are unnecessary, weaken patent protection, discourage investment and limit the potential benefits of innovation for Australians. These changes may encourage or make it easier for third parties to acquire innovative technologies without authorisation, which could have significant unintended consequences. The amendments could also permit compulsory licensing on grounds that are potentially broader than the circumstances outlined in AUSFTA Article 17.9.7.

Inadequate Regulatory Data Protection

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate that they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[151]

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

Strengthening RDP in Australia – in terms of the length and scope of protection - so it is aligned with global best practice would further enhance Australia's ability to compete for foreign investments in the knowledge- and innovation-intensive biomedical sector that can drive future economic growth. Australia should implement RDP terms that are consistent with international best practices.

[151] 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 https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf (last visited Oct. 28, 2020).

BRAZIL

PhRMA and its member companies operating in Brazil recognize the efforts of the Brazilian Government to liberalize economic opportunities by attracting foreign trade and investment. The current government has a tremendous opportunity to address long standing issues facing the industry in Brazil, including, restrictive patentability criteria and procedures, the lack of regulatory data protection (RDP) and government pricing policies. PhRMA and its member companies strongly support the launch of comprehensive trade negotiations to resolve these issues. Absent comprehensive negotiations, however, ongoing trade and investment discussions between the United States and Brazil present an important near-term opportunity to resolve these concerns.

Key Issues of Concern:

- **Regressive taxes on medicines**: Combined federal and state taxes add up to 31 percent to the cost of medicines in Brazil, one of the highest tax burdens on medicines in the world compared to the global average of 6 percent.[152] Proposals to eliminate taxes on certain products including medicines have previously lapsed. Fortunately, much-needed tax reforms – which would lower costs to patients, boost productivity and encourage investment – are being considered by the government and present an opportunity to address these concerns.

- **Restrictive government pricing and reimbursement policies**: Brazil's policies create market access barriers for PhRMA member companies and prevent timely patient access to new treatments and cures. Key challenges include government price ceilings on medicines sold to private and public purchasers as a condition of market entry, price increases capped below inflation despite rising production costs, and rigid requirements by the National Committee for Technology Incorporation (CONITEC) that prevent more flexible and value-based approaches to evaluating and paying for health care. While CONITEC has recently begun to adopt certain transparency measures, without further reforms transparency and due process within government pricing and reimbursement policies in Brazil will continue to be a concern.

- **Product Development Partnerships (PDPs) and government purchasing**: Brazil has developed a regulatory framework for the establishment of PDPs. While this framework provides improved transparency, Brazil still lacks clear rules regarding the purchasing preferences offered to PDPs. In addition, while the Ministry of Health (MoH) is tasked with reviewing and approving PDPs, it can nevertheless approve a PDP submitted by a third party for products with a valid patent in Brazil although it is restricted from purchasing that product through the third party.

[152] Brazilian Institute of Tax Planning, 2018.

- **Restrictive patentability criteria and procedures**: Since 1999, Article 229-C of Brazil's Patent Law has been interpreted to permit the health regulatory agency, the Brazilian National Health Surveillance Agency (ANVISA), to review all patent applications for pharmaceutical compound and/or process inventions. That article created a dual patent examination process for pharmaceutical inventions, resulting in both: contradictory and/or additive patentability requirements to those established by Brazilian Patent Law and adopted by the Brazilian Patent Authority (INPI); and duplicative, prolonged patent reviews that contribute to the existing patent backlog. Under the terms of regulatory changes adopted in 2017, ANVISA's opinion on the patentability of new biopharmaceutical inventions are no longer binding on INPI. This is a welcome step, but does not end Brazil's "dual examination" system. In addition, the Federal Prosecutor's Office has challenged the 2017 ANVISA regulatory changes and that challenge is pending review.

- **Patent backlogs**: With around 100,000 patent applications pending at INPI, Brazil's patent backlog still exceeds 10 years (and is even longer for pharmaceuticals), hindering innovation and significantly raising investment risk. We welcome INPI's recent efforts to tackle this examination backlog and look forward to its successful implementation. In 2019, Brazil announced a series of resolutions and plans to increase the efficiency of patent prosecution in Brazil. These include INPI's "Plan to Tackle Patent Backlog," which aims to reduce the current backlog by 80 percent and to examine new patent applications within two years from the applicant's examination request. PhRMA supports mechanisms to compensate for unreasonable patent examination delays. Article 40 of Brazil's IP Law is one example of the types of safeguards against undue patent office delays. Finally, we commend INPI's recently announced technology-neutral Patent Prosecution Highway (PPH) pilot program and hope to see that work expanded in the future.

- **Lack of regulatory data protection**: Although Brazil applies RDP for veterinary, fertilizer, and agrochemical products, the same protection is not provided to biopharmaceutical products.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Regressive Taxes on Medicines

Combined federal and state taxes add up to 31 percent to the cost of medicines in Brazil, one of the highest tax burdens on medicines in the world compared to the global average of 6 percent.[153] Recognizing the significant burden that these high taxes impose on Brazilian patients, the innovative pharmaceutical industry supports the reform

[153] *Id.*

proposals under consideration by Brazil's Congress to streamline and even eliminate taxes on medicines.

High tariffs and taxes can prevent access to new treatments for patients that need them. Under the WTO Pharmaceutical Agreement, 34 countries agreed to eliminate import duties on a wide range of medicines and other health products.[154] However, the majority of Latin American economies, including Brazil, are not parties to the WTO Pharmaceutical Agreement. Between 2006 and 2013, the value of worldwide biopharmaceutical trade in countries that are not parties to that Agreement increased at a compound annual growth rate of more than 20 percent. This means that a larger proportion of medicines distributed around the world are potentially subject to tariffs.[155] To help remedy this trend, Brazil should accede to the WTO Pharmaceutical Agreement.

Restrictive Government Pricing and Reimbursement Policies

Brazil's policies create market access barriers for PhRMA member companies and prevent timely patient access to new treatments and cures. Key challenges include government price ceilings on medicines sold to private and public purchasers as a condition of market entry, price increases capped below inflation despite rising production costs, and rigid requirements by CONITEC that prevent more flexible and value-based approaches to evaluating and paying for health care. While CONITEC has recently begun to adopt certain transparency measures, without further reforms transparency and due process within government pricing and reimbursement policies in Brazil will continue to be a concern.

Government Purchasing and PDPs

The Brazilian Government issued Federal Law 12.349/10 in 2010, granting preferences for locally manufactured products and services in public tenders. A price preference of up to 25 percent is automatically applied to locally produced medicines in government tenders. 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.

Meanwhile, a new PDP regulation (Portaria 2531/14, subsequently referenced in Consolidation Ordinance no. 5 in 2017) was issued in 2014 with participation of the private sector, which was intended to provide greater transparency and predictability. Since then, the Brazilian Government has announced several PDPs under the new regulation. It remains unclear what criteria were evaluated in assessing and approving these PDPs

[154] IQVIA (2020). Market Prognosis Country Report: Brazil.
[155] 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 Oct. 28, 2020).

and the purchasing preferences that will be extended to an approved PDP. In addition, the MoH does not consider or assess relevant intellectual property rights of products that are the object of a PDP application. As a result, the MoH has approved several third-party PDP applications for innovative and patent protected products. Recognizing these shortcomings, Brazil conducted a public consultation in 2018 toward revising PDP requirements, although the resulting updates to the Brazil's PDP ordinance did not progress.

As part of these efforts, in 2019, the MOH held a public consultation with industry to discuss updates to the PDP framework that seek to redefine eligibility criteria and update submission procedures and protocols for governance and monitoring. Nevertheless, the system continues to lack transparency and predictability. More recently, in July 2019, 19 PDP agreements were unexpectedly put into various phases of suspension for a wide range of reasons. Products included medicines to treat hepatitis C, autoimmune conditions and vaccines.

Intellectual Property Protection

Restrictive Patentability Criteria and Procedures

A significant problem facing the pharmaceutical industry in Brazil was created by Article 229-C, the 1999 amendment to the Brazilian Patent Law that authorizes ANVISA to conduct reviews of 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 patent examination conducted by 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 2017 and by ANVISA in August 2017, ANVISA may issue opinions on the patentability criteria of new biopharmaceutical inventions, although those opinions are no longer binding on INPI. However, ANVISA opinions are binding for patent applications for biopharmaceutical products and processes which are deemed as presenting a "health risk" (*i.e.*, substances whose use has been prohibited in Brazil). While communications between INPI and ANVISA have improved and biopharmaceutical patent applications are being granted, PhRMA continues to believe that Brazil must end its "dual examination" system and bring its patent system in line with global rules and norms.

In addition, the Brazilian Federal Prosecutor's Office has challenged the 2017 ANVISA amendments and that challenge is pending review.

Patent Backlogs

While PhRMA recognizes efforts underway at INPI to reduce the patent backlog, delays in patent grants (compounded by the dual examination process noted above) reduce the incentive for companies to bring innovative products to Brazil.

With around 100,000 patent applications pending at INPI, Brazil's patent backlog still exceeds 10 years (potentially longer for pharmaceuticals), hindering innovation and significantly raising investment risk. In June 2019, INPI published a new "fast track" resolution to standardize and increase efficiency within patent processing. In July 2019 INPI announced a new "Plan to Tackle Patent Backlog," aiming to reduce the current patent backlog by 80 percent within the next two years, and to complete the examination process for new patent applications within two years from the applicant's examination request.

PhRMA fully supports INPI's plan to tackle its patent backlog and suggests that the U.S. Government should support the Brazilian Government in fully implementing this plan. Brazil's recently announced technology-neutral PPH pilot program between INPI and major IP offices, including the United States, is highly encouraging. We look forward to working together with the Government of Brazil to expand fully that pilot program. Regardless, however, of these efforts, the existing patent backlogs and the potential for future patent office delays underscore the need for mechanisms to ensure the preservation of a portion of the patent term. As such, PhRMA and its members strongly support retaining Article 40 of Brazil's Patent Law, which helps offset some of the patent examination delays in Brazil.

Lack of Regulatory Data Protection

Brazilian law (Law 10.603/02) provides data protection for veterinary, fertilizer, and agrochemical products, but still does not provide similar protection for pharmaceutical products for human use, resulting in discriminatory treatment. Contrary to TRIPS Article 39, 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.

National Intellectual Property Strategy

Brazil is currently finalizing a national strategy on intellectual property. PhRMA appreciated the opportunity to submit comments on a draft strategy published in

September 2020. The draft National Intellectual Property Strategy could be a powerful framework to address longstanding intellectual property concerns and to proactively drive an intellectual property policy agenda that provides innovators the necessary certainty they need to collaborate with partners, support necessary research and development investments, and accelerate the launch of new medicines.

Although the final strategy has not yet been developed, the draft identifies essential policies related to the life science innovation, including: patent examination and backlog procedures, regulatory data protection, and others. Further initiatives such as the strengthening of the Brazilian PTO and enforcement actors are also provided for in the draft text. We urge Brazil to continue to work toward implementation of its national IP strategy and to clearly define a strategy and map out actions to eliminate the patent examination backlog. A successfully implemented IP strategy should align biopharmaceutical patentability and intellectual property enforcement criteria and procedures with international rules and best practices, including centralizing all patent examination processes within a single competent authority and provide regulatory data protection for biopharmaceutical products.

CANADA

PhRMA and its member companies operating in Canada are extremely concerned about Canada's pricing environment and intellectual property (IP) protections for patented products. Of particular concern are Canada's 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. In addition, Canada's IP regime continues to lag behind that of other developed nations in several respects.

Key Issues of Concern:

- **The Patented Medicine Prices Review Board (PMPRB)**: On August 21, 2019, Canada published amendments to the Patented Medicines Regulations ("Amended PMR") governing the PMPRB, which changes its mandate from ensuring "non-excessive" prices. The regulations amend the basket of reference countries (removing the U.S. and Switzerland from the basket and including other lower priced jurisdictions), introduce various new economic factors to determine whether a price is "excessive," and require manufacturers to report all indirect price reductions. The changes require manufacturers to report to the PMPRB health technology assessments (HTAs) produced by the Canadian Agency for Drugs and Technologies in Health (CADTH) and any other publicly funded agency. HTA analyses involve analytical decisions which can be subjective and are not an appropriate tool to set binding regulatory price ceilings. Further, manufacturers have concerns that PMPRB changes and CADTH proposals would undermine the protection of confidential business information.

  The Amended PMR constitutes an impermissibly broad exception to IP rights in contrast to Canada's obligation under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires that a member state not impose measures that "unreasonably conflict with a normal exploitation of the patent" and not "unreasonably prejudice the legitimate interests of the patent owner". Further, the PMPRB changes could have a serious negative impact on U.S. biopharmaceutical companies operating in Canada, the availability of new medicines for Canadian patients, and the competitiveness of Canada for research-based pharmaceutical investment. Canada has estimated that the Amended PMR will cost industry $13.2 billion CAD in lost revenue over 10 years at net present value; however, depending on how the regulations are implemented, the cost to industry could be as high as $24.9 billion CAD over the same period. It is expected that the Amended PMR will significantly undermine the marketplace for innovative pharmaceutical products, delay or prevent the introduction of new medicines in Canada and reduce investments in Canada's life sciences sector.

  In June 2020, the Federal Court of Canada held that the PMR amendment requiring manufacturers to report all indirect price reductions was invalid. Other

problematic elements of the regime remain subject to ongoing litigation. We urge the U.S. government to elevate concerns with Canada regarding the PMPRB regulatory changes.

- **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 provincial/territorial and federal public reimbursement plans to benefit Canadian patients. This results in significant delays in access to innovative medicines, while also decreasing the time that companies have to commercialize their innovations.

- **Weak patent enforcement**: The Canadian Patented Medicines (Notice of Compliance) Regulations (the "PM(NOC) Regulations")[156] include several key deficiencies that weaken Canada's enforcement of patents, including excessive and windfall damage awards to generic litigants, and limitations and inequitable eligibility requirements on the listing of patents in the Patent Register. Recent jurisprudence under the PM(NOC) Regulations has also resulted in a heightened level of liability for patent owners akin to punitive damages. PhRMA and its member companies are also troubled to see that Canada has used implementation of the Canada-EU Comprehensive Economic and Trade Agreement (CETA)[157] to implement reforms not required by that Agreement, which expose innovators to even greater potential liability under Section 8 of the PM(NOC) Regulations. PhRMA members are also concerned about potential damage awards which could stem from various common law theories within the Canadian provincial courts.

- **Inadequate patent term restoration (PTR)**: Under CETA, Canada is required to provide innovators with some compensation for delays in obtaining marketing approval for pharmaceuticals. The USMCA also requires Canada to provide PTR for unreasonable delays during the prosecution and issuance of any patent. However, in its CETA implementing regulations, Canada has chosen to implement an "export" exception that is inconsistent with the fundamental purpose of restoring a portion of the patent term lost due to the marketing approval process and has only adopted the minimum term of PTR negotiated under CETA further deviating from global standards. Furthermore, Canada's adoption of restrictive time limits and eligibility criteria will unduly and unreasonably limit patent term restoration eligibility in Canada in a manner that is contrary to the intent of the negotiation and the CETA text itself. Finally, Canada is interpreting the PTR regulations required by CETA in a narrow manner that is inconsistent with the treaty text.[158] PhRMA's

[156] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.
[157] *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 Oct. 28, 2020).
[158] GlaxoSmithKline Biologicals S.A. v. The Minister of Health, 2020 FC 397.

member companies believe Canada should support innovation by ensuring that its PTR system effectively ameliorates the effects of lengthy regulatory processes, which can significantly erode the duration of the IP rights of innovators.

- **Standard for the disclosure of confidential business information (CBI)**: In November 2014, Canada enacted legislation to update its Food and Drugs Act (Bill C-17).[159] Provisions in that law granted the Health Minister discretion to disclose a company's CBI without notice to the owner of the CBI and in accordance with a standard that is both inconsistent with other similar Canadian legislation and Canada's treaty obligations. On March 20, 2019, regulations were put in place respecting these authorities to release information about therapeutic products.[160] Further, on July 9, 2018, the Federal Court of Canada issued a decision ordering Health Canada to release vast amounts of pharmaceutical clinical trial data on five medications to a researcher, undercutting the federal government's attempts to keep the information confidential. The decision, which was not appealed by Health Canada, has the potential to exacerbate the negative impacts of the draft regulations and guidelines on biopharmaceutical innovators.[161]

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

The Patented Medicine Prices Review Board (PMPRB)

The PMPRB is a quasi-judicial body, created under the Canadian Patent Act.[162] 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/territorial government agencies, or private insurers.

On August 21, 2019, Health Canada published the Amended PMR in Canada Gazette, Part II.[163] The Amended PMR was largely unchanged from the proposals put

[159] *See* https://www.parl.ca/DocumentViewer/en/41-2/bill/C-17/royal-assent (last visited Oct. 28, 2020).
[160] Canada Gazette, Part II, Volume 153, Number 6 Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information) SOR/2019-62, available at http://canadagazette.gc.ca/rp-pr/p2/2019/2019-03-20/html/sor-dors62-eng.html (last visited Oct. 28, 2020).
[161] *Doshi v. Canada (Attorney General)*, 2018 FC 710.
[162] Patent Act, R.S.C. 1985, c.P-4, ss.79-103.
[163] Canada Gazette, Part II, Regulations Amending the Patented Medicines Regulations (Additional Factors and Information Reporting Requirements), Vol. 153, No. 17, Aug. 21, 2019, available at http://www.gazette.gc.ca/rp-pr/p2/2019/2019-08-21/html/sor-dors298-eng.html (last visited Oct. 28, 2020).

forward in Canada Gazette, Part I, on December 2, 2017.[164] The PMPRB changes were initiated as part of the Board's professed role as a "counterweight to the patent rights of pharmaceutical manufacturers."[165] The Amended PMR constitutes an impermissibly broad exception to IP rights in contrast to Canada's obligation under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which requires that a member state not impose measures that "unreasonably conflict with a normal exploitation of the patent" and not "unreasonably prejudice the legitimate interests of the patent owner".[166] The 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. The Amended PMR is scheduled to come into force on January 1, 2021.

Patented drugs account for only 6.6 percent of total health spending in Canada (2018).[167] Moreover, patented drugs have experienced near zero real cost growth over the last decade.[168] 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 access and 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 view. 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.

Through the Amended PMR, Canada amended the PMPRB's basket of reference countries with the goal of setting ceiling prices of patented medicines in Canada at OECD median. Specifically, the PMPRB removed the United States and Switzerland, the two jurisdictions in the OECD with higher prices than Canada. The amendments also added six jurisdictions with lower drug prices than Canada to the basket: Japan, Australia, Belgium, the Netherlands, Norway and Spain. The new basket will now consist of

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[164] Canada Gazette, Part I, Regulations Amending the Patented Medicines Regulations, Vol. 151, No. 48, Dec. 2, 2017, available at http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html (last visited Oct. 28, 2020).

[165] PMPRB 2015-16 Report on Plans and Priorities, available at http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1163 (last visited Oct. 28, 2020).

[166] TRIPS Article 28 provides that a patent "shall confer" on its owner the exclusive rights to prevent third parties without the owner's consent from "the acts of: making, using, offering for sale, selling, or importing for these purposes that product." In turn, TRIPS Article 30 permits WTO members to grant only "limited" exceptions to these exclusive rights, provided that such exceptions do not conflict with the "normal exploitation" of the patent and do not prejudice the legitimate interests of the patent owner. 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." *See* WTO, Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS/114/R, ¶¶ 7.54-55 (Mar. 2000), available at https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited Oct. 28, 2020).

[167] Based on analysis of information from the *Canadian Institute for Health Information*, available at https://www.cihi.ca/en/national-health-expenditure-trends-1975-to-2019 (last visited Oct. 28, 2020) and the PMPRB Annual Report 2018, available at https://www.canada.ca/en/patented-medicine-prices-review/services/reports-studies/annual-report-2018.html (last visited Oct. 28, 2020).

[168] *Id.*

Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, Spain, Sweden, and the United Kingdom. Despite being at the forefront of OECD economies, Canada has amended its list of reference countries to replace the United States and Switzerland with countries which are poorer and/or have onerous price control policies. The United States is Canada's largest trading partner and the pharmaceutical markets in both countries share many common features. While PhRMA and its members believe that international reference pricing is a flawed methodology that places short-term government objectives ahead of long-term strategies to ensure continued R&D into medicines that patients need most, it is particularly egregious for Canada not to reference the United States and other countries with pro-innovation pharmaceutical policies.

Canada also introduced new economic factors to determine whether a price is "excessive." The new economic factors to regulate prices 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 thresholds will impact the future viability of many drugs for rare diseases, oncology treatments, cellular and gene therapy, precision medicine and other similar innovations in Canada. While cost-effectiveness thresholds are used downstream in other nations in making reimbursement decisions, their utilization as part of a binding regulatory price ceiling is unique to Canada.

In the thirty years since the PMPRB was established, a variety of mechanisms have emerged in Canada for the government and industry to work together to ensure the affordability of medicines. These mechanisms include the Canadian Agency for Drugs and Technologies in Health (CADTH), the Institut national d'excellence en santé et services sociaux (INESSS), the Common Drug Review (CDR), the pan-Canadian Pharmaceutical Alliance (pCPA), and confidential product listing agreements, among others. Indeed, the specific change to include a cost-effectiveness factor as part of PMPRB's price evaluation overlaps with and duplicates the work of existing publicly funded agencies (*e.g.*, pCPA), and its major beneficiary would be for-profit private insurers as opposed to patients. Any expansion of the PMPRB's mandate to include "affordability" is therefore unnecessary and would harm U.S. innovative biopharmaceutical companies through additional downward pricing pressures.

In addition, the Amended PMR required 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 (including confidential rebates agreed to with public or private insurers). Given the lack of information on the purpose and use of this information, this requirement raised a number of legal concerns.

The Canadian innovative biopharmaceutical industry, led by its industry association Innovative Medicines Canada, challenged the Amended PMR on several grounds through a judicial review proceeding.[169] The hearing took place on June 1-2,

[169] *Innovative Medicines Canada et al. v. Attorney General of Canada*, T-1465-19, S.18.1 Application for Judicial Review.

2020, and Justice Manson of the Federal Court issued his decision on June 29, 2020.[170] The Applicants were partially successful in their arguments, as the Court held that the requirement for manufacturers to report all indirect price reductions is unlawful, void and of no force and effect because it extends beyond sales made by the patentee at the factory-gate. The existing provision of the Regulations will continue to operate as it currently reads. However, the Court upheld the other amendments relating to the new economic factors and the revised basket of reference countries. These amendments are scheduled to come into effect on January 1, 2021, and will apply to new and existing medicines for sales that occur after January 1, 2021 with the exception of the new economic factors which will apply to medicines that received a drug identification number after August 21, 2019, the date the Amended PMR were released.

Industry continues to challenge the remaining amendments, and filed an appeal with the Federal Court of Appeal on September 10, 2020. However, the appeal hearing will not occur before the amendments come into force on January 1, 2021. In addition, seven innovative pharmaceutical companies are challenging the constitutional jurisdiction of the PMPRB's legislative and regulatory framework in the Superior Court of Quebec on the basis that price regulation is a provincial responsibility.[171]

Moreover, the process of implementing the Amended PMR through changes to the PMPRB's Guidelines raise many additional points of uncertainty and risk for U.S. biopharmaceutical innovators. The PMPRB released its draft Guidelines on November 21, 2019, and released revised draft Guidelines on June 19, 2020, and final Guidelines on October 23, 2020. While the Guidelines are non-binding, they are indicative of the PMPRB's regulatory approach, and are intended to assist stakeholders in understanding how the regulations will be interpreted and applied. In this case, the final Guidelines are extremely complex and create further uncertainty. The Guidelines exacerbate concerns arising from the Amended PMR and if implemented as proposed, will have significant negative impacts on patentees and patients.

PhRMA recommends that the U.S. Government urge the Government of Canada to reconsider 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. The PMPRB's role must be placed in its proper context with the many other agencies already active in the Canadian pharmaceutical marketplace and should not be a means to contradict Canada's international obligations on patent rights.

The PMPRB is also required to report to the Federal Minister of Health on pharmaceutical trends and on R&D spending by pharmaceutical patentees. Due to the antiquated 1987 tax law formula used to measure R&D spending, which is referenced in

[170] *Innovative Medicines Canada et al. v. Attorney General of Canada*, 2020 FC 725, available at https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/481803/index.do?q=innovative+medicines+canada (last visited Oct. 28, 2020)
[171] *Merck Canada Inc., et al. v. Procureur Général du Canada et Procureur Général du Québec*, No. 500-17-109270-192 Avis de questions constitutionnelles.

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

Regulatory Barriers to Patient Access to New Medicines

Beyond the 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 PMPRB review, health technology assessments, price negotiations through the pan-Canadian Pharmaceutical Alliance (pCPA), and, finally, the execution of product listing agreements with individual public drug plans.

Listing data between 2012 and 2016 revealed that it takes an average of 602 days after Health Canada approval before a patient can access a new medicine through at least one Canadian public drug plan.[172] 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 and its members urge the U.S. Government to engage with the Government of Canada on these growing delays that are hindering patient access to new medicines.

Intellectual Property Protection

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. In 2015, the Canadian government helped resolve significant difficulties related to inappropriate court decisions that prevented the listing of patents relevant to combination inventions, which seriously undermined patent enforcement actions relevant to those inventions. However, serious and systemic deficiencies remain with the PM(NOC) Regulations. The regulations do not reliably provide "expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements," as required under the TRIPS Agreement. For example:

[172] Salek, S. et al., Factors Influencing Delays in Patient Access to New Medicines in Canada: A retrospective Study of Reimbursement Processes in Public Drug Plans, Frontiers in Pharmacology, Mar. 2019, available at http://innovativemedicines.ca/wp-content/uploads/2019/06/2019-delays-patient-access.pdf (last visited Oct. 28, 2020).

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,[173] 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 percent 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 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. As such, Section 8 unreasonably prejudices the legitimate interests of the patent owner. One legitimate right of a patent owner is to petition the government to enforce a patent which that government granted in the first place. Unless the patent owner has obtained its patent by fraud or otherwise knows that the patent is invalid or uninfringed, any grievance or damages claim by a

[173] 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 Oct. 28, 2020).

generic manufacturer in connection with a patent that is later found invalid or uninfringed should not result in punishment of a patent owner for relying in good faith on a patent duly issued by the Canadian Intellectual Property Office (CIPO).

PhRMA members are also concerned that Canadian courts have taken an approach to Section 8 damages that allows for excessive damages. Subsection 8(1) compensates for all losses actually suffered in the period during which the second person/company was held off the market – a provision that, as currently interpreted by the courts, has led to instances of overcompensation. The Courts have granted damages in excess of 100 percent of the total generic market, despite holdings that the provision is meant to be compensatory and not punitive in nature. Such overcompensation is contrary to the law of damages and reflects a punitive as opposed to a compensatory theory of damages.[174, 175]

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.

Also in the area of excessive damage liability, PhRMA members are concerned about ongoing litigation under various common law theories within the provincial courts. In spite of Canadian PM(NOC) Regulations governing compensatory damages for generic companies held off the market due to patent litigation, other proceedings have been allowed to proceed under various common law theories (Statute of Monopolies,

[174] 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 Oct. 28, 2020). 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.

[175] On April 23, 2018, Eli Lilly Canada (Lilly) applied to the Supreme Court of Canada for leave to appeal in respect of a March 2018 decision of the Federal Court of Appeal. The Federal Court of Appeal had dismissed Lilly's appeal of a trial decision awarding more than $70 million to Teva Canada (Teva) under Section 8. The Federal Court of Appeal granted Teva's cross-appeal seeking to add to its recovery lost sales and an adjustment to account for an under-reporting of sales in the data relied on by both parties' experts. *Eli Lilly Canada Inc v Teva Canada Limited*, 2018 FCA 53, available at https://decisions.fct-cf.gc.ca/fca-caf/decisions/en/307557/1/document.do (last visited Oct. 28, 2020). Lilly was denied leave by the Supreme Court of Canada on November 8, 2018.

Trademarks Act, unjust enrichment and others). These cases could result in damages or liability for PhRMA members which exceed the compensatory threshold.

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

Inadequate Patent Term Restoration

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

By way of implementing CETA, Canada 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 (CSP) Regulations.[176] At a fundamental level, the *sui generis* protection provided by the CSP does not appear to grant the full patent protections that PTR is intended to provide, and instead appears to be implemented subject to an exception for "manufacture for export." While this is permitted by the CETA text, this is not consistent with Article 20.46 of the U.S.-Mexico-Canada Agreement (USMCA) or PTR in other jurisdictions.[177] Implementing PTR so that it does not confer full patent rights, *e.g.*, providing an exception for "manufacturing for export" or other infringing activities, is not consistent with the fundamental purpose of restoring patent term lost due to the lengthy marketing approval process.

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

In particular, the CSP Regulations introduce a new and complex CSP application requirement whereby only those Canadian new drug submissions (NDSs) filed within 1 year of any first international drug submission filed for the same drug (in any of EU, US,

[176] Available at http://www.gazette.gc.ca/rp-pr/p2/2017/2017-09-07-x1/html/sor-dors165-eng.php (last visited Oct. 28, 2020).
[177] *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).

Australia, Switzerland or Japan) will be CSP eligible (the "Timely Submission Requirement"). The Timely Submission Requirement is a novel requirement in Canada that is unprecedented amongst the PTR regimes of Canada's major trading partners, including the United States. PhRMA is concerned that the 1-year time limit being enforced under the Timely Submission Requirement will inappropriately bar otherwise deserving and eligible innovative medicines from benefiting from the period of *sui generis* protection.

Moreover, 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.

Finally, Canada is interpreting the CSP Regulations in a manner that is inconsistent with CETA and in a way that disregards clear clinical evidence. The Federal Court recently reinforced Canada's requirement to comply with the rationale, purview and specific constraints of the statutory scheme and any relevant international law, including CETA. However, this decision is presently under appeal.[178]

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 amendments to the Food and Drugs Act,[179] which could allow for an unprecedented disclosure of CBI contained in clinical trial and other data submitted by pharmaceutical companies in the course of seeking regulatory approval for medicines. The amendments could significantly impact incentives for drug innovation and are inconsistent with Canada's international treaty obligations.

[178] On April 7, 2020, the Federal Court issued its first judicial review decision under the CSP Regulations. The Court held that the Minister's decision to deny a CSP for the drug Shingrix® was unreasonable. While the Minister was ordered to redetermine the matter on the merits, the Minister is appealing the court's decision. The parties disagree on whether a particular vaccine adjuvant is a medicinal ingredient for the purpose of applying the CSP Regulations. Protecting vaccine adjuvants as "medicinal ingredients" promotes innovation and is consistent with the object of CETA. In determining that the Minister's decision was unreasonable, the Federal Court held that Minister's rationale demonstrated "administrative tunnel vision" and failed to address "highly relevant considerations." The appeal will be heard in Q1 2021. *GlaxoSmithKline Biologicals S.A. v. The Minister of Health*, 2020 FC 397, available at https://decisions.fct-cf.gc.ca/fc-cf/decisions/en/item/468729/index.do?q=shingrix (last visited Oct. 28, 2020).

[179] *See* http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6676418&File=4 (last visited Oct. 28, 2020).

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, including similar provisions in more recent federal legislation,[180] are inconsistent with Canada's treaty obligations under USMCA and TRIPS, and are also inconsistent with the standards and practices of other national health regulators, including the U.S. Food and Drug Administration.

Both USMCA and the TRIPS Agreement require that CBI be protected against disclosure except where necessary to protect the public. For disclosure to the public, the 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.

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. USMCA and TRIPS do not refer to disclosure for the promotion of health, but rather to disclosure needed to protect the health of the public.

Finally, the 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.[181] 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 the amended Food and Drugs Act. However, the document is a non-binding guidance as opposed to binding law or regulations.

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[180] *Hazardous Materials Information Review Act*, Amendments to the Act, 2019, Subdivision H, Disclosure of Confidential Business Information, available at https://www.parl.ca/DocumentViewer/en/42-1/bill/C-97/royal-assent (last visited Oct. 28, 2020).

[181] *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-droguesdangereuses-amendments-modifications-eng.php (last visited Oct. 28, 2020).

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.[182]

More recently, in December 2017, Health Canada released a draft regulatory package that would amend the Food and Drug Regulations (Regulations) and facilitate automatic public access to manufacturer submitted clinical information following the issuance of a final Health Canada regulatory decision.[183] As previously noted, those Regulations were published March 20, 2019.

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

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

PhRMA members therefore urge the U.S. Government to press the Government of Canada to ensure that regulations to implement these amendments to the Food and Drugs Act are consistent with Canada's international treaty obligations.

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[182] *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 Oct. 28, 2020); 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 Oct. 28, 2020).

[183] 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 Oct. 28, 2020).

CHILE

PhRMA members are very concerned about recent actions by the National Congress that are pressuring Chile's government to issue compulsory licenses (CLs) for certain innovative medicines. These developments add to longstanding intellectual property (IP) problems, including Chile's failure to fully implement its patent enforcement and regulatory data protection (RDP) obligations under the U.S.-Chile Free Trade Agreement.

Since October 2019, Chile has faced significant social unrest. This has forced the government to radically review its policy and legislative agenda, including an originally planned plebiscite on October 25, 2020, to determine whether Chile will amend its Constitution.

Key Issues of Concern:

- **Compulsory licensing**: Action is needed to protect American innovation in Chile. Key provisions of the "Medicines II" bill have already been negotiated by legislators and are awaiting final consideration by a Senate conference committee, including articles on compulsory licensing. These Articles establish extremely vague and ambiguous grounds for the government and third parties to seek compulsory licenses in Chile. In addition, a series of politically-driven resolutions were passed by the Chilean Congress calling for the compulsory licensing of innovative medicines that provide a cure for many patients suffering from hepatitis C.

- **Weak patent enforcement**: PhRMA member companies believe that the Chilean Government's draft legislative and regulatory proposals would, if approved by the Chilean National Congress and implemented, represent a step toward compliance with Chile's treaty obligations. Unfortunately, this legislation, introduced in 2012, continues to be unlikely to move forward in the near term.

- **Unjustified delays during patent prosecution**: Patent applicants are not being adequately compensated for INAPI delays, due to arbitrary interpretations by the TDPI (Industrial Property Court) of what constitutes an unjustified delay during the patent prosecution process.

- **Proposed trademark limitations**: Chile's Congress is currently considering a bill to significantly limit the use of trademarks in all pharmaceutical products packaging through proposed amendments to the Medicines II Law. That bill also makes the use of the International Non-Proprietary Name (INN) mandatory in drug prescriptions and regulates the situations in which a doctor can prescribe using the medicine's corresponding trademark.

- **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.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Intellectual Property Protection

Compulsory Licensing

The "Medicines II" bill is now pending consideration in a conference committee of the Chilean Congress. Key provisions of that bill have already been negotiated and agreed upon by legislators, including articles on compulsory licensing. These articles seek to modify Article 51 N° 2 of the Industrial Property Law by introducing vague and ambiguous grounds to seek compulsory licenses on biopharmaceutical products. Specifically, the Article enables the government and third parties to seek a compulsory license if the relevant product is "inaccessible." Despite not defining the term "inaccessible," that Article underscores that a product could be determined "inaccessible" on economic, financial, and geographical grounds. A finding of inaccessibility or lack of supply, based on the vague grounds established by the bill, would permit the Chilean government to grant CLs. PhRMA and its member companies are concerned about possible adoption of this Article, which would be inconsistent with international best practices and Chile's international obligations, and would implement an erroneous understanding of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in order to allow for CLs to be granted on overly broad grounds.

Additionally, the Medicines II Bill expands Chile's discretion to consider and issue government use licenses. That provision enables the government and/or third parties to import, manufacture, or use a patented product without the authorization from the relevant patent holder(s). The Bill also proposes a new definition of the legal nature of medicines, opening the door for future legislation making it easier to restrict related patent rights.[184]

Moreover, a series of politically-driven Congressional resolutions have passed through the Chilean Congress calling for the compulsory licensing of innovative medicines that provide a cure for many patients suffering from hepatitis C, among other therapeutic areas:

[184] The "Medicines II" bill also proposes to significantly restrict pharmaceutical medical representatives from visiting doctors. These interactions provide an important forum for manufacturers and health care professionals to exchange valuable educational information about medicines to ensure medicines are used correctly.

- On January 11, 2017, the Chilean Chamber of Deputies of the National Congress passed Resolution No. 798.[185] 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 N° 19.039 to facilitate [medicines] acquisition at *competitive prices*."[186] It also calls for the prioritization of certain classes of medicines to be considered for compulsory licensing and highlights the alleged price reductions realized by certain countries after issuing CLs on biopharmaceutical products.

- In addition, the Chamber of Deputies approved Resolution No. 1014 in January 2018, seeking to establish that access to certain hepatitis C medicines is not consistent with the constitutional right to health, thus warranting, they assert, a CL.

- Further, on March 9, 2018, the former Minister of Health issued Resolution 399 declaring that the compulsory licensing of hepatitis C treatments would be justified on public health grounds. In June 2018, the Chamber of Deputies approved Resolution No. 68 requesting the Minister of Health to request directly a CL for hepatitis C medicines. On August 28, 2018, the new Minister of Health issued Resolution 1165 rejecting the patentee's challenge to Resolution 399/2018. As a result of this latest resolution, there remains a heightened risk of a CL being issued in Chile.

The research-based pharmaceutical industry is very concerned that these actions inappropriately expand the scope of the government's compulsory licensing authority to pursue objectives that are not clearly related to legitimate health emergencies.

Weak Patent Enforcement

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

During 2011, the Chilean Government 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:

[185] Resolution No. 798, Chamber of Deputies, available in Spanish at https://www.camara.cl/verDoc.aspx?prmId=4692&prmTipo=RESOLUCION (last visited Oct. 28, 2020).
[186] *Id.* (emphasis added) (unofficial translation).

- 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.

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 2008, the Chilean Government, through the Under Secretariat of Economy and specifically the DPI, issued a special resolution "Circular N° 9," in part to remedy these unacceptably long delays. One of the Circular'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 definitive decision within 4 to 5 years. Therefore, while PhRMA supports the Chilean Government's work to improve patent application processing times, it believes that some further work must be done to expedite a bit more patent application reviews in Chile. PhRMA commends Chile's recent implementation of a Patent Prosecution Highway (PPH) partnership with USPTO to further improve prosecution time of patent applications.

Furthermore, despite a right granted to applicants in the Chilean Patent Law to request an extension to the patent term to offset unjustified delays during the patent prosecution process, applicants are being denied adequate patent term compensation due to arbitrary interpretations by the TDPI of what constitutes "unjustified delay" and narrowly interpreting patent term restoration requests. Without any legal basis for doing so, the TDPI has determined that many types of delays that are outside of the applicants' control are in fact justified, resulting in inadequate patent term restoration in Chile.

PhRMA is hopeful that certain issues regarding patent prosecution, including the application of the 3 year prosecution rule, will be addressed by the new Industrial Property Law which should become law by the end of the 2020 or the beginning of 2021.

Trademarks

In January 2020, Chile's Senate approved the third constitutional stage of the "Medicines II" bill, which is now pending final consideration by a Senate conference committee. That bill, if enacted, will significantly limit the use of trademarks or other "fanciful" designations for any prescribed medicine. A trademark for a medicine designates its source and helps doctors and patients identify the quality, safety, and intrinsic effectiveness of a given product – reputational capital and goodwill that manufacturers strive to build over time. Restricting the use of trademarks for medicines would significantly deviate from the current trademark protection guaranteed in Article 19 of Chile's Constitution and from Chile's multilateral (*e.g.*, WTO TRIPS) and bilateral (*e.g.*, U.S.-Chile FTA) obligations.

The Bill also severely limits the prescription of medicines based on their trademarked names by requiring that prescribers use the International Non-Proprietary Names (INNs) instead. This requirement has already been reviewed and approved in the Senate conference committee.

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 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 Instituto de Salud Pública de Chile's obligation to not 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 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.

Although PhRMA recognizes that enactment of Supreme Decree 107 constituted 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 deficiencies.

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 health care system. China is taking positive steps to strengthen biopharmaceutical intellectual property (IP) protection and enforcement, align its drug regulatory review and approval process with international standards, and improve government reimbursement for innovative medicines. However, PhRMA and its member companies are concerned about non-transparent and unpredictable government pricing and reimbursement policies, downstream regulatory approval barriers, burdensome biological sample exportation policies, areas of divergence from international registration standards, rampant counterfeiting of medicines, and under-regulated active pharmaceutical ingredients (APIs). In addition, we remain concerned about lax IP protections, including ineffective regulatory data protection (RDP) and patent enforcement and inconsistent patent examination guidelines.

We commend the governments of China and the United States for securing Phase One of the Economic and Trade Agreement (Phase One Trade Agreement) between the two countries in January 2020. We look forward to the implementation of the Phase One provisions on supplemental data, early resolution of patent disputes, and patent term extension in a manner that results in meaningful improvement in IP protection for innovative medicines in China. We also welcome the countries' affirmation of their commitment to provide "effective protection and enforcement of pharmaceutical-related intellectual property rights, including patents and undisclosed test or other data submitted as a condition of marketing approval", and stand ready to work with both governments to ensure provision of these critical IP protections in China. Finally, industry commends the countries for their strong commitments to "ensure fair and equitable market access" (Article 1.2), "take effective and expeditious enforcement actions against counterfeit pharmaceutical and related products" (Article 1.18), and ensure "that the transfer of technology occurs on voluntary, market-based terms" (Chapter 2).

PhRMA is encouraged by China's ongoing work to strengthen its drug regulatory framework, including through the Drug Administration Law (DAL) (August 2019), which includes provisions on nationwide-adoption of the marketing authorization holder (MAH) system and facilitates drug review and approval; new revisions to the Drug Registration Regulation (DRR) (July 2020); the Central Committee of the Communist Party / State Council Opinions (CCP/State Council Opinions) on Strengthening Intellectual Property Rights Protection (IPR) (November 2019) and on Deepening the Reform of the Review and Approval System and Encouraging the Innovation of Drugs and Medical Devices (October 2017); and the draft NMPA Circulars (Nos. 52-55) issued in May 2017. NMPA's May 2017 accession to the International Council on Harmonization (ICH), June 2018 elevation to the ICH Management Committee and its subsequent efforts to implement ICH guidance documents further exemplifies China's regulatory reform efforts.

Many of the above-mentioned Opinions and draft proposals include provisions to bolster IP protection, and PhRMA is eager to continue supporting China in its reform effort

to strengthen RDP, patent enforcement and patent examination guidelines. Although we have not seen progress on reforms to advance RDP this year, we were encouraged to see that the recently approved amendment to the Patent Law (October 2020) included language to provide both patent term adjustment (PTA) (for patent office delays) and patent term restoration (PTR) (to compensate for a portion of the lengthy development and regulatory approval process), as well as a form of early patent dispute resolution (specifically elements of a "patent linkage" system). However, several important provisions related to these mechanisms were still ambiguous, leading to uncertainty about their scope, implementation and value for biopharmaceutical innovators in China and abroad. The draft measures for the Implementation of the Early Drug Patent Dispute Resolution System (September 2020) provide some necessary clarity on key issues, but some provisions in the draft are confusing and potentially problematic. Furthermore, we are very concerned that NMPA since January 2019 has granted at least 33 marketing approvals to local drug companies to make infringing copies of innovative medicines while the reference products in each case are still subject to patent protection. These actions have continued since the Phase One Trade Agreement was concluded and appear designed to benefit Chinese companies at the expense of innovators in the United States and elsewhere. We are further concerned that at least two of these infringing products have recently been invited to apply for inclusion on the National Reimbursement Drug List (NRDL). PhRMA strongly encourages China to move swiftly to implement the proposed reforms in a manner that enables biopharmaceutical innovators both in China and abroad to meet the growing needs of China's patient population and in a manner consistent with its commitments in the Phase One Trade Agreement.

Further, in order to meet the needs of China's patient population, particularly those with rare diseases and for whom there is unmet need, PhRMA recommends that China consider further strengthening of the regulatory framework to incentivize the development of treatments for people with rare diseases in China. PhRMA notes the documented success of regulatory incentives, namely orphan drug designation and companion regulatory exclusivity, in achieving significant increases in drug development and marketing authorization of these important treatment options in other regions.

On the regulatory side, the recently revised DAL and DRR continue to not define the term "new drug." However, China has maintained the definition of a new drug as one that has not yet been marketed anywhere in the world, and not simply new to China, in lower level application guidelines for drugs and biologics.[187] These guidelines also maintain the position that an innovative drug is one category of new drug and include separate categories for drugs/biologics already approved overseas. This position is inconsistent with international standards, under which new drugs are those that are new to a specific country, and potentially paves the way for China to treat drugs manufactured and approved abroad differently (***e.g.***, the expedited program for breakthrough drugs is

[187] Chemical Drug Registration Categorization and Application Requirements (NMPA No. 44 2020), available at https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20200630180301525.html (last visited Oct. 28, 2020); Biological Product Registration Categorization and Application Requirements (NMPA No. 43 2020), available https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20200630175301552.html (last visited Oct. 28, 2020).

only available for new drugs).[188] These developments undercut the laudable goals of the CCP/State Council Opinion, DAL, DRR and China's long-term innovation plans. This globally unique approach 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 drug research and development and collaboration with partners in China and around the world that promotes innovation. Given the problems that this definition creates, we urge China to amend the application guidelines and define "new" to mean newly approved for marketing in China, as opposed to new to the world.

Moreover, there are some regulatory requirements that create barriers to development in China. China also generally requires substantial testing for the Clinical Trial Applications (CTA) and, in connection with this testing, the production of detailed manufacturing information. The newly revised DRR that became effective on July 1, 2020 has removed the specific provision on testing product at the CTA stage and replaced it with a section on testing for registration applications more generally, leaving the requirement for CTA-related testing vague. In practice, however, we understand that CTA applicants must routinely submit to this testing and are required to submit substantial related manufacturing information, such as standard operating procedures, batch records, and validation reports. This is sensitive trade secret and confidential information that is not normally required at this stage of development.

In addition, Human Genetic Resource (HGR) regulations require approval of clinical research projects involving a foreign sponsor or other foreign party prior to the commencement of the clinical trial or research. The HGR regulations prohibit human sample collection by foreign parties and restrict the use, analysis, and transfer of such samples and related data except in the context of an approved collaboration with Chinese parties, such as medical institutions or enterprises with no foreign investment.[189] This process has added months (three to five months) to the timeline for trials with heavy penalties for non-compliance. This is a significant barrier to innovation in China.

On the government pricing front, PhRMA is encouraged by the 2017 and 2019 updates to the NRDL as well as the addition of 17 oncology medicines to the NRDL in 2018. In addition, we welcome China's efforts to develop a regular mechanism for government reimbursement and a value assessment system, including through the Interim Administrative Measures for the National Reimbursement Drug List in July 2020 and by initiating the 2020 update to the NRDL. 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 evidence-based methodologies for drug value assessment and an enhanced role for commercial health insurance.

[188] Drug Registration Regulation, Article 59 (NMPA 2020).
[189] Human Genetic Resource Regulations, Articles 21-22 (State Council No. 717, 2019) ("HGR Regulations").

A fair and transparent regulatory and legal process is another priority element for a sound and sustainable policy environment for innovative medicines 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.[190] PhRMA thus welcomes the commitment in Article 8.5 of the Phase One Trade Agreement to afford stakeholders at least 45 days to comment on all proposed measures to implement this Agreement.

Key Issues of Concern:

- **Government pricing and reimbursement**: PhRMA welcomes the 2017, 2019 and 2020 updates to the NRDL as well as the addition of 17 oncology medicines to the NRDL in 2018. We encourage the Chinese government to shift towards a more timely, transparent, predictable and evidence-based reimbursement system, in which manufacturers may apply for reimbursement at any time, evidence-based methodologies are adopted for product value assessment and completed within a pre-defined period following the application (*e.g.*, within 90 days), and negotiations between manufacturers and the responsible government agency take into account the product's value and the need to promote future innovation versus focusing solely on price and occur periodically (*e.g.*, semi-annually). PhRMA commends the National Healthcare Security Administration (NHSA) for establishing an annual reimbursement mechanism and negotiation process, and we urge China to continue taking steps to better align its pricing and reimbursement system with international best practices.

- **Regulatory approval process**: NMPA has undertaken significant reform efforts to accelerate the drug review and approval process and align its regulatory framework with international standards. PhRMA is encouraged with the development of expedited review pathways (breakthrough, conditional approval, priority review and special review) that will facilitate accelerated development and approval of new drugs. It is important that the process and timelines for these pathways are clearly defined. The revised DAL codifies existing expedited programs for conditional approval for urgently needed drugs used to treat life-threatening illnesses and other priority categories described above. The recently revised DRR establishes separate programs for breakthrough therapies, conditional approval, priority review, and special review to house these and other various categories. PhRMA recommends that NMPA develop regulatory guidance regarding the conversion of conditionally-approved medicines to regular approval. It is also important for NMPA to implement policies that leverage the best science

[190] *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 Oct. 28, 2020) (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.").

and innovation to improve the efficiency and predictability of this conversion process.

At the same time, there remain significant impediments to development that delay the clinical trial timeline in China. One worrying impediment is the additional approval or notification now applicable to all trials conducted in China by foreign companies or their affiliates that collect *any* samples that contain Chinese human genetic resources, regardless of whether those samples are for genetic testing. Pursuant to HGR Regulations that have been in effect since 1998, but were largely unenforced until 2015, foreign applicants must apply to the Human Genetic Resources Administration Office of China (HGRAC), under the Ministry of Science and Technology (MOST) before they can collect and transfer these samples and associated data. The trial may not commence until this process is complete. An additional, increasingly concerning impediment is NMPA's unusually detailed review of the manufacturing process at the CTA stage, which includes asking questions that would require revealing proprietary information about manufacturing steps and requesting additional data beyond what is required on the face of the application materials. This detailed analysis is not in line with international practice and is particularly concerning for innovative products such as complex biologics. The detailed analysis delays the clinical trials and raises concerns about potential disclosure of manufacturing CCI to third parties.

- **Weak patent enforcement**: Transparent mechanisms and legal standing to bring suit are needed in China to ensure parties are afforded a meaningful opportunity to resolve patent disputes before potentially infringing pharmaceutical products are launched in the market. We welcome the recently approved Patent Law (October 2020), which includes a provision that appears to provide a mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products before those products are launched. However, several important provisions related to these mechanisms are ambiguous, leading to uncertainty about their scope, implementation and value for biopharmaceutical innovators in China and abroad. PhRMA and its member companies stand ready to work with both governments on the implementation of an effective patent enforcement system in China, consistent with its commitments in Article 1.11 of the Phase One Trade Agreement and with a view to establishing an effective and commercially meaningful enforcement system for medicines patents in China.

- **Loss of patent term due to regulatory processes**: Patent Office delays, and lengthy regulatory approval processes for pharmaceutical products result in a significant loss of effective patent term for such products. Given these current challenges, we commend the inclusion of effective patent term extension provisions in Article 1.12 of the Phase One Trade Agreement and would refer the Chinese Government to the proposed revised language that we submitted in response to second draft amendment to the Patent Law in August 2020 (regarding the PTA and PTR provisions) that would ensure that the resulting mechanisms achieve their objectives of encouraging the development of innovative medicines.

- **Lack of regulatory data protection**: China committed as part of its accession to the World Trade Organization (WTO) to provide a six-year period of RDP against unfair commercial use for clinical test and other data submitted to secure approval of products containing a new chemical ingredient. In practice, however, China does not have a mechanism to grant RDP and the criteria are inconsistent with China's commitments. We thus strongly welcomed the draft NMPA measures on the Implementation of Drug Clinical Trial Data Protection (April 2018), which proposed up to six and 12 years of RDP for chemically synthesized drugs and therapeutic biologics, respectively. This draft measure represented a strong first step toward reform in this area, and we urge implementation of final measures that are consistent with international best practices and China's renewed commitment to provide RDP as affirmed in the chapeau to Section C of Chapter One of the Phase One Trade Agreement.

- **Restrictive patentability criteria**: In April 2017, the China National Intellectual Property Administration (CNIPA)[191] amended its Patent Examination Guidelines that would require examiners to take into account post-filing experimental data submitted by an applicant. Furthermore, in September 2020, the Supreme People's Court issued the Judicial Interpretation of Some Issues in Hearing Administrative Cases of Granting and Determination of Patent Rights, in which Article 10 prescribed that the Court would review post-filing experimental data.[192] PhRMA welcomed these positive steps, but concerns remain regarding CNIPA/SPC implementation, especially at the Patent Reexamination Board level.

  In addition, certain therapeutic methods, referred to as "specific therapeutic methods," essentially cannot be protected by patents in China. 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.

- **Counterfeit medicines**: We commend the two governments on the commitments in Section G of Chapter One of the Phase One Trade Agreement to combat counterfeiting. Over the last several years, China has implemented national plans to improve drug safety and crack down on the production and sale of counterfeit medicines, resulting in several positive and tangible actions on the enforcement front. However, the production, distribution and sale of counterfeit medicines and unregulated APIs continue to pose a problem in China and continue to pose a threat to China and its trading partners. The revised DAL expressly subjects APIs to applicable good manufacturing practice regulations, but also removes APIs from the scope of the definition of drug, which leaves the application of other drug

[191] In August 2018, the State Intellectual Property Office (SIPO) changed its name to the China National Intellectual Property Administration (CNIPA). Although many of the policies and draft proposals referenced in this submission were issued under the name of SIPO, we have used CNIPA consistently throughout this document.

[192] Provisions of Some Issues in Hearing Administrative Cases of Granting and Determination of Patent Rights (I) (Supreme People's Ct. September 11, 2020), available at http://www.court.gov.cn/zixun-xiangqing-254761.html (last visited Oct. 28, 2020).

regulations to APIs unclear. Also, the DAL removes the prohibited act of manufacturing or importing unapproved drugs from the definition of counterfeit drug. The DAL now further states that individuals who import small quantities of unapproved drugs that are approved abroad may receive lesser or no penalties. That provision is not limited to drugs that are not for resale. It is not yet clear how these provisions will affect enforcement against counterfeit drugs.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Pricing and Reimbursement

To appropriately address 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 evidence-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.

National Reimbursement Drug List

PhRMA welcomes the 2017, 2019 and 2020 updates to the NRDL as well as the addition of 17 oncology medicines to the NRDL in 2018. These important steps and the government's commitment to conduct annual negotiations will significantly improve the access and affordability of innovative medicines for patients in China. While any additions to the NRDL are a positive development, it appears that the negotiation process for these new medicines has lacked transparency and has diverged from global best practices that support sound government pricing and reimbursement systems. There remain major implementation challenges, such as low reimbursement percentages and hospital listing restrictions, and cost control regulations, which will continue to restrict patient access to innovative and life-saving medicines. Only 20 percent of new medicines launched globally in the past decade are available in China, and among these fewer than 40 percent are included in the NRDL.[193]

We appreciated the opportunity to comment on the NHSA draft Interim Administrative Measures for the National Reimbursement Drug List and welcomed the deletion of language that would have (1) prioritized products with "independent intellectual property" (*i.e.*, developed and owned by a Chinese legal entity) for inclusion in the NRDL, and (2) allowed local medical institutions to conduct secondary negotiations to achieve prices below the nationally negotiated reimbursement payment standard during the two-year NRDL contract renewal period. In addition, NHSA extended the marketing

[193] PhRMA analysis of IQVIA Analytics Link and FDA, EMA NHSA, NMPA and PMDA data. May 2020.

authorization cutoff date from December 31, 2019 to August 17, 2020, which made eligible for the NRDL at least an additional 22 innovative medicines and 15 indications for existing medicines from PhRMA members.

PhRMA recommends that the Chinese government continue to take steps 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 on a more regular basis. The drug clinical assessment should be transparent, evidence-based, focused on clinical benefits and independent of 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 Procurement Policies

In late 2018, NHSA initiated the "4 + 7" volume-based procurement (VBP) pilot program to centrally procure off-patent and generic products that passed a generic quality consistency evaluation (GQCE) for all public hospitals in 11 cities (*i.e.*, the four directly managed municipalities of Beijing, Shanghai, Chongqing and Tianjin, and seven key cities in other provinces), which collectively represent around a third of the pharmaceutical market. Twenty-five of the 31 molecules proposed for procurement were selected based on the lowest bidders, with an average price cut of 52 percent. The pilot program substantially lowered procured prices for off-patent and generic products, reducing the economic burden on Chinese patients.

In September 2019, the Chinese government expanded the program to most of China but modified the procurement methodology to allow three suppliers with the lowest bids. Subsequent procurements have increased the number of allowed suppliers. For example, in December 2019, the National Drug Joint Procurement Office (the procurement agency authorized by the NHSA) organized the second national VBP for 33 products and allowed six suppliers with the lowest bids. In August 2020, the National Drug Joint Procurement Office organized the third national VBP for 55 products and allowed eight suppliers with the lowest bids.

While allowing multiple winning bidders is a positive development, PhRMA urges the Chinese Government to ensure that by awarding all supply to those with the lowest bids the national VBP program does not reduce the number of quality suppliers in the market, increase the risk of drug shortages and hinder patient and physician choice in selecting the clinically most appropriate medicines. PhRMA encourages the Chinese government to provide additional sales channels to ensure that patients have the full range of treatment options available.

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, including shorter review times for CTAs and the expedited programs described above. Although there were a number of examples where NMPA granted expedited regulatory approval consistent with timelines in the U.S. and EU or even faster, China remains an outlier in the biologic and vaccine drug development and approval process compared to other regulatory authorities. We encourage China to address these issues rapidly, given the promise that a significant number of therapies currently in development have shown and the importance of predictable and timely review processes to encourage innovators to bring these new therapies to China for regulatory approval.

China continues to catch up with other countries with respect to the number of innovative medicines available. Statistics show that NMPA's Center for Drug Evaluation approved 88 small-molecule drug NDAs in 2019 compared with 132 in 2018, 113 in 2017 and 23 in 2016.[194] It approved 5 preventive biologic NDAs and 67 therapeutic biologic NDAs. Still, just eight percent of the new medicines launched between 2011 and 2017 are available in China.[195] Because of China's stringent regulatory requirements and lengthy review and testing procedures, a "drug lag" remains in China.

PhRMA is encouraged by China's recent legislative and regulatory developments including the recently revised DAL and certain aspects of the new DRR which implement reforms that will speed up the approval process for some drugs. This new legislation continues to support greater flexibility in the drug development process, including a shortened timeline for the approval of clinical trials, streamlined amendment and reporting processes for clinical trial applications, and strengthened channels for stakeholder-NMPA communications. Furthermore, we support NMPA's implementation of various conditional approval programs, including for two lists of drugs approved in the U.S., Europe, and Japan that China considers to be urgently needed for clinical use. We also support the issuance of guidance in July 2018 on the acceptance of overseas clinical trial data.

Additionally, NMPA's May 2017 accession to the ICH and successful election to the ICH Management Committee further exemplifies China's reform efforts. Being an ICH member will further encourage NMPA's harmonization with international regulatory standards, including but not limited to the China Pharmacopeia 2020, enforcement of GXP, and further implementation of standardized electronic submission for new drug applications (eCTD) and safety reporting, which will enable companies to pursue global simultaneous drug development and accelerate Chinese patient access to innovative

[194] 2019 Yearly Drug Evaluation Report, available at https://www.nmpa.gov.cn/zwgk/tjxx/tjnb/20200805110116109.html (last visited Oct. 28, 2020).
[195] PhRMA analysis of IQVIA Analytics Link.

medicines. Industry and other ICH stakeholders have high expectations for NMPA to implement fully ICH's technical guidelines in the coming years. CDE is working on implementing various ICH guidance documents and established related training programs.

Clinical Trial Applications

To help China further integrate into the global innovation network and reduce the time it takes for innovative medicines to reach patients, it is critical for China to shorten the CTA review and approval time. As discussed above, China now permits a new drug clinical trial to move forward if NMPA has not raised objections within 60 business days. Under the newly revised DAL and DRR, this 60-day implicit approval should apply to all trials. Also, the newly revised DAL now permits filing administration of clinical trial sites to proceed via a faster notification process to increase the availability of resources. This will significantly reduce the drug lag as China's CTA review time has represented the largest regulatory barrier for multinational companies in China. Therefore, PhRMA recognizes and applauds the important steps NMPA is taking to make the development process more efficient.

Based on PhRMA member company experience in other major markets, it is important for NMPA 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 coupled with science-based and risk-based decision making (principles embedded in ICH guidelines) that applies equally to both local and foreign manufacturers.

Specifically, we are encouraged that the recently revised DAL and DRR create a more uniform system that does not draw distinctions between local trials and international multicenter trials, building on prior reports in this area. For example, in 2017 NMPA began to permit International Multi-Center Trials (IMCTs) to commence in China in parallel with the rest of the world, with the exception of vaccine trials. IMCTs may now also support registration in China without going through a lengthy waiver process that NMPA imposed between 2013 and late 2017. These reforms coupled with the increasing acceptance of foreign data have the potential to further facilitate the drug development process. With respect to foreign data acceptance, further clarity on whether ethnic differences require additional clinical studies in China and whether this data can be accepted without filing a time-consuming clinical trial waiver application, will help to avoid any uncertainty in China's drug registration process.

One of the more significant recent impediments to development has been an additional approval or notification now applicable to all trials conducted in China by foreign companies or their affiliates that collect *any* samples that contain Chinese human genetic resources, regardless of whether those samples are for genetic testing. Pursuant to HGR Regulations that have been in effect since 1998, but were largely unenforced until 2015, foreign applicants must apply to the HGRAC, under MOST, before they can collect and transfer these samples and associated data. The trial may not commence until this

process is complete. While an amendment to the HGR Regulations in 2019 now permits manufacturers to submit a notification (rather than an approval application) for trials that are intended to support a marketing application in China, provided that no samples from the trial will be exported from China, the filing criteria is very stringent and the vast majority of cases do not qualify. In addition, other trials still require approval.

The HGR application process potentially adds months to the development timeline and restricts both the movement of samples and data inside of China and abroad. Under the 2019 amendment, applicants must file any data that they intend to transfer outside of China with the HGRAO. This situation presents a hurdle for China to participate in global development and contradicts various reform policies to encourage innovation. The additional conditions for HGR research by foreign companies, limitations on data transfer and storage, and intellectual property sharing requirements described below raise serious questions about China's compliance with its international commitments undertaken pursuant to WTO agreements and Article 2 of the Phase One Trade Agreement. At minimum, to improve and shorten the HGR process, clear and detailed guidelines on document requirements, standardized assessment and approval criteria and a systematic communication channel between HGRAO and sponsor are needed, consistent with China's due process and transparency commitments in Article 2.4 of the Phase One Trade Agreement.

PhRMA's view on intellectual property sharing related to certain biological material in connection with the HGRAO process is noted below.

An additional, increasingly concerning impediment to development is NMPA's unusually detailed analysis of the manufacturing process at the CTA stage, which includes asking questions that would require revealing proprietary information about manufacturing steps and requesting additional data beyond what is required on the face of the application materials. This is not in line with international best practice. The detailed analysis not only delays the clinical trials but also raises concerns about potential disclosure of manufacturing CCI to third parties. In these instances, NMPA has been unwilling to permit redactions of these records or accept less sensitive substitutes.

Drug Approvals Process

PhRMA welcomes a number of other key regulatory reforms described above because they represent positive movement in China's progress toward supporting a simultaneous global development/ registration framework in China. These reforms are consistent with industry's primary recommendations, including streamlined processes for IMCT registrations, strengthened expedited programs, acceptance of foreign clinical data to satisfy registration in China, structured agency consultation, and the establishment of an orphan disease list. Although the establishment of an orphan disease list is an encouraging step to better serve patients with rare diseases, it only contains 121 rare diseases of the about 8,000 rare diseases in total known today. As it is impossible to create a complete list, PhRMA suggests to replace this list with a definition of prevalence, as for instance is the approach in the United States. In addition, PhRMA encourages

China to pair the establishment of an orphan disease definition with an orphan drug regulatory framework that provides for the expedited development and review of orphan drugs, as well as regulatory incentives.

The newly revised DAL adopts a MAH system nationwide and applies it to ex-China applicants. This system unifies the previously separate imported and domestically made drug pathways in certain ways. Applicants can now receive a marketing authorization tied to a product and have the freedom to contract out manufacturing, whether in China or abroad, and distribution to multiple partners. Also, the newly adopted DAL unifies what were previously separate applications for the drug product, the active ingredient, excipients and packaging materials. Materials related to the latter three will be registered to certain applicants as part of a drug master file (DMF) system that began in 2017. Although the bundled system streamlines the review process, some of the required administrative and technical information for a DMF is burdensome and unnecessary to ensure product quality and safety.

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

Intellectual Property Protection

In 2017 and 2018, China released a series of proposed policies that had the potential to strengthen its intellectual property protection and enforcement system for innovative medicines. Specifically, these proposals could 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 April 2018 draft NMPA measures on the Implementation of Drug Clinical Trial Data Protection, propose up to six and 12 years of RDP for chemically synthesized drugs and therapeutic biologics, respectively. The CCP/State Council Innovation Opinion, which was issued in October 2017, was the first time that this level of the Chinese government has openly endorsed RDP and patent linkage in a meaningful way. In addition, the NMPA draft Circulars, which were issued in May 2017, proposed the establishment of a patent linkage system and specific RDP terms. Until the signing of the Phase One Trade Agreement in January 2020, little action had been taken to implement these proposals. On the contrary, the new DAL (August 2019) as well as the new DRR (July 2020) did not include any provisions to advance these critical IP protections. Even

worse, since January 2019, NMPA has repeatedly approved follow-on products while the reference products in each case are still subject to patent protection.

In light of this standstill and ongoing patent infringement, PhRMA and its member companies strongly welcome the IP commitments in the Phase One Trade Agreement and look forward to securing expeditious implementation of these commitments in a manner fully grounded in international best practices. We acknowledge the progress made this year in China to advance reforms (including the recently approved Patent Law in October as well as the draft measures for the Implementation of the Early Drug Patent Dispute Resolution System and the draft amendment to the CNIPA Patent Examination Guideline in September). However, further work is required to ensure that the final mechanisms are implemented in a manner that advances innovation and patient access, is consistent with China's international commitments, provides meaningful market access and ensures that U.S. biopharmaceutical companies can compete on a level playing field with China's domestic industry.

Weak Patent Enforcement

Consistent with Article 1.11 of the Phase One Trade Agreement, transparent mechanisms and a legal standing to sue 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, NMPA has repeatedly approved infringing copies of patented medicines since 2019, and research-based pharmaceutical companies currently have no effective legal means to resolve patent disputes prior to the marketing of those infringing drugs. Further, although China's laws and regulations provide for injunctive relief, in practice injunctions are rarely, if ever, granted in the context of preventing premature follow-on product market entry, due to high procedural barriers.

Since January 2019 there has been a significant uptick in NMPA granting market approvals to local drug makers for a variety of medicines used to treat common conditions – even though these drugs are all still under patent (including their basic compound patent). To date, we are aware of 33 such generic approvals. In taking these actions, NMPA has knowingly facilitated the infringement of patents owned by inventors based in the United States and elsewhere outside China. In addition, these actions continued after the signing of the Phase One Agreement.

Objections by innovative drug makers have not changed any outcome. In some cases, the Chinese companies have challenged the patents while applying for marketing approval, but no patent has been invalidated. The slowness of the Chinese patent court system and the near impossibility of securing preliminary injunctions to keep infringing products off the market already make it very difficult for innovative drug makers to stop patent violations. These NMPA actions seriously exacerbate the problem in China.

In addition, parallel patent enforcement proceedings through China's judiciary and CNIPA's Patent Reexamination 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 CNIPA'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.

In this light, we are encouraged by the recently approved Patent Law and the draft Measures for the Implementation of Patent Linkage which include elements of a patent linkage system, including: a) notice to innovators of potentially infringing follow-on applications referencing the original application prior to approval of such follow-on applications; and b) a stay of marketing approval pending the resolution of disputes concerning those patents. Critically, the Patent Law would also appear to create a cause of action to allow for the resolution of the patent dispute during the stay of marketing approval. We look forward to working with the Chinese and U.S. governments to ensure that China implements an effective patent enforcement system consistent with its commitments in Article 1.11 of the Phase One Trade Agreement.

Lack of Regulatory Data Protection

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).[196] While China's DAL and DRR anticipate a six-year period of protection for test data of products containing a new chemical ingredient,[197] in practice there is no mechanism in China to prevent the unfair commercial use of safety and efficacy data generated by innovative pharmaceutical companies.

Moreover, even if there were a mechanism for granting RDP in China, key aspects of the RDP provisions are inconsistent with TRIPS Article 39.3. 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.[198]

[196] 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.
[197] *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.
[198] 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." *See* Fact Sheet: 23rd U.S.-China Joint Commission on Commerce and Trade (Dec. 19, 2012), available at

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 all new pharmaceutical products.

Second, RDP should be granted to any product that is "new" to China, *i.e.*, has not been approved by NMPA. Proposals to date, however, suggest that China would only grant RDP to pharmaceutical products that are "new" to the world – in other words, products that make their international debut in China.[199] 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. PhRMA is concerned that this definition of "new drug" or similar concepts may continue to create risk that a drug approved or marketed first outside of China may receive weaker or no priority or protection in China. This approach would also be discriminatory in that it would favor domestic industry and innovation, contrary to China's international obligations.

As it stands, China provides no period of protection during which a non-originator (or follow-on) applicant is prevented from relying on the data submitted to NMPA or a foreign regulatory agency to secure approval of the originator product. This practice gives an unfair commercial advantage to the follow-on manufacturer by permitting it to rely on the full clinical data submitted by an innovator – which the follow-on manufacturer did not incur the costs to produce – while having to submit only a small amount of China-specific supplemental data to NMPA. NMPA 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.[200]

In light of these deficiencies, we welcomed the draft NMPA measures on the Implementation of Drug Clinical Trial Data Protection, which proposed up to six and 12

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https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2012/december/23rd-JCCT (last visited Oct. 28, 2020). Following many years of discussion in the JCCT and other venues, this commitment was a positive development. Unfortunately, this commitment remains unfulfilled.

[199] NMPA continues to draw distinctions between drug applications in China relative to approvals in other countries. The February 2016 NMPA "Chemical Drug Registration Category Work Plan," defined a "new drug" as a chemical entity that is "new to the world." Although this definition is contrary to international practice and the definition in the earlier DAL Implementing Regulation itself, NMPA continues to utilize this concept to grant priority to certain applications. NMPA and CNIPA are also proposing that only products "new to the world" would qualify for patent term restoration (in the January 2019 Patent Law draft) and the full regulatory data protection terms (in an April 2018 draft of NMPA measures on the Implementation of Drug Clinical Trial Data Protection). Applicants that submit marketing applications in China before or at the same time as other countries receive benefits; those who submit later in China receive less. The draft 2019 DRR contains a separate application category for drugs approved abroad but not in China, which could be used to perpetuate this disparate treatment of drugs approved abroad.

[200] Notably, 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.

years of RDP for chemically synthesized drugs and therapeutic biologics, respectively. However, the proposed location- and time-based conditions and limitations placed on the terms for innovative drugs are not consistent with China's international commitments, are not practical, and could well undermine the very goals that are driving these proposed reforms. In this respect, the Draft Measures would make it difficult – if not impossible – to obtain the benefits of RDP by forcing innovators into arbitrary choices concerning the location of development and timing of submissions. In some cases, the costs of these choices for the overall development program could exceed the benefits of RDP. Moreover, there remains significant uncertainty regarding the scope of the data protected and the criteria for protected categories, and we are very troubled by the broad post-approval data disclosure requirements. Consistent with its commitment in the chapeau to Section C of Chapter One of the Phase One Trade Agreement, now is the time for China to advance reforms to provide "effective protection and enforcement of pharmaceutical-related intellectual property rights, including … undisclosed test or other data submitted as a condition of marketing approval."

Lack of Patent Term Extension Mechanisms

PhRMA and its member companies applaud the U.S. and Chinese Governments for their commitment in Article 1.12 to provide effective patent term extension mechanisms to compensate for unreasonable delays that occur in granting patents (PTA) and unreasonable curtailment of the effective patent term as a result of the lengthy marketing approval process (PTR) for innovative medicines. 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. PhRMA members are encouraged by the proposed amendments to the Patent Law (January 2019), which include the provision of PTR in Article 43. As China looks to implement its Phase One Trade Agreement commitments, we would refer the Chinese Government to the proposed revised language that we submitted in response to the second draft amendment to the Patent Law (August 2020) to ensure that the resulting mechanism achieves its objectives of encouraging the development of innovative medicines.

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, CNIPA does not consistently accept data generated after a patent is filed to satisfy sufficiency and inventive step requirements, pursuant to Articles 26.3 and 22.3 of China's Patent Law, respectively. 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, CNIPA issued an amendment to its Patent Examination Guidelines that requires examiners to consider post-filing experimental data submitted by the applicant. This amendment sought to implement China's commitment, made during the 2013 JCCT, to permit patent applicants to file additional data after the application filing date. On October 4, 2020, CNIPA released a draft amendment to the Patent Examination Guidelines. That draft amendment proposed to include two examples as to when supplementary data should be permitted. The amendment appears to indicate that such data might be permitted to cure inventive step defects (*e.g.*, if the experimental method and similar experimental data are available in the original submission), but it is not clear whether these amendments (if adopted) will make a substantial difference in practice.[201]

PhRMA recognizes and welcomes these positive steps, but has repeatedly expressed concerns regarding the extent and implementation of the data supplementation amendment. First, the amendment to Section 3.5 makes 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 CNIPA 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, which seemingly continues to be the case even after the amendment to the Patent Examination Guidelines came into effect, 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."[202] We urge CNIPA to keep these considerations, goals and benefits in mind and provide additional guidance consistent with them as it moves to implement Article 1.10 of the Phase One Trade Agreement.

In addition, 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

[201] Notice on the Public Consultation on the Draft Revised Patent Examination Guidelines (First Batch of Draft for Comment) (CNIPA October 4, 2020).
[202] Available at http://documents.epo.org/projects/babylon/eponet.nsf/0/0791474853510FFFC125805A004C9571/$File/guidelines_for_examination_part_g_en.pdf (last visited Oct. 28, 2020).

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 the validity of patent No. ZL 00814590.3) and CNIPA (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 CNIPA to revisit this gap in China's patent system and conform China's practice to that of many other countries.

Loss of Patent Rights

Overly rigid requirements to prove patent ownership for subsidiary patents, a lack of clarity about what constitutes adequate proof of patent ownership, and short response timeframes have resulted in the loss of patent rights in Chinese Patent Office invalidation proceedings, without the possibility of appeal.

Lack of Transparency in Patent Prosecution

According to Rule 48 of the Implementing Regulations of the Patent Law, any person may, from the date of publication of a patent application till the date of allowance, submit his observations why the application does not satisfy the patentability criteria. In turn, section 4.9 of Part II Chapter 8 of the Patent Examination Guidelines provides:

> **The observations submitted by anyone** to the Patent Office on an invention application not in conformity with the provisions of the Patent Law shall be included in the application file. The examiner shall take them into consideration during substantive examination…. The handling of the observation submitted by the public does not need to be notified to the public concerned. (Emphasis added.)

The Examination Guidance does not indicate whether the observations/opinions submitted by "anyone" must be shared with the applicant.

Contrary to international best practice, patent applicants in China are not typically notified of the submission of third-party observations nor offered the opportunity to rebut any allegations that they contain even though these observations may influence the substantive examination of their patent applications. We strongly encourage China to

amend the Examination Guidelines and/or Implementing Regulations of the Patent Law to provide this basic transparency and due process as part of its patent prosecution process.

Mandatory intellectual property sharing related to certain biological material

As discussed above, any research conducted by foreign companies using Chinese human biological samples must be undertaken in collaboration with Chinese partners (*i.e.*, Chinese state hospitals) under the HGR regime. In both the original HGR Regulation and the 2019 amended version, there are provisions that require (1) that the foreign and Chinese party jointly submit any patent applications arising from the results of the collaboration (*e.g.*, results of exploratory research) and (2) that the two parties agree on an arrangement for sharing or, in the event that there is no arrangement, jointly share the rights and benefits to other intellectual property, including obtaining the consent of the other party to transfer those rights. While not necessarily impacting rights over the investigational product, applicants are required to submit their clinical trial agreements (including the IP-related provisions) and make declarations on forms[203] as to how they will share these IP rights with Chinese parties, sometimes requiring a negotiation with the HGRAO that creates uncertainty as to the rights over exploratory research.

In 2017, MOST released the Guidelines on Optimizing the Approval Process of Human Genetic Resources to streamline the approval process and allow for parallel reviews of CTAs and genetic testing (HGRAC). However, under the new process, foreign sponsors and vendors are required to sign an "undertaking letter," which certifies that 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 and create uncertainty 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 to ensure, consistent with Chapter 2 of the Phase One Trade Agreement, that any transfer of technology as part of securing marketing approval for innovative medicines occurs on voluntary, market-based terms.

Counterfeit Medicines

Pharmaceutical counterfeiting poses global public health risks, exacerbated by rapid growth of online sales of counterfeit medicines and the production and sale of unregulated APIs used to manufacture counterfeit products. China has increased enforcement efforts against counterfeited drugs in recent years, both through legislative

[203] The forms that are part of the notification process introduced by the 2019 amendment to the HGR Regulations do not require IP-related declarations, although applicants must still submit the clinical trial agreements.

reforms and increased police activity, and we commend the two governments on the commitments in Section G of Chapter One of the Phase One Trade Agreement to combat counterfeiting. In implementing these commitments it will be particularly important to address online distribution of counterfeit medicines and unregulated API. A number of stories involving counterfeit medicines continue to make national headlines, including a scandal in 2016 which uncovered nearly $88 million USD in substandard vaccines being circulated throughout 20 provinces.[204]

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

The new DAL also introduces provisions on a system for drug traceability. This includes building upon existing efforts to establish an online platform for collecting and publishing traceability records and a requirement for a unique identifier according to uniform coding rules on each drug package. In addition, the DAL also contains increased fines and longer debarment penalties for counterfeiting.[205]

The amended DAL is a start, but further measures are still required, including:

- amending the Criminal Code to ease the burden of proof to prosecute brokers or API suppliers who knowingly deal with illegal APIs;
- empowering NMPA or another authority to regulate any party that manufactures API even if that party has not declared an intent to do so;
- empowering NMPA (through implementation of the revised DAL) to penalize API manufacturers based on *prima facie* evidence of a product having medicinal use or being an "API" or a "chemical drug substance" without cGMP certification; and
- deepening cooperation with major Internet Service Providers, portal sites, and search engines for earlier identification and tracking of illegitimate API suppliers through B2B websites.

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

[204] Fake and Shoddy Drugs A Threat to the People a Challenge to Administrators, China Daily, Dec. 8, 2017, available at http://www.chinadaily.com.cn/opinion/2017-12/08/content_35258859.htm (last visited Oct. 28, 2020).
[205] *See* DAL Chapter 11. The potential fines for manufacturing or distributing counterfeit drugs increased from 2 to 5 times the value of the goods to 15 to 30 times the value of the goods with a minimum fine of RMB 1,500,000 (about USD 208,000). These entities can be debarred for 10 years. The maximum penalty for a responsible person increased from ten years' debarment to lifetime debarment from the pharmaceutical industry. For severe violations, the police department may detain the responsible person for five to 15 days.

crack down on unregulated API must go hand-in-hand with China's 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, including in 2018.[206] It also appears that China is beginning to spend more efforts tackling the sale of counterfeits on the Internet. In 2016, NMPA pursued 14 cases of online drug counterfeiting in collaboration with the Guangdong and Shenzhen MPAs.[207] In 2013, NMPA and the State Information Office jointly led a five-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 partnership with the private sector aimed at protecting Chinese patients.[208] Under the new E-Commerce Law and the new DAL, platforms that sell drugs must be registered with the government, verify the credentials of those who sell via their sites, and cease content and submit a report to the government related to any illegal activities it discovers.

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. This notably requires a holistic approach since not only finished counterfeit medicines are sold on the major online platforms in China but also separate materials (*i.e.*, API, secondary packaging, primary

[206] *See, e.g.*, China Launches Crackdown on Fake Food and Drugs, China Daily, Oct. 14, 2018, http://www.chinadaily.com.cn/a/201810/14/WS5bc2cf18a310eff303282339.html (last visited Oct. 28, 2020); N.Y. Times, "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 Oct. 28, 2020); Huffington Post, "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 Oct. 28, 2020).

[207] NMPA Notice on Crackdown of 14 Online Distribution of Counterfeit Drugs, Feb. 5, 2016, available at https://www.nmpa.gov.cn/xxgk/ggtg/qtggtg/20160205144801638.html (last visited Oct. 28, 2020)

[208] 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 NMPA. 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.

packaging, labels) especially on business to business platforms for these to be assembled in and outside China.

Finally, while we commend China for improvements in customs regulations, which include monitoring and seizure of imports and exports, Chinese Customs authorities rarely exercise their authority to monitor pharmaceutical exports. PhRMA believes that 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. Close cooperation and intense risk analysis with key intermediaries such as online e-commerce platforms and postal courier companies is critical to effectively monitor and detect small parcels with counterfeit medicines.

COLOMBIA

PhRMA member companies face urgent market access challenges and intellectual property (IP) issues in Colombia. Significant market access barriers have arisen from the Government's adoption of cost containment measures, which aim to address the sustainability of the Health System by disproportionately imposing price reductions on prescription drugs. Other barriers include 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. These standards are essential for ensuring the safety and efficacy of biosimilar products. Moreover, according to the provisions of the Council of State of December 2019, the Ministry of Health and Social Protection (MoH) has begun implementing Article 72 of Law 1753 of 2015, which, as part of Colombia's National Development Plan, would apply price and health technology assessment (HTA) measures for all new drugs before they could be granted marketing approval.

PhRMA's member companies also face a challenge concerning a new interpretation of the data protection Decree 2085 of 2002 by the Colombian food and drug regulatory authority (INVIMA). INVIMA has recently begun denying regulatory data protection upon approval of some new chemical entities, simply because they share a minor portion of their chemical structure with previously approved products. Finally, several concerning bills are being discussed in the Colombian Congress related to reforming the health care system and drug labelling, which would directly impact the industry.

Key Issues of Concern:

- **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 but was unsuccessful.

- **Cost containment measures focused exclusively on the biopharmaceutical industry**: Government measures to improve the sustainability of the Colombian health system have focused solely on the biopharmaceutical industry, and have not addressed issues within the pharmaceutical supply chain or other health sectors. Moreover, measures have been developed in an arbitrary, hasty and non-transparent way that leaves industry unable to plan for transitions.

  Further, 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.

- **Maximum reimbursement values**: In 2019, the Colombian MoH established reimbursement caps ("Valores Máximos de Recobro," or VMR) for more than one thousand reimbursed products reimbursed by the government. The maximum reimbursement values correspond to the maximum cost that can be reclaimed from ADRES by health-promoting entities (EPS). Maximum values per unit (as stated) for each active ingredient are calculated based on past reimbursement values during the reference period (2015-2018), adjusted for inflation. This formula skews toward lower pricing by taking the 25th percentile of these values for multi-sourced products and the 10th percentile for single-sourced products. This measure came into effect in May 2019, for a group of 50 drugs and on January 1, 2020, for the remaining group of drugs.

- **New drug price regulation methodology**: During 2019, the National Drug Pricing Commission began reviewing its drug pricing regulation methodology, which has been in place since 2013. The MoH is expected to make its system of international reference pricing more restrictive by expanding the number of reference countries from 17 to 19 and replacing higher-price markets (*e.g.*, Germany and Uruguay) with lower-price ones (*e.g.*, Greece, Italy, South Africa and Turkey). PhRMA has additional concerns about the new price regulation methodology, including the frequency of price adjustments and a new cost containment mechanism included in the most recent draft called the National Reference Price. This mechanism would reduce the price of medicines by adopting the lowest from either the International Reference Price or the historical data (from the prior 12 months) reported to the national health system . The final methodology is expected to be issued by the end of 2020 for implementation by March 2021.

- **Increased regulatory barriers under the National Development Plan**: Colombia's NDP, which was enacted as part of Law 1753 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 inserts price and health technology assessment (HTA) criteria into the regulatory approval process.

- **Compulsory licensing**: Compulsory licensing in Colombia is a continued and looming risk to manufacturers of innovative medicines in the United States. In December 2017, the MoH accepted a Declaration of Public Interest (DPI) petition for review that could lead to the compulsory licensing of the entire class of innovative treatments for hepatitis C. The petition was accepted contrary to Colombia's own procedures and appears to provide no justification for such an extreme and drastic action. Recently, a DPI request was made relating to a medication for acute myeloid leukemia. However, that DPI request was abandoned once a price reduction was reached between the Colombian government and the

drug's manufacturer. Although no compulsory licenses have been granted at this time, it remains an issue of deep concern for the industry.

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

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

- **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.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

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 not effective. Since issuing the Decree, the MoH has issued implementing guidelines, but these guidelines have not served to resolve the fundamental deficiencies of the abbreviated pathway.

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

Furthermore, per the Decree, a product approved via the "Abbreviated Comparability Pathway" will use the same non-proprietary name as the innovator, even though any similar biologic product would be a distinct biologic product from that of the originator or other biosimilar products. Assigning identical non-proprietary names to

products that are not the same could result in inadvertent substitution of the products and would make it difficult to quickly trace and attribute adverse events to the correct product.

The local innovative biopharmaceutical industry association AFIDRO has filed a legal challenge against the Decree, but as yet no decision has been issued. In the interim, industry will continue to work closely with all stakeholders to ensure that the quality of the information submitted for the approval of biosimilars meets international standards for demonstrating the similarity between the biosimilar and originator product.

Regulatory Decisions Inconsistent with Global Best Practices

Products approved by reference authorities such as the U.S. Food and Drug Administration, the European Medicines Agency and Brazil's National Health Surveillance Agency (ANVISA) are frequently either denied approval in Colombia or approved with deviations from their approvals in reference countries. The data provided for these drugs is pharmacologically the same as provided to reference country authorities, and no explanation is provided for why the outcome of their evaluation in Colombia would be different. These inconsistent outcomes underscore the need for ongoing collaboration between the MoH and INVIMA to ensure that the MoH adopts and applies regulatory assessment procedures that are consistent with international best practices.

Moreover, Decree 677 of 1995 establishes that, when a drug has been approved in at least two reference countries and has not been rejected in any other reference country, the pharmacological evaluation for that drug will only take into account a summary of the drug's clinical information. Despite this regulation, ANVISA in practice denies the approval of innovative molecules that comply with these requirement without any justification, which blocks the entry of innovative products and ultimately increases trade barriers.

Arbitrary and Non-Transparent Market Access Policies

Colombia sets a maximum price for both the public and private markets at the distributor level. These different channels are dissimilar in most characteristics, in that they serve different patient populations via different business models.

Moreover, 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. On September 24, 2019, the MoH issued its most recent circular through which the National Commission for the Regulation of Prices of Medicines and Medical Devices (CNRPMDM) limits the maximum sale price of more than 1,800 medications and chemical compounds, including products such as contraceptives, anti-hypertensives and psychiatric drugs. These products are facing an average price reduction of 50 percent since January 2019.

Cost-containment Measures Focused Exclusively on the Biopharmaceutical Industry

Facing sustainability issues within its Health System, the Government of Colombia has focused on measures targeting the pharmaceutical industry for cost containment, and has not proposed any measures that target other actors within the supply chain for medicines. PhRMA's member companies request that any new cost containment measures should be developed and implemented transparently and through a process that includes transition periods that allow industry to participate in the policymaking process and respond meaningfully to new cost containment measures.

The Government has also disclosed that it is considering a new initiative to cap the expenditure of medicines not included in the publicly funded Health Benefit Plan (HBP). The majority of such drugs are innovative medicines developed by the innovative pharmaceutical industry, including products manufactured by PhRMA members. This measure would establish a budget ceiling for drugs currently approved for marketing in Colombia but not included in the HBP; non-covered innovative drugs that are subsequently approved would be included under the same budget cap. As the proposed budget cap would remain set at its 2018 level, this policy would effectively block new innovative drugs from entering the country.

Maximum Reimbursement Values

In 2019, the Colombian MoH established reimbursement caps (VMR) for more than one thousand products reimbursed by the government. The maximum reimbursement values correspond to the maximum cost that can be reclaimed from ADRES by health-promoting entities (EPS). Maximum values per unit for each active ingredient are calculated based on reimbursement values during the reference period (2015-2018), adjusted for inflation. This formula skews toward lower pricing by taking the 25^{th} percentile of these values for multi-sourced products and the 10^{th} percentile for single-sourced products. This measure came into effect in May 2019, for a group of 50 drugs and on January 1, 2020, for the remaining group of drugs.

New Drug Price Regulation Methodology

During 2019, the National Drug Pricing Commission began reviewing its drug pricing regulation methodology, which has been in place since 2013. The MoH is expected to make its system of international reference pricing more restrictive by expanding the number of reference countries from 17 to 19 and replacing higher-price markets (*e.g.*, Germany and Uruguay) with lower-price ones (*e.g.*, Greece, Italy, South Africa and Turkey). PhRMA has additional concerns about the new price regulation methodology, including the frequency of price adjustments and a new cost containment mechanism included in the most recent draft called the National Reference Price. This mechanism would reduce the price of medicines by adopting the lowest from either the International Reference Price or the historical data (from the prior 12 months) reported to the national health system. The final methodology is expected to be issued by the end of 2020 for implementation by March 2021.

Increased Regulatory Barriers under the National Development Plan

Colombia's National Development Plan, which was enacted on May 7, 2015 as part of Law 1753, 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. Concerns include Article 72, which inserts price and HTA criteria into the regulatory approval process. Significantly, Article 72 states that for certain identified drugs, including innovative medicines, a health technology assessment by the Instituto de Evaluación Tecnológica en Salud (IETS) and the setting of a price by the MoH based on that evaluation should both be prerequisites for registration and renewal.

The MoH, following a warning from the Colombian Constitutional Court, implemented regulations for Article 72 that would separate INVIMA's market approval processes from HTA and price measures. However, the Council of State responded by issuing Decree 710 of 2018, which partially and provisionally suspended these regulations and again required assessments for new drugs by the IETS: "*The IETS must carry out the assessment … simultaneously with the Sanitary Register process before INVIMA. The assessment carried out by the IETS cannot be a condition for the granting of the Sanitary Register by that entity, which may issue it once its own assessment procedure is completed*."

At this time, the Council of State is reviewing an appeal filed against its provisional suspension. If a full suspension is declared, the assessment carried out by the IETS would be a requirement for the issuance of a marketing approval by INVIMA, as set forth in Article 72 of Law 1753 of 2015. It is additionally concerning for the industry that no maximum term is provided for IETS to carry out its assessments, as the 180-day term initially contemplated was removed by Decree 710. Without a fixed term for IETS to carry out its price and HTA assessments, these requirements could have the additional impact of severely delaying the market entry for innovative medicines in Colombia.

Intellectual Property Protection

Compulsory Licensing

On December 20, 2017, the MoH issued Resolution 5246 accepting for review a DPI petition filed by Fundación IFARMA. The petition calls for the compulsory licensing of the entire class of innovative medicines for the treatment of hepatitis C, following a similar petition granted against an innovative cancer medicine in 2016. That earlier petition did not result in the awarding of any compulsory licenses but was resolved through a price reduction for the medicine in question.

Resolution 5246 is both legally and procedurally deficient. It appears to be 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, a class within which significant competition already exists; b) hepatitis C drugs were recently the subject of significant price reductions in Colombia, which the Ministry itself has publicly asserted were between 80 and 90 percent; and c) there is no indication that a health-related emergency regarding hepatitis C exists in Colombia. To the contrary, the incidence of hepatitis C is quite low in Colombia.

The MoH could act on this deeply flawed petition at any time, potentially destroying an entire market for a class of innovative medicines developed in the United States. PhRMA urges USTR and other federal agencies to address this serious threat to American innovation through ongoing discussions under the U.S.-Colombia Trade Promotion Agreement.

Regulatory Data Protection Failures

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

This sudden and drastic change in procedure is inconsistent with the requirements of Decree 2085 of 2002 and contrary to the practice in other countries that provide regulatory data protection for such products. Such disregard of existing legislation undermines incentives to conduct clinical trials and develop new biopharmaceutical products in Colombia.

Restrictive Patentability Criteria

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

The failure to provide patents for second uses harms patients by undermining incentives for biopharmaceutical innovators to invest in evaluating additional therapeutic

benefits of known molecules (second uses) and provide more effective solutions for unsatisfied medical needs. The ACJ position is dispositive on the issue and no further domestic appeals or remedies are possible.

In addition, Colombia's Congress is currently considering a bill that would force biopharmaceutical innovators to disclose International Non-proprietary Names (INN) in all patent applications and to report INNs for previously granted patents. If it becomes law, this requirement would be inconsistent with Andean Community law.

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.

EGYPT

PhRMA and its member companies remain concerned about market access issues and the intellectual property (IP) environment in Egypt. PhRMA member companies struggle with stabilizing and growing their operations in a populous country with significant unmet medical needs that is undergoing major health system reforms to support universal health coverage. Relatedly, in August 2019, the Egyptian president approved a law establishing the Egyptian Drug Authority and the Egyptian Authority for Unified Procurement, Medical Supplies, and the Management of Medical Technology. The creation of these two authorities aims to support the reforming health system and medical industries, provide medication on a regular basis, counter monopolies in the health sector and combat counterfeit medicines in Egypt.

During the past several 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 Ministry of Health's (MoH's) pledge to implement the second phase of price adjustments in August 2017, to date the Egyptian Government did not implement this pledge resulting in significant financial losses for member companies and widely reported shortages of medicines. To avoid previous pitfalls and public outcry as a result of a wave of repricing, the MoH has adopted an open and flexible approach to support individual companies in alleviating some of the losses due to the devaluation of the Egyptian pound via repricing proposals.

PhRMA notes that the former Minister of Investment and International Cooperation and the Minister of Health, have shown a willingness to meet and discuss issues of concern and potential comprehensive solutions. 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. Accordingly, in addition to the short-term interventions, they have been actively engaging the industry in their current reform as an opportunity for the introduction of pro-innovation policies including a new pricing policy.

Key Issues of Concern:

- **Government pricing policies**: Despite the support of the MoH in alleviating some of the losses on an individual company basis, PhRMA member companies remain concerned that Egypt has yet to develop a transparent and fair pricing system that

would systematically address the drawbacks of the current pricing system, such as a methodology for absorbing currency fluctuations.

- **Weak patent enforcement and compulsory licensing threats**: Egypt lacks effective patent enforcement, enabling manufacturers to obtain marketing licenses for follow-on products prior to the expiration of the patent on the original product. Recently, the Egyptian government has taken steps to set up a ministerial committee with broad discretion to issue compulsory licenses.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Pricing Policies

Despite the support of the MoH in alleviating some of the losses on an individual company basis, our member companies remain concerned that Egyptian authorities have yet to develop a new transparent and fair pricing system that would systematically address the drawbacks of the current pricing system, such as a methodology for absorbing currency devaluations. On a positive note, industry is engaged in constructive discussions with the new Minister of Health on the gaps in the currently effective pricing Decree no. 499/2012 regarding the pricing of innovative medicines.

As part of the ongoing health system reforms and rollout of universal health coverage, the Egyptian president approved a law in August 2019, establishing the Egyptian Drug Authority and the Egyptian Authority for Unified Procurement, Medical Supplies, and the Management of Medical Technology. The creation of these two authorities aims to develop the health system and medical industries, provide medication on a regular basis, counter monopolies in the health sector, and combat counterfeit medicines in Egypt.

While the Egyptian government has been open to seeking input from the industry on the law during the drafting process, PhRMA strongly urges that the constructive dialogue continue, as this law and its executive regulations have set critical and unclear policies that will impact access to innovative products and hence the future of the innovative biopharmaceutical industry in Egypt.

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 on an originator’s patent. Some Egyptian 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 neighboring countries, regulators who receive a marketing application from a generics company are required to check for any existing patents applying to the reference drug. If an existing patent applies, the patent holder should be notified and the MoH should have a procedure in place whereby it can either: (i) defer review of the generics company's application for examination closer to the date of the patent's expiration, (ii) defer grant of the application until after a sufficient period to resolve the patent dispute, or (iii) grant a marketing license that is valid only after the expiration of the innovator's patent.

As Egypt is a World Trade Organization (WTO) member, has enacted patent laws, and issues patents through the Egyptian Patent Office, it follows that the Egyptian MoH should have in place an effective mechanism whereby it can defer marketing approval of newly licensed medicines until after the expiration of any applicable patents, or at least until after a sufficient period to allow for resolution of any underlying patent disputes.

Compulsory Licensing Decree No. 251/2020

In early February 2020, the Prime Minister issued Decree no. 251/2020 forming the Ministerial Committee stipulated in Article 23 of the Law with the authority to compulsory license or expropriate any patented product or process. The Decree and Egypt's Patent Law (Law no. 82/2002) give the committee broad discretion to take patents for almost any reason. The votes of only three of the five members of the committee are necessary to issue a compulsory license.

The fact that the Government of Egypt has established a ministerial committee at this specific time – nearly two decades after the Patent Law entered into force – and without any prior notification to or engagement with the private sector has sent an alarming signal to the companies we represent and to many other innovative industries. A compulsory licensing workshop hosted in Cairo in March by a well-known anti-innovation group added to fears that hasty and damaging action may be imminent.

EUROPEAN UNION

PhRMA member companies face a variety of government restrictions across Europe that jeopardize patient access to innovative medicines. As a result of Europe's on-going economic challenges, several European Union (EU) and European Free Trade Association (EFTA) Member States continue to seek additional cost savings at the expense of the innovative biopharmaceutical sector, thereby imposing a disproportionate burden on the United States to support research and development of new treatments and cures.

In addition, while the EU generally maintains intellectual property (IP) protections and other incentives that enable such research and development, PhRMA and its member companies are concerned by the potential future direction of a new European Commission (EC) Pharmaceutical Strategy for Europe and associated ongoing review of IP and other incentives for innovative medicines and orphan products that could result in weakening IP rights in one of the world's largest markets. As currently framed, the EU Pharmaceutical Strategy neither appropriately recognizes the significant contribution of innovative medicines to the patients and economies of Europe, nor does it properly address the EU's role in this innovative sector. There is a clear need for the EU to strengthen, rather than undermine, key conditions that promote and enable tomorrow's innovations. PhRMA member companies welcome the opportunity to collaborate with the EU in determining the best way to address these issues.

Key Issues of Concern:

- **Government price controls and patient access to innovative medicines**: Among numerous government price controls in effect, many EU and EFTA Member States set prices of patent-protected innovative medicines based on prices in less wealthy countries that are not representative of efficient markets for the normal exploitation of innovations and/or based on older products deemed to be within the same therapeutic class, including generics. Moreover, several countries in Europe are pursing initiatives to jointly procure innovative medicines, or jointly negotiate their prices to gain stronger bargaining power against innovative biopharmaceutical companies and lower prices. Other countries are proposing misguided requirements for disclosure of commercially sensitive information to further pressure companies to reduce prices. These and other government practices – coupled with rigid health technology assessment (HTA) interpretations of value – are putting at risk biopharmaceutical innovation and seriously harming patient access to needed medicines. As such policies continue to ratchet European prices lower, there are increased calls for cross-border sharing of confidential price information. Furthermore, although EU legislation[209] requires transparent and timely processes (*e.g.*, within 180 days) for national pricing and reimbursement

[209] European Council Directive 89/105/EEC, 1988, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31989L0105 (last visited Oct. 28, 2020).

decisions, delays for launched medicines average 504 days,[210] and therefore these requirements need to be enforced more rigorously and with broader oversight of national practices.

- **EU intellectual property incentives review**: The EU is conducting an analysis of the current EU legislative instruments and related incentives that aim to facilitate and support the investment in the development of medicinal products. PhRMA and its member companies are concerned that this review can result in the weakening of existing incentive mechanisms for biopharmaceutical innovation and create an unlevel playing field for transatlantic medicines trade and investment. Recently, the EU introduced changes to its legislation amending Regulation EC 469/2009 concerning the supplementary protection certificate (SPC) for medicinal products, to introduce an SPC export and stockpiling waiver (in force as of July 1, 2019). The waiver allows companies to manufacture generic and biosimilar products in Europe during the effective SPC period for export purposes to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. The SPC manufacturing waiver weakens the scope of the exclusive rights conferred by an SPC and sends a negative signal to the world that the EU is weakening its commitment to IP incentives and innovation. In addition to the SPC manufacturing waiver, PhRMA is also concerned with the ongoing review of pharmaceutical incentives in Europe where proposals are being considered to weaken existing incentives, including the evaluation of the Regulations concerning orphan and pediatric medicinal products, expected to culminate in Q4 2020.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Price Controls and Patient Access to Innovative Medicines

As detailed further below, many EU countries engage in government pricing and reimbursement practices that restrict availability, limit patient access, and fail to recognize the value of state-of-the-art medicines. Moreover, since the U.S. research-based industry is the world leader in the development of new medicines, PhRMA member companies and their innovative products disproportionately bear the brunt of these measures as they undermine the financial incentives for privately sponsored research and development. Furthermore, although EU legislation requires transparent and timely processes (*e.g.*, within 180 days) for national pricing and reimbursement decisions, these requirements need to be enforced more rigorously and broader oversight of national practices should be in place.

[210] EFPIA Patient W.A.I.T. Indicator 2019 Survey, 2020, available at https://www.efpia.eu/media/554526/patients-wait-indicator-2019.pdf (last visited Oct. 28, 2020). Note that the Patient W.A.I.T. indicator also reflects delays which are not requirements under European Council Directive 89/105/EEC.

Austria

Since 2017, Austria has adopted a spate of new cost-containment measures. Although one of the wealthiest countries in Europe,[211] Austria nevertheless sets the ceiling price for reimbursed and non-reimbursed patented medicines to not exceed the average price across 26 EU countries including Bulgaria, Croatia and Romania. In practice, however, medicines reimbursed by the statutory social insurance system are subject to additional price concessions and heavy prescribing restrictions.[212]

Industry has grown increasingly concerned about the unilateral nature of these recent measures, which were made without meaningful opportunity for engagement and despite the clawbacks already required as part of a framework agreement that was in place at the time. In fact, since 2008, the industry and the social insurance institutions have worked together on a contractual basis to support the efficiency of health insurance, in particular with patients. However, this framework agreement expired in 2018 and has not been renewed.

Belgium

The Belgian government sets maximum manufacturer's selling prices (MSP) for all reimbursed prescription medicines, and also institutes several cost containment measures that target innovative medicines. For example, sales of reimbursed medicine are clawed back from manufacturers through turnover tax (7.73 percent), subsidiary tax (2.5 percent), orphan drugs tax (up to 5 percent), marketing tax (0.13 percent) and per pack fees. Domestically manufactured new medicines are permitted a 10 percent price premium in the manufacturing cost component of their MSP calculation, to the disadvantage of imported products.[213]

Czech Republic

While the Czech government has increased investment in health care and expanded access to innovative medicines, the country's pharmaceutical share of total health spending has nevertheless declined considerably in the past decade from 22.1 percent in 2009 to 16.0 percent in 2018 due to rigid cost containment regulations such as its "double referencing" system.[214] Under this system, the price of a new medicine cannot exceed the average price of the lowest three countries among 19 EU countries. In addition, in most cases, the reimbursed price will then be set at the lowest EU price of a therapeutic cluster of medicines, which can combine patented, off-patent and generic medicines.[215]

[211] IMF World Economic Outlook, 2020.
[212] IQVIA (2019). Pricing and Reimbursement Country Report: Austria.
[213] IQVIA (2019). Pricing and Reimbursement Country Report: Austria.
[214] IQVIA (2020). Market Prognosis: Czech Republic.
[215] *Id.*

In addition to facing some of the lowest prices in Europe, innovative medicines in the Czech Republic are subject to non-transparent and lengthy reimbursement processes that reduce patient access. The target timeline for pricing decisions is 75 days from receipt of an application, and 165 days for joint pricing and reimbursement decisions. In practice, decisions take more than a year on average.[216] One additional provision of the Czech health care legislation which could represent a significant threat to PhRMA member companies is mandatory delivery of medicinal products to wholesalers based on their market share, which imposes inappropriate limits on a manufacturer's freedom to select and contract with specific wholesalers and obstacles to entering the market.

Denmark

Although Danish law does not directly regulate prices, the government decides which medicines are reimbursed and in effect sets the prices of those products through an agreement with the local innovative pharmaceutical industry association that requires international reference pricing, price caps, tendering and other cost-containment measures. In 2019, approximately 20 percent of new medicines in Denmark failed to secure general reimbursement.[217] Moreover, the government rejected reimbursement applications over concerns that the medicines might be used outside of the target patient population, creating unforeseen expenditure.

Manufacturers also face pricing pressure from parallel imports across Europe, which comprise approximately 25 percent of the Danish retail market and which are eligible for hospital tenders. Finally, except for a 2 percent annual inflationary adjustment, the prices of medicines have been capped since 2006.[218] Overall, these practices have created uncertainty for biopharmaceutical innovators and have resulted in a situation in which Denmark, despite its relative wealth, spends much less per capita on medicines than the OECD average.

Finland

Finland operates highly restrictive pricing and reimbursement policies. Although there is no price setting formula, the government sets prices of innovative medicines based on the prices of older medicines in a therapeutic cluster and prices in other European Economic Area (EEA) countries. In addition, almost all new products are initially only able to apply for basic reimbursement that covers just 40 percent of a medicine's cost. New medicines in Finland also undergo frequent and unpredictable reimbursement reviews which can be triggered by any number of issues. In 2017, the average price reduction for reimbursed products was 4.3 percent.[219] Although a risk-sharing system established in 2017 has improved reimbursed access, cost containment measures over the past 15 years have brought the country's pharmaceutical spending as

[216] *Id.*
[217] IQVIA (2020). Market Prognosis: Denmark.
[218] *Id.*
[219] IQVIA (2020). Market Prognosis: Finland.

a percentage of total health spend well below the OECD average.[220]

France

Characterized by a notoriously slow market access process, France heavily regulates the price of new innovative medicines and has established a goal of saving €920 million in 2020 through price cuts alone. Over time, France has adopted punitive policies toward innovators through layered mechanisms such as taxes, price-volume clauses that trigger price cuts or clawbacks, and an industry-wide clawback when national spending growth on reimbursed medicines exceeded 0 percent for retail medicines and 3 percent for hospital medicines. Clawbacks were up to 70 percent of net sales revenue.[221]

Additionally, there are serious challenges with France's HTA system, which rates the clinical added value of a product as major (ASMR I), important, (ASMR II), moderate (ASMR III), minor (ASMR IV) or no clinical improvement (ASMR V), with corresponding impacts on pricing. In practice, only one-third of new innovative medicines are assigned ASMR ratings of I, II or III which means that the French government judges two-thirds of new innovative medicines as providing only moderate, minor or no clinical improvement. The average delay for a product to complete France's centralized pricing and reimbursement process is about a year and half, which significantly exceeds EU requirements of 180 days.[222] However, for certain products that treat severe or rare diseases and that have not yet received European marketing authorization, this delay in market access can be moderated through the Temporary Use Authorization (ATU) process.

Moreover, positive signals have recently been sent to the innovative biopharmaceutical sector. Following an agreement signed between the local innovative pharmaceutical industry association, Les Entreprises du Médicament (LEEM), and the French government to hasten lengthy reimbursement processes, President Macron announced an approximately €300 million reduction in price cuts for 2021, from €920 million to €640 million. Furthermore, the ATU process will be simplified and made more attractive by the beginning of 2021. Nevertheless, the upcoming medicines spending bill for 2021 remains challenging, particularly on rebates. Overall, market growth is lower than in peer countries as French authorities seek savings from medicines to preserve social security finances.

Germany

Germany's Pharmaceutical Market Restructuring Act (AMNOG) of 2011 restructured its pharmaceutical market away from market-based pricing toward a government-controlled and payer-led system of clinical evaluation and price-setting. Under AMNOG, new medicines are reimbursed at manufacturer prices for one year, while

[220] OECD Health Statistics (last accessed Sept. 2020).
[221] IQVIA (2019). Pricing and Reimbursement Concise Guide: France.
[222] *Id.*

the government oversees a rigid early clinical benefit assessment by the Federal Joint Committee (G-BA) and price negotiations with the umbrella organization of the German payers that are tied to the outcome of the G-BA assessment and prices in 15 EU countries. The prices of products deemed not to provide additional clinical benefits based on this assessment are generally limited to the price of the comparator selected by the G-BA or to the lower price of a therapeutic cluster of products.[223] Lowest-cost comparators and generics are often considered by the G-BA to be appropriate comparators; however, research shows that in 43 percent of cases, medical societies opposed the comparator because it was clinically inappropriate.[224] In addition, since 2010 Germany has operated a price freeze through 2022 on reimbursed medicines deemed to provide added clinical benefit.

One of the chief complaints with the AMNOG procedure concerns the serious restrictions on the types of study designs and clinical endpoints that are admissible for demonstrating proof of additional clinical benefit. By 2019, this rigid process and requirements resulted in G-BA deeming 60 percent of all assessments of innovative medicines to demonstrate no additional clinical benefit in the specified patient subpopulation (54 percent of non-orphan innovative medicines were deemed to demonstrate no additional clinical benefit in any patient subpopulation).[225] In contrast, many of these treatments have been widely recognized as important and even breakthrough therapies in the United States and other countries. Recent analysis has shown that the system is so unfavorable that 17 percent (42 of 242) of innovative medicines assessed under AMNOG procedure have been withdrawn from the market during or after the price negotiations, with some re-assessments made that allowed some products to be reintroduced at a later date.[226]

In July 2019, a new law (GSAV) enabled the G-BA to also recognize registry data in the assessment of certain medicines (*e.g.*, medicines for orphan conditions or with conditional approval). It remains to be seen whether this new law will facilitate greater recognition of real-world data and a less rigid assessment system, or if the G-BA will create additional pricing hurdles for certain medicines. The GSAV also calls for the introduction, after three years, of mandatory automatic substitution in pharmacies for biosimilars.

Greece

Greece's pharmaceutical environment remains among the most challenging in Europe given onerous price controls and excessive mandatory clawbacks and rebates that undermine innovation and significantly delay patients access to new medicines. The government budget for outpatient medicines declined by 62 percent from €5.1 billion in 2009 to €1.9 billion in 2014 and has since remained flat, while the amount of budget

[223] IQVIA (2019). Pricing and Reimbursement Concise Guide: Germany.
[224] Bleß et al., "Impact of scientific opinions in the benefit assessment of medicinal products," IGES Institute, 2016.
[225] Kearney analysis of AMNOG procedure database, 2019.
[226] *Id.*

overrun increased significantly over this period. The clawback for 2019 was expected to reach €797 million, which is a 38 percent increase over 2018 and an amount equal to 41 percent of the public budget for outpatient medicines.[227] The Greek government has committed to increase the vaccines budget and exempt it from clawbacks, as well as abolish a mandatory market entry rebate for innovative medicines (which is required on top of other rebates) that requires companies to pay back 25 percent of an innovative medicine's sales for two years following admission to the reimbursement list.

Hungary

Government pricing and reimbursement of medicines in Hungary has been under substantial pressure since the Pharma Economic Act of 2007 and the two Széll Kálmán austerity plans. With the amount spent on pharmaceutical reimbursement frozen since 2010, Hungary additionally cuts the prices of innovative medicines by capping the prices for new products in Hungary to the lowest price at launch in any EU country. Hungary also engages in a "blind bidding system" for therapeutic reference pricing groups which can be comprised of both patented medicines that have been marketed for at least one year and off-patent medicines. The system requires manufactures to submit "blind" price reductions to the National Health Insurance Fund of Hungary (NEAK) every six months.[228]

Ireland

Ireland's commercial operating environment remains challenging for the innovative biopharmaceutical industry. Ireland continues to lag many other European countries when it comes to availability of new medicines, ranking 19 out of 34 for speed of patient access to some new treatments.[229] Meanwhile, the industry is among the Irish economy's strongest performers, with robust growth in medicines exports contributing positively to the national gross domestic product. Nonetheless, the weak adoption of new medicines continues to harm Ireland's reputation and health care standards.

In July 2020, the local innovative pharmaceutical industry association, the Irish Pharmaceutical Healthcare Association (IPHA), and the Irish government agreed to a six-month extension to the Framework Agreement on the Supply and Pricing of Medicines to the Health Services for 2016-2020. The extension is intended to give policymakers additional time to deal with COVID-19 and to secure the supply of medicines. The extension also provides for the application of industry savings to fund some new medicines which were in a backlog caused by the previous government's decision to stop paying for the latest treatments. The main challenge for industry and patients continues to be the insufficient budget for innovative medicines that ultimately delays the reimbursement process and access. Finally, IPHA and the Irish government aim to have a new multi-annual agreement by the end of January 2021, based on the principle of joint funding for new treatments.

[227] IQVIA (2019). Pricing and Reimbursement Concise Guide: Greece.
[228] IQVIA (2020). Pricing and Reimbursement Concise Guide: Hungary.
[229] EFPIA Patient W.A.I.T. Indicator 2019 Survey, 2020, available at https://www.efpia.eu/media/554526/patients-wait-indicator-2019.pdf (last visited Oct. 28, 2020).

Italy

Italy employs cost containment measures for innovative medicines at national, regional and local levels. For example, national procurement tenders can force patented medicines to compete against generic medicines, where price is the only selection criteria.

Policies that govern spending on medicines in Italy also heavily penalize PhRMA member companies. These more innovative product portfolios are mainly present in hospital and direct purchasing channels, accounting more than 85 percent of spending. Unfortunately, hospital budgets for medicines are significantly underfunded, and companies are called upon to refund 50 percent of budget overruns, paying back a total of €3.1 billion over 2013-2018. The gap between government funding and actual expenditure has widened over the past several years. In contrast, in the retail channel, government funding more than covers the actual expenditure (a difference of €900 million in 2019), yet the surplus is used to pay for non-pharmaceutical spending. This imbalanced funding and the clawback system have resulted in innovative U.S. companies paying for 47 percent of the clawback despite accounting for only 30 percent of spending on medicines.

In 2019, the industry and the Italian government signed an agreement which provided for the payment of the outstanding clawback together with a rebalancing of government financing to ensure that government funds not used for spending on retail medicines would be applied to increase funding for hospital medicines. The industry paid the requested clawback, but as of October 2020 the imbalanced clawback system remains unchanged.

In September 2020, the Italian Medicines Agency (AIFA) published draft guidelines on the pricing of medicinal products. The draft guidelines include potentially critical elements on the assessment and choice of comparators, information on marketing in other countries, and domestic public funding and R&D incentives received by companies. AIFA is expected to release final guidelines by the end of October 2020 following a public consultation.

Netherlands

PhRMA and its member companies are concerned about the Netherlands government's rising interest in using compulsory licensing as a way to lower spending on medicines. In 2019, the government commissioned an academia-led compulsory licensing committee to examine legal and economic issues related to the use of compulsory licensing. In June 2020, the commission completed its work as it was unable to reach a joint conclusion. The Ministry of Economic Affairs took note of the commission's work and concluded that the existing legal framework was sufficient. The industry believes that any future discussions about compulsory licensing need to consider the devasting effects on innovation and the research and development environment more generally.

Another area of concern is the use of compounding as a way to abrogate intellectual property rights and lower spending on medicines. With national elections scheduled for early 2021, there is a heightened risk of some candidates promoting this approach. However, a recent ruling by the highest court of the Netherlands concluded that any compounded medicine must comply with all existing legislative and regulatory requirements before it can be reimbursed.

The Netherlands has also recently intensified cost containment measures on innovative medicines. For example, the government began a pilot program in 2015 that places innovative medicines into a reimbursement "lock" system that denies patient access until completion of a health technology assessment and subsequent discounts. The Netherlands initially implemented this system on a case-by-case basis but announced in May 2018 that it would apply to all new medicines with an annual cost exceeding €50,000 per patient (when combined costs exceed €10 million) or a combined cost of €40 million.[230] Decision making criteria lack transparency, and there is no time limit on the lock period, currently estimated to be 380 days.[231] The Netherlands also erodes the prices of innovative retail medicines deemed by the Ministry of Health, Welfare and Sport to be therapeutically interchangeable by setting reimbursement prices to not exceed the average price of the therapeutic group, which can include off-patent medicines and generics. Additionally, beginning in 2020, all medicines were subject to an updated international reference pricing system that replaced Germany with Norway, where prices are an average of 9-13 percent lower than those in the Netherlands. It is estimated this change will reduce prices in the Netherlands by 5-10 percent and reduce annual spending on medicines by around €300 million.[232] In addition to facing these cost containment measures, most new medicines in the Netherlands are required to navigate a 29-step path from regulatory approval to reimbursement formulary listing that takes 736 days to complete on average.[233]

In September 2020, the Ministry of Economic Affairs and the Ministry of Finance announced a €20 billion national growth fund to stimulate public and private investment, including in education and research and development. This presents many opportunities for public-private partnerships in the life sciences and health care. Recently, the local innovative pharmaceutical industry association, Vereniging Innovatieve Geneesmiddelen (VIG), published an eight-point plan to make the Netherlands a more attractive environment for biopharmaceutical innovators.

Poland

Total health care spending in Poland was 6.3 percent of GDP in 2019 (of which 4.6 percent of GDP was from public sources), ranking 33 of 37 OECD countries.[234] In this context, the share of public spending on medicines has remained relatively stable and

[230] IHS Global Insights (May 2018). Netherlands expands criteria for inclusion of high-cost drugs in "reimbursement lock," renegotiates price of Tecentriq® and Soliris®.
[231] Association of Innovative Medicines in the Netherlands, June 2020.
[232] IQVIA (2020). Market Prognosis: Netherlands.
[233] IHS Global Insights, 2019.
[234] OECD Health Statistics (last accessed Sept. 2020).

under the 17 percent ceiling at which point industry clawbacks are mandated; however, the ratio has decreased from nearly 17 percent in 2017 to 15 percent in 2020. Despite the introduction of several innovative medicines to Poland in recent years, the government has constricted this share growth through a combination of therapeutic reference pricing that can tie the price of patented medicines to the lowest price generics, price cuts, fixed margins, high co-pays and other cost containment measures.[235] Poland's government pricing and reimbursement system is discriminatory, non-transparent and significantly backlogged, taking more than 823 days on average from EMA marketing authorization to patient access.[236] As a result, Poland lags far behind most other developed countries in the availability of innovative medicines.[237] More recently, the government announced in February 2018 that public health care spending would continue to be increased to reach 6 percent of GDP by 2023. While the 2019 budget was finalized with a $1 billion increase to the total health care budget, there was no increase for medicines, prompting concerns from patient groups.[238]

Romania

The Romanian health care system has historically been one of the most underfunded in Europe, comprising an estimated 4.6 percent of GDP in 2019 (of which 3.6 percent of GDP was from public sources).[239] While this percentage of GDP has remained stable over time, budget challenges remain due to several factors including the many contribution exemptions introduced over the years.

Innovative medicines in Romania face a series of government price controls, cost-containment measures and administrative hurdles that significantly delay patient access. From 2015-2018, the average time between EMA marketing authorization and government reimbursement of new medicines was 812 days.[240] The government sets prices based on the lowest price in a basket of 12 EU countries, and the reimbursement process is strongly dependent on the completion of reimbursement processes in other European countries. While this pricing policy was originally intended to protect patients in a lower GDP per capita country, it has ultimately led to product shortages and a lack of patient access, all of which is exacerbated as wealthier European countries seek to reference lower Romanian prices. Moreover, the inclusion of new medicines on the reimbursement list is an unpredictable process, often delayed by budget constraints.

[235] IQVIA (2020). Pricing and Reimbursement Concise Guide: Poland.
[236] EFPIA Patient W.A.I.T. Indicator 2019 Survey, 2020, available at https://www.efpia.eu/media/554526/patients-wait-indicator-2019.pdf (last visited Oct. 28, 2020).
[237] PhRMA analysis of IQVIA Analytics Link and FDA, EMA and PMDA data, June 2020.
[238] IHS Global Insights (May 2019). Polish patient groups oppose MoH's decision to increase healthcare funding without raising drug reimbursement.
[239] World Bank report for Romania, Aug 15, 2019, available at http://documents1.worldbank.org/curated/en/902651569031265960/pdf/Romania-Health-Program-for-Results-Project.pdf (last visited Oct. 28, 2020).
[240] EFPIA Patient W.A.I.T. Indicator 2019 Survey, 2020, available at https://www.efpia.eu/media/554526/patients-wait-indicator-2019.pdf (last visited Oct. 28, 2020).

Recently, the government's clawback on innovative medicines was capped at 25 percent of sales, but the amount that manufacturers must pay is based on prices that include wholesaler and retailer markups. Moreover, this 25 percent clawback tax discriminates against foreign-based innovative companies as medicines produced in Romania are taxed at 15 percent and generics are taxed at 20 percent. Overall, the lack of health care funding, onerous pricing policies, and long delays in accessing innovative medicines need to remain high on the political agenda and are currently being discussed in an Inter-Ministerial Working Group with the industry.

Spain

During the financial crisis of 2010-2012, Spain imposed aggressive cost containment measures that remain in place despite the country's economic rebound. Since 2010, these measures have collectively reduced pharmaceutical spending by 30 percent. Specific measures included the reimbursement delisting of more than 400 medicines, frequent direct and indirect price cuts, imposition of a 7.5 percent mandatory discount on reimbursed innovative medicines, restricted access for certain patient subpopulations and changes in pharmaceutical co-payment policies (*e.g.*, pensioners began contributing a 10 percent co-payment, subject to caps and other limits). In an effort to provide greater predictability and avoid further *ad hoc* cost-containment measures, the local innovative pharmaceutical industry association, Farmaindustria, and the current administration recently agreed to tie growth in public spending on original branded medicines to GDP growth. However, in practice, historical market access barriers and government price controls persist.

Additional market access challenges have emerged with recent administrations. These include therapeutic reference pricing of innovative medicines based on a group of products that includes generics and biosimilars, mandatory prescribing by active ingredient for small molecules and biologics, and mandatory automatic substitution of biosimilars. Only 55 percent of new medicines reviewed by Health Minister's Advisory Committee in 2018 were admitted to reimbursement. In 2019, an unprecedented level of rejections and delays by the Ministry of Health have negatively impacted patient access to new medicines.

Sweden

Although Sweden is one of the wealthiest countries in Europe, the proportion of national health expenditure accounted for by pharmaceuticals has fallen from 14.5 percent in 2000 to just 9.8 percent in 2018. Moreover, the Swedish Krona has declined against the Euro for more than a decade, accounting for approximately 60 percent of the decline in the overall price index with European countries since 2014. According to the Dental and Pharmaceutical Benefits Agency (TLV), about 60% of the price reductions for innovative medicines over 2014-2019 were due to changes in exchange rates. With more than 25 countries referencing Sweden – including Canada, Germany, and Switzerland – the global knock-on effects of the currency devaluation are significant.

Innovators face an increasingly challenging and non-transparent environment for government pricing and reimbursement. For example, manufacturers must submit a proposed price to the TLV as part of their combined pricing and reimbursement application. Unless the medicine has been identified as a candidate for a managed entry agreement, the application is either accepted or rejected in a nontransparent fashion. Although rejections can be appealed, the manufacturer is not permitted to provide new evidence to support its case. In making pricing decisions, the TLV employs an opaque "value-based" system which compares new products against comparators it deems therapeutically equivalent, including medicines used outside the reimbursement system and medicines used off-label. The TLV also engages in frequent re-assessments of reimbursed medicines, which commonly result in price cuts, new restrictions and even delisting.

Switzerland

Switzerland has compulsory private health insurance, but the government regulates which medicines are reimbursed and sets the prices of those products based on the prices in other European countries (all with lower GDP per capita) as well as based on the prices of alternative therapies which may represent a lower standard of care.

Moreover, the pricing and reimbursement system lacks predictability and transparency, and fails to appropriately account for currency appreciations as well as the local cost structure. For example, in 2015 Switzerland expanded the basket of countries used in its international reference pricing system for setting and adjusting prices of patented medicines. However, given the strength of the Swiss franc relative to other currencies in the basket (Euro, UK Pound, Swedish Krona and Danish Krone), the practice has become even more damaging as many of these currencies continue to lose value. Compounding this issue, in 2017 the Swiss Government began setting prices based on giving equal weight to the average international reference price and the average therapeutic reference price. Every year, one-third of the reimbursement list is subject to price adjustments based on this approach. For the group of 543 original brand medicines reviewed in 2018, 288 (53 percent) had their prices cut by an average of 19 percent. Similarly, for the group of 478 original brand medicines reviewed in 2019, 257 (54 percent) had their prices cut by an average of 17 percent. Manufacturers may also be required to pay back revenue after a product's first triennial price review if the price was reduced by more than 3 percent and if the previous price generated more than CHF 20,000 in excess revenue.

Over the past two years, government pricing authorities began using additional tools such as capitation, pay for performance, indication-based pricing, budget impact tests and rebating for drugs using in combination or by indication. As a result of these combined policies, Switzerland has experienced more pronounced market access delays for certain innovative medicines in recent years.

Intellectual Property Protection

EU Incentives Review

In June 2016, under the Dutch Presidency of the Council of the EU, the European Member State 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, accessibility and affordability of medicines. The Commission undertook a review process which concerns the following pieces of legislation: SPCs (Regulation EC 469/2009), Medicinal products for human use (Directive 2001/83/EC and Regulation EC 726/2004), Orphan medicinal products (Regulation EC 141/2000) and Pediatrics (Regulation EC 1901/2006). The review involves a number of studies, many of which have been completed.

While the review is still ongoing, PhRMA and its member companies are very concerned that it could 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. For example, the Commission has published a study and staff working document providing an analysis of orphan and pediatric incentives critical for the development of medicines for underserved populations. While it is now preparing a preliminary impact assessment, we understand that proposals to reduce the existing incentives are being considered that would further undermine the ability of innovative companies to bring new medicines to European patients. As noted in PhRMA's broader comments on the EU Pharmaceutical Strategy, there is a clear need for the EU to strengthen, rather than undermine, key conditions (including IP protections) that promote and enable tomorrow's innovations.

Supplementary Protection Certificates

As part of the broader incentives review, PhRMA is very concerned about the recently introduced SPC manufacturing waiver which weakens the scope of the exclusive rights conferred under an SPC and may encourage other countries to reduce or eliminate intellectual property protections.

On May 28, 2019, the EC published legislation amending the SPC Regulation (469/2009) to introduce an SPC manufacturing waiver. The waiver allows companies to manufacture generic and biosimilar products in Europe during the effective SPC period for export purposes to third (non-EU) countries and stockpile during the last six months of the validity of the SPC for the EU market. This legislation reduces IP rights and sends a signal to the world that Europe is weakening its commitment to IP incentives and innovation.

SPCs are a critical part of the European IP 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."[241] The SPC Regulation itself declares that: "[p]harmaceutical research plays a decisive role in the continuing improvement in public health."[242] 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."[243]

Preventing potential abuses of a the SPC waiver will 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. In the end, it may well be impossible to ensure that the exemption is used only to achieve its intended purpose. This could further reduce the effective protections SPCs are intended to provide.

In addition, the SPC waiver may be copied by other economies and may also encourage other countries to maintain or even weaken their already-low patent protection standards – 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.[244] If a leading developed economy like the European Union bends the rules, others are sure to break them.

[241] *See* EC Regulation No. 469/2009 concerning the supplementary protection certificate for medicinal products (May 6, 2009), available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R0469 (last visited Oct. 28, 2020), at Recital 4.
[242] 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), available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31992R1768 (last visited Oct. 28, 2020).
[243] Regulation No. 469/2009.
[244] 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*, Sep. 2017, available at https://doi.org/10.1093/jiplp/jpx161 (last visited Oct. 28, 2020).

INDIA

PhRMA and its member companies support the India's efforts to create a stronger business, innovation, and health care environment through the Make in India initiative, the National Intellectual Property Rights (IPR) Policy 2016, the National Health Policy 2017, and the National Health Protection Scheme (NHPS) announced in February 2018 to provide health insurance coverage up to INR 500,000 (approximately USD 7,000) to 500 million Indians and the opening of health and wellness centers under the Ayushman Bharat Mission. These efforts can advance improved access to health care 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 and its member companies members remain concerned about the challenging regulatory and policy environment in India.

Market access challenges persist and, despite important announcements to expand health care programs, the Indian Government has not increased investment in this critical area, leaving public health care spending at only 1.6 percent of GDP during 2019-2020,[245] and with only 37.2 % percent of the population covered under any health insurance in 2019.[246] Moreover, there are cumbersome procedures related to compensation which prevent India from becoming a part of global clinical trial programs and thereby limit patient access to innovative medicines in India.

Pharmaceutical innovators saw positive signs from the Indian Government in 2019, including the release of the Manual of Patents Practice and Procedure (MPPP) that was notified by the Office of the Controller General of Patents Designs & Trademarks (CGPDTM) on November 26, 2019. However, no real policy or practical changes have been realized. 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 National IPR Policy, 2016, 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.

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.

[245] Economic Survey 2019-2020, Ministry of Finance, Chapter 10, available at https://www.indiabudget.gov.in/economicsurvey/doc/vol2chapter/echap10_vol2.pdf (last visited Oct. 28, 2020).
[246] *See* National Health Profile 2019, available at http://www.cbhidghs.nic.in/showfile.php?lid=1147 (last visited Oct. 28, 2020).

Key Issues of Concern:

- **High tariffs and taxes on medicines**: Medicines in India face high effective import duties for active ingredients and finished products with the basic import duties averaging around 10 percent. When combined with the Integrated Goods and Service Tax, the effective import duty can exceed 20 percent. Additionally, the Goods and Service Tax (Central GST & State GST) on medicines ranges from 5-12 percent.[247]

- **Discriminatory and non-transparent government pricing and procurement policies**: PhRMA and its member companies commend the Department of Pharmaceuticals (DoP) for amending Paragraph 32 of the Drug Price Control Order 2013 (DPCO) to provide exemptions from price controls for five years from the commencement of marketing in India for patented products and for life for orphan drugs. However, the potential benefit of the provision is yet to be seen as there is significant delay in implementation, and applications made by industry remain pending. Moreover, there remain significant concerns of an evolving pricing regime that is discriminatory, unpredictable and opaque, including the threat of further amendments or dilution of Paragraph 32 that would harm the innovative industry. Further, possible inclusion of patented medicines in the National List of Essential Medicines (NLEM) and thereby a threat of direct price setting under the DPCO, would significantly reduce the benefits of patent protection and create an unviable business environment for the innovative industry. The broad authority granted to the National Pharmaceutical Pricing Authority (NPPA) and continued lack of transparency and predictability in the decision-making process inhibits further investment in India.

- **Discriminatory government procurement policies**: In 2020, the government began prohibiting global tenders in which the value of the goods to be procured is less than INR 200 crores (approximately USD 27 million). In addition, the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry issued a Public Procurement Order that discriminates against non-local bidders (less than 20 per cent local content) in all government tenders.

- **Unpredictable environment for clinical research:** While the Government is keen to reinvigorate clinical research in India, ambiguities and discriminatory practices in the Indian regulatory space continue to hinder that effort. In particular, the granting of waivers of India's local clinical trials requirements is highly subjective and unpredictable. While revisions to the Clinical Trials Rules, 2019, promisingly proposed that local clinical trials could be waived if the clinical trials were conducted in certain countries, the list of relevant countries has yet to be published. Further, the provision allowing for deemed approval of clinical trials

[247] *See* Central Board of Indirect Taxes and Customs, Tariffs on Chapter 30 (Pharmaceuticals), available at http://www.cbic.gov.in/resources//htdocs-cbec/customs/cst1718-020218/Chap-30-01052018.pdf;jsessionid=B8490083D262DD476149822F19D8A442 (last visited Oct. 28, 2020).

applications is discriminatory in nature, as it does not apply to drugs whose research and development was conducted outside of India. These issues perpetuate a burdensome environment for clinical research that undermines the availability of new treatments and vaccines for Indian patients.

- **Unpredictable patent environment**: India's legal and regulatory systems pose procedural and substantive barriers at every step of the patent process, including: impermissible hurdles to patentability posed by Section 3(d) of India's Patents Act, 1970, patent grant delays due to cyclic filings of pre-grant oppositions followed by rampant post-grant opposition proceedings, onerous patent application disclosure requirements and conditioning patent grant on unclear and subjective access and benefit sharing 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. Patent applicants continue to face 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.

- **Lack of patent enforcement**: One of the most significant challenges facing biopharmaceutical innovators seeking marketing approval in India is that marketing and manufacturing approvals are not transparent or coordinated between federal and state agencies. Indian law allows the Central Drugs Standard Control Organization (CDSCO) to approve third-party manufacturers to commercialize copies of innovator chemically-synthesized products, regardless of whether those products infringe on an innovator's patent(s). After four years of the medicine's first approval in India, a license from any of the state drug regulators to manufacture and market the product in India suffices – resulting in irreparable harm to patients, innovators, and other follow-on producers. Coincident with changes to Indian customs procedures that eliminated patent enforcement at the border, biopharmaceutical innovators are seeing an increased incidence of infringing products manufactured outside India in neighboring territories being illegally imported into India. Not only do such products violate patents granted in India, they may also potentially threaten patient safety.

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

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

High Tariffs and Taxes on Medicines

PhRMA member companies operating in India face high import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10 percent, due to the integrated GST imposed on imports, the effective import duty can exceed 20 percent. 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.

GST was implemented in July 2017 and, while it is expected to significantly reduce layers and complexity in the indirect tax system, it levies a 5-12 percent tax on medicines. Proposals to exempt certain life-saving drugs from GST and customs duties should be expanded to all medicines.[248]

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,[249] which calls for greater access to health care for low-income patients, and the NHPS in February 2018.[250] The National Health 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 percent of GDP by 2025.

While the aforementioned calls to action are laudable, India nevertheless has insufficient numbers of qualified health care personnel, inadequate and poorly equipped health care facilities, and most importantly lacks a comprehensive system of health care financing that would pool financial risk through insurance and help to share the cost burdens. While Prime Minister Modi has launched Ayushman Bharat, India has a shortage of doctors. This is further fueled by limited government investment and low allocation for health care in the national budget.[251] Despite the encouraging and ambitious goals in the new National Health Policy and the MoH's goal of increasing health spending

[248] Hindu Business Line, "GST: The right prescription," Aug. 5, 2016 (updated Jan. 17, 2018), available at http://www.thehindubusinessline.com/specials/pulse/gst-the-right-prescription/article8949378.ece (last visited Oct. 28, 2020).
[249] *See* National Health Policy, available at https://main.mohfw.gov.in/sites/default/files/9147562941489753121.pdf (last visited Oct. 28, 2020).
[250] National Health Protection Scheme, available at https://www.indiabudget.gov.in/doc/bspeech/bs201819.pdf (last visited Oct. 28, 2020).
[251] Center for Disease Dynamics, Economics & Policy (CDDEP), "Access Barriers to Antibiotics," available at https://cddep.org/publications/access-barriers-to-antibiotics/ (last visited Oct. 28, 2020).

as a percentage of GDP to 2.5% by 2025, government spending on health care is currently 1.6% which is one of the lowest levels in the world.[252] Without increased resources (both in terms of government spending and through reducing barriers for commercial health insurance), and a full implementation of the reform, high out-of-pocket spending on health care and pressure on the cost of medicines will persist.

Discriminatory and Non-Transparent Government Pricing Policies

Despite decades of government price controls in India, ostensibly seeking to improve patient 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.[253] Instead, India should focus on the key barriers to access in India, including insufficient financing, infrastructure, and quality.

In 2014, an Inter-Ministerial Committee was constituted to suggest a methodology to be applied to pricing of patented medicines in India.[254] Earlier, a DoP Committee on Price Negotiation for Patented Drugs report (February 2013) recommended an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines, with those patented medicines to be provided through health insurance. A final decision on the 2014 Inter-Ministerial Committee recommendations is yet to be made. However, PhRMA members are highly concerned that the 2013 proposals could be adopted, which would significantly reduce the benefits of patent protection, *de facto* discriminate against importers in order to pacify the domestic industry and create an unviable and unbalanced government pricing framework and business environment for innovative pharmaceutical companies.

The DoP is considering amending the DPCO 2013 to possibly include several provisions such as fixing retail prices of all drugs by way of a Trade Margin Rationalization formula. The proposed measure would extend the scope of stringent price controls in India based on a Wholesale Price Index (WPI) that would impose ceiling prices on new drugs and require annual price revisions for non-scheduled drugs.

PhRMA and its member companies commend the Department of Pharmaceuticals (DoP) for amending Paragraph 32 of the Drug Price Control Order 2013 (DPCO) to provide exemptions from price controls for five years from the commencement of marketing in India for patented products and for life for orphan drugs. However, the potential benefit of the provision is yet to be seen as there is significant delay in implementation, and applications made by industry remain pending. Moreover, there

[252] *See* National Health Profile 2019, available at http://www.cbhidghs.nic.in/showfile.php?lid=1147 (last visited Oct. 28, 2020).
[253] Analysis based on IMS MIDAS Data.
[254] 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, available at https://pharmaceuticals.gov.in/sites/default/files/Inter-Ministerial%20Committee%20on%20Prices%20of%20Pateneted%20Drugs.pdf (last visited Oct. 28, 2020).

remain significant concerns of an evolving pricing regime that is discriminatory, unpredictable and opaque, including the threat of further amendments or dilution of Paragraph 32 that would harm the innovative industry. Further, possible inclusion of patented medicines in the NLEM and thereby a threat of direct price setting under the DPCO, would significantly reduce the benefits of patent protection and create an unviable business environment for the innovative industry. The broad authority granted to the NPPA and continued lack of transparency and predictability in the decision-making process inhibits further investment in India.

Furthermore, expansion of price controls to a larger range of medicines will not substantially improve access to medicines in India; the real access barriers are insufficient health care financing, poor access to physicians, and inadequate health care facilities.[255] For example, even medicines and vaccines that are offered free of charge often do not reach the patients who need these medicines.[256] A 2015 study by IMS titled "Analyzing the Impact of Price Controls on Access to Medicines" found that price controls are neither an effective nor a sustainable strategy for improving patient access. The study found that the primary beneficiaries of price controls have been high-income patients, rather than the intended low-income population.[257] 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.[258]

PhRMA members believe that competitive market conditions are the most efficient way of allocating resources and rewarding innovation; however, the research-based biopharmaceutical industry recognizes the unique circumstances in India and is committed to engaging with the Government to discuss pragmatic public policy approaches through industry and public consultations that will enable the development of simple and transparent government pricing and reimbursement mechanisms that provide access to medicines, reward R&D and innovation, encourage clinical trials, include the patient perspective, and encourage continued investment into unmet medical needs.

[255] "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 Oct. 28, 2020).
[256] *See, e.g.*, 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 Oct. 28, 2020).
[257] IMS, "Assessing the Impact of Price Control Measures on Access to Medicines in India," June 2015.
[258] 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, available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf (last visited Oct. 28, 2020; Vernon, John, "Drug Research and Price Controls," *Regulation*, Winter 2002-2003, available at https://www.cato.org/sites/cato.org/files/serials/files/regulation/2002/12/v25n4-7.pdf (last visited Oct. 28, 2020).

Discriminatory Government Procurement Policies

On May 15, 2020, the General Financial Rules 161(iv)(b) were amended to prohibit global tenders where the value of the goods to be procured is less than INR 200 crores (approximately USD 27 million). In addition, on September 16, 2020, the Department for Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce and Industry issued a Public Procurement Order that discriminates against non-local bidders (less than 20 per cent local content) in all government tenders.

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.

We welcome the fact that the MOHFW and CDSCO have undertaken regulatory reforms, including adoption of New Drugs and Clinical Trials Rules, 2019, 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. However, as noted above, the New Drugs and Clinical Trials Rules, 2019 include significant ambiguities and several discriminatory provisions, which create uncertainties in the regulatory process for clinical trials and threaten the overall clinical research environment in India. These issues must be addressed in order to increase the availability of new treatments and vaccines for Indian patients.

Further, certain challenges that existed in the Drugs and Cosmetics Rules, 1945 continue to exist in the New Drugs and Clinical Trials Rules, 2019. Rule 41 of the New Rules, which describes attributable causes of injury for clinical trials participants, is overly broad and lacks a legally or scientifically sound process for determining causality of injury. Definitions for “trial related injury” and “standard of care,” remain uncertain. Furthermore, many provisions in the New Rules are ambiguous and highly subjective. For example, the provisions on local clinical trial waiver lack clarity; the list of countries to be notified by the regulator under the New Drugs and Clinical Trials Rules, 2019 for seeking waiver of local clinical trial is yet to be notified; the provision on deemed approval is discriminatory in nature as it is limited to drugs whose research and development was conducted in India; and the New Rules do not designate an appellate authority. Further, with no guidelines for the Subject Expert Committee (SEC) reviewing the applications for clinical trials heightens the existing subjectivity. Furthermore, requests for review of SEC decisions tend to be reviewed by the same SEC panel.

As a result, adoption of the New Rules leaves great uncertainty relating to future costs and liabilities associated with conducting clinical trials in India, resulting in many sponsors not launching clinical trials in India until these uncertainties have been resolved.

Research shows that if India were to address outstanding concerns, India could see an increase in the number of new clinical trials per year to above 800, adding over $600 million in economic gains.[259] Greater clarity and predictability are needed for administrative procedures and regulations *qua* drug registration applications, drug labelling standards and drug review standards and procedures in order to make the latest research products available in India.

Intellectual Property Protection

India announced the new National IPR Policy in May 2016.[260] The Policy recognizes the tremendous economic and socio-cultural benefits that a strong IP regime could bring to India through economic growth, employment, and a vibrant R&D environment. While the Government has established the Cell for IPR Promotion and Management under the National IPR Policy to conduct an IPR awareness campaign across the country in educational institutions, no concrete measures have been taken to improve the IP regime, *i.e.*, to promote innovation.

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, 2016 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

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

TRIPS Article 27 requires that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that an invention is

[259] Pugatch Consilium, "Quantifying the Economic Gains of Strengthening India's Clinical Research Policy Environment," Sep. 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 Oct. 28, 2020).
[260] 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 Oct. 28, 2020).

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

Additional substantive requirements for patentability beyond those enumerated in the TRIPS Agreement are inconsistent with India's international obligations. For example, Article 27 of the TRIPS Agreement provides an exclusive list of the types of subject matter that can be precluded from patent coverage, and this list does not include "new forms of known substances lacking enhanced 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.[261]

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, 1970, excludes method of treatment claims, effectively 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 unreasonable restrictive standards for patentability. Patent revocations using "hindsight" analyses made during pre- and post-grant oppositions have cited a lack of inventiveness concluding that inventions were based on "old science" or failed to demonstrate an inventive step. In addition, the lack of clear rules guiding pleading and evidentiary standards during pre-grant opposition proceedings create further uncertainty relating to the patentability of inventions. Further, pre-grant opposition procedures under Section 25 of India's Patents Act, 1970, have created significant uncertainty and delayed the introduction of new inventions by undermining patent office efficiency and delaying patent prosecution. The existing patent backlog and the absence of mechanisms such as patent term adjustment further complicate this process and contribute to the loss of patent life.

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

Weak Patent Enforcement

Indian law permits CDSCO to approve third-party manufacturers to commercialize copies of innovator chemically-synthesized products, regardless of whether those products infringe on an innovator's patent(s). After four years of the medicine's first approval in India, a medicine is deemed to no longer be a new drug.[262] As such, approval from CDSCO is not required and a mere license from any of the state drug regulators to manufacture and market the product in India suffices. State regulatory authorities are not required to verify or consider the remaining term of the patent protection on the original product. Therefore, an infringer can obtain marketing/ manufacturing 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, 2016 calls for identification of important areas of potential policy development related to ambiguities between IP laws and other laws or authorities whose jurisdictions impact administration or enforcement of patents.[263] At a minimum, India should amend its rules for "new drugs" in the New Drugs and Clinical Trials Rules, 2019, by increasing the period a drug is considered "new" from four years to ten years (thereby extending the period before which a manufacturer can seek approval for a follow-on product).

India also does not provide mechanisms for notification or resolution of patent disputes prior to marketing approval of generic products. Such mechanisms are needed to prevent the marketing of patent infringing products and resolve disputes in a timely manner. The SUGAM initiative launched in November 2015 to implement e-Governance with respect to the licensing system within India's 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 Rules[264] to omit Item 8 which previously required new drug applicants to disclose the "patent status of the drug."[265] This action further eroded the ability of patent owners to effectively and timely notify generic manufacturers and state drug regulatory authorities of existing patents related to medicines approved by CDSCO or get timely and adequately notified of filing of applications for marketing or manufacturing approval by any subsequent applicant. CDSCO's Notification GSR 19(E), dated January 10, 2019, falls short in providing an opportunity to facilitate notification of manufacturing applications between government agencies and patent holders under the SUGAM initiative. The industry has submitted many formal representations urging the Ministry of Health and Family Welfare (MOHFW) to take immediate steps to increase transparency and cooperation between central and state medicines regulatory authorities. At a minimum, MOHFW should ensure all biopharmaceutical manufacturers, the relevant Indian authorities and the broader public

[262] As per Rule 2(1)(w) of the New Drugs Clinical Trials Rules, 2019 a drug (apart from a modified or sustained release form of a drug or novel drug delivery system of any drug or a vaccine, r-DNA derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug) "*shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licensing Authority ….*"
[263] *See* Secs. 3.8 and 3.8.3 of the National IPR Policy.
[264] Form 44, Schedule A, Drugs and Cosmetics Rules, 1945.
[265] *Id.*

have timely notice of marketing and manufacturing applications filed with central and state regulators.

With regard to patent enforcement, in at least one specific case, the patent holder was forced to wait seven years before receiving a court decision upholding its patent. In that case, the court ultimately did not grant an injunction because by the time the decision was issued the patent was close to expiration.[266] In another case, a company waited two years for a Court to grant an injunction. During that time the infringing product was marketed and sold.[267] Recent cases[268] also reveal that defendants have started to obtain market authorizations and manufacturing licenses without the knowledge to the innovator and preemptively filed declaratory suits as to the non-infringement of the patents in a civil court so as to delay grant of any injunction orders. Moreover, while some innovators have been recently successful in obtaining interim injunctions, that relief is often very limited because infringers are only enjoined from future infringing acts, *i.e.*, it does not prohibit the marketing of products already manufactured and/or launched.

The Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015 (as amended in 2018) provides for the creation of commercial and commercial appellate divisions in high courts, and commercial courts at the district level to assist in addressing disputes in a timely manner. While this is a promising development, these courts are overburdened with cases and will require a significant amount of technical expertise and commitment of resources to be properly implemented. Patents involve technical issues and therefore, designation of a specialized patent bench with the appropriate knowledge is critical for accurately examining and interpreting the issues involving complex technologies.

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.[269] Further, the continued lack of a technical member required to be appointed under the Patents Act, 1970 on India's Intellectual Property Appellate Board coupled with the absence of a duly appointed Chairman heightens uncertainty as far as patent holders' access to the appeal rights provided under the Patents Act, 1970 is concerned.

Compulsory Licensing

The grounds for issuing a CL in India under the Patents Act, 1970 are broad, vague and appear to include criteria that are not clearly related to legitimate health emergencies. While the Indian Government continues to take a more measured and cautious approach

[266] *F. Hoffman-La Roche Ltd v. Cipla*, RFA(OS) 92/2012, Delhi High Ct., (Nov. 27, 2015), available at http://delhihighcourt.nic.in/dhcqrydisp_o.asp?pn=258821&yr=2015 (last visited Oct. 28, 2020).
[267] *Merck Sharp & Dohme Corp. v. Glenmark Pharms*, Delhi High Ct., 2015 (64) PTC417(Del).
[268] FAO(OS) 158/2019 – Natco Pharma Ltd. vs. Bayer Healthcare LLC, order dated July 11, 2019.
[269] 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 Oct. 28, 2020); "National Intellectual Property Rights Policy," May 12, 2016, available at http://dipp.nic.in/sites/default/files/National_IPR_Policy_English.pdf (last visited Oct. 28, 2020).

in responding to recent CL cases, the MOHFW continues to entertain potential recommendations to impose CLs on certain anti-cancer and rare disease medicines under the special provisions of Section 92 of India's Patents Act, 1970, which would cause further difficulty for patent owners to defend their patents. Moreover, some Indian pharmaceutical companies routinely initiate requests for voluntary licenses under Section 84(6)(iv) of the Patents Act as a precursor to seeking a CL, reducing CLs to a commercial tool rather than a measure of last resort. Internationally, in various multilateral forums, India has advocated for the broad adoption and implementation of 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, 1970, 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."[270] Notwithstanding the commercially sensitive nature of information required to satisfy Section 146, it also provides an impermissible basis for local companies to seek CLs, as occurred in 2012. Moreover, the rationale for requesting this information is unclear, and appears merely to be a disguise for facilitating questionable administrative challenges to existing patents. While industry raised these shortcomings in its comments to the draft Patents (Amendment) Rules, 2019 (which was notified vide GSR 396(E) dated May 31, 2019, and awaiting final Notification) they have not been addressed.

We believe that resort to CLs is not a sustainable or effective way to address health care needs. Voluntary arrangements independently undertaken by our member companies can better ensure that current and future patients have access to innovative medicines. Statements from the Government incorrectly imply that CLs are widely used by other governments, both developed and developing.[271] 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. Further, India must eliminate burdensome working reporting requirements under Form 27 and maintain the confidentiality of the working statement disclosures.

Administrative Burdens

PhRMA welcomes the Indian Government's ongoing work to address India's patent examination backlog including the commitment to reduce examination periods

[270] India Patents Act, Section 146(2).
[271] *See, e.g.*, Nirupama Rao, The Hill (op-ed), "India honors – not dishonors – patent laws," available at http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws (last visited Oct. 28, 2020). These misstatements of wide-spread use of CLs in the U.S. and the premise that CLs can resolve access problems in India have been refuted by OPPI and PhRMA.

from up to seven years to 18 months from initial submission. Backlogs undermine incentives to innovate and hinder timely patient access to valuable new treatments and cures. Because the term of a patent begins on the date an application is 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 in India. Generic manufacturers are also affected by patent examination backlogs. So long as a patent application is unreasonably delayed, generic manufacturers cannot assess whether they will have freedom to operate. That lack of certainty could discourage the launch of generic medicines or expose generic companies to damages once the patent is granted. In addition to increasing the number of patent examiners, it is equally important to assess administrative procedures that unduly extend patent examination timelines.

Section 8 of the 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.

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 readily 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.[272]

[272] *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://164.100.69.66/jupload/dhc/MAN/judgement/16-03-2015/MAN13032015S10452014.pdf (last visited Oct. 28, 2020); *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).

Additionally, 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.

Further, 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.[273]

We welcome the Guidelines provided for the examiners in the MPPP that was notified by CGPDTM on November 26, 2019. Of particular promise, Section 8 directs patent examiners to utilize resources available at WIPO DAS (Digital Access Service) and WIPO CASE (Centralised Access to Search and Examination) and to recognize the evolved jurisprudence by the Indian Courts. We also welcome that the initial proposal in the draft MPPP to expand the definition of "person interested" beyond the definition provided under the Patents Act, 1970 has been dropped in the final MPPP.

We also welcome the adoption of a Patent Prosecution Highway (PPH) programme between the Indian Patent Office (IPO) and the Japan Patent Office (JPO) and the release of the Procedure Guidelines for the PPH. However, the guidelines lay down procedures to file a PPH request in certain specified technical fields only, namely, Electrical, Electronics, Computer Science, Information Technology, Physics, Civil, Mechanical, Textiles, Automobiles and Metallurgy while JPO may receive applications in all fields of technology. We believe that PPH requests in India should be extended to all fields of technology, including biopharmaceuticals.

Regulatory Data Protection Failures

Contrary to its TRIPS Article 39.3 obligation, India fails to prevent unfair commercial use of the regulatory data submitted by an innovator in securing marketing approval in India or in a third country. Rather, when a pharmaceutical product has been previously approved by a Regulatory Authority in India or in another country, India requires only limited clinical data (in some cases involving as few as 16 Indian patients). This is *in lieu* of requiring submission of the entire dossier by the applicant for review by India's regulatory authority. Moreover, in some instances when an applicant seeks approval for a generic or biosimilar product that has already been approved in other

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

countries , Indian authorities waive the requirement to submit even this data.[274] In those circumstances, any subsequent approval of the drug granted to an entity who is not an innovator in India is based entirely on the prior approval granted to the innovator in a third country.

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

[274] *See* Rules 75 and 80 of the MOHFW, "The New Drugs and Clinical Trials Rules, 2019," available at http://www.egazette.nic.in/WriteReadData/2019/200759.pdf (last visited Oct. 28, 2020).

INDONESIA

PhRMA and its member companies see tremendous opportunities to contribute further to Indonesia's health care goals. However, longstanding market access and intellectual property (IP) barriers in this large and growing market continue to hinder possible partnerships from delivering on their full potential.

The Indonesian Government appears sincere in its desire to address these barriers, notably through recent regulatory reforms in the 2020 Omnibus Law. The Law revises 76 existing laws including a significant partial revision of the 2016 Patent Law and the 2014 Halal Law. PhRMA's member companies are encouraged by this reform and the steps taken to achieve meaningful results and improvements to the IP environment in Indonesia.

Additionally, PhRMA recognizes that the Indonesian government has initiated a process to more comprehensively amend the 2016 Patent Law. This process has included positive steps such as meetings with stakeholders in Jakarta and we are hopeful that legislation will be passed in 2021. Such revised legislation would be an even more significant indication that Indonesia is serious about positively changing their investment environment and perception globally. 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 protections.

Key Issues of Concern:

- **Forced localization requirements**: While the recent revisions to Article 20 of the 2016 Patent Law in the 2020 Omnibus Bill are a positive step forward, other forced localization requirements still remain in Decree 1010. PhRMA looks forward to additional measures to address outstanding concerns regarding Decree 1010 to ensure that Indonesian patients have access to new medicines.

- **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. To this end, PhRMA's member companies are encouraged by the fact that the government procurement agency is considering implementation of Multiple Criteria Decision Analysis (MCDA) for procuring pharmaceuticals.

- **Mandatory halal certification**: On September 25, 2014, the Indonesian Parliament passed the Halal Products Law. The Law 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 and the broader public health agenda.

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

- **Compulsory licensing**: In July 2020, Indonesia issued Presidential Regulation No. 77/2020 on government use of compulsory licenses (CLs). The regulation was published in final form without consulting stakeholders. The regulation broadly enables government agencies to request CLs for pharmaceutical products to address emergency needs in the public interest. If a CL is granted and the government is unable to implement the patent, it may appoint a third party to do so. Despite efforts in 2019 to address and revise existing CL regulations to more appropriately align with global norms and best practices, this new regulation and the process by which it was developed and issued sends a troubling signal to innovators.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

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. The guidelines for Drug Registration (popularly known as the Brown Book) developed by Food and Drug Monitoring Agency (BPOM), issued in July 2011 and revised in 2013 and 2016, were comprehensively renewed in November 2017; some of the provisions in this latest 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. While PhRMA's member companies acknowledge the initial steps taken by BPOM to engage in consultations, key concerns remain unresolved with the existing provisions in Decree 1010 and Decree 1799.

Recently, on October 5, the Indonesian parliament passed the government-initiated Omnibus Bill into law that revises 76 existing laws, including partial revision of the 2016 Patent Law. Specifically, the Omnibus Law revises Article 20 of the 2016 Patent Law, such that a manufacturer is no longer required to locally produce the product in order to be considered "working" the patent in Indonesia. This is as a very positive development to strengthen the IP environment in Indonesia. As a result of this change, patent holders are required to ensure the availability of the patented products in Indonesia in order to preserve their patents, which can be achieved through importation or licensing.

Another important issue is the local content requirement (LCR) established as a result of Presidential Instruction No. 6/2016, as a means to accelerate the development of the pharmaceutical and medical device industry in Indonesia. Under the regulation, an LCR calculation is imposed as a 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 access barrier to new medicines and health care for patients.

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

Cost-Focused Formulary Decisions

FORNAS serves as a basis for pharmaceutical reimbursement and public-sector procurement. 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. Moreover, although products can be added or removed annually, formal updates to the FORNAS only take place every two years. Recent moves to delist products on arbitrary cost-effectiveness grounds have raised additional concerns.

Consistent with the guidelines, listing decisions should reflect all of the evidence submitted, including clinical evidence demonstrating the product's safety and efficacy. To this end, PhRMA and its member companies are encouraged that the government procurement agency is considering implementation of more holistic assessment approaches (*e.g.*, such as multiple criteria decision analysis) for procuring medicines. PhRMA encourages the establishment of a more transparent, credible and evidence-based decision-making process in FORNAS.

Mandatory Halal Certification

Indonesia's Mandatory Halal Certification Bill, enacted in September 2014, mandates Halal certification and labeling for food and beverages, medicines, cosmetics, chemical products, biological products, and genetically-engineered products. The legislation establishes a new Halal certification authority called BPJPH, 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 MoH, Regulation No 31/2019 on the implementation of the Halal Law was signed by the President on April 29, 2019, stipulating a phased implementation of the law. According to the Decree of Minister of Religious Affairs no. 26/2019, dd. October 15, 2019, manufacturers will be required to provide halal certification for over the counter drugs between October 2019 to October 2029 and for prescription drugs between October 2021 to October 2034. However, it is understood that the President and the MoH are drafting further regulations that will provide biopharmaceutical products with a 30-year grace period.

The newly issued Omnibus Law includes revisions to the Halal Law that are intended to streamline the process of halal certification, simplify the certification renewal process and provide clearer timelines. PhRMA's member companies recognize and support the religious and cultural sensitivities of all Indonesians, but are concerned that these measures may have negative implications for patient health. In particular,

significant questions remain regarding the process for securing halal certification, labeling, and how the government will ensure that the new requirements do not impact patient access to the medicines they need.

Intellectual Property Protection

Restrictive Patentability Criteria

The Patent Law precludes patents on new uses (indications) and establishes an additional patentability criterion of "increased meaningful benefit" for certain forms of innovation, such as new salts or new dosage forms. These restrictions undermine support for important innovations and are contrary to existing international obligations by imposing additional or heightened patentability criteria in a manner that discriminates against particular classes of technology. While this issue has been partially addressed through revisions to the Patent Office's internal technical guidelines, the underlying 2016 Patent law provisions remain unchanged. Such requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing.

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 Patent Law appears to be inconsistent with the framework provided by the TRIPS Agreement. Moreover, the 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 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 July 2020, Indonesia issued Presidential Regulation No. 77/2020, on government use of CLs. The regulation was published in final form without consulting stakeholders. The regulation enables government agencies to request CLs for pharmaceutical products to address emergency needs in the public interest and establishes a process to evaluate requests. If a CL is granted and the government is unable to implement the patent, it may appoint a third party to do so, subject to certain conditions. While the government must notify the patent holder when a request is accepted for review, there is no formal procedure allowing patent holders to dispute claims in a request or recommend alternatives. If a CL is granted to address emergency needs, the right holder must continue to pay fees to maintain the patent. The regulation also does not expressly permit or prohibit imports or exports of products manufactured under CLs.

We understand the Indonesian government has no immediate plans to issue a CL on any particular product, but this action is very concerning – particularly in the current climate. While the regulation is not targeted at particular products, it clearly poses a potential immediate threat to COVID-19 treatments and vaccines and could be used against other products the government deems necessary for emergency purposes in the future. Additionally, despite efforts in 2019 to address and revise existing CL regulations to more appropriately align with global norms and best practices, this new regulation and the process by which it was developed and issued sends a troubling signal to innovators.

The 2016 Patent Law and implementing regulations create 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, Article 79 of the Patent Law unnecessarily requires disclosure of private licensing agreements. However, we welcome that the newly issued Omnibus Law decouples the local production requirement from CLs, and aligns Indonesia's patent working requirements with international rules and practices to include the manufacture, importation, and/or licensing of a patented invention in Indonesia.

PhRMA and its member companies also welcome the process the MLHR has initiated to separately amend the existing Patent Law (2016). Indonesia should make clear in the revised 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 health care needs. Voluntary arrangements independently undertaken by member companies better ensure that current and future patients have access to innovative medicines.

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. New leadership at BPOM have focused their efforts on combatting counterfeit food and medicine products, but the budget and resources for this effort remain inadequate. Increasing and enforcing the penalties for criminals caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as unsafe medicines will greatly assist Indonesia's efforts to reduce the harmful impact of counterfeit medicines.

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 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 Indonesian patients.

JAPAN

A decade ago, Japan made important reforms in the areas of drug pricing, drug evaluation and approval, and vaccine policy that made its system more transparent, more supportive of innovation, and more conducive to innovative biomedical research and development. These changes reduced regulatory delays in the introduction of new drugs and reduced Japan's "drug-lag." However, the environment related to pricing and reimbursement in Japan has significantly deteriorated since 2016, and particularly between 2018 and 2019. The Japanese government has pursued, and the Central Social Insurance Medical Council (Chuikyo) has approved, a number of new price cutting mechanisms and 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.

Japan imposed out-of-cycle price cuts on pharmaceuticals in 2019 claiming these were necessary in conjunction with the increase of the consumption tax from eight to ten percent. During the 2020 pricing reform, Japan failed to make necessary improvements to its Price Maintenance Premium (PMP) system to ensure it was science-based, non-discriminatory and fairly evaluated innovative products and innovative companies. On top of this, the Japanese government made a sudden announcement that the approval of new indications for a product will trigger another price cutting mechanism, despite clear evidence that the costs of medicines within the Japanese health care system are under control and that there are significant areas within the system for further efficiency and cost savings that remain unexplored. Further, these reforms to the system are being developed with limited meaningful opportunities for stakeholders to provide timely input. Similarly, several new policies are being implemented in a non-transparent manner and in a growing number of cases in a way that is contrary to their stated intent. All of this has raised serious questions about the fairness, transparency and predictability of the reform process and its outcome to date.

Key Issues of Concern:

- **Inappropriate and discriminatory revisions to the PMP system**: The drug pricing package announced in December 2017, included several new pricing policies that run counter to the government's pledge to fuel innovation in Japan and efforts to appropriately value innovation. PhRMA member companies are concerned that the number of innovative products that qualify for the PMP have been reduced dramatically and fewer PhRMA member companies qualify for the full benefit of the PMP under the new company requirements for the PMP. According to the Ministry of Health, Labor and Welfare (MHLW), approximately 30 percent of patented medicines no longer qualify. Unfortunately, when the Japanese government undertook a review of the outcome of the new PMP rules in 2019, they made only minimal changes. The PMP system continues to severely and inappropriately undervalue U.S. intellectual property. Further, the PMP eligibility criteria that are biased in favor of domestic companies were not adequately revised, seriously calling into question Japan's commitment to fair and non-discriminatory policies.

- **Health technology assessment (HTA)**: In 2018, the Japanese government cut the prices of several leading innovative products that were subject to an ongoing cost-effectiveness assessment pilot program. For these products, the price premium granted at launch for innovativeness and clinical benefit was later reduced based on a poorly justified cost-effectiveness threshold of JPY 5 million yen per quality-adjusted life year. Given the challenges experienced during the pilot program, the Japanese government decided to re-review the outcome of the pilot program for several products. In April 2019, the new HTA system was formally implemented, which is broader in scope than originally proposed (although still limited to revising the price premium granted at launch), and inconsistent with international norms. In particular, the HTA criteria ignore many aspects of a product's value. Furthermore, the system has been developed with limited, meaningful opportunities for the innovative biopharmaceutical industry and other stakeholders provide input. PhRMA continues to remain concerned about the current direction of the new HTA system in Japan and its potential to significantly undervalue U.S. innovation and limit patient access to new medicines. It is also troubling that certain stakeholders continue to advocate for Japan to use HTA for reimbursement listing. Such a new policy would not only have significant implications related to previous bilateral U.S.-Japan trade understandings, but would almost certainly delay patient access to innovative medicines.

- **Other government pricing policies of concern**: The introduction of optimal use guidelines and repeated changes to various repricing rules have been imposed suddenly and without meaningful stakeholder involvement. These actions by the Japanese government reduce the predictability and transparency of the drug pricing system in Japan and threaten to undervalue innovative U.S. products.

- **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. Further, the Japanese government has signaled its intention to expand the scope of the new HTA system within the next few years, despite acknowledged limitations in capacity and expertise. These frequent, non-transparent changes to the rules for setting prices at reimbursement listing as well as for repricing of existing products, combined with the other recent changes to the government pricing and reimbursement system, have made the Japanese market highly unpredictable.

- **Pricing reform initiatives continue to lack transparency**: As the Japanese government developed its detailed plans to carry out the drug pricing reform initiative over the last three years, there were few formal attempts by the decision-making bodies to seek input from stakeholders, including the innovative pharmaceutical industry. For example, despite the key policy issues being debated by the government throughout 2018 to 2020, the Japanese government has not once released the proposed new rules for public comment. In addition, the industry was only invited to testify before the Chuikyo on two occasions in 2019 and 2020, and the time allotted for testimony has typically been rigidly limited. Details on the

topics for discussion at important meetings of the Chuikyo are not always shared with stakeholders in advance. Further, except for the formal hearings at which industry was invited to testify, industry representatives were only able to attend Chuikyo meetings as observers. 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 system.

- **Regulatory policies**: The Japanese Government continues to seek to accelerate and expand drug development in Japan, ensure that patients have prompt access to the newest drugs and support the pharmaceutical industry as a key driver of economic growth in Japan. To achieve these goals, more flexible approaches are needed in the approval and regulatory process to promote simultaneous global development. This includes acceptance of a pooled strategy for the ICH E17 guideline, Japanese sample size for multi-regional clinical trials and long-term clinical studies, and to increase the number of drugs designated and approved early under the Sakigake designation and conditional early approval systems so they are equivalent to similar systems in the U.S. and EU.

- **Vaccines**: In order to ensure that Japanese citizens have access to the world's newest and most innovative vaccines, Japan needs to execute the National Vaccine Plan and to develop a system that provides for permanent and full funding of all recommended vaccines, transparency in the evaluation and adoption of new vaccines into the recommended (*i.e.*, funded) vaccination schedule, and a science-based process to determine the benefits of vaccines and to manage adverse events.

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

- **Effective patent enforcement**: Recent actions by MHLW to approve generic versions of an innovative product even though JPO had upheld two of the four claims on the patent identified by the innovator as relevant to its product, raise concerns for industry as to Japan's commitment to effectively enforce patents. Further, while injunctive relief is typically available in Japan, such relief can take months to secure, thereby frustrating the ability of the innovator to seek an injunction before potentially infringing products are allowed to enter the market.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Inappropriate and Discriminatory Revisions to the PMP System

The introduction of the PMP in 2010 as a two-year pilot project (followed by its renewal in 2012, 2014 and 2016), has been a critical factor in promoting innovation in Japan, eliminating the drug lag, ensuring that Japanese patients have timely access to innovative medicines, and 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 percent ceiling on the 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 or launch of new drugs. Therefore, the top public policy priority of PhRMA's member companies over the years has been to advocate 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 implemented in April 2018, 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. Particularly for the third set of products, in essence, this new system equates "innovativeness" with the speed and the order in which products launch. PhRMA is opposed to such a non-science-based evaluation of innovation, and notes that several U.S., globally-leading products have been deemed "non-innovative" under the new criteria and stripped of their PMP eligibility. This clearly demonstrates that the new system fails to appropriately value U.S. innovation.

Companies with products eligible to receive the PMP were 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 was limited to 25 percent but not exceeding 30 percent, even if there are many companies with the same score. All of the eligible products from these companies were awarded the full premium. Eligible products marketed by the middle tier or bottom tier of companies were awarded 90 percent or 80 percent of the premium, respectively.

While the Japanese government undertook a review of the new PMP rules in 2019, only very minor changes were made to the system. PhRMA believes that limiting the number of companies eligible for the full PMP cannot be a true test of innovativeness. Further, these criteria continue to inappropriately favor larger companies, and specific elements of the PMP company eligibility criteria appear to be inherently biased towards domestic companies, seriously calling into question Japan's commitment to fair and non-discriminatory policies pursuant to its WTO obligations.

In addition to the failure to provide adequate meaningful opportunities for interested stakeholders, including the U.S. industry to provide input into the development of these policies, the Japanese government has also failed to publish clear rules on how some of the new policies are being interpreted and implemented.

PhRMA believes further revisions are needed to ensure that the system is science-based, fairly evaluates innovation and promotes research and development.

Health Technology Assessment

PhRMA agrees that appropriate HTA systems have the potential to assist governments in making informed decisions about allocating resources. However, deficient HTA processes can run counter to their key objectives and risk denying or delaying patients' appropriate access to medical technologies, inefficiently allocating resources, constraining clinical freedom, and harming innovation through pure cost containment methods.

In 2018, the Japanese government cut the prices of several leading innovative products that were subject to an ongoing cost-effectiveness assessment pilot program. For these products, the price premium granted at launch for innovativeness and clinical benefit was reduced based on a poorly justified cost-effectiveness threshold of JPY 5 million per quality-adjusted life year, ignoring many other elements of a product's value. Given the challenges experienced during the pilot program, the Japanese government decided to review the outcome of the pilot program for several products.

In April 2019, the Japanese government implemented the new HTA system which is broader in scope than originally proposed and is out of line with international norms. The system remains focused on cost-effectiveness thresholds and does not take into consideration many other aspects of a product's value (although such submissions are accepted), including assessed values incorporated into the initial pricing premium, as well as broader clinical, societal and economic benefits not captured by an incremental cost-effectiveness ratio. By primarily serving to reduce the price premiums granted at launch for superior products, the adopted approach perversely acts to remove the incentives for medicines that deliver better patient outcomes. Further, the system has been developed without meaningful opportunities for interested stakeholders, including the innovative industry, to provide input. Unfortunately, the MHLW presentations to the Chuikyo did not fully include proposals put forward by the industry and other materials on our learnings from other markets. Furthermore, PhRMA remains concerned about the Japanese

government's plan to potentially expand the scope of the HTA system in Japan and, in turn, significantly undervalue U.S. innovation and ultimately harm patient access to new medicines.

Other Government Pricing Policies of Concern

The introduction of optimal use guidelines and repeated changes to various repricing rules have been imposed suddenly and without meaningful stakeholder involvement. These actions by the Japanese government reduce the predictability and transparency of the drug pricing system in Japan and threaten to undervalue innovative 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 repricing rules should be revisited in their entirety and the effect of optimal use guidelines on the health insurance system should be strictly limited so that patients' early access to innovative medicines is ensured.

The industry also recommends that other unfair or unreasonable rules in Japan's drug pricing and reimbursement system be corrected as follows:

1. *Revisit Repricing Rules*: Over the past few years, new or strengthened repricing rules have been applied in Japan. For example, in 2016 the huge seller repricing rule was introduced, starting in 2018 some of the repricing rules have been applied on a quarterly basis instead of a biennial basis and in 2020 a special rule for indication change repricing was introduced. Such frequent changes and tightening of the repricing rules significantly impair the predictability of drug prices and reduce the incentive to invest in R&D for additional indications. PhRMA believes that the complex repricing rules need to be revisited and restructured by reexamining the requirements of each rule, the necessity for huge seller repricing, the application of repricing to similar drugs, and the mechanism to evaluate the usefulness of an additional indication.

2. *Reward for innovative additional indications*: The MHLW should consider not only the strengthening of the repricing rules, but also the mechanism by which the reward for innovative additional indications can be reflected in the drug price. According to the current rules, when pediatric or orphan indications are added, a corrective premium can be granted at the time of repricing. In the same manner, when adding highly innovative indications, corrective premiums should be added at the time of repricing.

3. *Apply Innovation and Usefulness Premiums*: Under the existing pricing method for new drugs, certain premiums may be granted where the drug shows greater innovation or usefulness than its comparator or existing treatments. However, most new drugs eligible for the price premium still receive no, or relatively low, premiums. One reason for this is that even if evidence of usefulness is available, a premium is often not applied when the supporting evidence is not evaluated in the PMDA review report. PhRMA believes that even if such evidence is not

included in the PMDA review report, it should be accepted for determining whether a premium is applied as long as the evidence can withstand scientific and objective evaluation.

4. *Relax the 14-day Limit Rule for New Drug Prescriptions*: Prescriptions for newly approved drugs can only be written for a 14-day supply during the first year after reimbursement price listing. This restriction imposes a physical and financial burden on patients who are forced to visit their doctors twice a month for the first year simply to receive a prescription. It also imposes a burden on overworked doctors who have to see a patient as many as 26 times during this first year simply to renew a prescription.

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. This will be discussed in 2020 and is of serious concern to the innovative pharmaceutical industry. 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 percentage difference between the NHI price and the current market price.

Pharmaceutical Regulatory Reform and Related Issues

1. Simultaneous Global Development of Drugs

PhRMA welcomes the government's continued support of simultaneous global development and efforts to promote multiregional clinical trials (MRCT) in order to eliminate the drug lag and expedite the availability of life-saving and life-enhancing drugs to patients. Therefore:

- PhRMA encourages the government to increase its global and regional regulatory harmonization efforts, especially to include the reduction of market-specific requirements that can delay simultaneous global development. In particular, PhRMA hopes the MHLW and Pharmaceuticals and Medical Devices Agency (PMDA) will be increasingly flexible in the approval and regulatory process for promoting simultaneous global development, including the acceptance of a pooled strategy for the ICH E17 (MRCT) guideline, Japanese sample size for MRCT and long-term clinical studies.

- PhRMA encourages harmonization of the following CMC data points: (1) globally aligned science- and risk-based specification setting for commercial products; (2) flexibility of requirements for CMC data for expedited approval pathways; (3) harmonization of pharmacopoeias; (4) bio-equivalency (BE) data requirements

for drug products under development, including adherence to ICH M9 guidelines; and (5)CMC data requirements for biological products.

- PhRMA encourages PMDA to continue to ensure consistency across its review offices as they consider drug development strategies based upon the scientific aspects of each drug.

- The threat of drug-resistant pathogens to antibacterial drugs is a worldwide issue. PhRMA encourages the Japanese government to consider measures to promote drug development for Antimicrobial Resistance (AMR), such as the creation of internationally harmonized clinical development guidelines for AMR.

2. Improved Efficiencies at PMDA

PhRMA appreciates and applauds the significant efforts made by PMDA to meet its review performance goals for standard and priority files, as well as its efforts to meet the demands for consultations in an expeditious manner. PhRMA values its participation in PMDA's Working Groups on consultations and review practices. PhRMA looks forward to continuing its active participation in these groups and hopes that its participation will lead to the development and implementation of concrete process improvements that will aid PMDA in continuing to meet its performance goals.

3. Revision of Post-Approval Change Process and Reduction in Review Times

PhRMA appreciates the opportunity to discuss Japan's post-approval changes to manufacturing and control processes and will continue to provide constructive recommendations based on global best practices for revising the system so that it is more aligned with those systems used by other major regulatory agencies. PhRMA further appreciates the efforts to reduce the review times of partial change applications and encourages PMDA to include biologic products, especially those arising from recombinant technology, in those review targets.

4. Risk Management System

Reform of the safety system and risk management is an important undertaking by the government, and PhRMA has supported the government's preparation and implementation of its Risk Management System (*i.e.*, Risk Management Plan (RMP)). The RMP went into effect on April 1, 2013. Recognizing that there is currently no global PV standard, PhRMA and its member companies support the development of such a standard to facilitate the implementation of an RMP that provides effective and efficient safety measures and enable mutual collaboration between the U.S., EU and Japan. PhRMA looks forward to continuing to engage collaboratively with academia and regulatory authorities on the implementation of this concept and process.

5. AMED – the Japan Agency for Medical Research and Development

PhRMA welcomes the creation of AMED in April 2015 as a new agency designed to enhance translational research, to support drug development from the laboratory through the clinical development process and into the marketplace, and to coordinate the national government's health care research and development budgets now assigned to different ministries without strategic coordination. PhRMA emphasizes the need to ensure that AMED's programs will be open to all pharmaceutical companies, whether Japanese or foreign based.

6. Sakigake Program and Conditional Early Approval System

PhRMA welcomes the enforcement of the "Sakigake" program and the conditional early approval system under the revised Pharmaceuticals and Medical Devices Law, which will encourage the early evaluation and approval of important new drugs. To avoid a drug lag for innovative products in Japan, PhRMA encourages the government to adopt a flexible approach to the acceptance requirements for applications in order to increase the number of drugs designated and approved early under the Sakigake designation and conditional early approval systems. This will ensure Japan's expedited approval pathways are equivalent to similar systems in the U.S. and EU.

Preventive Health Care and Vaccines

Prevention plays a critical role in protecting a population's health and well-being. However, more effective and efficient awareness initiatives aimed at the public should be undertaken. Vaccines are particularly important in reducing disease burden and medical expenses, as well as improving the quality of life. The past several years have seen some important changes, including a revision in 2013 of the Preventive Vaccination Law, implementation of a National Vaccine Plan and adoption of six vaccines into the national immunization program (NIP). The next revision to the Law is expected to be finalized in 2021, although the timeline remains unclear due to the COVID-19 pandemic. In preparation for the next revision, responsible committees within MHLW, such as the Basic Policy Committee, have begun discussions on the direction of policy reforms.

The following outstanding issues continue to require attention:

1. Lack of transparency and timeliness in the NIP decision-making process at MHLW

The current recommendation process is not transparent as it relates to the evaluation and adoption of new vaccines. As a result, vaccine manufacturers lack crucial information as to what data are necessary to receive a national recommendation and when the data should be presented. Furthermore, the vaccination decision-making process is unclear. While a Vaccination Policy Committee under MHLW exists, the timeline of a new vaccine's evaluation, the criteria by which it is evaluated, and the committee's ability to change vaccination policy, are not transparent. For example, in October 2019, MHLW's Vaccination Policy Committee made the decision to include

rotavirus vaccines into the NIP from October 2020. This decision came eight years after the vaccine's regulatory approval in Japan. It is essential that decisions related to vaccines be based on science. This is especially important in any evaluation of adverse events and attendant actions.

2. Lack of international regulatory harmonization

Quality standards for vaccines and pre- and post-approval vaccine supply processes, including the current national testing requirement, should be streamlined and harmonized with global standards in order to supply innovative vaccines in a timely manner. Japan faces sporadic outbreaks due in part to shortage of available vaccines. The most recent example is measles that started in the spring of 2018 and continued into 2019. In addition, a rubella outbreak in the summer of 2018 prompted the issuing of a warning for pregnant women traveling to Japan by foreign governments, including the U.S. Centers for Disease Control and Prevention. Introduction of vaccines from outside Japan is one effective option in such circumstances, and in order to facilitate and accelerate this, there should be a more harmonized regulatory system, including modernization of various requirements such as Minimum Requirements for Biological Products.

3. Lack of broad recognition from Japanese citizens on the value of vaccines

Although the revision of the Preventive Vaccination Law provided for full national funding for most recommended vaccines, including several foreign-origin vaccines, the changes did not apply to several other vaccines that are already approved. The value of vaccines should be recognized by a funding system and NIP process that incentivize manufacturers to develop and bring new vaccines to Japan as quickly as possible, together with a nationwide program to educate citizens, and especially parents, about the importance of vaccinations.

4. Countermeasures against vaccine shortage risks

To mitigate supply shortage risks, MHLW has proposed manufacturers and distributors increase their inventory of vaccines. Details on implementation should be further discussed by taking into consideration the different circumstances of each vaccine. Given that an increase in inventory alone will not completely address the root causes of supply instability, PhRMA believes further discussions are needed. In particular, the international harmonization of regulatory standards and required testing should be further promoted to lower the entry barrier to the Japanese market.

With these issues in mind, PhRMA recognizes the importance of the beginning of a National Vaccine Plan in Japan and the creation of a Japan version of the U.S. Advisory Committee on Immunization Practices (ACIP). PhRMA supports their fair operation and urges that the Committee on Immunizations be given the maximum possible responsibility and autonomy to make recommendations based on scientific evidence and fair assessment of innovation. A priority should be full execution of the National Vaccine Plan.

Intellectual Property

Patent Term Restoration

Japan's PTR system permits term extensions for subsequent approvals for a product, such as for a new use of a previously approved product. PhRMA members appreciate Japan's PTR laws, as they acknowledge the value that additional approvals can provide to patients. However, PhRMA urges the JPO to review its practices in granting PTR for subsequent approvals, to take into account the full regulatory review period in determining the length of any extensions. In particular, the current JPO practice, which provides an extension period based only on what is considered "necessary testing" for the subsequent approval, often results in extension periods for subsequent approvals that are shorter than the extension period of the first approval. As a result, the current practice can act as a disincentive to conduct research on additional medical uses and indications, including new formulations for an approved product.

Effective Patent Enforcement

Generally, PhRMA's members value the highly predictable and reliable intellectual property protections provided in Japan. Predictable and reliable IP protections are particularly important to our sector given the significant resources required to develop innovative medicines, as well as the inherently risky nature of developing new medicines which must not only be developed but also must be shown to be safe and effective for treatment of a particular disease or condition. Less than 12 percent of all potential new drugs entering clinical trials result in an approved medicine, and in most cases, new products in our sector fail to deliver returns that meet or exceed investment.[275]

However, recent actions by the MHLW throw the predictability of Japanese IP protections into question. Specifically, while MHLW appropriately takes the position that it should not arbitrate patent disputes, it essentially did so this past summer when it unilaterally determined that it was appropriate to approve multiple generic versions of an innovative product even though the JPO had upheld two of the four claims on the underlying method of use patent. In other words, MHLW took it upon itself to interpret whether the upheld patent claims covered the innovative product.

The innovative manufacturer in this instance has initiated patent infringement suits against each of the approved generics. That, however, has served to highlight another deficiency in Japan's patent enforcement system. Specifically, now that the MHLW has approved these generics versions, those products will be able to enter the market as soon as the Health Ministry adds these products to the National Health Insurance price standard list. It is expected that this will occur in December. While injunctive relief is typically available in Japan, such relief can take months to secure, thereby frustrating the ability of the innovator to seek an injunction before potentially infringing products are

[275] Research!America, U.S. Investments in Medical and Health Research and Development, 2013-2017, Arlington, VA, Fall 2018, available at https://www.researchamerica.org/sites/default/files/RA-2017_InvestmentReport.pdf (last visited Oct. 28, 2020).

allowed to enter the market in December. As a result, the manufacturers of each of the approved generics may be put in the position of having to decide whether they will launch at risk despite the ongoing litigation. In short, this situation creates significant uncertainty for innovators and generic manufacturers alike, and could ultimately result in products being prescribed to Japanese patients that ultimately have to be withdrawn from the market based on the outcome of the pending litigation. It is exactly this uncertainty that well-functioning and effective patent enforcement systems are designed to avoid.

KOREA

PhRMA and its member companies remain highly concerned with several market access and intellectual property (IP) 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. Korea's pricing practices are inconsistent with its commitments under the U.S.-Korea Free Trade Agreement (KORUS).

Recognizing these deficiencies, PhRMA and its member companies commended the U.S. Government for securing a commitment from Korea to amend its premium pricing policy for global innovative drugs to ensure non-discriminatory and fair treatment for U.S. pharmaceutical exports. While it was hoped that Korea would use this opportunity to demonstrate its broader pledge to appropriately value innovative medicines, Korea has implemented this commitment in a manner that eviscerates the ability of any company to qualify for premium pricing and is in contradiction with the spirit of their 2018 commitment. PhRMA stands ready to work with the U.S. and Korean Governments to secure amendments to Korea's pricing and reimbursement policies consistent with Korea's broader KORUS obligations.

Key Issues of Concern:

- **Impermissible government pricing and reimbursement policies**: On multiple levels, Korea's pricing policies contravene its KORUS commitments and negatively impact the rights of U.S. innovators. Korea values innovative medicines using a cost-effectiveness threshold established when Korean GDP per capita was significantly lower, then can cut prices further based on the prices of off-patent and generic medicines and by setting price ceilings to not exceed the lowest price set by other countries. The government can also require additional concessions as a condition of reimbursement and can impose *ad hoc* price cuts and volume caps. Combined, these price controls constitute a failure to "appropriately recognize the value of the patented pharmaceutical product," in violation of KORUS Article 5.2(b).

- **Lack of transparency, predictability and due process in government policymaking**: Compounding these challenges, Korea also does not provide meaningful transparency and due process for companies that apply for reimbursement, contrary to Korea's commitments under KORUS Article 5.3. Applicants are often not provided with the written basis for evaluations and decisions, and Korea has never honored its commitment in KORUS Article 5.3(5)(e) and the side letter thereto, to make available an independent review mechanism.

- **Unduly strict patentability criteria for selection inventions**: The patentability requirements for a selection invention in Korea are overly strict as compared to the

standards in other countries, and fall short of substantially protecting useful chemical, biological, and pharmaceutical inventions. Many valuable inventions in the chemical, biological, and pharmaceutical fields that are filed worldwide have difficulties to meet these strict requirements in Korea. The current practice in Korea does not reflect the nature of these types of inventions and should be harmonized with the standards in other countries, so that these valuable inventions are protected.

- **Issues with patent term restoration (PTR)**: While Korea has implemented PTR, there are two significant issues. First, the PTR calculation should include all relevant essential clinical trials used for the approval of the Korean product, including international clinical trials that are submitted as a part of the Korean dossier for approval of the product. Failure to do so has a discriminatory effect on companies outside Korea that conduct necessary trials, on which the Korean Ministry of Health relies in approving the drug, outside of Korea. Second, there is a lack of due process in the PTR procedures. If the Patent Office determines a certain duration of PTR that is less than the full amount originally requested by the patentee, and the patentee challenges that determination and subsequently loses the challenge, no PTR is granted; even the duration previously determined by the Patent Office is lost. This all-or-nothing approach significantly undermines a patentee's right to appeal, effectively deterring appeals of erroneous calculations, and undermines the patentee's rights.

- **Patent enforcement concerns**: While Korea has implemented a patent linkage mechanism pursuant to its KORUS commitment, certain key issues of concern remain. These issues include the discretion afforded to the Ministry of Food and Drug Safety (MFDS) as to whether to list a patent in the Green List or to permit a change to the patent listing and the limited period of only nine months for a sales stay. In addition, an automatic stay is only granted against the first generic/biosimilar application; no stays are granted against subsequent generic/biosimilar applications certifying against the same patent(s).

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Impermissible Government Pricing and Reimbursement Policies

Since the implementation of a positive reimbursement list system in 2007, new drug prices are determined based primarily on cost reduction rather than a holistic assessment of a medicine's value. Multiple pricing regulations are layered to set artificially low prices for innovative medicines and volume caps, which violates Korea's international obligations and results in reduced access to innovative medicines for Korean patients and doctors. Only 35 percent of new medicines launched globally since 2011 are available in Korea.

Korea's Drug Reimbursement Evaluation Committee (DREC) under the Health Insurance Review & Assessment Service (HIRA) assesses the cost-effectiveness of innovative medicines using a low threshold on how much can be paid for health gains, with few products exempted. This cost-effectiveness threshold was set in 2007 and has not been increased even though Korean GDP per capita is now 50 percent higher. Manufacturers are often required to make repeated price concessions as they move through the many DREC subcommittees before the final reimbursement recommendation, despite the ostensibly different roles and responsibilities of each subcommittee. Regardless of the price recommended by the cost-effectiveness evaluation, if the government is still not satisfied with the price, then it can require price-volume agreements (PVAs) and risk-sharing agreement (RSAs) to force additional concessions as a condition of reimbursement.

Following DREC review and recommendation of a maximum reimbursement price, the National Health Insurance Service (NHIS) conducts a price negotiation with the manufacturer. Inappropriate tools used by NHIS to achieve lower prices include basing prices on off-patent and generic medicines and by setting price ceilings to not exceed the lowest price set by other countries. The Ministry of Health and Welfare (MOHW) has the ultimate authority for approving all pricing and reimbursement decisions.

Over the last decade, the Korean Government has used *ad hoc* measures to further reduce prices of innovative medicines, such as Actual Transaction Pricing investigations and price cuts associated with volume and new indication expansions. For example, for products costing the National Health Insurance system more than WON 1.5 billion, prices are cut by 10 percent if sales increase by more than 10 percent in the first year, and the increase in sales exceeds WON 5 billion. Other aspects of Korea's pricing system have created incentives for larger hospitals to force biopharmaceutical companies to supply drugs at lower prices. The result is that innovative medicines are subject to repeated and excessive price cutting mechanisms.

Combined, Korea's pricing policies contravene negatively impact the rights of U.S. innovators and constitute a failure to "appropriately recognize the value of the patented pharmaceutical product," in violation of KORUS Article 5.2(b).

Moreover, Korea's pricing and reimbursement regime goes far beyond a "limited exception" to the patent holder's exclusive rights, and thus is inconsistent with KORUS Article 18.8(3) and Korea's broader TRIPS obligations. TRIPS Article 28 provides that a patent "shall confer" on its owner the exclusive rights to prevent third parties without the owner's consent from "the acts of: making, using, offering for sale, selling, or importing for these purposes that product."[276] In turn, TRIPS Article 30 permits WTO members to grant only "limited" exceptions to these exclusive rights, provided that such exceptions do not conflict with the "normal exploitation" of the patent and do not prejudice the legitimate interests of the patent owner.[277] The *Canada – Pharmaceutical Patents* panel appropriately recognized that the "normal exploitation" of a patent includes the realization

[276] TRIPS Article 28.
[277] *Id.* Article 30.

of anticipated "economic returns" during a defined period of exclusivity "as an inducement to innovation."[278] This TRIPS jurisprudence supports a parallel reading of KORUS Article 18.8(3).

Under terms of a premium pricing policy for global innovative drugs approved in June 2017, Korea impermissibly provided reimbursement price preferences and other advantages to products developed by local companies. These policies discriminated against U.S. and other foreign-based innovative biopharmaceutical companies and were the subject of renegotiated KORUS commitments agreed to in 2018. Following this agreement, HIRA revised the premium pricing policy for global innovative drugs effective from January 2019. However, the new criteria are so strict and unworkable that it is highly unlikely that any innovative medicine would be eligible for premium prices. While it was hoped that Korea would use this opportunity to demonstrate its broader pledge to appropriately value innovative medicines, Korea has implemented this commitment in a manner that eviscerates the ability of companies to qualify for premium pricing and is contrary to the spirit of the commitment it made to the U.S. Government.

Lack of Transparency, Predictability and Due Process in Government Policymaking

Since 2010, MOHW has repeatedly changed its pharmaceutical pricing and reimbursement policies without considering the long-term implications for innovation and market predictability, resulting in an uncertain business environment for innovative pharmaceutical companies in a manner that is inconsistent with Korea's transparency and due process obligations under KORUS Article 5.3.

Korea also does not provide meaningful transparency and due process for companies that apply for reimbursement. The various subcommittees involved in the reimbursement process do not share the outputs of their deliberations, and applicants are

[278] WTO, Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS/114/R, ¶¶ 7.54-55 (adopted Mar. 17, 2000), available at https://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited Oct. 28, 2020). Similarly, the TRIPS Agreement negotiating history indicates that the "rights conferred" by a patent within the meaning of TRIPS Article 28 include the right to sell pharmaceutical products at prices that would permit recoupment of investments and provide an incentive to develop innovative products. In a 1987 statement, the United States set forth this view, stating that "price control" was not a legitimate reason to deny intellectual property protection or to "impose conditions that preclude reasonable compensation for use of an invention or creation." Statement by the United States at Meeting of 25 March 1987, MTN.GNG/NG11/W/2 (Apr. 3, 1987), at 3. As the United States expressed at that time, "[s]uch policies interfere with obtaining and maintaining intellectual property rights and thus reinforce the direct distortion of trade that results from such policies." *Id.* Others involved in the TRIPS negotiations made similar statements. At a September 1989 meeting, a participant discussed providing patentees "the right to exclude others from making, using or selling the patent or invention for a specified time" and asserted that "[t]hese rights were necessary to provide patentees with the necessary economic incentive 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.

often not provided with the written basis for evaluations and decisions, as well as reasonable opportunities for appeal. Moreover, the data used for NHIS budget impact analysis and other government evaluations are not shared with applicants prior to reimbursement negotiations.

Finally, under Article 5.3(5)(e) of KORUS and the side letter thereto, Korea agreed to "make available an independent review process that may be invoked at the request of an applicant directly affected by a [pricing/reimbursement] recommendation or determination." Korea has taken the position, however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the independent review mechanism because the NHIS does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. However, this interpretation completely negates the original purpose of the independent review mechanism, which should apply to the negotiation process for prices of all reimbursed drugs, particularly patented medicines.

Intellectual Property Protection

Unduly Strict Patentability Criteria for Selection Inventions

The patentability requirements for a selection invention in Korea are overly strict as compared to the standards in other countries, and fall short of substantially protecting useful chemical, biological, and pharmaceutical inventions. Specifically, if an invention is in a genus-species relationship with a prior art reference, the invention is classified into a selection invention, and, in order to be patentable, is required by Korea to have a qualitatively different or qualitatively the same but quantitatively remarkable effect which is clearly described in the specification. Many valuable inventions in the chemical, biological, and pharmaceutical fields that are filed worldwide have difficulties to meet these strict requirements in Korea. The current practice in Korea does not reflect the nature of these types of inventions and should be harmonized with the standards in other countries, so that these valuable inventions are protected.

Patent Term Restoration

While Korea has implemented PTR, there are two significant issues. First, the PTR calculation should include all relevant essential clinical trials used for the approval of the Korean product, including essential clinical international trial that are submitted as a part of the Korean dossier for approval of the product. Failure to do so has a discriminatory effect on companies outside Korea that conduct necessary trials, on which the Korean Ministry of Health relies in approving the drug, outside of Korea.

Second, there is a lack of due process in the PTR procedures. If the Patent Office determines a certain duration of PTR that is less than the full amount originally requested by the patentee, and the patentee challenges that determination and subsequently loses the challenge, no PTR is granted; even the duration previously determined by the Patent Office is lost. This all-or-nothing approach significantly undermines a patentee's right to

appeal, effectively deterring appeals of erroneous calculations, and undermines the patentee's rights.

Patent Enforcement

Consistent with its IP obligations under KORUS,[279] effective March 15, 2015, Korea implemented the framework of an effective patent enforcement system. PhRMA continues to monitor a number of key issues concerning this system. First, the system provides overly broad discretion to MFDS to determine whether to list a patent in the Green List or to permit a change to the patent listing. Second, the system only provides for a nine-month sales stay. In the ordinary course, this is not an adequate period of time to resolve a patent dispute (consistent with Article 18.9(5)(b) of KORUS) before an infringing product is allowed to enter a market. Third, the sales stay system mechanism is problematic in that the patentee cannot request a sales stay against an infringing follow-on product unless a sales stay is also sought against non-infringing follow-on products. Further, an automatic stay is only granted against the first follow-on application; no automatic stays are granted against subsequent follow-on applications certifying against the same patent(s).

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

MALAYSIA

PhRMA and its member companies operating in Malaysia are alarmed by recent Government of Malaysia actions which undermine intellectual property (IP) protection and, if unaddressed, could inspire other countries to take similarly damaging actions. Addressing serious market access and IP concerns in Malaysia will help narrow America's $27B trade deficit with Malaysia.

Key Issues of Concern:

- **Listing pharmaceuticals on the national formulary**: As of 2016, Malaysia adopted a new process for listing products on the Ministry of Health (MoH) Medicines Formulary. While this was a welcome development, PhRMA and its members are concerned that the final guidelines require 12 months of post-marketing surveillance data prior to listing and that there is no mechanism to ensure that patients who benefited from the medicines during local clinical trials maintain access during this period. In addition, if a product is not approved for listing on the Formulary, the applicant should be provided a detailed explanation for that decision so that it can better understand the criteria for listing and to determine if it may negotiate an alternative access scheme with the government. MoH listing decisions, both by the body responsible for conducting health technology assessment (HTA) analysis and making listing recommendations, and by the panel responsible for the ultimate listing decision currently lack transparency and appear to be based on ambiguous criteria.

- **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 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).

- **Halal pharmaceuticals**: In December 2017, the MoH published a guideline on prescribing and administration of non-halal pharmaceuticals. 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. Furthermore, it is important to ensure that patients, in partnership with their health care providers, are prescribed the appropriate medicine for their conditions.

- **Compulsory licensing**: Through a flawed and non-transparent process, the Malaysian government issued an unjustified compulsory license (CL) for a breakthrough innovative medicine developed in America that provides a cure for patients suffering from hepatitis C. This action was taken despite the fact that the U.S. manufacturer had agreed to include Malaysia in its voluntary license program.

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. Currently, the Malaysian government is considering legislative amendments that could further promote vague and ambiguous grounds for compulsory licensing and introduce unnecessary procedures that would undermine patents.

- **Inadequate IP protection and enforcement**: Malaysia does not have a patent enforcement system that provides for the early resolution of patent disputes before marketing approval is granted to 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.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Medicines Price Control

Industry is aligned with the Malaysian Government to improve patient access to medicines. However, the proposal on Medicines Price Control to set ceiling wholesale and retail price for medicines will not address the long-term health care cost challenges, and could delay patient access to new medicines. Further, the proposed phased implementation of Medicines Price Control to apply first on single-source products which are generally patent protected appears to discriminate against foreign companies.

Listing Pharmaceuticals on the National Formulary

Industry welcomes advances from the Malaysian Government for companies to directly request inclusion on the national formulary through guidelines introduced in January 2016. However, industry is disappointed that the process lacks transparency and appear to be based on ambiguous criteria. In addition, the final guidelines require six months of post-marketing surveillance data prior to listing. 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 complete. 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.

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 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). These discriminatory preferences for locally manufactured pharmaceuticals discourage an open and competitive marketplace in Malaysia.

Halal Pharmaceuticals

In December 2017, the MoH published a guideline on prescribing and administration of non-halal pharmaceuticals.[280] PhRMA's member companies are strongly supportive of religious and cultural sensitivities, but strongly believe that it is important to ensure that patients, in partnership with their health care providers, are prescribed the appropriate medicine for their conditions.

Intellectual Property Protection

Compulsory Licensing

In September 2017, the Malaysian government utilized a non-transparent process to issue a CL on a patent-protected innovative U.S. medicine. This unnecessary and unjustified measure was taken in a unilateral and non-transparent fashion, despite the fact that the U.S. manufacturer had decided to include Malaysia in its voluntary licensing program. The CL has sent a devastating signal to America's biopharmaceutical innovators that their patents are not safe in Malaysia. If this action is not met by a strong response, the Government of Malaysia may use CLs 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. The manufacturer had decided to include Malaysia in a mutually beneficial voluntary licensing scheme for hepatitis C when the government moved forward with a CL for use in state-owned hospitals. Industry experience clearly demonstrates that collaborative access policies enable significantly better treatment access outcomes.[281]

[280] Guideline on the Use of Medicines with Non-halal Ingredients, available at https://www.pharmacy.gov.my/v2/ms/dokumen/panduan-penggunaan-ubat-ubatan-mengandungi-unsur-tidak-halal.html (last visited Oct. 28, 2020).
[281] *See, e.g.*, "Malaysia to make drug to treat Hepatitis C," *The Star* (Mar. 8, 2019), available at https://www.thestar.com.my/news/nation/2019/03/08/malaysia-to-make-drug-to-treat-hepatitis-c (last

The non-transparent manner in which this decision was made raises serious questions around whether appropriate consideration was given as to how it may impact Malaysia's access to innovative medicines in the future. The sudden and unexpected announcement of a CL was made immediately following a meeting between President Trump and then-Prime Minister 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 MoH 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. The sudden nature of this decision denies U.S. manufacturers any sense of predictability around Malaysia's regulatory decision-making in the future. The lack of industry stakeholder input is also troubling given the immediate significance of such a decision to the global market for medicines, and to the potential long-term ramifications for U.S. producers of innovative medicines and other cutting-edge inventions.

In August 2019, Malaysia's intellectual property office, MyIPO, released for public comment a "consultation paper" on proposed amendments to the Patents Act 1983.[282] The consultation paper and commenting period were not widely publicized. While the consultation paper lacked specific textual proposals, PhRMA members are very concerned that the proposed amendments could promote vague and ambiguous grounds for compulsory licensing, restrictions on what can be patented, and unnecessary procedures that would undermine granted patents. Considering the preliminary nature of that consultation paper and limited information, PhRMA provided MyIPO an initial response calling for the Malaysian government to engage in a meaningful and transparent consultation process.

Regulatory Data Protection (RDP)

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[283]

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

visited Oct. 28, 2020); "Five Takeaways: Bridging access and innovation in healthcare policy," Observer Research Foundation (Oct. 31, 2019), available at https://www.orfonline.org/research/five-takeaways-bridging-access-and-innovation-in-healthcare-policy-57163/ (last visited Oct. 28, 2020).

[282] Consultation Paper on Proposed Amendments to the Patents Act 1983 [Act 291] (Aug. 30, 2019).

[283] 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 https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf (last visited Oct. 28, 2020).

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...."[284]

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….[285]

As such, Malaysia requires the marketing authorization application of the new medicine to be filed within 18 months from the first worldwide regulatory approval in order to be considered as a "new chemical entity" and, thus, eligible for RDP in Malaysia. If the 18-month deadline is not met, the product loses data protection, allowing a follow-on molecule to be approved based on the originator's regulatory data during what should have been the RDP period. It is challenging – if not impossible – to meet the 18-month application requirement if the first worldwide registration was not in the EU or the United States (both are relied upon for the Certificate of Pharmaceutical Product application).

In addition to this inappropriate restriction on products eligible for RDP in Malaysia, the actual term of the protection in Malaysia is measured from the date of first approval in the world. Thus, if a new chemical entity is registered in Malaysia one year after first approval in the world, Malaysia only provides four years of RDP. Indeed, the only instance in which an innovator can receive the full five years of RDP in Malaysia is if they seek marketing approval in Malaysia first.

Malaysia's flawed Directive improperly penalizes innovators for first seeking marketing approval in other countries. As in other markets that seek to promote research and development into innovative medicines, Malaysia should measure the term of the RDP protection from the time that the new molecule is approved in Malaysia.

Finally, Malaysia fails to provide any RDP for biologics. Made from living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Without the certainty of a substantial period of

[284] *See* paragraph 1.2 of Directive BPFK/PPP/01/037.
[285] *Id.*

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

Effective Patent Enforcement

PhRMA members encourage Malaysia to 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 and launch 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.

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.

MEXICO

PhRMA and its member companies operating in Mexico are increasingly concerned with recent changes to Mexico's pharmaceutical policies, particularly with respect to market access delays due to challenges in accessing public formularies and new public procurement processes, weak patent enforcement and other significant intellectual property (IP) issues, and, more broadly, with growing legal uncertainty and a lack of transparency around government decision-making processes. With the United States-Mexico-Canada Agreement (USMCA) now in effect, it is critical that Mexico implement and maintain systems that are consistent with its trade commitments.

Key Issues of Concern:

- **Market access delays**: The Federal Commission for Protection against Health Risks (COFEPRIS) has put on hold the marketing authorization process for pharmaceutical products since the beginning of this administration. In addition, significant existing market access barriers remain due to lengthy, non-transparent and unpredictable reimbursement processes. A lack of transparency around the development of a National Medicines Compendium and disease-specific treatment guidelines, as well as challenges and uncertainty in accessing the formularies of public health institutions, create additional delays which restrict patient access to innovative medicines. The recent restructuring of COFEPRIS so that it reports into the Undersecretariat of Prevention and Health Promotion raises broad constitutional and statutory concerns related to the independence and autonomy of COFEPRIS, as well as calling into question whether COFEPRIS reforms will be implemented consistent with Mexico's USMCA commitments.

- **Challenges with new public procurement practices**: In 2019, the Mexican government further consolidated and transferred authority for the public procurement of medicines from the individual public health institutions to the Ministry of Finance. Several tenders have since been conducted that lack clear process and requirements, and that are inconsistent with Mexican public procurement and antitrust laws as well as Mexico's commitments under the North American Free Trade Agreement (NAFTA) – in force at that time – and USMCA. These many significant changes and unreasonable implementation timelines have resulted in supply chain challenges and product shortages for Mexican patients.

- **Weak patent enforcement and regulatory data protection failures**: Mexico amended relevant portions of its IP law ahead of the USMCA entering into force on July 1, 2020. However, implementing regulations for these amendments have not yet been issued, so it is too early to assess whether the amendments will address the deficiencies in Mexico's 2003 Linkage Decree. Despite Mexico's commitments under NAFTA and now under USMCA, PhRMA member companies are currently 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 exception rather than the norm. Further, Mexico still lacks measures to restore a portion of the patent term lost during the lengthy development and regulatory approval process, and consolidation of substantive regulatory data protection (RDP) in a federal law, including a specific provision of RDP for biologics, is still pending.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Market Access Delays

The local innovative pharmaceutical industry association, Asociación Mexicana de Industrias de Investigación Farmacéutica (AMIIF), has estimated that on average it takes 1,500 days for Mexican patients to access innovative medicines, and this delay is growing given the changes made by the current administration. Key reasons are the excessive times required for public formulary inclusion and the five-year marketing authorization renewal process, both of which significantly exceed stated timelines. COFEPRIS had made improvements in the marketing authorization process despite limited resources. However, since the beginning of the current administration, further progress has stalled as the agency ceased communication with the pharmaceutical industry and put on hold the work and processes of its New Molecules Committee.

Once COFEPRIS grants marketing authorization, there remain significant barriers for patients, primarily those covered by public institutions, in accessing important medicines. This additional delay is caused by the lengthy, non-transparent, and uncertain reimbursement system used in Mexico, which adds, on average, two years to patient access timelines in the public sector (if a medicine is made available at all). In addition, inclusion into the basic formulary of a public health institution does not automatically result in the purchase and subsequent availability of those medicines to patients.

More specifically, after COFEPRIS grants marketing authorization, the National Health Council (NHC) decides which medicines should be included on the national formulary. Until 2018, recommended prices of patented and unique medicines (or those with exclusive distributors) for all public health institutions were negotiated with the Coordinating Commission for the Negotiation of Prices of Medicines and Other Medical Supplies under the supervision of the Ministry of Public Function (SFP) and the Mexican Antitrust Authority (COFECE). 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), then procured the medicines at the negotiated prices. While this process had significant flaws, it has been largely supplanted since the beginning of the current administration.

The announcement on August 19, 2020, that COFEPRIS would be restructured so that it reports into the Undersecretariat of Prevention and Health Promotion has further complicated the possibility of reforming the agency's market approval processes, and raised significant concerns under both Mexican statutory and constitutional law related to the continued independence and autonomy of COFEPRIS. It is critical that marketing authorization decisions in Mexico are scientifically grounded, and that a new compound or biologic is assessed solely on its safety, efficacy and quality. The existing lack of transparency at COFEPRIS and its unwillingness to engage with industry will only serve to exacerbate concerns that the marketing authorization process is not appropriately focused on the scientific assessments COFEPRIS is tasked to perform.

Challenges with New Public Procurement Practices

In 2019, the Mexican government further consolidated and transferred authority for the public procurement of medicines from the individual public health institutions (*e.g.*, IMSS, ISSSTE, Seguro Popular, *etc.*) to the Ministry of Finance. The NHC supports this centralized process by developing disease-specific treatment guidelines aimed at reducing the number of medicines on the National Medicines Compendium, but without clear criteria and transparency. Several tenders have been conducted under this process, based on new rules that lack transparency in process and requirements, and that are inconsistent with Mexican public procurement and antitrust laws, as well as Mexico's obligations under NAFTA (in force at that time) and USMCA.

Of particular concern, in 2019 Mexico bypassed its normal procurement process and conducted open international tenders. While the Mexican government asserted that the price preference granted under such tenders for Mexican products would be extended to products originating in its FTA trading partners, the speed and lack of transparency around how the awards were granted raised questions as to whether those assurances were honored.

Since the implementation of this restructured procurement process, the country has experienced significant supply chain complications due to distribution problems, administrative inefficiency and corruption. As a result, Mexico has experienced persistent nationwide shortages of medications, including treatments for diabetes, hypertension, cancer and HIV.

Recent actions by the Mexican government are being made without meaningful stakeholder consultation and are further contributing to an uncertain business environment:

- In January 2020, the Mexican government published modifications to laws that would allow procurement and importation of medicines that have not been approved by COFEPRIS. Instead, the products will simply need regulatory approval from either (1) the country of origin; (2) regulatory authorities in Australia, Canada, Europe, Switzerland or the United States; (3) PAHO/WHO Regional Reference Authorities which additionally include Argentina, Brazil, Chile, Cuba and

Colombia; or (4) any of the 53 authorities participating in the Pharmaceutical Inspection Cooperation Scheme (PIC/S). We urge the Mexican government to limit the procurement process to products approved by COFEPRIS and that meet all relevant regulatory standards.

- On August 11, 2020, the Mexican government amended the Federal Procurement Law to exclude medicines from its requirements, thereby permitting the procurement of medications, vaccines and medical equipment directly from international organizations – such as the Pan American Health Organization (PAHO) and the United Nations Office for Project Services (UNOPS) – outside of Mexico's normal procurement process. The changes to the Procurement Law apply to open tenders, restricted tendering, qualification of suppliers and selective tendering. The reforms do not establish a clear methodology for procurement through international organizations, nor do they include any specifications on how market research will be conducted to determine whether it is appropriate and efficient to purchase medications through international organizations. Moreover, the measure does not ensure that suppliers from the United States will be allowed to participate in the tenders. This exclusion opens a wide range of medicines procurements to being conducted outside of the normal legal framework.

Chapter 13 of the USMCA obligates Mexico to adhere to agreed-upon multilateral standards in how it conducts government procurements for goods and services, including maintaining open tendering procedures under Article 13.4.4. One of the limited exceptions to this commitment (Article 13.2.4(e)(iii)) states that Chapter 13 does not apply to procurement conducted "under the particular procedure or condition of an international organization, or funded by international grants, loans, or other assistance if the applicable procedure or condition would be inconsistent with this Chapter." While this exception enables government projects to allow for the participation of international organizations, it does not provide a mechanism for the Mexican government to sidestep its USMCA commitments by procuring all products from an international organization. As such, the amendment to the Mexico Procurement Law, which permits the direct procurement of medicines with international organizations without restrictions, appears to exceed the limited exception provided by Article 13.2.4 of the USMCA.

Furthermore, as of September 2020, a new initiative is under discussion with Congress to further amend the Federal Procurement Law. Discussions to date on these proposals do not appear to have considered Mexico's government procurement commitments. On the contrary, many of the proposals deviate from those commitments and could become barriers to trade. For example, conditions originally agreed and accepted by winning suppliers could be discretionarily altered by the Ministry of Exchequer. Other provisions, under the banner of "market research," would allow for "abbreviated tendering", *i.e.*, procurement timelines inconsistent with the periods anticipated for tendering contracts under the USCMA. Other proposals suggest that "market research" could be used to exclude tenders from certain countries, including the United States. This raises broad national treatment concerns as well as inconsistencies with Mexico's government procurement commitments under the USMCA. The innovative

biopharmaceutical industry is concerned that if these proposals are enacted, many of the benefits anticipated by U.S. manufacturers under the USMCA would be eliminated.

PhRMA's member companies are deeply concerned that these continuing procurement changes and shifting implementation timelines could result in further shortages of medicines for Mexican patients. Based on industry's experience with the new procurement practices, as well as the nature of the proposed changes, we urge the Mexican government to provide greater clarity in process and requirements, ensure consistency with Mexican law and international commitments, and allow for appropriate lead times so that companies can make any necessary operational adjustments to ensure continued supply for Mexican patients. A coalition of biopharmaceutical industry stakeholders in Mexico (Cámara Nacional de la Industria Farmacéutica, or CANIFARMA), which includes AMIIF, has appealed the reforms to the Federal Procurement Law. A hearing in this matter is set for November 23, 2020.

Differentiated Packaging

In November 2019, the Mexican government enacted an amendment to the General Law of Health which requires different packaging for pharmaceutical products supplied to the Federal Health Service. In September 2020, draft implementation regulations were published on the National Commission for Regulatory Improvement (CONAMER) website. One of the measures proposed in these regulations would require manufacturers to print "Not allowed for sale" or "Governmental Property" on the blister package of medicines sold to the Federal Health Service. Compliance with this measure would require manufacturers to use special packaging for medicines intended for the Mexican public market. Since proper handling of medicines prohibits the manipulation of blister packs after packaging, this would, in practice, require pharmaceutical manufacturers to develop a separate line of production (as well as inventory) of pharmaceutical products intended for Mexican government purchasers. Making the investment necessary to fulfil this requirement will be particularly challenging for procurements that do not include a minimum purchasing commitment. Aside from the additional cost involved in creating such lines of production, PhRMA's members are concerned that imposing such a requirement could result in shortages in the market in the midst of a pandemic.

Further, it is unclear as a technical matter as to why Mexico is requiring different packaging for blister packs. At no point has Mexico notified its trading partners of these new technical requirements, nor has it explained the technical justification for imposing them. As such, these requirements would appear to be a technical barrier to trade that imposes unnecessary obstacles contrary to Mexico's commitments in the WTO Technical Barriers to Trade Agreement as well as corresponding provisions in the USMCA.

Intellectual Property Protection

Weak Patent Enforcement

Several deficiencies have confounded the effective enforcement of patents in Mexico. Recognizing that these deficiencies hinder its new commitments to protect and enforce patents in the USMCA, Mexico amended relevant portions of its IP law on July 1, 2020 in order to address them. However, implementing regulations for these amendments have not been released, and at this point PhRMA and its member companies are unable to assess whether these changes will address the deficiencies in Mexico's patent enforcement system as outlined below.

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, although the decree has not been 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 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.

Further, PhRMA member companies are unable to obtain accurate and timely information from COFEPRIS prior to marketing authorization being granted on a generic or biosimilar drug where the innovator product is used as a reference. As a result, innovators have little to no notice that a potentially patent infringing product is entering the market. Securing effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains the exception rather than the norm. Although injunctions may be initially granted subject to the payment of a bond, counter-bonds, or in some proceedings only on applications, motions may be submitted by the alleged infringer to lift the injunction and allow the challenged product to enter the market.

Finally, even if an innovator successfully enforces its IP rights in Mexico, seeking monetary damages is extremely burdensome. In order to claim damages from patent infringers in Mexico, litigants are required to first obtain a final administrative action and then seek damages through a civil action, actions that can take longer than ten years.

Mexico has repeatedly committed to provide effective patent enforcement mechanisms in NAFTA, the WTO Agreement on Trade-Related Aspects of Intellectual

Property Rights (TRIPS), and most recently in the USMCA. It is critical that Mexico act on its commitments by implementing an effective patent enforcement system. In order for Mexico to succeed in this effort, it will be essential that Mexico reject calls from some in Congress as well as prior COFEPRIS proposals that would inappropriately limit the scope of Mexico's patent linkage system. PhRMA and its member companies encourage the Mexican Government to hasten patent infringement proceedings, use all available legal mechanisms to enforce Mexican Supreme Court decisions, and implement procedures necessary to provide timely and effective preliminary injunctions.

Lack of Patent Term Restoration (PTR)

Mexico remains one of the few members of the OECD that does not provide PTR for effective patent term lost during the lengthy development and regulatory approval process. This situation is exacerbated by the current delays of COFEPRIS in approving medicines, resulting in significant patent term lost due to no fault of the inventor or patent owner. PhRMA appreciates that Mexico has agreed to implement such term restoration in the USMCA subject to a 4.5 year transition. Nonetheless, the lack of such protection undermines the term of patent protection in Mexico and consequently undermines the ability of our members to sustainably bring new therapies to Mexican patients. PhRMA urges USTR and other federal agencies to encourage Mexico to implement appropriate PTR provisions as soon as possible.

Regulatory Data Protection Failures

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.[286]

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

RDP is essential for all medicines, and particularly critical for biologic therapies. Produced using living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Unlike generic versions of

[286] 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 https://static1.squarespace.com/static/5a9eb0c8e2ccd1158288d8dc/t/5ac66afc6d2a732e83aae6bf/1522952963800/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18%2C_2014..pdf (last visited Oct. 28, 2020).

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.

In June 2012, COFEPRIS issued guidelines to implement RDP for a period not less than five years – an important step toward fulfilling Mexico's international obligations. PhRMA members initially welcomed this decision as an important confirmation of Mexico's obligations and its intention to fully implement the NAFTA and TRIPS provisions.

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

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.

NEW ZEALAND

PhRMA and its member companies operating in New Zealand remain concerned over the direction the Government of New Zealand is taking with respect to the policies and operation of New Zealand's publicly-funded prescription medicines system as well as broader intellectual property (IP) protections. The prescription medicines ecosystem continues to impose stringent cost containment strategies,[287] and operates in a non-transparent manner, creating an unfavorable environment for innovative medicines.

Key Issues of Concern:

- **Government pricing and reimbursement**: The reimbursement decisions severely limit patient access to new medicines in New Zealand and have significantly delayed funding for new medicines in the country.

- **Biotechnology taskforce recommendations**: Despite steps taken toward an enhanced relationship between the Government and the research-based biopharmaceutical industry a decade ago, those recommendations have not been implemented. Positively, however, in 2012 the Ministry of Business, Innovation and Employment (MBIE) released a guideline on government procurement including principles that PhRMA member companies would strongly support if applied to the 20 District Health Boards whose medicines budgets are managed by the Pharmaceutical Management Agency (PHARMAC).

- **Amendments to the Patents Act 2013**: As part of the modernization of its IP laws, MBIE has completed its consultation on amendments to several laws including the Patents Act (2013). However, it appears that MBIE's advice to the New Zealand Government will see the latter sign off on terms that would limit unreasonably innovators' ability to secure and enjoy patent rights. For example, the proposed amendments seek to eliminate certain aspects of well-accepted and internationally recognized patent prosecution practice. Furthermore, the consultation and process failed to consider positive reforms such as patent term adjustment mechanisms to account for delays in patent processing or pharmaceutical patent term restoration to account for a portion of the time taken to secure marketing approval.

- **Therapeutic Products Bill introduced**: The Therapeutic Products Bill was introduced in early 2019 to reform and replace the Medicines Act 1981. It contains many well aligned principles to modernize the legislation for future technologies such as gene and cell-based therapies. However, the bill does not take the opportunity to reform regulatory data protection (RDP) terms contained in the Medicines Act 1981. Proposed changes to the drafted legislation may also see the New Zealand government remove the innovative pharmaceutical industry's ability

[287] Government reference pricing and parity pricing; cross-therapeutic deals; tendering, sole supply, price/volume contracts; special authority and restricted indications; delayed listing (on average three times longer than Australia) and no legislated timeframes for decision making or government oversight of transparency of decision-making processes.

to undertake direct to consumer advertising of branded prescription medicines, while allowing all other sectors (such as medical devices and over-the-counter medicines) to continue the practice. The significant fines and penalties that would apply to breaches of this legislation are deeply concerning, as it is unclear exactly what standards or guiding principles will be used to determine their application.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Pricing and Reimbursement

Though not explicitly stated, New Zealand's reimbursement decisions suggest a pharmaceutical product must achieve a cost per QALY (quality adjusted life year) of less than NZ$10,000 to NZ$15,000 to be considered cost effective. This is despite public spending in other areas of health proceeding at up to NZ$100,000 per QALY. This approach, combined with the need to stay within a capped budget, means that many of the most effective medicines are not available to New Zealand's patients. In fact, research indicates that between 2009 and 2014, 88 percent of new medicines available in Australia were *not* available in New Zealand. Almost 10 percent of these medicines are for diseases with no current treatment available in New Zealand. In 2014, Australia made available 17 new medicines through its Pharmaceutical Benefit Scheme (PBS), while New Zealand listed just one. The data also showed that the process for listing in New Zealand was slower than in Australia, taking two years longer on average for New Zealand to fund the same medicines compared to Australia.[288]

Ongoing monitoring of the Pharmaceutical Schedule listing trends by New Zealand's innovative pharmaceutical industry association, Medicines New Zealand, continues to show the lag in patient access. In June 2020, updated analysis showed that there were still over 100 medicines on the "medicines waiting list," which had been recommended for funding by PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) as cost-effective treatments and yet not approved for reimbursement by PHARMAC. These medicines include treatments for rare disorders, diabetes, depression, breast, lung and prostate cancers and rheumatoid arthritis. Some of these medicines have been on the list for up to fifteen years, and the average waiting time is now over four -and-a half years.[289] This list has grown rather than decreased since its initial assembly in 2015. Between 2015 to 2020, the number of medicines on the waiting list increased at an average net rate of five new listings per year. Despite modest increases in funding for the medicines budget from the New Zealand Government over

[288] Taylor C., and Wonder, M. *Exploring the implications of a fixed budget for new medicines: a study of reimbursement of new medicines in Australia and New Zealand*, Australian Health Review, Early online publication (March 2015).
[289] Barca C, Funding Medicines in New Zealand: revision of the medicines waiting list. Subscripts Ltd., Auckland New Zealand, available at https://www.medicinesnz.co.nz/fileadmin/user_upload/Medicines_Waiting_List_Report_to_30_April_2020_Final__June_2020_.pdf (last visited Oct. 28, 2020).

the past year, the increasing number of pharmaceuticals yet to receive public reimbursement decisions is a concern for the public health system, as well as the health care professionals and the patients within the system.

PHRMA's member companies are advocating for the following key policy reforms in New Zealand:

1. Patient Outcomes: A national medicines policy should ensure the provision of quality medicines in a way that is responsive to patients' needs and achieves optimal health outcomes.

2. Comparable Access: A national medicines policy must ensure that New Zealanders have at least comparable access to medicines and access to other health technologies as citizens of other OECD countries.

3. A Core Health Strategy: Medicines play a vital role in the prevention, amelioration and treatment of disease, and as such a national medicines policy is integral to the achievement of all national health strategies and should have equal standing and priority. Medicines access should be aligned with other health policies and not disproportionately targeted for cost containment.

4. Integrity and Public Confidence: The current bundling of multiple products into a single funding contract creates incentives for the Government to subordinate clinical judgment to budget imperatives. Determinations about which medicines are cost effective and are of clinical merit must be conducted independently before being used to inform decisions about which products can be funded.

5. Transparency and Rigor of Processes and Decision Making: Public confidence will be enhanced if decision making processes are underpinned by transparency, fairness, timeliness and high standards of consultation and review. All stakeholders must be able to understand the true basis of decisions and rationales should be clearly stated. What is considered "value for money" should be comparable to other OECD countries. Transparency and accountability are key principles in New Zealand's public institutions, with the exception of pharmaceutical funding. It is critical that these principles be applied equally to pharmaceutical funding.

6. Recognition of the Value of Innovation: A national medicines policy should recognize the value of innovation and innovative pharmaceuticals through the adoption of procedures that appropriately value the objectively demonstrated therapeutic significance of pharmaceuticals.

7. Responsive Budget Management: The pharmaceutical budget should be determined by people's need for treatment and access benchmarks. Rather than conduct health technology assessments (HTAs) of products after the capped budget has been set, thus simply creating a priority list of new products competing

for the limited funding available, HTAs should be used to establish budget estimates on an annual basis. The capped budget is a concern as a recent report has highlighted that in real terms (inflation and population adjusted) the core pharmaceuticals budget decreased about 0.3 percent between 2007 to 2018. As such, New Zealand would need to make an additional investment in prescription medicines of $375 million annually just to return to 2007 investment levels.[290]

8. Partnership: The achievement of timely access to medicines, quality use of medicines and other national medicines policy objectives is greatly enhanced by the maintenance of a responsible and viable industry environment. Coordination of health and industry policies and a consistent and more welcoming environment for innovation will better enable effective partnership with Government and other stakeholders to achieve improved health and economic outcomes.

Biotechnology Taskforce Recommendations

The New Zealand Government's Biotechnology Taskforce made the following recommendations in 2003 to enhance its relationship with the pharmaceutical industry and stimulate research investment:

- Introduce certainty and predictability into prescription pharmaceutical public funding by setting ongoing three-year funding allocations rather than year-to-year funding allocations from the Government budget.

- Develop a public policy action agenda for the industry building on the local industry association's report "Bio-pharmaceuticals – A Pathway to Economic Growth."

- Review the channels through which the Government engages with the pharmaceutical industry.

The first recommendation was achieved initially with an announcement in September 2004 of annual budgets through 2007. Unfortunately, this policy was rescinded and the subsequent budget for 2008-2010 was not published. To date, the Government has not implemented the second and third recommendations.

A Health Select Committee report in June 2011 recommended enhancing the engagement with the pharmaceutical industry around clinical research yet the Government declined to implement this recommendation. In a positive development, in 2012 the MBIE released a guideline on Government procurement. Among other recommendations, the guideline includes the following principles: (1) Be accountable, transparent and reasonable; (2) Make sure everyone involved in the process acts responsibly, lawfully and with integrity; (3) Stay impartial – identify and manage conflicts of interest; and (4) Protect suppliers' commercially sensitive information and IP.

[290] NZIER (2018), Community Pharmaceuticals Expenditure Trends, Wellington New Zealand, available at https://nzier.org.nz/publication/community-pharmaceuticals-expenditure-trends-1 (last visited Oct. 28, 2020).

These are the same principles that PhRMA and the innovative pharmaceutical industry would like to see New Zealand adopt as part of its pharmaceutical pricing and reimbursement system.

Intellectual Property Protection

Amendments to the Patent Act (2013) and the Therapeutic Products Bill

PhRMA and its members are disappointed to see that the Therapeutic Products Bill and the proposed amendments to the Patents Act (2013) do not reflect needed reforms to enhance biopharmaceutical intellectual property protection in New Zealand.

As part of modernizing its intellectual property laws, MBIE initiated consultations on amendments to various laws, including the Patents Act (2013). However, the MBIE recommendations will limit unreasonably innovators' ability to secure and enjoy patent rights. For example, MBIE seeks to eliminate the ability for patent applicants to file divisional applications based on prior divisional applications. MBIE also proposes to cease recognizing multiple and partial priorities within a single patent claim and to prohibit "Swiss" patent claim structures. These practices are recognized in top patent offices, including those in the United States and Europe.

While the Patents Act amendments appear contrary to international best patent practices, the modernization efforts also miss the opportunity to introduce positive reforms most such as patent term adjustment to account for delays in patent processing, and pharmaceutical patent term restoration to account for the time taken to secure marketing approval.

Similarly, the proposed new medicines legislation – the Therapeutics Products Bill – does not reform New Zealand's regulatory data protection regime to reflect international best standards. The bill does not seek to increase the RDP term for biologics, even though the period of protection for biologics in New Zealand (five years), is well below the OECD average. Conversely, in November 2016, New Zealand passed the Agricultural Compounds and Veterinary Medicines Amendment Act, which increased the RDP term for "innovative agricultural compounds" including veterinary medicines from five years to 10 years. Appropriately, this legislation was passed to allow the New Zealand agricultural sector to gain greater access to innovative modern veterinary medicines from overseas. As New Zealand looks to update the Medicines Act (1981) and futureproof its health technology legislation to prepare for new medical technologies (*e.g.*, gene therapies), we are hopeful that the government will reconsider its position, and will similarly increase the RDP term for biologics to ensure that patients in New Zealand have greater access to innovative medicines in the future.

THE PHILIPPINES

PhRMA members face serious and imminent market access and intellectual property (IP) threats in the Philippines. PhRMA members are deeply concerned about the government's fading commitment to the free market. The Philippine Government is creating an environment that seeks to institutionalize price regulation, disregard IP, and imposes discriminatory policies. Of particular concern are mandatory price cuts of up to 50 percent and a proposed additional price reductions of up to 96%. These measures adversely impact PhRMA member companies operating in the Philippines.

The impending price cuts, compulsory licensing proposals and burdensome regulatory processes threaten access to innovative medicines in the Philippines.

Key Issues of Concern:

- **Price control mechanisms**: Despite recent passage of the Universal Healthcare Act and National Integrated Cancer Control Act that both contain tools to reduce prices for medicines, the Department of Health (DoH) has imposed draconian price cuts in the Philippines through the Maximum Retail Price (MRP). Issued in February 2020, the initial list covers 133 drug formulations with a mandatory price reduction of up to 50 percent from prevailing market prices. The policy also contains provisions to cover another set of 72 drug formulations, with initial price reduction proposals ranging from 50% up to a staggering 96%. These policies are the beginning of future intended cuts, as the DoH has stated they intend to cover up to 54% of all prescription drug formulations in the market with these policies. The cuts are estimated to decrease industry's annual revenues by approximately PHP 57 billion (over USD 1 billion).

- **Government-mandated discounts**: The mechanism for cost-sharing for discounted medicines for seniors and individuals with disabilities remains unclear and places, in practice, the entire cost burden for the discounts on manufacturers and retailers.

- **Philippine National Formulary (PNF):** While PhRMA member companies welcome the appropriate use of evidence to inform formulary decisions, they are concerned that existing delays in introducing innovative medicines could be further exacerbated by the recent establishment of health technology assessment (HTA) as a prerequisite for PNF inclusion. Specifically, in January of this year, the DoH halted the nomination process in order further solidify certain HTA details. Furthermore, the HTA process and methods guides were only recently published, including Administrative Order 2020-0041 (The New Implementing Guidelines on Health Technology Assessment to Guide Funding Allocation and Coverage Decisions in support of Universal Health Care).

- **Vaccinations**: The innovative pharmaceutical industry welcomes legislative proposals in the Philippines to expand the current list of mandatory vaccines for

national immunization. However, our members are concerned by proposals to politicize this process by requiring the DoH to seek approval from the Philippine Senate and House of Representatives for the inclusion of a new vaccine in the National Immunization Program (NIP), rather than remaining a technical decision by the DoH.

- **Regulatory hurdles**: The current target for approval (and issuance of the Certificate of Product Registration (CPR)) is 254 calendar days. However, in practice, the process takes two to four years. With new management in place, coupled with the monitoring of the Anti-Red Tape Agency (an agency tasked with monitoring the efficiency of government agencies), PhRMA members have seen improvements in the regulatory process. Another hurdle is the FDA's backward step of unnecessarily reinstituting local Post Marketing Surveillance (PMS) studies versus relying on Periodic Safety Update Reports (PSURs). This has led to significant additional costs for PhRMA members, as well as delayed access to medicines.

- **Intellectual property protection**: The Cheaper Medicines Act amended the Philippines Intellectual Property Code to limit the patentability of new forms and uses of pharmaceutical products. The Act appears to be inconsistent with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) since the limitation appears to be designed to discriminate against certain technologies. Additionally, the Philippines does not have a robust system or a set of coordinated procedures across relevant government agencies such as the Intellectual Property Office and the Food and Drug Administration to allow patent holders to effectively and efficiently resolve patent disputes prior to the marketing of generic copies of pharmaceutical products by third parties.

- **Compulsory licensing guidelines:** In 2019, the DoH proposed a guideline on the use of compulsory licenses (CLs). PhRMA and its member companies are concerned that the Guidelines may be inconsistent with international best practices and the Philippines' international obligations, in that they appear to be based on an erroneous understanding of TRIPS, allow for the grant of CLs on overly broad grounds, provide inadequate opportunity for patent holders to respond to CL petitions and discriminate against pharmaceutical patents.

- **Counterfeit medicines**: According to a report by the United Nations Office on Drugs and Crime, 193 of 673 counterfeit crimes reported from 2013 to 2017 in Southeast Asia were perpetrated in the Philippines, the highest in the region. While campaigns to address counterfeit activities continue in partnership with PhRMA's member companies, industry is concerned by FDA proposals that would potentially exacerbate the problem by no longer treating the sale of an unauthorized drug in the Philippines as the sale of a counterfeit drug.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Pricing Policies

Despite recent passage of the Universal Healthcare Act and National Integrated Cancer Control Act that both contain tools to reduce prices for medicines, DoH has imposed draconian price cuts in the Philippines through the MRP. Issued by the President in February 2020, Executive Order No. 104, entitled "Improving Access to Healthcare through the Regulation of Prices in the Retail of Drugs and Medicines," covers an initial list of 133 drug formulations with a mandatory price reduction of up to 50 percent from prevailing market prices. The policy also contains provisions to cover another set of 72 drug formulations, with initial price reduction proposals ranging from 50% up to a staggering 96%. The combined list includes molecules for hypertension, diabetes, cardiovascular disease (CVD), chronic lung diseases, neonatal diseases, major cancers, chronic renal disease, psoriasis and rheumatoid arthritis, among others.

These policies are the beginning of further price regulations to come in the future, as the DoH intends to cover 1,154-2,394 preparations or 26-54 percent of the medicines available in the market. The local innovative pharmaceutical trade association (PHAP) estimates that this could reduce industry's annual revenues by approximately PHP 57 billion or almost USD 1.1 billion if fully implemented.

To fully operationalize this plan, the DoH released in August 2020 guidelines to implement MRP under Administrative Order No. 2020-0039. The AO includes the: (1) constitution of a Drug Price Advisory Council, responsible for drug price evaluations and for recommending which drugs will be under price regulation and at what level; (2) the medicine review process, including the basket of countries for external reference pricing, medicine selection algorithm (incorporating public nomination of medicines for MRP), and formula for calculating MWP and MRP; (3) implementation guidelines, including exhaustion of inventory, publication and posting requirements; and (4) monitoring and evaluation (impact assessment).

As part of these actions to move away from allowing the free market to dictate prices in the Philippines, the DoH has also proposed to Congress the creation of a Drug Price Regulatory Board (DPRB) to oversee the MRP mechanism, with the sole task of regulating medicine prices.

Proposed Constitution of Price Negotiation Board and Guidelines on Price Negotiation

The DoH is undertaking an online consultation for the creation of a Price Negotiation Board (PNB), which would negotiate prices on behalf of the DoH and the Philippine Health Insurance Corporation (PhilHealth), a corporation attached to DoH in-charge of managing the country's social health insurance. If implemented, it is critical that the negotiation criteria, budget allocation and target population are developed through meaningful consultations and clearly identified before negotiations begin. Fundamentally, however, the creation of this Board will merely add another layer in the process, and will

not address core issues related to access and affordability. As such, PhRMA's members would strongly encourage the government to consider facilitating access to public funding through measures such as accelerated formulary inclusion, government procurement and multi-year contracts.

Other Government-Mandated Price Reductions/Policies

In addition to MRP, the Philippines continues to impose price cuts in the form of medicine discounts for special sectors such as senior citizens, persons with disabilities, national athletes, solo parents, and many others. Ambiguities in the implementation of laws related to the 20 percent discount granted to senior citizens and persons with disabilities have resulted in the cost of the discount being borne entirely by manufacturers and retailers, *i.e.*, with no contribution from the Government, disproportionately burdening PhRMA member companies.

The Philippine National Formulary

While PhRMA member companies welcome the appropriate use of evidence to inform formulary decisions, they are concerned that existing delays in introducing innovative medicines could be further exacerbated by the recent establishment of health technology assessment (HTA) as a prerequisite for PNF inclusion. Specifically, in January of this year, the DoH halted the nomination process in order further solidify certain HTA details. Furthermore, the HTA process and methods guides were only recently published, including Administrative Order 2020-0041 (The New Implementing Guidelines on Health Technology Assessment to Guide Funding Allocation and Coverage Decisions in support of Universal Health Care).

An outdated PNF not only negatively affects patient access to essential medicines and vaccines; it also becomes a barrier for PhRMA member companies to participate in government procurement of medicines and vaccines. It is imperative, therefore, that a fit-for-purpose and a transparent and efficient PNF listing process be put in place by the government.

Vaccines

PhRMA and its members welcome legislative proposals in the Philippines to expand the current list of mandatory vaccines for national immunization. However, we are concerned by proposals to politicize this process by requiring the DoH to seek approval from the Philippine Senate and House of Representatives for the inclusion of a new vaccine in the NIP, rather than remaining a technical decision by the DoH.

New Product Registration

The FDA's registration process has been known to be inefficient and slow, posing barriers to the introduction of medicines into the market. The current target for approval (and issuance of the Certificate of Product Registration (CPR)) is 254 calendar days.

However, in practice, the process takes two to four years. With new management in place coupled with the monitoring of the Anti-Red Tape Agency (an agency tasked with monitoring the efficiency of government agencies), PhRMA members have seen improvements in the regulatory process.

A more immediate hurdle is the FDA's issuance of Circular No. 2018-012, which unnecessarily reinstituted local PMS studies versus relying on PSURs. We believe that the requirement to conduct local PMS studies that are "uncontrolled and observational in nature" is a retrogressive step, exacerbating the operating environment for innovative pharmaceutical manufacturers with significant additional costs, as well as delayed access to these medicines for patients.

Intellectual Property Protection

Cheaper Medicines Act

PhRMA members continue to have concerns that certain provisions in the Cheaper Medicines Act adversely affect effective protection of intellectual property and result in certain market access barriers. For example, certain provisions appear to create additional patentability requirements for new forms and uses of pharmaceutical products, thereby discriminating against the pharmaceutical sector, and raising questions as to its consistency with the TRIPS Agreement. There is also a need to engage the judiciary to ensure more consistent interpretation of intellectual property protections in the Philippines.

Effective Patent Enforcement

It is important that the Philippines adopt processes and mechanisms to allow for the efficient resolution of patent issues prior to the marketing of follow-on products by third parties. Such a mechanism was in place before a 2005 DoH Administrative Order (A.O. No. 2005-0001) took effect that required pharmaceutical patent holders to pursue costly and time consuming legal remedies to protect products from patent infringement prior to patent expiration. PhRMA member companies recommend that the government take a holistic approach with respect to IP rights to ensure that patents are effectively enforced by the Government of the Philippines. This would include a coordinated effort by the IPOPHL and the FDA to preclude issuance of a CPR for a follow-on medicine by FDA until the relevant patents on the originator product have expired, or there has been sufficient time for resolution of a patent infringement dispute.

Compulsory Licensing Guidelines

In 2019, the DoH proposed a guideline on the Use of Special CLs and CLs. PhRMA and its member companies are concerned that the Guidelines may be inconsistent with international best practices and the Philippines' international obligations, in that they appear to be based on an erroneous understanding of TRIPS, allow for the grant of CLs on overly broad grounds, provide inadequate opportunity for patent holders to respond to

CL petitions (as well as appeal from CL grants) and discriminate against pharmaceutical patents.

PhRMA believes governments should grant CLs in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

Counterfeit Medicines

The Government of the Philippines continues to expand its anti-counterfeiting activities in partnership with PhRMA member companies and raise public awareness regarding the dangers of unsafe medicines. Nonetheless, according to a report by the United Nations Office on Drugs and Crime released in 2019, around 193 of 673 counterfeit crimes reported from 2013 to 2017 in Southeast Asia were perpetrated in the Philippines, the highest in the region. Moreover, PhRMA and its members are concerned by FDA proposals in the context of drafting Implementing Rules and Regulations of the Special Law on Counterfeiting that would potentially exacerbate the problem by no longer treating the sale of an unauthorized drug in the Philippines as the sale of a counterfeit drug.

RUSSIA

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

Key Issues of Concern:

- **Localization barriers and government procurement restrictions**: Despite being in the process of acceding to the World Trade Organization (WTO) Agreement on Government Procurement (GPA), Russia continues to pressure local production of medicines through its government procurement system (*e.g.*, restrictions on public procurement of imported medicines where there are at least two pharmaceuticals with locally produced finished dosage forms, so-called "three's a crowd"), and as of 2019, a 25 percent price preference if "three's a crowd" is not applicable. Moreover, Russia has recently released a list of more than 200 "strategically important medicines" that must be produced in Russia. The Ministry of Industry and Trade (MoIT) has also proposed introducing quotas in state procurement of essential medicines to boost "import substitution."

- **Deteriorating government pricing environment**: On October 18, 2018, a new pricing methodology for products included on the Essential Drug List (EDL) came into force that impacts ceiling price calculation and the international reference pricing methodology. In addition, in December 2019, the Russian Government approved Resolution No. 1683 that requires the re-registration of all maximum selling prices for EDL medicines in 2019-2020. These regulations may discourage local investment and hinder the launch of new medicines, promoting a downward spiral for pharmaceutical prices in Russia. On December 19, 2019, the Ministry of Health (MoH) annulled its Order No. 871n (Oct. 26, 2017) and adopted new Order No. 1064n, which sets forth the procedure for determining the initial auction prices for medicines. Motivated by significant disruptions to state tenders and drug shortages caused by Order No. 871n, MoH Order No. 1064n seeks to improve the regulatory framework for calculating a medicine's initial auction price. On August 29, 2020, the Russian Government introduced the possibility to impose price control measures on medicines not included on the EDL.

- **Compulsory licensing and restrictive patentability criteria**: The Russian Government is pursuing draft legislation and other measures that appear to improperly limit certain types of patents for innovative medicines and create vague and arbitrary criteria enabling Russia to seek compulsory licensing actions of patented medicines. In addition, Russian courts in two cases have granted compulsory licenses (CLs) to generic companies for innovative foreign medicines based on an extremely low evidence test and standard of proof.

- **Weak patent enforcement**: There is no effective mechanism in place in Russia 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 during the period of patent protection. Because Russian courts rarely grant preliminary injunctions in patent infringement cases related to pharmaceuticals, pharmaceutical innovators face significant legal challenges in seeking to effectively protect their innovative products against infringement, resulting in significant damages that are rarely compensable. In light of these problems, PhRMA and its member companies are encouraged by recent legislative proposals to implement a Unified Register of Pharmacologically Active Substances Protected by Patent at the level of the Russian Federation and EAEU (which may serve as a basis for patent status check during the registration of generic medicines).

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Localization Barriers and Government Procurement Restrictions

Russia is in the process of acceding to the GPA and currently participates in the Committee as an observer.[291] Notwithstanding the GPA accession process, Russia continues discriminatory practices in its government procurement practices.

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 EDL. According to Resolution No. 1289, if two or more EAEU pharmaceutical manufacturers bid on a tender for an EDL product, then any foreign bid for that same tender must be rejected. Medicines not covered by Resolution No. 1289 remain subject to the tender preferences established by the Ministry of Economic Development (MoED), where local companies receive a 15 percent price preference.

On May 12, 2018, the Russian Government adopted Resolution No. 572 "On Amendments to the Resolution of the Russian Government No. 1289", amending the "three's a crowd" regulation and introducing the regulatory framework for additional preferences in state procurement of essential medicines for products made using locally manufactured active pharmaceutical substances. On November 5, 2018, the Order of the Ministry of Finance dated June 4, 2018, No. 126n entered into force and introduced additional preferences for local (EAEU) full-cycle medicines, applied from January 1, 2019. The order states that if EAEU finished dosage forms and EAEU full-cycle products participate in a tender, an EAEU full-cycle product is expected to win, if its price does not

[291] *See* https://www.wto.org/english/news_e/news16_e/gpro_22jun16_e.htm (last visited Oct. 28, 2020) and https://www.wto.org/english/tratop_e/gproc_e/memobs_e.htm (last visited Oct. 28, 2020).

exceed the lowest price suggested for EAEU finished dosage form by more than 25 percent.

On August 3, 2020, the Russian Prime Minister signed Resolution No. 1164, which excluded application of the "three's a crowd" rule during state procurement of 9 international non-proprietary names of reference medicines for the treatment of leukemia and lymphoma in children until December 31, 2021.[292] Although the industry welcomes this decision, PhRMA and its member companies believe that "three's a crowd" rule must be excluded for all medicines.

The Russian Government has also taken several steps to isolate certain segments of the pharmaceutical market for sole-supply contracts given to Russian companies. For example, in March 2018, the Russian Government signed Decree No. 520-r appointing the National Immunobiological Company (NIB) as the sole supplier of certain blood products subject to procurement in 2018-2019 by several state purchasers. Furthermore, in April 2018, the Russian Government signed Decree No. 744-r appointing NIB as the sole supplier of certain local full-cycle immunobiological products (including vaccines) in 2018-2019 purchased by the MoH under the National Immunization Schedule. Many other measures aimed at supporting local manufacturers are under development and implementation in Russia. For instance, on November 16, 2019, the Russian Government signed Resolution No. 1464 and approved the Rules for granting subsidies from the federal budget to Russian organizations for the partial reimbursement of expenses to implement industrial projects related to "modern technologies", including the launch and sale of medicines. And on December 27, 2019, the Russian Government signed Resolution No. 1908, which approved rules for the provision of federal subsidies to stimulate demand and increase the competitiveness of Russian industrial products.

In July 2020, Law No. 44-FZ on public procurement was amended to allow the Government to set quotas for locally-manufactured products to be purchased through public tenders. Subsequently, a draft Government Resolution was discussed in September 2020, which would introduce a 40 percent quota for local products in state procurement for medicines on the EDL medicines, as a means to further boost import substitution. This industrial policy measure is highly inappropriate for medicines and if implemented it will raise further barriers for U.S. companies' participation in state tenders for medicines with no available alternative, thereby negatively impacting patient access to innovative medicines.

Finally, since 2018, the Russian Government has been developing a "Pharma 2030" strategy, which plans to prioritize the development of innovative pharmaceutical products.[293] PhRMA members companies welcome these efforts and have been actively participating in discussion of the "Pharma 2030" strategy. As yet, however, the revised draft is still being discussed by stakeholders and it is not clear what the final document will propose.

[292] Available at https://gmpnews.ru/2020/08/rossiya-snyaty-ogranicheniya-na-goszakupki-zarubezhnyx-preparatov-dlya-lecheniya-lejkoza/ (last visited Oct. 28, 2020).
[293] *See* https://www.kommersant.ru/doc/3812344 (last visited Oct. 28, 2020).

Deteriorating Government Pricing Environment

On October 18, 2018, new pricing registration rules and a new pricing methodology came into force. These measures change the methodology for calculating maximum ceiling prices for EDL medicines and skew the international reference pricing basket used to set prices towards the lowest price in the following countries: Belgium, the Czech Republic, France, Greece, Hungary, The Netherlands, Poland, Romania, Slovakia, Spain, Turkey and the country of origin. In addition, Federal Law 134-FL "On Amending the Law on the Circulation of Medicines in Terms of Regulation of Prices for the Medicines Included in the List of Vital and Essential Drugs" came into force on June 7, 2019 and could result in a downward price spiral that threatens biopharmaceutical innovation.

In accordance with Federal Law No. 134-FZ, all prices for EDL medicines are subject to obligatory re-registration in 2019-2020. On December 16, 2019, the Russian Government approved Resolution No. 1683 "On Amendments to Certain Acts of the Russian Government in Relation to Registration and Re-registration of Maximum Selling Prices for Essential Medicines" (Resolution No. 1683). As part of that resolution's re-registration process, all 2019-2020 prices for EDL medicines are set based on a step-down coefficient of the price of the innovator product. Products that are not re-registered by January 1, 2021 can no longer be sold. The holder of the registration certificate must file an application to the MoH to lower the price for any EDL medicine sold in Russia where the price decreases in a reference country. Prices for generic and/or biosimilar medicines are re-registered by the MoH based on calculations made by the Federal Antimonopoly Service (FAS) without respective applications from the market participants.

On December 19, 2019, MoH annulled its Order No. 871n (Oct. 26, 2017) and adopted new Order No. 1064n, which sets forth the procedure for determining the initial auction prices for medicines. Motivated by significant disruptions to state tenders and drug shortage caused by Order No. 871n, MoH Order No. 1064n seeks to improve the regulatory framework for calculating a medicine's initial auction price.

Due to the COVID-19 pandemic, the Russian Government introduced the right to exercise specific price control measures on medicines not included in the EDL. From July 27, 2020 to August 21, 2020, public discussions were held regarding the draft Resolution of the Russian Government "On Approval of the Rules for Formation of the List of Medicines not included on the List of Vital and Essential Medicines in Respect of Which it is Possible to set the Maximum Selling Prices of the Manufacturers, Maximum Wholesale and Retail Markups."[294] Under this new regulation, the Russian government can set the prices of non-EDL medicines for a period of 90 days in case of an emergency, in response to the threat of infectious diseases that pose a danger to others or if retail prices increase. PhRMA and its member companies are concerned that this legislation could result in arbitrary decisions.

[294] Project ID 02/07/07-20/00106397, available at https://regulation.gov.ru/projects#npa=106397 (last visited Oct. 28, 2020).

Interchangeability of Medicines

Federal Law No. 475-FZ, amending the Law on the Circulation of Medicines, reduces the existing list of non-interchangeable medicines and sets out a number of options for considering the interchangeability of medicines under one international non-proprietary name (INN). Several subsequent regulations and decrees have been issued pursuant to this law, which is expected to go into full effect on January 1, 2021. Law No. 475-FZ contains several provisions that may adversely affect patients, including establishing a pathway for "non-medical switches." As such, PhRMA members are closely monitoring these developments, regulatory practice and the decisions of the medical experts responsible for the interchangeability determinations.

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 economies of its member states, establishing a free trade area, unbarred financial interaction and unhindered labor migration. One of the first sectors to be integrated is the pharmaceutical sector through the 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 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. From January 1, 2021, all new pharmaceutical registrations will need to be registered under the EAEU regulations, and all medicines on the market must meet these registration requirements by January 1, 2026 (or they will be withdrawn from the market).

Although the first EAEU market authorization was approved in 2018 in Kazakhstan[295] and the first market authorization under EAEU rules was issued by the MoH in November 2019,[296] a number of technical issues with electronic dossier format remain unresolved, which creates additional barriers for the formation of the common EAEU market.

The EAEU unified system should ensure integrity and continuous communication with national information systems so that applicants in all territories of the EAEU can follow the mutually recognized procedures. The innovative pharmaceutical industry stands ready to work with the Government and EEC to ensure that there is a robust regulatory review system and continued patient access throughout the EAEU.

[295] Available at https://gmpnews.ru/2019/02/faktycheskoj-datoj-zapuska-edinogo-rynka-lekarstv-eaes-mozhet-stat-konec-marta-nachalo-aprelya/ (last visited Oct. 28, 2020).
[296] Available at https://pharmvestnik.ru/content/news/Minzdrav-Rossii-vydal-pervoe-registracionnoe-udostoverenie-po-pravilam-EAES.html?utm_source=Fbpost&utm_medium=Group&utm_campaign=Minzdrav_Rossii&fbclid=IwAR2moYAg2p6ByiW12Xcs_BX1HuksJ69Fk-5uSUfEurqbB7XvW_xhZBJBUuY (last visited Oct. 28, 2020).

Track and Trace System

At the end of 2018, the Russian Government adopted Resolution No. 1556, which introduces a new, compulsory system for tracking pharmaceuticals from manufacturer to end user. Members expressed serious concerns to the Russian government on the technical requirements of the proposal as well as the aggressive implementation timeline.

Mandatory labeling for all medicines was to commence on January 1, 2020, but due to non-readiness by various stakeholders, the deadline was postponed to July 1, 2020. Recognizing that there continued to be difficulties in implementing the track and trace system, Federal Law No. 206 was signed on July 13, 2020, to exempt products manufactured before October 1, 2020. This built on Government Resolution (No. 955) dated June 30, 2020, which allowed for import of medicines manufactured before October 1, 2020, to be imported without applying identification codes in order to avoid potential drug shortages. The industry stands ready to work with the Russian Government and EAEU Commission to ensure that the new track and trace requirements are not implemented in a manner that imposes unnecessary obstacles to trade and medicine shortages for Russian patients.

Good Manufacturing Practice

Since January 2016, Russia has required local Good Manufacturing Practice (GMP) certificates for foreign producers as part of the drug registration application. Industry has reported increased denials of GMP certificates, highlighting the lack of process for paper review of corrective actions submitted by inspected sites. As a result, most sites that received a negative decision had to be re-inspected.

In May 2020, Government Decree No. 1314 automatically extended the validity of GMP certificates issued in 2019 for 12 months in light of the restrictions on the ability to conduct GMP inspections due to the COVID-19 pandemic. Industry greatly appreciates its constructive dialogue with the GMP inspectorate and the MoIT to identify alternative means for conducting GMP inspections.

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. To date, however, MoH has only listed approximately 250 orphan diseases,[297] while the European Organization of Rare Diseases list identifies more than 5,000 orphan diseases.

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.

[297] Available at https://www.rosminzdrav.ru/documents/8048 (last visited Oct. 28, 2020).

Biologic and Biosimilar Products

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

Intellectual Property Protection

Compulsory Licensing

PhRMA and its member companies are deeply concerned by ongoing compulsory licensing threats in Russia and by proposed plans to expand the use of this drastic measure.

There has been an overall rising trend in court cases seeking compulsory licenses (CLs) for dependent patents. In its decision dated June 8, 2018, the Moscow Arbitration Court (1st Instance) granted a CL for an innovative cancer medicine developed in the United States to a local generic drug company.[298] This decision was based on an extremely low evidence test and standard of proof. The dependent patent was later annulled by Rospatent on November 26, 2018, and the court case was dismissed. In early 2019, the Moscow Arbitration Court (1st Instance) issued a CL against another innovative manufacturer based on a counterclaim by the same local generic drug company;[299] the decision was upheld by the appellate court, the IP Court (Oct. 2019) and by the Russian Supreme Court (Feb. 2020).[300] These decisions establish dangerous precedents based on low or incorrect standards of proof and misinterpretations of cases where compulsory licenses have been granted internationally.

Furthermore, 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. According to the Competition Development Plan, the Russian Government plans to submit a draft law to the State Duma that would allow compulsory licensing on the vague and unduly broad grounds of whenever it is determined to be in the interests of national security and health protection, under article 1360 of the Russian Civil Code (i.e., government use of an invention).[301] Building on the Competition Development Plan, on

[298] Available at http://kad.arbitr.ru/Card/322413fa-38a7-4085-9cc7-3c8ff9fd7d92 (last visited Oct. 28, 2020).
[299] Available at http://kad.arbitr.ru/Card/3a0440d1-5ba5-4049-ac4c-7be5b9edc09c (last visited Oct. 28, 2020).
[300] Available at https://kad.arbitr.ru/Document/Pdf/3a0440d1-5ba5-4049-ac4c-7be5b9edc09c/71db5389-d61e-4190-a963-a1ccf50d0184/A40-166505-2017_20200220_Opredelenie.pdf?isAddStamp=True (last visited Oct. 28, 2020).
[301] *See* http://fas.gov.ru/news/27693 (last visited Oct. 28, 2020).

January 12, 2018, the Russian Government issued Decree No. 9-r, which approves the Roadmap for Development of Competition in Healthcare (the Roadmap). As one of its priorities, the Roadmap called for amendments to Article 1360 of the Russian Civil Code by the end of 2018 that would enable the Russian Government to authorize compulsory licensing. Those discussions are still ongoing.

From March 25 until April 19, 2019 public discussions were also held in relation to a draft Resolution[302] aimed at establishing a procedure for government use of an invention (under article 1360 of the Russian Civil Code). The draft describes the circumstances under which the government use of an invention is possible, such as the tender procedure for election of a licensee and provisions for royalty determination. The draft broadly interprets the provisions of article 1360 of the Russian Civil Code, lacks transparency and contains a number of legal gaps. Despite this, on November 22, 2019, the Russian Government submitted the Draft Federal Law on amending article 1360 of the Civil Code to the State Duma, where it now remains under consideration.

The Russian Government also appears to be using the pretext of implementing a limited amendment to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to force legislation that could dramatically expand the use of compulsory licensing that do not appear to be consistent with TRIPS rules. On March 3, 2020, the Government submitted to the State Duma the Draft Federal Law "On Amendments to the chapter 72 of the Civil Code" considering provisions in the new article 1360[1] on using of an invention for manufacture of medicinal product for export without the consent of the patent holder in accordance with international treaty.[303]

The Draft Law was proposed following the adoption of the Federal Law No. 184-FZ "On Approval of the Protocol Amending the TRIPS Agreement," which ratified the TRIPS Protocol governing the use of compulsory licensing for export purposes to provide medical aid at the request of less developed countries. The lack of clarity in the text could result in arbitrary implementation. The Draft Law is yet another attempt to allow for the use of compulsory licensing for export purposes. The Draft Law is currently under consideration by the parliament.

Restriction of Antimonopoly Immunities in Antitrust Regulations

In 2020, the Federal Antimonopoly Service (FAS) made available for public discussions several versions of the Draft Law "On Amendments to the Federal Law 'On Protection of Competition' in Terms of Establishing Antitrust Requirements for Agreements and Actions for Granting or Disposing of Exclusive Rights to the Results of Intellectual Activity or Means of Individualization of a Legal Entity, Goods, Works or Services" speaking to the application of antitrust regulations vis-à-vis intellectual

[302] Available at https://regulation.gov.ru/projects/List/AdvancedSearch#departments=41&npa=89840 (last visited Oct. 28, 2020).
[303] Available at https://sozd.duma.gov.ru/bill/912458-7 (last visited Oct. 28, 2020).

property.[304] PhRMA and its member companies are concerned that the FAS is seeking to abolish so called "antimonopoly immunities" that provide appropriate exemptions from the antitrust regulations for holders of intellectual property. Other issues that industry is monitoring closely are the extent to which the Law would allow FAS to authorize parallel imports and compulsory licensing, which may create a pathway for various abuses and disrupt stability in the market. Notably, in July 2020, the Ministry of Economic Development issued a negative opinion on the proposed draft law as part of its required regulatory assessment.

Restrictive Patentability Criteria

On May 27, 2016, FAS published on its official website, the draft *Roadmap for Development of Competition in the Healthcare Sector*. As noted above, the Roadmap was approved by the Russian Government on January 12, 2018, via Decree No. 9-r. The Roadmap, *inter alia*, proposes 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, and new pharmaceutical forms and manufacturing methods). In December 2018, the Ministry of Economic Development issued Order No. 527 on "double patenting" of pharmaceutical compositions and their uses. PhRMA and its members are monitoring the implementation of the relevant amendments.

Weak Patent Enforcement

Russia does not maintain an effective mechanism for 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 – and in turn participate in state tenders – even though 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 or for price registration on the EDL.

Further, while there have been some positive court decisions (including by the Russian Supreme Court[305]), there are still very few mechanisms available to enforce the relevant court decision. Furthermore, Russian courts rarely grant injunctive relief and some lower courts do not appear to follow the Supreme Court's decision. For example, on November 12, 2019, the Arbitration court of Moscow (on remand) yet again rejected a patent violation claim filed by an innovative manufacturer against a local manufacturer of

[304] Project ID 02/04/02-20/00099621, available at https://regulation.gov.ru/projects#npa=99621 (last visited Oct. 28, 2020).
[305] Available at http://kad.arbitr.ru/Card/414811f6-22f6-4719-a406-23e3c00a82eb (last visited Oct. 28, 2020) (upholding the findings of the lower courts that registration of a generic, as well as registration of its price, may be a threat to the original patent protecting the active ingredient. As a result of this case, a generic manufacturer was ordered by the court to apply to the MoH to annul its registration certificate.).

a generic product.[306] On appeal, the Tenth Arbitration Court of Appeal dismissed the claim.[307] However, on further appeal to the Intellectual Property Rights Court, the Court (in an August 11, 2020 decision[308]) remanded the case for a second time to the Arbitration Court of Moscow to a different judicial panel to be considered *ab initio*. In short, pharmaceutical innovators face significant legal challenges effectively protecting their innovative products against infringement, resulting in significant damages that are rarely compensable.

Such practices are contrary to Russia's obligations under TRIPS and the assurances Russia made to the WTO Working Party on the Accession of the Russian Federation to 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 WTO Working Party that it would "counteract ... infringements of intellectual property through improvements in enforcement." However, considering the current efforts by the Government to improve the situation, the industry stands ready to contribute to the formation of an effective IP protection environment.

Encouragingly, in 2019 the Russian Government assigned Rospatent and the MoH to review amendments to the Law on the Circulation of Medicines in order to provide effective patent enforcement (*e.g.*, mechanisms to allow for early resolution of patent disputes before potentially infringing products enter the market). Predictable and effective patent enforcement procedures are especially important as it relates to the establishment of the common Eurasian Economic Union (EAEU) market for medicines. In early 2020, the Eurasian Economic Commission discussed the creation of a Unified Register of Pharmacologically Active Substances Protected by a Patent for an Invention in EAEU Member States, which the Russian Government approved in August. Industry stands ready to work with MoED, Rospatent and MoH to ensure that the proposed amendments are drafted and implemented in a manner that ensures robust patent protection for innovative medicines and provides business certainty for innovators and follow-on manufacturers alike.

[306] Available at http://kad.arbitr.ru/Document/Pdf/53f07f2a-fe8f-4674-aef4-d6d19f474c42/33ba38a0-eaf7-4517-a879-37c96d4080b4/A41-3828-2018_20191112_Reshenija_i_postanovlenija.pdf?isAddStamp=True (last visited Oct. 28, 2020).
[307] Available at https://kad.arbitr.ru/Document/Pdf/53f07f2a-fe8f-4674-aef4-d6d19f474c42/eb9d1d4e-c497-480a-a307-78d0213b38b7/A41-3828-2018_20200203_Postanovlenie_apelljacionnoj_instancii.pdf?isAddStamp=True (last visited Oct. 28, 2020).
[308] Available at https://pharmvestnik.ru/content/news/Arbitrajnyi-sud-v-treti-raz-rassmotrit-delo-mejdu-Bayer-i-Nativa-po-sorafenibu.html (last visited Oct. 28, 2020).

Regulatory Data Protection Failures

As part of its accession to the WTO, Russia agreed to provide six years of regulatory data protection (RDP).[309] While the Law on Circulation of Medicines[310] provides for this protection, Russia's weak judicial system creates concerns for PhRMA members in light of amendments to Russia's Law on the Circulation of Medicines passed in 2014. Specifically, beginning in 2016, the amendments allowed competitors to apply for marketing approval of follow-on medicines as early as four years after marketing authorization for a reference small molecule drug and three years after marketing authorization of a reference biologic medicine. The absence of a clear definition of the circumstances that constitute "use for commercial purposes" and the lack of injunctive relief in Russia (as noted above), has led to at least one instance of a follow-on product being approved to launching on the market before the expiry of the full 6-year RDP term.

This issue becomes especially important in light of the common EAEU medicines market, which is due to go into effect on January 1, 2021. With this milestone in mind, in April 2020, MoH released draft amendments to the Law of Circulation of Medicines to implement the new system. Troublingly, the proposed amendments excluded Article 18 ("Submission and Analysis of an Application for State Registration of a Medicine for Human Use") from the Law on Circulation of Medicines, which, *inter alia*, contains the RDP provisions. Following a public consultation and industry advocacy, the relevant RDP provisions (parts 18, 20 and 21 of Article 18) were restored. Nonetheless, the Draft Law is in the regulatory assessment stage and has not yet been submitted to the Russian Government or the Russian State Duma. Beyond the RDP provisions in Russian law, in light of the EAEU common pharmaceutical market, it will be essential to have a robust and well-functioning RDP system established at the level of the EAEU. Industry is working with the Eurasian Economic Commission to share best international practices on RDP regulations.

Parallel Imports

Currently, parallel imports are prohibited from countries outside the EAEU, based on the regional principle of exhaustion of trademark rights. However, the EAEU has discretion to allow parallel imports and recent Russian court decisions are already eroding trademark rights. In April 2017, the Board of the EEC approved the draft Protocol on Amendments to the Treaty on the Eurasian Economic Union of May 29, 2014. If approved by all EAEU member states, the Protocol would grant the Eurasian Intergovernmental Council the authority to use the international principle of exhaustion of trademark rights in respect to certain products (pharmaceuticals are one of the product groups under discussion). PhRMA and its member companies remain concerned that such exemptions may at some point be renewed and cause medicine shortages in exporting countries and compromise the security of medicine supply chains.

[309] Report of the Working Party on the Accession of the Russian Federation to the World Trade Organization, WT/ACC/RUS/70, WT/MIN(11)/2 (Nov. 17, 2011), at para. 1295, incorporated in Protocol on the Accession of the Russian Federation, WT/MIN(11)/24, WT/L/839 (Dec. 17, 2011), at para. 2.
[310] Federal Law No. 61-FZ, dated Apr. 12, 2010, "On the Circulation of Medicines".

Moreover, during the meeting between the EEC Minister of Competition and heads of the antimonopoly bodies of the EAEU member states in September 2019, the FAS stated that it is necessary to finish the EAEU discussions on parallel imports and at the initial stage enable the Eurasian Intergovernmental Council to authorise the usage of the international principle of exhaustion of trademark rights in respect to certain product groups.[311] As of yet, no action has been taken to implement this mechanism, but PhRMA and its member companies remain concerned that proposals to implement parallel imports in the pharmaceutical sector may at some point be renewed.

In the meantime, the ability of trademark owners to protect their rights against parallel imports is already being limited by the courts. On February 13, 2018, the Russian Constitutional Court published its position on parallel imports. The Court ruled that it is not allowed to apply similar sanctions against the parallel importer of an original product and the parallel importer of a counterfeit product, except in cases when the original product may cause harm similar to a counterfeit product. This Constitutional Court interpretation may affect existing court practice on parallel imports and increase the number of cases when the trademark owner is not able to prevent parallel imports or obtain compensation from parallel importer.

[311] Available at https://gmpnews.ru/2019/10/fas-predlagaet-konsolidirovat-usiliya-stran-eaes-v-oblasti-prinuditelnogo-licenzirovaniya/ (last visited Oct. 28, 2020).

SINGAPORE

PhRMA member companies face several market access barriers in Singapore despite the country otherwise serving as a strong model for protecting intellectual property, supporting clinical trials and incentivizing manufacturing. With continued collaboration between PhRMA member companies and the Government of Singapore, and with U.S. Government support, we are confident that we can resolve outstanding issues and strengthen the country's global leadership position.

Key Issues of Concern:

- **Drug formulary listing practices in the public sector**: Public healthcare institutions exercise their own autonomy in maintaining independent formulary and subsidy lists with undisclosed evaluation criteria and varied timelines across different hospitals and polyclinics. Public hospital listing relies on physician lead decisions and submissions to initiate the process. Manufacturers cannot initiate this process which can result in delayed access and inconsistent availability of treatment options across the institutions for some patients.

- **Government drug subsidies**: The Agency for Care Effectiveness (ACE) is the national health technology assessment agency in Singapore. Established by the Ministry of Health (MoH), it conducts drug evaluations to recommend government subsidy decisions on treatments and produces guidance on the appropriate use of treatments for public hospitals and institutions in Singapore. Industry acknowledges the recent efforts to improve engagement but believes that further opportunities remain for greater industry and general public involvement in the initiation and subsidy decision-making input process.

  There is also an opportunity for government subsidies to be provided on a timelier basis and for a greater number of medicines. In the current process, only two drugs may be considered, with a third drug considered only on an exceptional basis which can limit patient and physician treatment options. A protracted review process including infrequent Drug Advisory Council meetings for final decisions also delays patient access to innovation.

  Through its Healthy SG Task Force, the government recently announced plans to subsidize all vaccines included in the National Adult and Childhood Immunization schedules. This is a positive move that should enhance coverage rates, but the industry requests greater ongoing public-private collaboration in the formulation, implementation and monitoring of this policy to ensure success for all stakeholders involved. Strong industry concerns remain regarding handling of commercially sensitive information. PhRMA member companies engaged with the MoH with a good faith understanding that price confidentiality would be observed; however, the dissemination of information about the program contrasted to this understanding. In addition, the implementation of price caps on manufacturers poses a threat to access to innovation and cutting-edge vaccines development.

- **Review of Medishield Life program**: Medishield Life (MSL) is a national health care insurance that provides hospital and limited outpatient benefits and the program is currently under review. As the healthcare financing stakeholders in the Ministry of Health and the MSL Council consider these changes, it is imperative that it consults with all stakeholders including the pharmaceutical industry to ensure that the revised program does not delay or restrict patient access to innovative oncology therapies. Positively, in September 2020 it was proposed to expand Medishield Life benefits in 2021 and we welcome the public consultations on these proposals.

- **Challenges in conducting clinical trials**: Singapore is consistently recognized as a leading location to conduct clinical trials as a result of its high-quality sites and renowned researchers. However, the high cost and slow speed of setup of clinical trials in Singapore are observed as key barriers. Besides high administrative and resource costs, patients enrolled in clinical studies are charged at private patient rates. Lack of coordinated setup and infrastructure compounded with already inherent challenges of low patient enrolment and retention are significant obstacles for establishing effective clinical trial research and development.

- **Intellectual property protection**: Singapore generally maintains a strong intellectual property protection and enforcement system. However, Singapore artificially limits patent term restoration (PTR) for biopharmaceutical inventions to the product registration period in Singapore, even when that registration relies on clinical trials conducted outside of Singapore. Improvements to the manner in which Singapore provides PTR, as well as its data protection regime would support the country's goal of becoming a global hub for biomedical innovation.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Drug Formulary Listing Practices in the Public Sector

While PhRMA member companies are encouraged by the formation of three new public institution clusters, gaps between market access and timeline variances could be improved through a standardized evaluation process across the health care institutions within each cluster. Moreover, industry engagement in the formulary evaluation process and policy decision-making processes should be improved. PhRMA's member companies believe that such measures will enhance consistency and transparency of the listing process in public formularies and a broader range of medicinal choices will create more effective treatment options for patients and physicians in public institutions.

Government Drug Subsidies

PhRMA's member companies recognize ACE's effort to work toward a process that allows greater involvement both of the industry during the listing initiation and subsidy decision-making input processes and of the general public in the near future. This could enhance the quality of submissions and speed of decision making, thereby expediting access to innovative new medicines in the public sector.

The government announced in July 2020 plans to subsidize all vaccines included in the National Adult and Childhood Immunization schedules by November 2020, in line with recommendations from the Healthy SG Task Force. This is a positive move that should enhance coverage rates, however, strong concerns remain on price confidentiality. PhRMA member companies engaged with the MoH with a good faith understanding that price confidentiality would be observed; however, the dissemination of information about the program proved otherwise. In addition, the implementation of price caps on manufacturers poses a threat to innovation and cutting-edge vaccines development.

Review of Medishield Life Program

The Ministry of Health needs to carefully consider the impact of any potential changes to national health care insurance in Singapore, including Medishield Life which provides hospital and outpatient benefits. ACE recently held an industry briefing announcing potential changes to oncology care coverage under this insurance program. While containment of health care expenditures is a key concern of the government, this needs to be carefully balanced with timely availability and broad accessibility of innovative oncology therapies to cancer patients in Singapore. As the healthcare financing officials in the MoH and the MSL Council consider these changes, PhRMA member companies encourage both organizations to continue engaging in dialog on the upcoming Medishield Life changes, and involve all impacted stakeholders such as health care professionals, public health care institutions and patient groups in guiding its decision moving forward. It is imperative that the revised program does not delay or restrict patient access to innovative oncology therapies.

Challenges in Conducting Clinical Trials

Clinical trials in Singapore can be better promoted by managing the high cost of clinical trials and accelerating the speed of setup and recruitment through standardizing clinical trial agreement/contract across all public institutions. Industry welcomes the setup of CRIS (Consortium for Clinical Research & Innovation, Singapore) with the goals to centralized activities to achieve operational efficiencies, scale and scalability, consistencies of practice, and better governance/compliance across the research platforms and programs in Singapore. PhRMA member companies urge the MoH to continue work with industry to find collaborative solutions to encourage conducting more clinical trials in Singapore.

Intellectual Property Protection

Singapore generally maintains a strong intellectual property protection and enforcement system. PhRMA members fully support the country's objective of and progress toward becoming a global hub for biomedical science and innovation hub. To fully realize this goal, and in keeping with the U.S.-Singapore Free Trade Agreement, Singapore should adjust its PTR mechanism to compensate the patent holder for the time invested in conducting clinical trials either in Singapore or in any other market when such data is a condition of obtaining marketing approval in Singapore.

PhRMA continues to urge Singapore to improve its regulatory data protection regime. In particular, Singapore should extend regulatory data protection to new formulations, combinations, indications and dosage regimens.

SAUDI ARABIA

PhRMA and its member companies welcomed Saudi Arabia's bold "Vision 2030" plan, which aims to transform the country into "a vibrant society, a thriving economy, and an ambitious nation" by the year 2030.[312] To achieve this goal, Saudi Arabia established the National Industrial Development and Logistics Program (NIDLP), which identifies the pharmaceutical industry as one of the promising and competitive industries prioritized for development.[313] Specifically, the NIDLP aspires to further promote innovation in the pharmaceutical sector to encourage increased local production as well as research and development.[314] In addition to the NIDLP, the Vision 2030 program also establishes the National Transformation Program, which sets strategic objectives for improving health care in Saudi Arabia and increasing the quality of life and life expectancy of citizens.[315]

As part of these efforts, in 2019 Saudi Arabia established a new authority responsible for intellectual property (IP) protection and enforcement (Saudi Authority for Intellectual Property – SAIP) to create and develop IP regulations, guidelines and mechanisms for IP protection and enforcement in coordination with other relevant agencies, including the Saudi Food and Drug Authority (SFDA). The Ministry of Justice established a commercial court dedicated to resolving commercial law disputes including IP cases.

Biopharmaceutical innovators have sought to engage SAIP and relevant ministries to inform these developments and establish an IP regime in Saudi Arabia that can achieve the bold goals of Vision 2030. However, continued actions by SFDA are undermining these positive developments and the investment climate in Saudi Arabia. SAIP has issued proposed regulations on compulsory licensing and regulatory data protection (RDP) that further weaken – rather than improve – IP protections in the Kingdom.

Key Issues of Concern:

- **Pricing guidelines do not appropriately value innovative medicines**: The SFDA pricing guidelines set prices for medicines in Saudi Arabia by taking the lowest price in a basket of reference countries (*i.e.*, a form of international reference pricing). This flawed methodology does not appropriately recognize the value of innovative medicines for the Saudi health system and patients. Recent proposals to revise the guidelines would compound the flaws of the current system by requiring repricing every two years.

[312] *See, e.g.*, Kingdom of Saudi Arabia, Vision 2030, p. 13. (2017), available at https://vision2030.gov.sa/sites/default/files/report/Saudi_Vision2030_EN_2017.pdf (last visited Oct. 28, 2020).
[313] Kingdom of Saudi Arabia, National Industrial Development Logistics Program, Delivery Plan 2018-2020, pp. 10, 98 (Jan. 2019), available at https://vision2030.gov.sa/sites/default/files/attachments/NIDLP%20Delivery%20Plan%20-%20English%20Jan%202019.pdf (last visited Oct. 28, 2020).
[314] *Id.*, pp. 87, 113-14.
[315] Ministry of Health, Health Sector Transformation Strategy, p. 13, available at https://www.moh.gov.sa/en/Ministry/vro/Documents/Healthcare-Transformation-Strategy.pdf (last visited Oct. 28, 2020).

- **Government procurement system lacks transparency and discriminates in favor of local manufacturers**: Frequent renegotiation of tenders, combined with the lack of clear timelines, have resulted in an unpredictable government procurement system. The recent creation of the Local Content and Government Procurement Authority (LCGPA) to identify lists of products that must be procured from local manufacturers, combined with 30 percent price preferences for medicines made with locally manufactured active pharmaceutical ingredients (API), serve to discriminate against foreign manufacturers and increase uncertainty in the Saudi market.

- **Ensuring the new health technology assessment (HTA) system supports value-based health care**: Industry stands ready to work with the Saudi authorities to ensure that the new HTA system is not used exclusively as a cost-containment tool, but rather supports Saudi patient access to innovative medicines and moves the country towards the value-based health care system outlined in the Saudi Health Sector Transformation Strategy.

- **Ineffective patent protection, patent enforcement and RDP**: In mid-2017, the SFDA started granting marketing approval to generic versions of innovative medicines during the term of the patent(s) protecting those treatments or the period of RDP. SFDA's repeated approval and related price listings of generic copies of innovative medicines is contrary to Saudi Arabia's own patent enforcement and data protection rules. These actions also contradict the country's World Trade Organization (WTO) commitments. SAIP has issued proposed regulations on compulsory licensing and RDP that have further weakened or would further weaken IP protections in Saudi Arabia.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access

Pricing Guidelines Do Not Appropriately Value Innovative Medicines

The Saudi Government uses international reference pricing (IRP) to set the prices of medicines. As a general matter, IRP suffers from serious flaws as a mechanism for pharmaceutical pricing. It assumes similarity across all countries in the reference basket and implicitly imports the pricing policies of those countries without accounting for circumstances that justify price differentiation. Importantly, IRP ignores the local value of the product, patient benefits and physician requirements, existing standards of care, placement within the health care system, patterns of disease burden, socioeconomic factors including ability to pay, stage in the pharmaceutical life cycle, etc. IRP also ignores circumstances unrelated to a product's value such as budget overruns that lead to price cuts.

In August 2020, SFDA issued a new draft pricing regulation that would compound the flaws of the current pricing guidelines by requiring repricing of all products every two years. If implemented, the new pricing regulation will have detrimental effects on the innovative biopharmaceutical sector in Saudi Arabia.

Government Procurement System Lacks Transparency and Discriminates in Favor of Local Manufacturers

The tendering and purchasing of pharmaceuticals in Saudi present many challenges. Although the tendering system is supposed to be closed, the practice of routine price renegotiations limit predictability, sustainability and fair competition. The lack of clear timelines for the procurement process hinders the ability of companies to plan and invest in bringing new medicines to the market and exposes Saudi Arabia to the risk of supply shortages. In addition, Saudi Arabia recently adopted a newly designed therapeutic class review process, whereby only a single product is identified for inclusion on formularies and for procurement. Such approaches unduly restrict patient and physician choice in identifying the most appropriate treatment for each patient. Finally, contrary to current practice, the National Unified Procurement Company for Medical Supplies (NUPCO) should not disclose confidential negotiated net prices as it harms competition and access to innovation.

In addition to these deficiencies in the procurement process, Saudi Araba recently constituted the LCGPA to identify lists of products that government institutions must procure from local manufacturers. The first list of products has been released, and it identifies more than 100 medicines that are limited to local providers. Additionally, Saudi Arabia recently announced a price preference initiative of up to 30 percent for local medicines made using API manufactured in the country. These actions discriminate against foreign manufacturers and increase uncertainty in the Saudi market.

Ensuring the New HTA System Supports Value-based Health Care

When designed well and used appropriately, HTA of medical tests, treatments and health care services can represent one of many tools to support well-informed, patient-centered health care. When misapplied, HTA has the potential to impose one-size-fits-all policies that impede patients' and physicians' ability to tailor care to individual needs and preferences. Poor forms of HTA can also hinder progress in developing innovative new therapies that address unmet medical needs.

PhRMA members recognize the ongoing efforts of the Saudi authorities to build an HTA system and stand ready to offer their expertise based on international experience. While PhRMA's members appreciate that the proposed HTA system's primary goal is to inform decisions on effective use of resources, it is critical that it not be used exclusively as a cost-containment tool, but rather is designed to improve patient choice and access. Rather than overlaying the proposed HTA system on the already complex pricing and reimbursement framework, PhRMA members recommend that the new HTA system progressively replace certain features of the existing system that are incompatible with

the value-based health care approach that Saudi Arabia is trying to achieve through its Health Sector Transformation Strategy, including IRP and the current tendering process. We therefore encourage the newly established HTA entity in Saudi Arabia to engage PhRMA members in an open dialogue and seek their support to inform a fit-for-purpose HTA framework for the country.

Intellectual Property Protection

Ineffective Patent Protection, Patent Enforcement and RDP

Despite creating mechanisms to provide for effective patent enforcement and RDP, in mid-2017 the SFDA started granted marketing authorization to domestic drug companies to produce copies of innovative medicines produced in the United States and other countries during the period of patent or RDP protection. Furthermore, the Ministry of Health (MoH) has proceeded to procure the infringing products despite multiple appeals from the relevant innovators and, in one case, despite a favorable Saudi court decision. The local drug companies are now distributing these copies to the MoH and selected hospitals. Rather than end this practice, SFDA is actively soliciting on its website for manufacturers to seek approval for generic products even where the innovative product is still subject to IP protections.

SFDA's actions appear designed to benefit Saudi Arabia's local industry at the expense of U.S. innovators, as evidenced by the tenders awarded by NUPCO. These actions harm U.S. manufacturers, infringe proprietary technology and damage U.S. exports. Contrary to the country's aspirations to promote local investment, IP infringement, and the lack of effective enforcement sends a hostile message to U.S. inventors and investors that their valuable IP rights are not secure in Saudi Arabia.

These actions also appear contrary to Saudi law and to Saudi Arabia's WTO commitments. For example, Article 5 of a Council of Ministers' Trade Secrets Protection Regulation (decision No. 3218, dated 25/03/1426 H, May 4, 2005), as amended by Ministerial Decision No. 431 of 1.5.1426H (June 8, 2005) states that the submission of confidential tests or other data, obtained as a result of substantial efforts, for the approval of the marketing of drugs or agricultural products which utilize a new chemical entity, shall be protected by the competent authority against unfair commercial use for at least five years from the approval date. Unfortunately, the Kingdom of Saudi Arabia has not complied with its own regulation and WTO commitments which gave rise to the regulations. Specifically, Saudi Arabia confirmed during its accession to the WTO that:

> [Its] Regulations provided for protection of undisclosed tests and other data submitted to obtain approval of a pharmaceutical or agricultural chemical against unfair commercial use for a minimum period of five years from the date of obtaining the approval including the establishment of the base price. No person other than the person who submitted such data could, without the explicit consent of the person who submitted the data, rely on such data in support of an application for product approval. Any

> subsequent application for marketing approval would not be granted a market authorization unless the applicant submitted its own data, meeting the same requirements applied to the initial applicant, or had the permission of the person initially submitting the data to rely on such data.[316]

The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) imposes more than a non-disclosure obligation. Rather, TRIPS Article 39.3 additionally requires WTO member states to 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, protected data may not be used to support marketing approval for follow-on products for a set amount of time unless authorized by the original submitter of the data.

In September 2020, SAIP published new draft regulations for the protection of confidential business information, including regulatory test data. Far from improving on a prior draft issued in December 2019, the new draft would further weaken RDP in Saudi Arabia. Among other things, the draft fails to grant RDP on a national basis, lacks clarity with respect to the scope of products covered, contains overly broad exceptions to RDP and continues to lack the necessary mechanisms for effective enforcement.

In addition to making no progress on RDP, in April 2020, SAIP issued damaging final regulations on the compulsory licensing of patents, which have the potential to frustrate Saudi Arabia's efforts to promote innovation and economic growth. The final regulations largely disregard comments pharmaceutical innovators provided on draft regulations SAIP published in July 2019. PhRMA believes governments should grant compulsory licenses (CLs) in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options. By allowing SAIP to take patents away three years after they are lawfully granted for almost any reason and without prior notice to the patent holder, the regulations risk encouraging excessive use of CLs and denying patent holders the right to adequately defend their property interests.

Biopharmaceutical innovators have repeatedly engaged or sought to engage SAIP and other relevant Saudi ministries to address these concerns and to improve IP protection in the Kingdom. While some limited progress has been achieved, SFDA continues to act in ways that violate IP protections and that invite others to violate such protections. Rather than serve as a champion of innovation, SAIP appears dedicated to weakening IP protection and enforcement.

[316] Report of the Working Party on the Accession of the Kingdom of Saudi Arabia to the World Trade Organization, WT/ACC/SAU/61 (Nov. 1, 2005) ¶ 261, available at https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/WT/ACC/SAU61.pdf (last visited Oct. 28, 2020).

TAIWAN

PhRMA and its members have long supported closer economic ties between Taiwan and the United States, including opportunities to build on the bilateral Trade and Investment Framework Agreement and to contribute further to Taiwan's national health care goals. We commend positive steps by the Government of Taiwan to improve intellectual property (IP) protections for innovative medicines, including the establishment of a patent linkage (PL) system effective August 20, 2019. We also value ongoing discussions with the Government of Taiwan on health policy reform measures designed to bring stability and predictability to the national pharmaceutical market.

If implemented in a manner consistent with international best practices, the PL system will greatly improve Taiwan's climate for biopharmaceutical research and development. PhRMA is particularly pleased that the PL implementation rules include biologic treatments, which are likely to account for most new medicines developed in the coming years. However, we are concerned that the Taiwan Food and Drug Administration (TFDA) is excluding patents from the PL system that protect new doses, new dosage forms or new unit strengths. PhRMA is also concerned that Taiwan's drug pricing and reimbursement process does not appropriately value and reward innovation.

PhRMA looks forward to working with the Taiwan Government to support full implementation of an effective PL system that is consistent with international best practices and to address serious concerns regarding Taiwan's pricing and reimbursement policies. We appreciate the commitment of the Government of Taiwan to continue its dialogue with PhRMA and its member companies as part of broad stakeholder consultations. This communication will ultimately help achieve the common goal of Government and industry: enabling patients to live longer, healthier, and more productive lives. PhRMA urges the Taiwan Government to continue developing sound IP protections and drug pricing and reimbursement policies with stakeholder involvement. We also urge USTR and other federal agencies to continue their engagement with the Taiwan Government to support and monitor PL implementation and to ensure a transparent and predictable new drug pricing and reimbursement process that follows the government's official pricing methodologies.

Key Issues of Concern:

- **Government pricing and reimbursement mechanisms**: Beginning with implementation of the second generation of National Health Insurance (NHI) in January 2013, the process of new drug reimbursement review and decision making has become much more complicated due to the Pharmaceutical Benefit & Reimbursement Scheme (PBRS). Under the scheme, average prices and approval rates for new medicines continue to be low and do not adequately reflect or reward the value of those innovative medicines. Furthermore, the approval process is inefficient and negotiations can be lengthy, resulting in product evaluation times that can exceed two years. Moreover, the government pricing and reimbursement system fails to recognize various forms of pharmaceutical innovation, instead only

focusing on cost containment. As an example, the current system groups new drugs and new indications together for pricing review, forcing joint price negotiations for both, rather than individually processing them in a timely manner.

- **Insufficient budget for new drugs and indications**: Under the current structure, most new drugs and indications are either rejected or experience delays in inclusion in the formulary due to insufficient budget allocation. This challenge significantly impacts patient access to needed new drugs and indications, especially for life-threatening diseases such as cancers. PhRMA appreciates the Taiwan Government's budget proposal for new drugs and indications for 2021 which is more adequate than that of 2020. However, due to the COVID-19 pandemic and the impact to economic growth, the result may not be as positive as originally planned. For 2021, the Taiwan Central Bank recently forecasted 3.3% economic growth. We urge the Taiwanese government to plan a more optimistic budget for new drugs and indications for 2022.

- **Drug expenditure target (DET)**: Under the price adjustment scheme instituted in October 2013, only compound and combination patented products are afforded some protection from price cuts. In order to encourage innovation, these price protections should be available to all products during their patent term, as well as to all products with regulatory data protection (RDP). As a starting point, we recommend that NHIA provide price protection to single-source products for which no alternatives are available, including products which carry no patent protection but have been granted 5 years of RDP. PhRMA recognizes the efforts of the Ministry of Health and Welfare (MoHW) with respect to the DET, and we support the continued piloting of DET to improve the methodologies and implementation. We urge the Government of Taiwan to engage industry on implementation to ensure continued patient access to high quality innovative medicines. Any pharmaceutical expenditure regulations should appropriately recognize the value of innovative medicines.

- **Intellectual property protection**: In July 2019, the Taiwan Food and Drug Administration (TFDA) published the final PL regulation on its website and shortly thereafter the Executive Yuan approved implementation of the PL system effective August 20, 2019. While we applaud the establishment of a PL system, we are concerned that the TFDA is excluding from the PL system patents that protect new doses, new dosage forms or new unit strengths. If allowed to continue, this action will seriously undermine the value of Taiwan's PL system. PhRMA and its member companies stand ready to work with the Taiwan Government to support full implementation of the PL regulation. In December 2017, Taiwan's legislature passed important amendments to the Pharmaceutical Affairs Act to provide three to five years of RDP for new indications.

For these reasons, PhRMA requests that the U.S. Government continue to engage the Taiwan government to ensure robust implementation of the PL system and to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Pricing and Reimbursement Mechanisms

Despite constructive engagement with the National Health Insurance Administration (NHIA) regarding the PBRS, average drug prices in Taiwan continue to be low compared to median A10 countries and even by global standards.[317] According to the latest NHIA report, "Comparisons of New-drug Approved Prices and International Drug Prices in Recent Years," current new-drug approval practices have resulted in prices far below levels which would sufficiently incentivize innovation.

A key factor suppressing prices for new drugs in Taiwan is that the price of most new drugs are determined based on those of reference drugs in Taiwan, many of which have previously gone through several annual price cuts and stand at new low prices at the time of comparison. Moreover, under the current NHI reimbursement mechanism, the lowest price among new drugs in the same therapeutic field is used as the benchmark price for reimbursement. This mechanism not only fails to reflect the clinical differences among individual new drugs, but also cannot reasonably reflect the value of new drugs. In addition, too often the reimbursement of new uses is also highly challenging.

Finally, uncertainty over the prices approved by NHIA has increased in the past couple of years. NHIA-approved prices are often much lower than what companies had forecasted based on NHIA's pricing methodologies, and re-submission and re-negotiation of prices takes a considerable amount of time. This results in lengthy review times, particularly for oncology medicines. We urge NHIA to improve the transparency and predictability of its pricing processes, so that companies may bring new medicines to patients in Taiwan with reasonable certainty of their timing and reimbursement.

In summary, low reimbursement prices decrease incentives to bring innovative medicines to Taiwan and to make further investments. PhRMA and its member companies urge NHIA to review and revise the current pricing system to more appropriately value innovative medicines.

Insufficient Budget for New Drugs and Indications

Under the current structure, most new drugs and indications are either rejected or experience delays in inclusion in the formulary due to insufficient budget allocation. This challenge significantly impacts patient access to needed new drugs and indications, especially for life-threatening diseases such as cancers. PhRMA appreciates the Taiwan Government's budget proposal for new drugs and indications for 2021 which is more adequate than that of 2020. However, due to the COVID-19 pandemic and the impact to economic growth, the result may not be as positive as originally planned. For 2021, the

[317] Chen G.T., Chang S.C., and C.J. Chang . New Drug Reimbursement and Pricing Policy in Taiwan. Value Health Reg Issues. 2018 May; 15:127-132, available at https://pubmed.ncbi.nlm.nih.gov/29704659/ (last visited Oct. 28, 2020)

Taiwan Central Bank recently forecasted 3.3% economic growth. We urge the Taiwanese government to plan a more optimistic budget for new drugs and indications for 2022.

Drug Expenditure Target

Under the price adjustment scheme instituted in March 2017, the government implemented a price adjustment designed to maintain national spending targets that ultimately granted only compound and combination patented products some protection from price cuts, creating an unfair price adjustment mechanism for other patented drugs. PhRMA recognizes the efforts of the MoHW with respect to the DET, and we urge the Government of Taiwan to engage industry on implementation to ensure continued patient access to high-quality, innovative pharmaceuticals. Any regulations on drug expenditure should fairly recognize the value of innovative medicines.

In the interest of rewarding innovation, developing new medicines for Taiwan's unmet medical needs, and ensuring that Taiwanese patients have access to innovation, PhRMA strongly recommends that the U.S. Government encourage the Taiwanese Government to implement a fair and reasonable price adjustment policy under the DET. Furthermore, the Taiwanese Government should engage in renewed consultation with the innovative biopharmaceutical industry to ensure that government pharmaceutical pricing and reimbursement policies are transparent and offer due process to interested stakeholders and are based on scientific evidence and patient needs and benefits.

Intellectual Property Protection

Effective Patent Enforcement and RDP

In July 2019, the TFDA published the final PL regulation and shortly thereafter the Executive Yuan approved implementation of the PL system effective August 20, 2019. We commend the Taiwan government for taking this important step to improve Taiwan's climate for biopharmaceutical research and development. Specifically, the PL implementation rules confirm that the PL system includes both chemically synthesized and biologic medicines. Since biologics are the fastest growing segment of innovative medicines development and already account for a substantial share of pipeline products, applying the regulations to biologics and biosimilars will extend benefits of the amendments for domestic and overseas innovators alike.

While PhRMA applauds the establishment of a PL system, we are concerned that the TFDA is interpreting Taiwan's new linkage system in a way that is unduly narrow. Specifically, the TFDA has interpreted Taiwan's Pharmaceutical Affairs Act (PAA) to exclude patents protecting new doses, new dosage forms or new unit strengths from the linkage system. According to TFDA, drugs in these categories are not "new drugs," and consequently, the permit holders for these drugs are not eligible to submit patent information to the PL system under Article 48-3 of the PAA. This interpretation is inconsistent with the PAA and contradicts the purpose and policy behind a linkage system, as well as the expectations by all stakeholders that the system provide an efficient

means to timely resolve any patent dispute before a generic or biosimilar version of an innovative drug is launched.

PhRMA urges TFDA to acknowledge that permit holders are, and must be, eligible to submit patent listing information on patents claiming a drug's new dosage form, new dose or new unit strength. Delisting, or not being allowed to list, the patents for a drug's new dosage form, new dose or new unit strength provides a significant loophole to follow-on manufacturers who may seek to sidestep the PL enforcement mechanism and the protections that it provides to an innovative product by simply seeking approval of the new dosage form, new dose or new unit strength.

In the longer-term, this action would undermine the certainty that PL is designed to provide and would discourage companies from researching, developing and launching new dosage forms, new doses or unit strengths in Taiwan. It is vital to encourage this type of development because a drug's dosage form, dose, or unit strength can have a valuable impact on its safety, effectiveness, or convenience – and better serve patient needs. For example, changes to the formulation and delivery of a drug have been shown to be effective in encouraging adherence across a number of therapeutic areas. Implementing a robust PL system in Taiwan is a critical step towards ensuring that companies continue to innovate in ways that improve patient outcomes in Taiwan. We look forward to continuing to work with the Government of Taiwan to ensure full and timely implementation of the new PL system.

Also, in December 2017, Taiwan's legislature passed amendments to the Pharmaceutical Affairs Act to provide three to five years of RDP for new indications. PhRMA and its members commend Taiwan for implementing these RDP amendments.

THAILAND

PhRMA's member companies face significant market access and intellectual property (IP) concerns in Thailand. Thailand does not provide equitable and reasonable market access to new medicines developed and manufactured in the United States. Furthermore, many of the reforms proposed by the Government of Thailand are out of step with international or regional best practices.

Key Issues of Concern:

- **Discrimination and unpredictability in government procurement policies**: The Thai Government continues to implement procurement policies that facilitate procurement privileges for the domestic Thai industry. These policies have created a discriminatory and unpredictable investment climate that create challenges for U.S. companies seeking to compete on a level playing field in Thailand.

- **Uncertain IP protections and enforcement**: Uncertain IP protections and lack of enforcement hinder the ability of U.S. innovators – in particular, biopharmaceutical innovators – to fairly access the Thai market. Key IP concerns in Thailand include patent backlogs and failure to provide meaningful regulatory data protection (RDP).

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Maximum Price Setting for Government Procurement

The Thai Ministry of Public Health (MoPH) and the National Drug System Development Committee are authorized to establish a "median procurement price" for pharmaceuticals. In practice, this price is not calculated as a median, but rather used as a "maximum procurement price" (MPP) for each medicine.

The MPP process, combined with Thailand's recent preference for domestic companies, harms U.S. innovators and could delay or prevent the introduction of new medicines. Fortunately, the recent Public Procurement Act introduced in August 2017, mandates the creation of a Reference Price Subcommittee for Pharmaceutical and Medical Supplies, which would be responsible for handling reference price issues and standardizing the procedure. The innovative biopharmaceutical industry seeks the expedited formation of this subcommittee as well as the inclusion of members from the private sector so that all stakeholders may collaborate on fair and equitable policies that address the fiscal concerns of the Thai government in the procurement of pharmaceuticals, as well as the concerns of innovators and the need of Thai patients.

Preferential Procurement of Thai "Innovation" List

In 2016, the Thai Government established the Thai Innovation List, an initiative to develop domestic industrial capacity in several innovation sectors, including pharmaceuticals. Only Thai majority-owned companies qualify to be listed. Once listed, Thai companies receive special government procurement privileges including an earmark for at least 30 percent of orders by Thai government agencies. Paradoxically, it appears that to qualify as a pharmaceutical innovator and be eligible for inclusion on the list, the Thai company needs only to demonstrate that their generic copy is bioequivalent to the originator product. As such, the so-called Thai Innovation List exists solely to favor local generic companies to the exclusion of U.S. and other foreign research-based biopharmaceutical companies.

The Innovation List was created under the Thailand 4.0 policy to incentivize innovation development. However, by excluding international companies, it deters international collaborative investment to promote innovation in Thailand. A more inclusive criteria that values research investment and embraces the creation of innovation without a nationality focus would foster a more investment-friendly environment.

Inconsistent and Non-Transparent Oncology Preauthorization System (OCPA)

The OCPA was established in 2006 as a direct reimbursement system to hospitals for "high-cost cancer drugs" administered to patients under the Civil Servants Medical Benefit Scheme (CSMBS). The system was intended to reduce out-of-pocket disbursements for its beneficiaries, by identifying those products for which hospitals would be directly reimbursed through prior authorization and approval based upon a pre-defined protocol of individual cancer drugs in the list.

Unfortunately, the process and criteria involved in the OCPA lack predictability and are applied inconsistently between different companies and different products. Further, recent revisions to the OCPA will result in "non-direct reimbursement" for certain innovator products, based on unclear selection criteria.

Specifically, while many innovative medicines, including cancer drugs, had been directly reimbursable by the CSMBS immediately upon being granted marketing authorization, revisions to OCPA procedures in February 2018 structured reimbursements on a tiering or "Group" system: drugs in Group 1 or Group 2 will continue to be directly reimbursable, while those in Groups 3 will require patients to provide advance payment for their medicines and then apply to OCPA for reimbursement, and the cost of drugs in Group 4 will be fully paid by the patient. These revisions, which were due to government budget constraints, will create a barrier to access for patients who cannot afford to pay for their drugs out-of-pocket, even if reimbursed later. The criteria for how drugs will be placed into each of these Groups is unclear, and potentially revolve around which drugs have the lowest net procurement price. Only one product per indication will be allowed in Group 1, meaning that patients on other drugs will be forced to pay for their drugs or switch to the product placed in Group 1.

To ensure patient access to innovative medicines, the government should establish transparent procedures and criteria for OCPA reimbursement evaluation, with due consideration to therapeutic outcomes and clinical needs rather than pure cost containment.

Preferential Procurement Privileges for the Government Pharmaceutical Organization (GPO)

The GPO, a Thai State-owned enterprise that manufactures pharmaceutical products in Thailand, benefits from preferential procurement privileges. Per Ministerial Regulation B.E.2560 (2017), the MoPH must procure at least 80 percent of medicines on the National List of Essential Medicines from the GPO or the Thai Red Cross and other central government and regional government offices must procure no less than 60 percent from these entities. In addition to these procurement preferences, under the Drug Act B.E. 2510 (1967), the GPO is not required to obtain FDA approval prior to launching medicines on the Thai market. There is no such exemption for private sector manufacturers or sellers, all of whom must obtain market authorization from the Thai FDA prior to selling their products in the Thai market.

Further procurement privileges are also being extended to local vaccine producers under National Vaccine Committee Regulations on “Vaccine Procurement in Government Sector” that went into effect on August 14, 2020.

Intellectual Property Protection

Patent Backlogs

Although the Department of Intellectual Property (DIP) has taken some important initial steps to help clear the patent backlog – including hiring more patent examiners – the waiting-period for a patent review and grant in Thailand remains 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.

Additionally, though some of the recent draft amendments to the Patent Act seek to streamline some procedures during the patent application process, other draft provisions could undermine efforts to support innovation and further exacerbate Thailand’s backlog. For example, one of the proposed amendments seeks to introduce a third party observation mechanism that would allow third-parties to file challenges against

a patent application up to the date of patent grant as well as to modify the opposition period to be both pre-grant opposition after substantive examination. The opposition should be established according to international practice of post grant opposition to sustainably solve the patent backlog and enhance investment climate towards innovation development.

Regulatory Data Protection Failures

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

PhRMA's member companies strongly encourage the Royal Thai Government to institute meaningful RDP. Specifically, Thailand should: (1) implement new regulations that do not permit generic or biosimilars producers to rely directly or indirectly on the originators' data, unless consent has been provided by the originator, for the approval of generic or biosimilar pharmaceutical products during the designated period of protection; (2) bring the country's regulations in line with international standards by making clear that data protection is provided to test or other data submitted by an innovator to obtain marketing approval; (3) provide protection to new indications; and (4) require TFDA officials to protect information provided by the originator by ensuring it is not improperly made public or relied upon by a subsequent producer of a generic or biosimilar pharmaceutical product.

Compulsory Licensing

Despite assurances that Thailand would be judicious in its use of CLs and consult with affected parties as required by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Thailand continues to 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. PhRMA believes governments should grant CLs in accordance with international rules and only in exceptional circumstances and as a last resort. Decisions should be made through fair and transparent processes that involve participation by all stakeholders and consider all relevant facts and options.

TURKEY

PhRMA and its member companies face market access challenges in Turkey due to ongoing localization policies, unpredictable registration timelines and reimbursement processes, strict and unpredictable government pricing systems and deficiencies in its intellectual property (IP) framework. Ongoing currency issues related to the application of an artificially low Euro/Turkish Lira exchange rate are causing severe pressure on prices of pharmaceuticals and threatening patient access to new medicines and the sustainability of the industry.

Over the past 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 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, still more attention needs to be paid to the impact of Turkish government policies on the innovative pharmaceutical industries' research and development process, including the potential of PhRMA member companies to invest in Turkey.

Key Issues of Concern:

- **Localization policies**: Following the implementation of the 10th Development Program and provisions in Article 46 of the 64th Government Action Plan (released on December 10, 2015), the Turkish government has initiated a localization program which calls for the delisting of imported products from the reimbursement list if they are not produced locally, and provides preferential reimbursement arrangements for health care products produced domestically. PhRMA member companies began receiving notices in February 2017 that their products would be delisted within 12 months unless localization plans were in place. Subsequently, new waves of product delisting were announced in May and November 2018.

  On April 2, 2019 the European Union (EU) formally launched a case at the World Trade Organization (WTO) against these forced localization measures. Because parties to the dispute have failed to reach a settlement during the consultation process, the WTO Dispute Settlement Body (DSB) agreed on September 30, 2019 to establish a panel. These forced localization policies could have significant long-term consequences for the industry's operating environment and for patient access to certain medicines in the country.

- **Fixed exchange rate**: The Turkish Government continues to set sub-optimal levels for the overall pharmaceutical budget that disregard exchange rate fluctuations. The practice Turkey uses of an international reference pricing system that employs a fixed FX rate instead of market value to convert the value of the

Euro into local currency is deeply problematic. Although Turkish regulations specified that the exchange rate would be updated at the beginning of the year to reflect 70 percent of the average exchange rate the preceding year, the Turkish Government changed the regulation (only a day before the execution) to lower this to 60 percent of the average exchange rate starting from 2019. Such actions create uncertainty in the Turkish marketplace. This practice coupled with Turkey's currency fluctuations are causing severe pressure on pharmaceutical prices and is threatening both supply continuity and the sustainability of the industry. Industry is requesting the immediate resolution of this issue through a progressive move towards the use of a market-based exchange rate.

- **Local inspection requirements**: PhRMA and its member companies welcome efforts by the Turkish Drug and Medical Device Agency (TITCK) to improve the regulatory approval procedures of highly innovative and/or life-saving products with 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 lack of efficient procedures for conducting GMP inspections. PhRMA and its member companies commend Turkey for becoming a PIC/S (Pharmaceutical Inspection Convention and Co-operation Scheme) member to better align its GMP inspections practices with the other members of the scheme. However, GMP inspection delays continue to add to registration delays, hindering patient access to innovative medicines and negating the benefits of the patent and data protection periods for many products.

  In addition, the Ministry of Health (MoH) has recently begun requiring companies to submit a two-year budget analysis as part of the GMP and registration prioritization submission, inappropriately linking pricing and reimbursement to the separate science-based determination of whether a potential new medicine (and the facility in which that medicine is manufactured) is safe and effective.

- **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 in 2016, better aligns Turkey with the European Patent Convention, certain provisions in the new law inappropriately 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. Critically, the RDP term begins with first marketing authorization in the European Union (EU) 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.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Localization Policies

PhRMA and its members have serious concerns about the Turkish government's implementation of its forced localization efforts for medicines. In 2018, the Turkish Government began to implement policies[318] announced in December 2015, calling for the delisting of certain products manufactured outside of Turkey from the reimbursement list.

As part of the first wave of delisting notices, which impacted 71 products in total with the addition of new products in 2018, PhRMA members began receiving notices in February 2017 that their products would be delisted within 12 months unless they submitted plans to "localize" these products in Turkey. The second phase of product delisting notifications, impacting 176 products, was announced in May 2017, of which 119 products were delisted as of July 31, 2018. Another delisting under the scope of Phase II was carried out in November 2018. Further action under the third and subsequent waves has halted as of this submission, and no formal announcements have been made regarding subsequent phases.

PhRMA and its members believe that these measures are inconsistent with Turkey's national treatment obligations under several WTO Agreements and constitute a significant restriction on trade.[319] An administrative lawsuit challenging the validity of this measure has been filed by the Association of Research-Based Pharmaceutical Companies (AIFD). The hearing was held on October 3, 2019, followed by a verdict in favor of Social Security Institution. AIFD has appealed the verdict, which is currently pending. In addition, on April 2, 2019, the EU initiated a WTO dispute raising the inconsistency of this measure with Turkey's national treatment obligations, among other commitments. Following the end of the consultation period, the DSB agreed to establish a panel on September 30, 2019. Briefing was completed by the end of June 2020 and a decision is expected by mid-2021.

[318] *See*, *e.g.*, Article 46 of the 64th Government Immediate Action Plan.
[319] *See*, *e.g.*, the General Agreement on Tariffs and Trade (GATT), Art. III:4 (requiring that imported products "shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements"), as incorporated into Article 2.1 of the WTO Agreement on Trade-Related Investment Measures. Compelling manufacturers of patented pharmaceuticals to produce locally in order to remain or be added to the reimbursement list as part of the fifth phase of implementation of this policy would also be inconsistent with Article 27.1 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (requiring 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*" (emphasis added)).

The vast majority of medicines sold in Turkey are distributed through the Social Security Institution (SSI) reimbursement list, and exclusion from this list effectively bars market access for these products. This forced localization in Turkey could have significant long-term consequences for the ability of U.S. biopharmaceutical companies to operate in Turkey and for patient access to certain medicines in the country.

Fixed Exchange Rate and Non-transparent Government Pricing and Reimbursement

In Turkey, pharmaceutical pricing is regulated by TITCK. Pharmaceutical companies are still burdened with a substantial price discount from the lowest price in a basket of five European countries (France, Portugal, Spain, Italy and Greece) and the country of origin. Over the last couple of years, TITCK has begun to annually adjust the fixed Euro/Turkish Lira exchange rate used to set prices under the Pricing Decree. However, per that decree, the annual exchange rate is set at 60 percent of the preceding year's average real exchange rate, automatically building in further discounts for the Government. Setting aside the inappropriateness of fixing the exchange rate in this manner, each year the goal posts have moved with either the fixed percentage not being met, as in 2018, or the percentage rate being changed (from 70 to 60 percent), as in 2019. Overriding the regulation for two consecutive years 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 and for which there is no international reference product available would be permitted to negotiate prices directly with the MoH based on cost and pharmacoeconomic 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 at the time of calculation 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.

The reimbursement system is based on a positive list and reimbursement decisions are made by the inter-ministerial Reimbursement Commissions, led by the SSI under the Ministry of Family, Labor and Social Services (MoFLSS). The reimbursement decision process lacks transparency and is not subject to clearly defined decision criteria. Further, contrary to best practices in health technology assessment, the process is not based on pre-defined evaluation criteria, does not require the publication of an official medical evaluation decision/report to support the assessment and does not consider the perspectives of patients, physician associations and other relevant stakeholders. On the

economic evaluation front, companies are required to submit cost-effectiveness analyses during reimbursement submission; however, the evaluation of these submissions is opaque. Further, on the rare occasion that a company receives a formal written decision, it is a simple one-page document stating acceptance or rejection, without any explanation of the grounds on which the decision was made.

Pharmaceutical Product Registration

Marketing of new drugs in Turkey is governed by the regulatory procedures prescribed by the TITCK affiliate of the 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 (Registration Regulation).[320] Although this regulation requires TITCK to assess and authorize the registration of medicinal products within 210 days of the product's dossier being submitted, and efforts have been taken to improve the regulatory process, a 2020 survey by AIFD indicates that the median regulatory approval period is 261 days for high priority products, 377 days for prioritized products and 938 days for products in the normal prioritization category.[321] 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. To partially mitigate these delays, industry is requesting that prioritized products are also included in the scope of the parallel GMP and registration application, similar to highly prioritized products.

The delays at TITCK have been compounded by the fact that between November 2019 through to August 2020 the Scientific Advisory Commissions did not operate. While new Commission members were recently appointed and the Commissions resumed meeting in August 2020, the frequency of their meetings is very limited due to COVID-19. TITCK estimates that there are approximately 1,800 registration dossiers pending, 700 of which are for priority designated products. Recognizing that even prior to COVID-19 TITCK was reviewing approximately 700-750 marketing authorization processes per year, it is clear that it will take many years to reduce this backlog unless TITCK recruits more members to the Commissions and allows for online meetings.

In May 2016, TITCK published a "Guideline for the Operating Procedures and Principles of the Priority Evaluation Committee of Medicinal Products for Human Use" and PhRMA's member companies appreciate TITCK's efforts to create an expedited pathway for product registration. While not included in the May 2016 TITCK document, the agency is inappropriately 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.

TITCK is also in the process of updating the Registration Regulation to achieve harmonization with the relevant legislation of the EU. While the initial draft was promising, subsequent amendments raise a number of concerns, including (1) no provisions to bring

[320] Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).
[321] Based on AIFD Survey 2020.

Turkey's RDP mechanism into line with EU practices; (2) vague definition of manufacturing sites; (3) inadequate clinical trial data requirements for combination products; (4) redefinition of "generics" as "equivalent," blurring the lines between these distinct terms; and (5) deviation from global best practices to reduce the standards for biosimilars.

Promisingly, on May 27, 2020, TITCK was accepted as a full member of the International Council for Harmonisation (ICH). The ICH provides valuable work toward harmonizing international drug development and regulatory standards. In light of TITCK's commitment to act as a full ICH member, it is important that this Regulation meets international standards.

Local Inspection Requirements

The MoH's revisions to the Registration Regulation have compounded the country's registration delays.[322] 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 the 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, with a median inspection period of 309 days for highly prioritized products (GMP 1).[323]

On a positive note, the TITCK's 2018-2022 Strategic Plan stipulates that the Agency is responsible for accelerating the GMP inspection and certification processes of priority medicines which are needed on the market within 1 year. However, the absence of strategic performance indicators for products prioritized by TITCK may give rise to uncertainty in the GMP inspection processes of these products.

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 commends Turkey for joining PIC/S in January 2018, this is but the first of many steps that will be required before Turkey could enter into mutual recognition agreements with the United States and other trading partners.

[322] 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).
[323] Based on AIFD Survey 2020.

Financial Impact Projection Request in GMP and Registration Prioritization Applications

TITCK recently began to request a "two-year financial impact projection" in their assessment process for "prioritization of good manufacturing practices (GMP)" and "prioritization of registration" applications for innovative products. Prioritization of GMP and registration inspections should be based on a clinical and technical evaluation based on scientific data, not the proposed price of the drug or its price in other markets (particularly when prices in other countries may not yet be available or indicative of the actual price/appropriate price in Turkey). Industry is concerned that, given the difficulties in obtaining the information needed for the budget impact projection, this requirement also results in further delays in prioritization and overall registration decisions. Such projections may also be inadequately used as a cost-containment tool, thus delaying the launch of innovative medicines developed by U.S. biopharmaceutical companies in Turkey.

Orphan Drug Guidelines

Since 2009, the MoH has been developing a pathway for orphan medicines in Turkey. Although there have been some successful workshops to progress the issue, there remains no published pathway.

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 in its "Pharmaceutical Sector Strategy and Action Plan of 2015." This study called for the creation of a national orphan drug policy. The innovative pharmaceutical industry looks forward to working with key stakeholders, including the MoH, SSI, MoSIT, Ministry of Trade, Ministry of Industry & Technology, Ministry of Treasury and Finance and civil society organizations, to establish a market access pathway and appropriate incentives to facilitate the development and commercialization of medicines to treat rare diseases and thereby better ensure that Turkish citizens have access to the medicines they need. As part of this process, it will be critical for Turkey to define rare diseases and orphan drugs based on international best practices, including EU prevalence standards.

Intellectual Property Protection

Weak Patent Enforcement

In January 2017, Turkey enacted a new Industrial Property Law (No. 6769) that addresses IP, including patents. However, the IP Court judges 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 court-appointed expert panels, which often consist of a single patent attorney and lecturers from universities. Despite the new law on court appointed experts, the expert examination system also lacks appropriate procedural safeguards. While relevant case law provides that the IP Court judge can deviate from the expert panel's opinion where he or she

provides a reasoned opinion to the contrary, in practice, decisions in the majority of cases mirror the opinions of the panel.

Compulsory Licensing

In addition, PhRMA and our member companies are concerned about the compulsory license (CL) provisions of Industrial Property Law No. 6769. That law inappropriately expands the discretion to consider CLs in cases of non-use of the patent and in cases where a third party claims that domestic demands are not being met. The vagueness of that provision creates tremendous uncertainty for patent holders and may be abused by competitor third parties. 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.

Furthermore, compulsory licensing is included as a provision in the draft registration regulation. According to the draft regulation, a guideline will be published for execution. The scope and content of this guideline is not yet known.

Regulatory Data Protection Failures

In 2005, the Turkish Government took positive steps toward establishing protection for the commercially valuable regulatory data generated by innovative pharmaceutical companies, and now provides RDP for a period of six years for products starting from the first MA registration in any of the EU-Turkey Customs Union member states. Several aspects of this regime are however of significant concern for the innovative pharmaceutical industry.

First, the period of RDP currently begins on the earliest marketing authorization in any country of the EU-Turkey Customs Union. Considering the extended regulatory approval times and delays stemming from the GMP certification approval period, current estimates are that it could take one to three years to register a new medicine in Turkey, i.e., long after approval in the EU. Under these adverse circumstances, new products receive, in practice, no more than one to two years of RDP in Turkey, undermining incentives needed for innovators to undertake risky and expensive research and testing.

In addition, if a product is patented in Turkey, RDP ends when that patent expires, even if this is prior to the end of the six-year RDP term. RDP is a form of protection that serves a different purpose than patent protection and is independent and separate from patent protection. Therefore, it should not be limited to the period of patent protection.

RDP in Turkey is further undermined by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.[324] This Regulation, contrary to EU standards, does not provide RDP for combination products, unless the combination

[324] Official Gazette No. 27208 (Apr. 22, 2009).

product introduces a new indication. Innovative companies invest considerable amounts of time and effort to develop products that provide increased efficacy and safety for the benefit of patients, as well as new indications, from new combinations of separate molecules.

Finally, Turkey does not provide RDP for biologics. 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 RDP, innovators will not have the incentive needed to conduct the expensive, risky and time-consuming work to discover and launch new biologics.

UKRAINE

PhRMA and its members are highly troubled by the reintroduction of proposed intellectual property legislation that would impose impermissible exclusions on patent-eligible subject matter as well as restrictive patentability criteria. As the government of Ukraine begins to roll-out national health care insurance and drug reimbursement to its population, PhRMA member companies believe that expanding limited reimbursement lists, bolstering the inadequate medicines budget (which is below the level requested by the Ministry of Health (MoH) and required by law), and reforming its discriminatory and non-transparent procurement practices are essential.

Key Issues of Concern:

- **Limited reimbursement list and inadequately funded medicines budget**: Patients in Ukraine largely pay out-of-pocket for most medicines due to inadequate hospital funding and an extremely limited out-patient reimbursement list that is not set to expand nor clearly consider new products. A new system of health technology assessment to guide reimbursement list decisions is in an early stage of development and is expected to be launched in 2021.

- **Public procurement system challenges and reform**: Public procurement of medicines has long been a major challenge in Ukraine as procurements are riddled with duplication, corruption, inefficiency and conflict of interests due to multiple, non-harmonized lists that lack transparency and favor local producers. Recent reform efforts promise to restructure and modernize the system, although considerable work is needed.

- **Adoption of new intellectual property law**: Intellectual property policies and laws in Ukraine are not certain or predictable. Following years of considering various bills seeking to overhaul Ukraine's intellectual property law, the Verkhovna Rada recently approved Law 816 "on Amending Certain Legislative Acts of Ukraine on Patent Law Reform". That Law appears to introduce impermissible patentable subject matter exclusions, restrictive patentability criteria and inappropriately allows for export and stockpiling during the supplementary protection certificate (SPC) term.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Limited Reimbursement List and Inadequately Funded Medicines Budget

PhRMA members companies welcome Ukraine's pivotal new national health care reform law signed in January 2018, 2018-VIII, "On state financial guarantees of medical care of the population," which established the National Health Service of Ukraine (NSZU)

to provide mandatory national health care insurance and reimbursable medicines for its population.

Although the law requires the government to pay for medicines used during in-patient care, due to the government's failure to provide appropriate funding for public-sector hospitals, many patients are nevertheless forced to pay for these treatments out-of-pocket. Moreover, the vast majority of citizens with national health care currently pay out-of-pocket for outpatient medicines, although a pilot reimbursement scheme was launched in April 2017 for essential medicines for cardiovascular conditions, type 2 diabetes, and asthma. While the pilot was expected to expand to other therapeutic areas based on a transparent evaluation of products relevant to include in the list, this has not occurred yet. Moreover, the pilot has been focused on domestic manufacturers. Due to the COVID-19 pandemic, changes are expected no earlier than 2021.

Ukraine is the only European country in which patients pay out-of-pocket for most medicines. While PhRMA members understand the budgetary pressures that Ukraine faces as it rolls out national health care insurance, we encourage the government to expand its reimbursement list, reduce the complexity and time required for listing decisions, and make appropriate allocations to support the modernized health system it seeks to create.

Public Procurement System Challenges and Reform

Public procurement of medicines has long been a major challenge in Ukraine as procurements are riddled with duplication, corruption, inefficiency and conflict of interests due to multiple, non-harmonized lists that favor local producers and lack transparency. Moreover, the bidding process is often delayed and lengthy, which can subsequently create challenges for the timely manufacturing and supply of medicines.

The Ministry of Health (MoH) began work to reform the procurement system in 2015 by shifting larger procurements to relevant international organizations (*e.g.*, Crown Agents and UNDP). MoH established a working group on reforming the system of procurement of medicines and medical products, and in August 2018, the Cabinet of Ministers established the Central Procurement Organization (CPO) to procure medicines and medical products at local, national and international levels using longer-term framework agreements and e-procurement tools. MoH also announced the introduction of managed entry agreements for innovative medicines. However, the new system involving the CPO, as well as the older model with international organizations, covers only a portion of purchases. This reflects an inconsistent approach to the management of public health needs and generates opportunity for duplication, corruption and inconsistent standards.

Nonetheless, PhRMA is encouraged by this work and recent draft legislation to reform public procurement. We urge the MoH to monitor performance to ensure that the country's renewed approach to procurement eliminates corruption, minimizes

inefficiency, facilitates transparent criteria and decision-making, reflects patient needs, and encourages a level playing field for local and foreign producers.

Intellectual Property Protection

Proposed Intellectual Property Law

PhRMA members are concerned with the unpredictability and uncertainty created by recent amendments to Ukraine's Patent Law. The Law contains appears to introduce impermissible patentable subject matter exclusions, restrictive patentability criteria, and vague patent term restoration procedures.

TRIPS Article 27 requires that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that an invention is new, involves an inventive step, and is capable of industrial application. Article 7 of Ukraine's Patent Law excludes from patentability certain types of biopharmaceutical inventions, including, "new forms of a medicinal product known from the state of the art, including salts, compound esters, simple ethers, compositions, combinations and other derivatives, polymorphs, metabolites, pure forms, particle sizes, isomers, new dosages or any new property or new use of a known medicinal product". Furthermore, that article appears to impermissibly introduce restrictive patentability criteria for biopharmaceutical inventions. Specifically, the Law requires that biopharmaceutical inventions are not patentable unless "they do not differ significantly in efficiency."

These provisions appear inconsistent with Ukraine's obligations under TRIPS Article 27 requiring that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

Furthermore, while PhRMA and its member company commend the Ukraine for establishing an SPC system to compensate for a portion of the lengthy development and marketing approval process (akin to patent term restoration (PTR) in the United States), it is disappointing that the Law does not grant the full patent protections that PTR is intended to provide. Specifically, the Law appears to grant exceptions to the patent rights during the SPC term to allow for "manufacture for export" throughout the SPC term and stockpiling during the last 6 months of the SPC term. This is not consistent with the fundamental purpose of PTR, which is to restore a portion of the patent term – and all of the rights that patents provide – that was lost due to the lengthy development and marketing approval process.

UNITED ARAB EMIRATES

The United Arab Emirates (UAE) has made great progress in recent years to provide an increasingly competitive environment for operating and investing in the life sciences and innovative biopharmaceutical sector. This effort has resulted in attracting the regional headquarters for many international companies, increased investment in clinical research, and expanding regional logistics, warehousing and manufacturing operations. There is a continuous dialogue on policy issues with pharmaceutical companies and their local trade association Policies promoting transparency, predictability in the business environment and intellectual property protection have served as mainstay elements contributing to the growth of the sector. In recent years, the UAE has taken additional steps, including accelerating licensing procedures to ensure that patents have timely access to cutting-edge vaccines and medicines.

Nevertheless, in 2017, a significant concern arose related to intellectual property protections for innovative pharmaceutical products. Specifically, contrary to UAE law and its international commitments, the Ministry of Health and Prevention (MOHAP) registered generic pharmaceutical products for sale in the UAE that appeared to infringe the patents on innovative medicines produced by our member companies. Following significant engagement with the UAE Government on the concerns raised by these actions, the UAE has responded with Decree 321. This highly promising decree provides the framework for a regulatory data protection (RDP) system (with eight years of protection) and includes provisions calling for the return of effective patent enforcement in the UAE. Industry looks forward to continuing its constructive engagement with the UAE government to ensure that the Decree (and in particular the proposed exceptions in Article 5) are consistent with the UAE's international commitments and that it is implemented in a manner that provides effective and meaningful patent protection and RDP for all innovative pharmaceuticals (including biologics).

Key Issues of Concern:

- **Effective patent enforcement and regulatory data protection**: Contrary to Ministerial Decree 404, in 2017, MOHAP registered generic pharmaceutical products for sale in the UAE that appeared to infringe the patents on innovative medicines produced by our member companies. At that time, the patents in the countries of origin remained in force and thus should have been honored in the UAE as required by Decree 404. Moreover, the UAE has not historically had an adequate RDP framework to ensure that generic and biosimilar manufacturers cannot prematurely rely on the confidential information that innovators must submit to regulatory authorities to demonstrate the safety and efficacy of a medicine for marketing approval. Promisingly, on September 21, 2020, the UAE released Decree 321, which has the potential to address these deficiencies.

For these reasons, PhRMA requests that the U.S. Government support industry's efforts to seek prompt and appropriate implementation of Decree 321.

Intellectual Property Protection

Effective Patent Enforcement and Regulatory Data Protection

The UAE's commitment to protect IP started in earnest with the issuance of Ministerial Decree No. 404 on April 30, 2000, which prohibits the registration of any pharmaceutical product until the expiry of the patent term of the original product. Furthermore, the UAE clarified its commitments in Decree 404 via a letter to the U.S. Ambassador (Memorandum of Understanding or MOU) which specifically clarifies that for any drug registration application filed after January 1, 2000, the "protection period shall be extended and remain valid during the validity period of protection related to patent in the Country of Origin of the original drug."

Contrary to Decree 404, in 2017, MOHAP registered generic pharmaceutical products for sale in the UAE that appeared to infringe the patents on innovative medicines produced by our member companies. At that time, the patents in the countries of origin remained in force and thus should have been honored in the UAE as required by Decree 404.

PhRMA and its member companies engaged extensively with MOHAP and MOE to address the pharmaceutical industry's concerns that MOHAP may register generic or biosimilar pharmaceutical products for sale in the UAE without regard to our member companies' intellectual property. Following this consultative process, the UAE issued Decree 321 on September 21, 2020. This highly promising decree provides eight years of RDP and anticipates the implementation of new systems in the UAE to ensure the effective enforcement of patents on innovative pharmaceutical products (including the enforcement of Decree 404 for innovative products approved prior to Decree 321 being published in the official gazette).[325] Industry looks forward to continuing its constructive engagement with the UAE government to ensure that the Decree (and in particular the proposed exceptions in Article 5) are consistent with the UAE's international commitments and that it is implemented in a manner that provides effective and meaningful patent protection and RDP for all innovative pharmaceuticals (including biologics).

[325] Consistent with the MOU between the United States and the United Arab Emirates, it will be critical for the UAE to provide clarity on how it will define the country of origin of the original drug in order to ensure that the appropriate term of patent protection is provided.

UNITED KINGDOM

PhRMA and its member companies operating in the United Kingdom (UK) continue to work with the UK Government, the National Institute for Health and Care Excellence (NICE), NHS England and NHS Improvement, as well as National Health Service (NHS) partners to support implementation of policies that strengthen the innovative pharmaceutical industry and address long-standing market access and pricing issues. Of particular concern are the continued lack of patient access to innovative medicines, intellectual property (IP) threats from Brexit and the need for continued support for the government's life sciences strategy.

Key Issues of Concern:

- **Government restrictions on reimbursement and patient access to innovative medicines**: Because of long-standing market access barriers such as rigid health technology assessment (HTA), mandated discounts to meet unreasonable cost-effectiveness thresholds and insufficient health care budgets, the ability of UK patients to access the latest, innovative medicines remains problematic. In comparison to peer countries, adoption of some of the newest medicines often remains low and slow in some care settings.

- **Continued need to deliver on ambitions for the life sciences sector**: The UK Government was elected on a platform which included ambitious commitments for innovative, R&D intensive sectors including the life sciences sector. PhRMA and its member companies welcome the proposed changes contained in the 2017 Life Sciences Industrial Strategy (LSIS) report. However, we continue to encourage the full implementation of LSIS policies in the NHS and elsewhere to enhance the UK life sciences environment and to foster adoption of new life sciences technologies for the benefit of UK patients.

- **Intellectual property and other threats from Brexit:** With the UK's exit from the European Union (EU), it is important that the United Kingdom maintain strong IP protections, including effective periods of regulatory data protection and supplementary protection to restore a portion of the time lost during the marketing approval process. Ongoing and future U.S.-UK trade negotiations provide an opportunity for the United Kingdom to affirm high-standard IP standards.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Government Restrictions on Reimbursement and Patient Access to Innovative Medicines

New products in the United Kingdom can be launched upon regulatory approval, potentially making it one of the world's fastest countries for market access.

However, UK patients experience materially longer delays in accessing new medicines due to cost-containment policies and slow adoption by the NHS.[326] For every 100 patients in comparable countries who get access to a new medicine in its first year of launch, just 21 patients in the United Kingdom receive the same (even if the medicine has been recommended by NICE). Even five years after the launch of a new medicine, only 75 patients in the United Kingdom receive the same.[327]

Another key reason why UK patients experience reduced access to new medicines is the high rate of either outright rejections by NICE or "optimized" recommendations that unduly restrict the patient populations who can access those medicines. When making recommendations, NICE assesses medicines using a baseline cost-effectiveness threshold of between £20,000 and £30,000 per quality-adjusted life year (QALY). This baseline threshold has not been revised – even in line with inflation – since NICE's inception in 1999, which means that the threshold has declined in real terms by over 30 percent over the past two decades. Innovative medicines exceeding a cost per QALY threshold of £30,000 (or £50,000 for end-of-life interventions) are generally viewed as not cost-effective, leaving patients without access to clinically superior products. In addition, as companies develop new therapeutic advances, often in areas where there are many older off-patent medicines that are much lower in cost, demonstration of cost-effectiveness becomes exceedingly difficult. Moreover, NICE's inflexibility surrounding new medicines for which there is greater uncertainty about data (*e.g.*, due to the immaturity of data or single-arm trials) disproportionately impacts patient access to treatments for small patient populations (*e.g.*, rare conditions) or for subsets of populations (*e.g.*, targeted therapies).

Using primarily cost per QALY to measure cost-effectiveness in this way fails to appropriately recognize the value of innovative medicines. In this context, between March 2000 and May 2019, just 55 percent of all technology appraisals were recommended by NICE in line with marketing authorization; while 24 percent were recommended in a restricted subset of patients, 3 percent under the Cancer Drug Fund (CDF), and 3 percent in research only – and 15 percent were rejected altogether. Recommendations for cancer medicines were even more restrictive with just 52 percent of cancer appraisals recommended in-line with marketing authorization; while 12 percent were recommended in a restricted subset of patients, 9 percent under the CDF, 2 percent in research only – and 24 percent rejected altogether.[328] Industry welcomes the ongoing review NICE Methods Review and looks forward to meaningful reforms, which will support UK patients getting access to new medicines. Ultimately, given the well-known limitations of QALYs, the United Kingdom should introduce a broader and more flexible framework to ensure that its assessments of innovative medicines more appropriately recognize the comprehensive health and non-health benefits to patients, the health system and society.

[326] IQVIA, P&R Concise Guide: United Kingdom (2017).
[327] Office for Life Sciences, "Life sciences competitiveness indicators," June 2019.
[328] National Institute for Health and Care Excellence (NICE), available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/summary-of-decisions (last visited Oct. 28, 2020).

PhRMA members recognize the UK Government's interest in controlling NHS spending, but spending on medicines is not currently a driver of growing health care costs. On the contrary, in the five years up to 2019, NHS spending on the majority of branded medicines was capped to 1.1 percent growth on average per year, a decline of 0.4 percent after inflation while overall NHS spending rose at 3.3 percent over the same period. Innovations in prevention and treatment will be vital to creating a more effective and resilient UK health system, as well as to improving health outcomes and providing high-quality care. Indeed, with the new Voluntary Scheme, the UK Government has certainty that spending on branded medicines will not rise more than 2 percent per year, so there is no reason not to bring access requirements for new products in line with other leading nations. Currently, the VPAS commitments have still not come to fruition and uptake of new medicines approved by NICE remains low and slow due to system fragmentation and insufficient health care budgets.

Therapeutic Tendering of Patented Medicines

The NHS has traditionally subjected off-patent medicines to competition through public procurement that invites bids from manufacturers of the same generic medicine. Recently, however, NHS England has used public procurement for entire therapeutic classes of patented medicines with the aim of obtaining prices below the prices that NICE established when making coverage recommendations. In addition to disrupting established incentives for patented medicines, this emerging practice undermines NICE guidance, ignores clinical non-interchangeability of products and represents a fundamental shift in the UK model. Therapeutic tendering of patented medicines sends a strong anti-innovation signal to the industry. The United Kingdom should abandon the practice of therapeutic tendering and provide access consistent with available guidance and choice.

Delivering on ambitions for the life sciences sector

PhRMA members welcomed the proposed changes contained in the 2017 Life Sciences Industrial Strategy (LSIS) report. The report was developed with the Association of the British Pharmaceutical Industry (ABPI) and its industry partners, and led by Professor Sir John Bell. When the current UK Government was elected in 2019, it ran on an ambitious platform with goals to increase R&D expenditure to 2.4% of GDP across the economy and make the United Kingdom a leading hub for life sciences.

To deliver on these objectives, the ABPI continues to call for implementation of all the recommendations in the LSIS. The UK Government has now published a new R&D Roadmap, and it is critical that this Roadmap is followed working in partnership with the life sciences sectors. This could be a powerful way to support the sector's economic contribution to the United Kingdom, but will only be meaningful if coupled with other reforms to ensure that UK patients have access the latest innovative medicines. To realize the UK's ambitions, the Government should:

- Continue to invest in the UK's strong science base;
- Ensure the United Kingdom continues to have globally competitive and attractive economic incentives to support the sector and secure inward investment;
- Build foundations and infrastructure for the research, development and production of innovative therapies in the United Kingdom;
- Transform the NHS into an early adopter of new medicines and technologies which are adopted at pace and scale;
- Ensure that the ongoing NICE Methods review results in meaningful reforms;
- Enable the NHS to make best use of data and digital tools to support research and improve patient care;
- Recognize the potential challenges and opportunities for the industry as a result of Brexit and beating COVID-19, and prioritize regulatory cooperation and the ability to trade medicines following the transition period; and
- Continue to be a leader in intellectual property rights globally.

Intellectual Property Protection

Effective intellectual property protections and enforcement is essential to develop new medicines for patients who need them. As the United Kingdom exits the European Union, it is important that the United Kingdom maintain robust IP protections and that the United Kingdom and European Union systems remain sufficiently aligned to ensure business continuity and certainty for PhRMA member companies. In addition, the United Kingdom should seek to benefit from the opportunity to distinguish its innovation environment for the life sciences from the European Union by enhancing incentives where the European Union has unfortunately weakened its innovation framework. For example, the United Kingdom should consider eliminating the recently adopted EU "SPC waiver" that undermines life sciences innovation by exempting from infringement manufacturing of inventions during the SPC term.

Brexit does not change the UK's membership under the European Patent Convention (EPC), and any patent granted under the EPC can still be validated and enforced in the United Kingdom after Brexit. However, other IP rights already obtained or available in the United Kingdom under EU law or applications thereof, should continue to be in force as a matter of UK law. In addition, such rights should be available to be granted immediately upon Brexit for new products. Further, as the United Kingdom works with the European Union to determine their post-Brexit relationship, it will be critical that the United Kingdom measure the provision of SPCs from the date of UK marketing authorization (rather than the earliest date of authorization in the European Union or United Kingdom, as proposed now). Continuing to make the duration of IP protection offered in the United Kingdom potentially still dependent on the acts of EU authorities is an illogical move in the scenario of a 'no deal' exit, where the UK and EU medicines regulatory systems will be operating independently of each other.

Despite industry having raised these specific concerns strongly with the UK Government this issue remains unresolved. This is extremely concerning as it will lead to the weakening of the UK IP protection framework – making the United Kingdom less

competitive at a time when it has ambitions to become a 'science super power' and retain its commercial attractiveness in the eyes of global pharmaceutical companies.

As the UK Government considers future free trade agreements post-Brexit, as well as the UK's opportunities to build its life-sciences sector, it should seek to affirm its commitment to strong IP protections. In particular, it should enshrine the provision of stable RDP, orphan and pediatric exclusivities that meet the highest international standards (at a time when some in the European Union are seeking to undermine those incentives), and recognize that it is never appropriate to threaten compulsory licenses in order to secure price cuts.

VIETNAM

PhRMA's member companies continue to need a more predictable and sustainable legal framework to operate and invest in Vietnam. In recent years, implementation of key regulations that guide the registration and public procurement of pharmaceuticals have imposed additional administrative barriers that hinder market access for pharmaceutical products. Furthermore, many of the reforms proposed by the Government of Vietnam are still out of step with international or regional best practices, and there is a lack of strict intellectual property (IP) enforcement in the country.

PhRMA supports continuous dialogue between Government, industry and relevant stakeholders to achieve effective revision and implementation of measures that will ensure (i) quality assurance for patient safety, (ii) harmonization of regulatory requirements and reduction of unnecessary administrative burdens, (iii) fair and equal access to the market, and (iv) a predictable investment environment for U.S. companies.

Key Issues of Concern:

- **Legal entity**: U.S. companies now have the option to establish a more stable legal entity in Vietnam, namely a Foreign Invested Enterprise (FIE), which allows companies to directly import medicines into the country. PhRMA's members welcome the opportunity to explore a broader scope of activities which can be conducted as an FIE.

- **Registration of pharmaceuticals**: In November 2018, Vietnam introduced a more streamlined and harmonized process for drug registration in the new Circular 32/2018/TT-BYT ("Circular 32"). Despite this, since September 2019 (when the Circular entered into effect) until today, there remain technical and administrative requirements (most notably Vietnam's specific requirements related to the Certificate of Pharmaceutical Product (CPP)) that inhibit products from obtaining and maintaining MAs. As a result, new medicines have yet to be approved for circulation, and MA renewals are not approved on time. These drug registration issues will lead to critical medicine and vaccine shortages if not urgently addressed.

- **Government procurement and reimbursement:** Given the growth of universal health care coverage in Vietnam (90 percent of the market in 2019), in the mid- to long-term, the country will need innovative and sustainable health financing solutions to meet future health care demand. Today, while the pricing of drugs is already well-managed, PhRMA's member companies continue to face pressure from public tender regulations that focus on addressing short-term budget saving objectives. Meanwhile, it still takes a significantly longer amount of time for new medicines to enter the market. This presents an increasingly unsustainable investment environment for U.S. innovative pharmaceutical companies. PhRMA's members welcome dialogues with the Vietnam Government on enabling faster access, while identifying sustainable health financing solutions that focus on

quality and outcome-delivery, for the long-term benefits of patients, trade and investment.

- **Intellectual property protection**: The adoption of IP protections that conform to international obligations and standards, including meaningful regulatory data protection (RDP), clarification of the scope of patentable subject matter, and implementation of effective patent enforcement mechanisms, would greatly assist Vietnam in creating a more predictable environment for investment in innovation and enhance transparency and predictability.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

Market Access Barriers

Legal Entity

Foreign companies currently operating Representative Offices in Vietnam now have the option to establish an FIE, a more stable, sustainable legal entity that can import pharmaceuticals. Establishing a new operating model requires significant time, expertise, and investment to ensure strict adherence to international standards for quality and safety. It is critical, therefore, that the Vietnamese Government continues to provide strong support for companies to establish FIEs and effectively operationalize these entities. PhRMA's members seek dialogues with the Vietnamese Government to further explore the range of activities that may be conducted by an FIE and incentives for further investment, such as clinical trials, manufacturing, collaboration with local partners, *etc*.

Registration of Pharmaceuticals

In terms of regulations, several administrative barriers to market access remain in place, in particular the CPP requirements. To register for marketing authorization in Vietnam, companies are required under Circular 32 to submit a CPP from the country of origin or certain reference countries with their technical dossiers. Regulatory authorities worldwide, including the U.S. Food and Drug Administration, have recognized and adopted the WHO Certification Scheme when granting CPPs. Vietnam, however, deviates from the WHO format and requires additional information, such as the name and address of each manufacturer of active pharmaceutical ingredient used in the medicine. In addition, Vietnam contacts the CPP-issuing authority to verify the authenticity of CPP submitted by the company, which can further delay registration in Vietnam. These requirements are excessively onerous, do not address Vietnam's concerns about fraudulent dossiers and counterfeit medicines and result in delays and entry barriers for new medicines.

No product license renewal has been approved since 2018 due to the implementation of Circular 32, which is seriously impacting drug supply in Vietnam. The local innovative pharmaceutical industry association (PharmaGroup) recently conducted

a survey, the results of which indicated that as of September 2020, not one of the 818 renewal dossiers submitted had been approved and that 224 existing MAs have expired. This includes essential medicines for acute, chronic diseases or life-saving, branded drugs without alternatives, and across therapeutic areas. It is crucial for the Vietnamese Government to urgently address this issue to enable continuous supply of medicines for patient treatment (by installing an automatic extension of MAs' validity), and promptly revise Circular 32 to ensure that the drug registration process does not result in technical or administrative concerns that could limit market access, create trade barriers for U.S. pharmaceutical companies or otherwise impact patient access to new drugs.

Furthermore, regarding market access for vaccines, PhRMA's members are concerned that new vaccine registration dossiers are being rejected by the Drug Administration Department of Vietnam (DAV), because the necessary technical documents have not been certified by the National Institute for Control of Vaccine and Biologicals (NICVB). Currently, NICVB lacks the technical resources (compounded by the COVID-19 pandemic) to certify these documents in a timely manner. Recognizing these logistical difficulties, we strongly encourage DAV to allow applicants to submit their vaccine registration dossiers for appraisal, and then supplement their applications (prior to marketing approval) with the necessary certifications from the NICVB.

Government Procurement

Government procurement of pharmaceuticals in Vietnam represents more than 87 percent of the total market value. As a result, any decisions related to government procurement have a significant impact on quality of care, product supply and patient access in the country. At the same time, Vietnamese patients still have slow access to innovative pharmaceuticals compared to other countries. From 2014 to 2019, only seven of the 166 newly launched molecules in the United States and EU5 (Germany, France, UK, Italy, and Spain) have been launched in Vietnam. Moreover, these seven molecules were launched an average of 38 months later than global first launch.

PhRMA members are hopeful regarding the introduction of new regulations for the procurement of pharmaceuticals in public hospitals, under which all brand name products, both on- and off-patent, will be able to negotiate prices. If conducted fairly and transparently, such price negotiation could be a win-win solution allowing patient access to existing and new medicines, ensuring continuity in treatment, and enabling a more predictable environment for U.S. pharmaceutical companies to bring new products to Vietnam. As Vietnam continues to revise the Circular regulating the process for tender in public health care establishments, it is important to ensure predictability in policy, to avoid sudden major disruptions to patient access and provide a sustainable environment for investment.

Reimbursement

Under current practice, once a pharmaceutical product is granted marketing authorization, it is not eligible for reimbursement until the marketing authorization is

renewed three years later. Furthermore, the National Reimbursement List (NRL) is only reviewed every two years. This process itself takes around two years or longer, during which time no new information or newly-licensed products can be considered for reimbursement. Altogether, new pharmaceuticals may therefore have to wait five to six years for inclusion in the NRL, effectively delaying Vietnamese patient access to new medicines.

In order to ensure the earliest access to new, innovative pharmaceuticals in Vietnam, the NRL should be reviewed and updated frequently, either through continuous inclusion or at least every six months. Furthermore, products approved in reference/stringent regulatory authorities such as the U.S. FDA should be automatically eligible for reimbursement as soon as they are granted marketing authorization in Vietnam.

Intellectual Property Protection

Innovative pharmaceutical companies continue to face burdensome delays in the granting of patent protection in Vietnam. Furthermore, Vietnam does not provide an effective patent enforcement mechanism, nor adjust the patent term to compensate for the delay in granting patent protection, thus eroding the effective term of patent protection available for innovative medicines.

As part of the implementation of Vietnam's obligations under TRIPS, the Data Protection Circular (Circular 05/2010/TT-BYT) provides, on paper, for five years of RDP. In practice, however, this protection has proved illusory. The Circular is not clear on whether the five-year term of RDP applies in cases that involve a generic manufacturer relying on or referencing innovator data in support of its marketing approval application. Furthermore, the Circular conditions RDP on requirements that: (1) member companies submit a separate application for data protection, rather than receive automatic protection upon marketing approval as international standards and TRIPS require; (2) the application be filed within 12 months of first global approval; (3) data be classified as a "trade secret" under Vietnamese law, which as defined may not cover undisclosed confidential business information; and (4) the innovator prove "ownership" of the data in cases of dispute rather than the third party or government challenger. Finally, RDP is granted at the sole discretion of the Drug Administration of Vietnam; as a result, RDP is rarely granted in Vietnam.

The adoption of a strong patent enforcement system, automatic RDP, and other intellectual property protections that conform to international standards, would create a more predictable environment for investment, promote innovation and enhance Vietnam's healthcare system.