

**(2017) National Trade  
Estimate Report on  
Foreign Trade Barriers  
(NTE)**

Submitted by

The Pharmaceutical Research and  
Manufacturers of America  
(PhRMA)

**(October 2016)**

**This page is intentionally left blank**

October 27, 2016

**FILED ELECTRONICALLY**

Mr. Edward Gresser  
Trade Policy Staff Committee  
Executive Office of the President

Re: Request for Public Comments Regarding the National Trade Estimate Report on Foreign Trade Barriers, 81 Fed. Reg. 46994 (July 19, 2016)

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 2017 National Trade Estimate Report (NTE).

As a key component of America's high-tech economy, the research-based biopharmaceutical sector supports nearly 4.4 million jobs across the economy, including more than 850,000 direct jobs, and contributes nearly \$1.2 trillion in economic output on an annual basis when direct, indirect, and induced effects are considered.<sup>1</sup> In 2015, US biopharmaceutical goods exports exceeded \$55 billion. And these exports have grown in recent years, more than tripling between 2002 and 2015.<sup>2</sup> Our sector also continues to be one of the most research-intensive in America: last year, PhRMA's member companies alone invested an estimated \$58.8 billion in researching and developing new medicines.<sup>3</sup>

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 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<sup>4</sup> to an average \$2.6 billion today including the cost of failures,<sup>5</sup> with

---

<sup>1</sup> TEconomy Partners. The economic impact of the U.S. biopharmaceutical industry. April 2016.

<sup>2</sup> PhRMA analysis of U.S. Department of Commerce, International Trade Administration. TradeStats Express™: National Trade Data for NAICS Code 3254 Pharmaceuticals and Medicines, available at <http://tse.export.gov/TSE/TSEHome.aspx> (last visited Oct. 27, 2016).

<sup>3</sup> Pharmaceutical Research and Manufacturers of America, 2016 Profile, available at <http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf> (last visited Oct. 27, 2016).

<sup>4</sup> 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.

<sup>5</sup> Tufts Center for the Study of Drug Development (CSDD). Cost of developing a new drug. Briefing. Boston, Mass.: CSDD. Published November 2014 (accessed Mar. 2015).

overall development costs more than doubling in the last decade due to growing complexities.<sup>6</sup> 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% chance of being approved,<sup>7</sup> and only two out of ten approved drugs produce revenues that match or exceed average research and development costs.<sup>8</sup>

The attached submission outlines the principal trade barriers that our member companies face worldwide. Per your request, the submission is divided into country-specific files. The challenges are many, 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 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 addressing discriminatory 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, governmental policies around the globe over the last year have continued to have a deleterious impact on patients' access to innovative medicines.

We also remain particularly concerned that many World Trade Organization (WTO) Members are implementing industrial policies, including local manufacturing requirements and discriminatory intellectual property regimes, which 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 WTO Agreements on Trade-Related Investment Measures, Trade-Related Aspects of Intellectual Property Rights (TRIPS), Technical Barriers to Trade, and the General Agreement on Tariffs and Trade.

In addition, numerous markets fail to provide adequate protection of our member's intellectual property rights. All WTO Members, pursuant to the TRIPS Agreement, are obligated to establish functional intellectual property protection systems.

---

<sup>6</sup> Previous research by DiMasi and Grabowski 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.

<sup>7</sup> PhRMA adaptation based on Dimasi JA. Cost of developing a new drug. Tufts Center for the Study of Drug Development (CSDD). R&D Cost Study Briefing (Nov. 18, 2014), available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016).

<sup>8</sup> 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).

In addition to providing strong patent protection, such systems must safeguard test and other data against disclosure and unfair commercial use. In particular, this data should not be used prematurely to support other applications for marketing approval by competitors. PhRMA urges continued 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 ultimately for the benefit of patients, who should have greater access to life-saving and life-enhancing new medicines. PhRMA member companies are actively engaged in helping to solve the health problems of the developing world, and America's research-based biopharmaceutical companies are among the largest funders of the research and development necessary to cure neglected and major diseases of the developing world, including malaria, tuberculosis, sleeping sickness and dengue fever. Specifically, in 2013 innovative biopharmaceutical companies led all other sectors in global corporate giving, with nearly 90% of the contributions in the form of in-kind product donations; moreover they invested nearly \$400 million into new cures and treatments for neglected diseases in 2014 alone – making them the third largest funder in the world, ahead of all country governments except the United States.<sup>9</sup> Without these efforts, which are threatened when market barriers are erected, intellectual protections are eroded, and the incentives for innovating new medicines are undermined, access to effective, sustainable healthcare for the developing world's patients would be impossible.

PhRMA appreciates the opportunity to contribute to the 2017 NTE. We commend the continuing efforts of the Office of the U.S. Trade Representative and Departments of Commerce and State 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 T. Taylor

---

<sup>9</sup> Policy Cures. Neglected disease research and development: emerging trends (2014), available at <http://www.policycures.org/downloads/Y7%20GFINDER%20full%20report%20web%20.pdf> (last visited Oct. 27, 2016).

**This page is intentionally left blank**

PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA (PhRMA)

---

**NATIONAL TRADE ESTIMATE REPORT ON  
FOREIGN TRADE BARRIERS (NTE) 2017**

**This page is intentionally left blank.**

## Table of Contents

<b>PhRMA 2017 NTE OVERVIEW .....</b>	<b>1</b>
<b>ALGERIA .....</b>	<b>24</b>
<b>ARGENTINA .....</b>	<b>30</b>
<b>AUSTRALIA .....</b>	<b>34</b>
<b>BRAZIL .....</b>	<b>42</b>
<b>CANADA .....</b>	<b>48</b>
<b>THE PEOPLE'S REPUBLIC OF CHINA .....</b>	<b>59</b>
<b>COLOMBIA .....</b>	<b>71</b>
<b>ECUADOR .....</b>	<b>77</b>
<b>EGYPT .....</b>	<b>81</b>
<b>THE EUROPEAN UNION.....</b>	<b>84</b>
<b>INDIA.....</b>	<b>89</b>
<b>INDONESIA.....</b>	<b>101</b>
<b>JAPAN .....</b>	<b>107</b>
<b>JORDAN .....</b>	<b>115</b>
<b>KOREA.....</b>	<b>118</b>
<b>MALAYSIA.....</b>	<b>122</b>
<b>MEXICO .....</b>	<b>128</b>
<b>NEW ZEALAND .....</b>	<b>132</b>
<b>PERU.....</b>	<b>137</b>
<b>ROMANIA .....</b>	<b>142</b>
<b>RUSSIA .....</b>	<b>145</b>
<b>SINGAPORE .....</b>	<b>152</b>
<b>TAIWAN .....</b>	<b>154</b>
<b>THAILAND .....</b>	<b>158</b>
<b>TURKEY .....</b>	<b>162</b>
<b>VENEZUELA.....</b>	<b>170</b>
<b>VIETNAM .....</b>	<b>175</b>

## PhRMA 2017 NTE OVERVIEW

Trade barriers and the failure to comply with international obligations by U.S. trading partners are threats to the ability of our companies to develop life-saving medicines. Discriminatory measures can hamper and even prevent our member's ability to export, and in turn jeopardize the innovative biopharmaceutical sector's ability to create new high-value U.S. jobs, including science, technology, engineering and math (STEM) that are essential to fueling an indigenous 21<sup>st</sup> century globally competitive workforce.

### **I. The U.S. Biopharmaceutical Sector: Protecting and Growing America's Competitiveness and Developing Tomorrow's Cures and Treatments for the World's Patients**

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.<sup>10</sup> Innovators in this critical sector depend on strong intellectual property protection and enforcement and on fair and transparent 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 850,000 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.<sup>11</sup> As highlighted in Figure 1 below, they work in partnership with universities, clinical researchers, patient organizations, healthcare providers and others to bring new treatments and cures to patients who need them at home and abroad – introducing nearly 550 new therapies since 2000<sup>12</sup> and investing in many of the over 7,000 new drugs currently in development worldwide.<sup>13</sup>

---

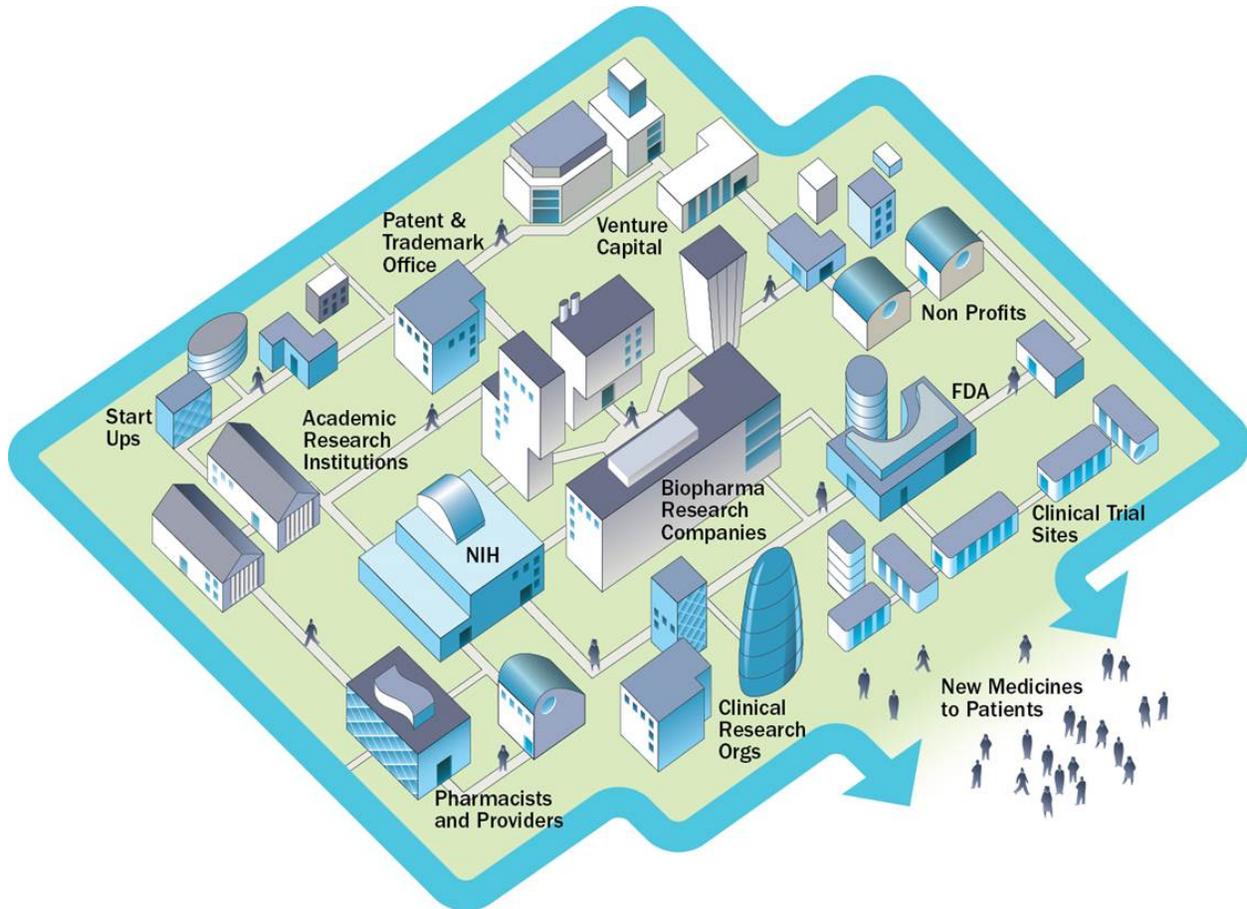
<sup>10</sup> Battelle Technology Partnership Practice, *The Biopharmaceutical Research and Development Enterprise: Growth Platform for Economies around the World*, Battelle Memorial Institute, May 2012, available at [http://www.phrma.org/sites/default/files/pdf/phrma\\_growthplatformforeconomiesaroundtheworld\\_20120508.pdf](http://www.phrma.org/sites/default/files/pdf/phrma_growthplatformforeconomiesaroundtheworld_20120508.pdf) (last visited Oct. 27, 2016).

<sup>11</sup> TEconomy Partners. *The economic impact of the U.S. biopharmaceutical industry*. April 2016.

<sup>12</sup> U.S. Food and Drug Administration, "Summary of NDA Approvals & Receipts, 1938 to the present," available at <http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm> (last visited Oct. 27, 2016); and U.S. Food and Drug Administration, Center for Drug Evaluation and Research, *Novel Drugs 2015*, Jan. 2016, available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DrugInnovation/UCM481709.pdf> (last visited Oct. 27, 2016).

<sup>13</sup> *Adis R&D Insight database*, accessed Mar. 2015.

**Figure 1: Collaboration and the biopharmaceutical R&D process**



Pioneering work by biopharmaceutical innovators in the United States contributes significantly to economic growth and supports good-paying jobs in all 50 states. In 2014, biopharmaceutical research and development activity added \$1.2 trillion to the U.S. economy and supported more than 4.4 million American jobs, including indirect and induced jobs.<sup>14</sup> In 2015, the industry exported more than \$55 billion in biopharmaceuticals, more than triple its level of exports in 2002.<sup>15</sup>

Even more important than the biopharmaceutical sector's role in the U.S. economy is its contribution to global patient health. Biopharmaceutical innovation extends lives, improves worker productivity and cuts healthcare costs. Between 1950 and 2009, life expectancy for women and men in the United States increased by a full

<sup>14</sup> TEconomy Partners. The economic impact of the U.S. biopharmaceutical industry. April 2016.

<sup>15</sup> PhRMA analysis of U.S. Department of Commerce, International Trade Administration. TradeStats Express™: National Trade Data for NAICS Code 3254 Pharmaceuticals and Medicines, available at <http://tse.export.gov/TSE/TSEHome.aspx> (last visited Oct. 27, 2016).

decade and continues to rise<sup>16</sup> – adding trillions of dollars to the U.S. economy.<sup>17</sup> 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.<sup>18</sup>

For example, the AIDS death rate has dropped nearly 85 percent since the approval of antiretroviral treatments in 1995.<sup>19</sup> Today, a 20-year old diagnosed with HIV can expect to live another 50 years.<sup>20</sup> New medicines have cut heart disease deaths by 30 percent, according to the Centers for Disease Control and Prevention.<sup>21</sup> More than 80 percent of the increase in life expectancy of cancer patients since 1980 is attributable to new treatments.<sup>22</sup> New hepatitis C therapies approved since 2013 cure over 90 percent of patients – a more than two-fold increase from previously available treatment options.<sup>23</sup>

PhRMA member companies are building on these achievements and pioneering new treatments and cures for some of the world's most devastating diseases. They are developing close to 400 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

---

<sup>16</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2014*, Table 16, May 2015, available at <http://www.cdc.gov/nchs/data/hus/hus14.pdf> (last visited Oct. 27, 2016).

<sup>17</sup> Between 1970 and 2000, increased longevity added about \$3.2 trillion per year to national wealth in the United States. See Murphy, Kevin M. and Robert 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. 27, 2016).

<sup>18</sup> Lichtenberg, Frank 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. 27, 2016).

<sup>19</sup> 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. 27, 2016).

<sup>20</sup> *Id.*

<sup>21</sup> 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 <http://www.cdc.gov/media/dpk/2013/dpk-vs-heart-disease.html> (last visited Oct. 27, 2016).

<sup>22</sup> 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; A more recent article by the American Cancer Society (dated Jan. 7, 2016) reported that cancer death rates have been reduced nearly 23 percent since 1991. See <http://www.cancer.org/cancer/news/news/cancer-statistics-report-death-rate-down-23-percent-in-21-years> (last visited Oct. 27, 2016).

<sup>23</sup> See, for example, U.S. Food and Drug Administration News Release, "FDA approves Viekira Pak to treat hepatitis C," Dec. 19, 2014, available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm427530.htm> (last visited Oct. 27, 2016).

treatment for smallpox.<sup>24</sup> Advances in biotechnology and genomics are propelling the discovery of new medicines to treat a range of chronic and infectious diseases. Derived from 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.<sup>25</sup>

New medicines can lower the overall cost of treating these and other devastating diseases. They can increase worker productivity by reducing medical complications, hospitalizations and emergency room visits. For example, the use of cholesterol-lowering statin drugs has cut hospitalizations and saved the U.S. healthcare system at least \$5 billion.<sup>26</sup> Every \$24 spent on new medicines for cardiovascular diseases in OECD countries saves \$89 in hospitalization costs.<sup>27</sup> Treating high blood pressure according to clinical guidelines would result in annual health system savings of about \$15.6 billion.<sup>28</sup> Moreover, a recent study demonstrated that appropriate use of diabetes medicines saved 15% and 20% per month in medical spending after 1 year of initiating treatment<sup>29</sup> and an estimated reduction of more than 1 million emergency department visits and hospitalizations annually, for an annual savings of up to \$8.3 billion.<sup>30</sup>

PhRMA members are working to overcome significant systemic challenges that can prevent the poorest patients from accessing medicines. Together with governments and others, they are leading more than 340 initiatives with more than 600 partners to help shape sustainable solutions that improve the health of all people.<sup>31</sup> In the last decade, biopharmaceutical innovators provided over \$9.2 billion in direct assistance to healthcare for the developing world, including donations of medicines, vaccines, diagnostics, and equipment, as well as other materials and labor.<sup>32</sup> Between 2000 and

---

<sup>24</sup> PhRMA, 2013 Medicines in Development – Infectious Diseases Report, Pharmaceutical Research and Manufacturers of America, Dec. 2013, available at <http://phrma.org/sites/default/files/pdf/MedsInDevInfectiousDiseases2013.pdf> (last visited Oct. 27, 2016).

<sup>25</sup> *Id.*

<sup>26</sup> 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 <http://content.healthaffairs.org/content/31/10/2276.full.pdf> (last visited Oct. 27, 2016).

<sup>27</sup> 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. 27, 2016).

<sup>28</sup> Cutler, D.M., G. Long et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation," *Health Affairs*, Jan. 2007, available at <http://content.healthaffairs.org/content/26/1/97.full> (last visited Oct. 27, 2016).

<sup>29</sup> Jha AK, Aubert RE, Yao J, Teagarden JR, Epstein RS. Greater adherence to diabetes drugs is linked to less hospital use and could save nearly \$5 billion annually. *Health Affairs*. 2012;31(8):1836-1846.

<sup>30</sup> Slejko JF, Ho M, Anderson HD, Nair KV, Sullivan PW, Campbell JD. Adherence to statins in primary prevention: yearly adherence changes and outcomes. *J Manag Care Pharm*. 2014;20(1):51-57.

<sup>31</sup> See Global Health Progress, available at <http://www.globalhealthprogress.org>.

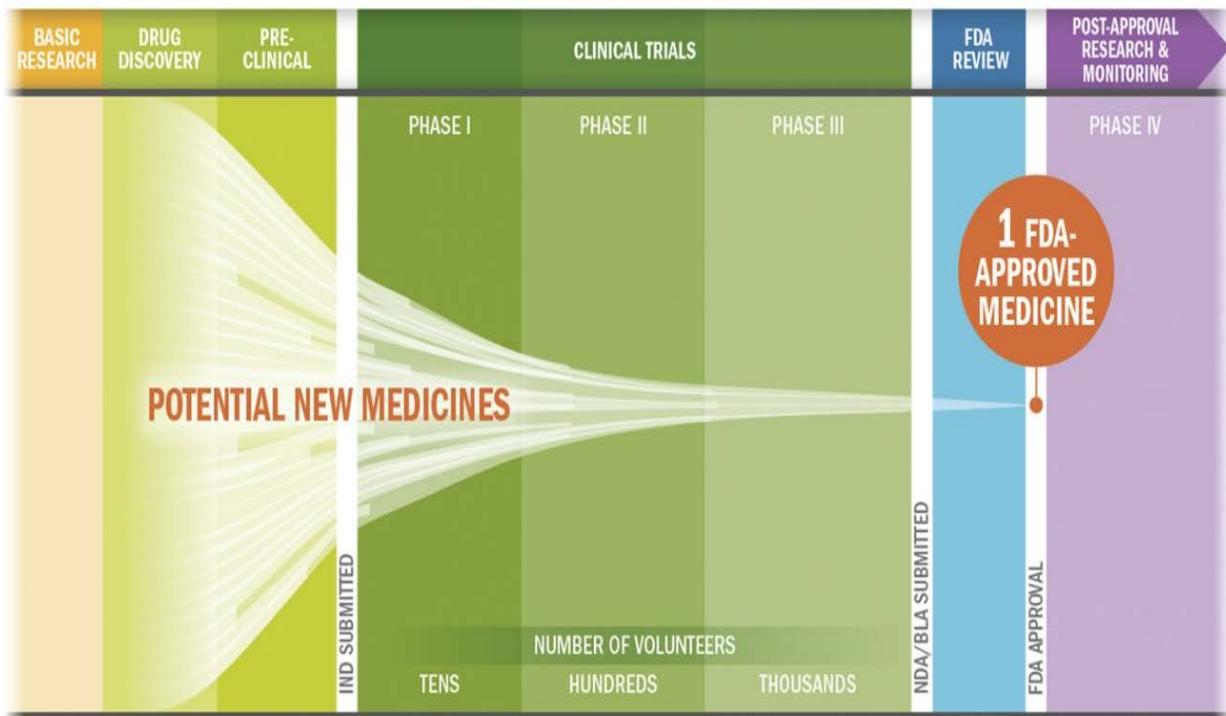
<sup>32</sup> International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), "The IFPMA Health Partnerships Survey," *validated by LSE Health and Social Care at the London School of*

2011, they contributed an estimated \$98.4 billion dollars toward achieving health-related Millennium Development Goals.<sup>33</sup>

**B. The Biopharmaceutical Research and Development Process – Ensuring a Level-Playing Field for U.S. Biopharmaceutical Innovators**

Unlike products made by other innovative industries, new medicines are not market-ready at the time they are developed. As highlighted in Figure 2 below, 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.<sup>34</sup>

**Figure 2: The biopharmaceutical research and development process**



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

*Economics and Political Science*, Mar. 2006, available at: [http://www.policy-centre.com/downloads/IFPMA\\_LSE\\_Report\\_08Mar06.pdf](http://www.policy-centre.com/downloads/IFPMA_LSE_Report_08Mar06.pdf) (last visited Oct. 27, 2016).

<sup>33</sup> Morris, Jeremiah et al., *The Pharmaceutical Industry’s Contributions to the United Nations Millennium Development Goals*, Hudson Institute, May 2013, available at [http://www.hudson.org/content/researchattachments/attachment/1260/the\\_pharmaceutical\\_industry\\_s\\_contributions\\_to\\_the\\_un\\_millennium\\_development\\_goals.pdf](http://www.hudson.org/content/researchattachments/attachment/1260/the_pharmaceutical_industry_s_contributions_to_the_un_millennium_development_goals.pdf) (last visited Oct. 27, 2016).

<sup>34</sup> 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*, available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016). U.S. Food and Drug Administration, *Drug Approval Process*, available at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (last visited Oct. 27, 2016).

In 2013, the innovative biopharmaceutical industry sponsored nearly 6,200 clinical trials across all 50 states.<sup>35</sup> 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.<sup>36</sup> In each of the last three years, the U.S. biopharmaceutical sector invested more than \$50 billion annually in research and development.<sup>37</sup> 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.<sup>38</sup> 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.<sup>39</sup>

Advances in the treatment of diseases typically are not driven by large, dramatic developments, but more commonly build on a series of incremental improvements over time. The best clinical role and full value of a particular therapy typically emerges years after initial approval as further research is conducted and physicians and other healthcare providers gain real-world experience. Incremental improvements and the further development of therapeutic classes of medicines often leads 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.<sup>40</sup> And more than 60 percent of therapies on the World Health Organization's (WHO's) Essential Medicines List relate to improvements on older treatments.<sup>41</sup> This step by step transformation in

---

<sup>35</sup> Battelle Technology Partnership Practice, *Biopharmaceutical industry-sponsored clinical trials: impact on state economies*, Battelle Memorial Institute, Feb. 2015, available at <http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-sponsored-clinical-trials-impact-on-state-economies.pdf> (last visited Oct. 27, 2016).

<sup>36</sup> 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. 27, 2016).

<sup>37</sup> PhRMA, *Annual Membership Survey*, 2015.

<sup>38</sup> IFPMA, *New Frontiers of Biopharmaceutical Innovation, 2012*, available at [http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA\\_New\\_Frontiers\\_Biopharma\\_Innovation\\_2012\\_Web.pdf](http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf) (last visited Oct. 27, 2016).

<sup>39</sup> DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016).

<sup>40</sup> See G. Jin 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. 27, 2016).

<sup>41</sup> See J. Cohen and K. Kaitin, "Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice," *American Journal of Therapeutics*, Jan.-Feb. 2008.

knowledge has led to increased survival, improved patient outcomes and enhanced quality of life for many patients.<sup>42</sup>

## II. Practices that Undermine Innovation and Access to New Treatments

Strong protection and enforcement of patents, regulatory test data and other intellectual property, and fair and transparent market access to overseas markets provide powerful incentives that drive and sustain substantial investments in valuable treatments and cures. Where markets are open and intellectual property is protected and enforced, biopharmaceutical innovators have the predictability and certainty they need to invest in researching, developing and launching new medicines. Too often, however, American biopharmaceutical manufacturers face an un-level playing field, with global trading partners implementing policies that discriminate against foreign competitors.

### A. 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, Turkey** and **Vietnam**, 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.

Many of these discriminatory measures appear to violate the most basic principles of the global trading system found in the General Agreement on Tariffs and Trade, and the WTO Agreements on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Technical Barriers to Trade (TBT) and Trade-Related Investment Measures (TRIMS). They deny adequate and effective intellectual property protection for biopharmaceutical innovators and fair and equitable market access for new medicines, vaccines and other health technologies. Some examples of the most serious kinds of 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 a number of countries provide tax and other incentives for companies to conduct research and development and to manufacture in their countries, an alarming number are seeking to grow their economies by discriminating against foreign innovators. For example, **Turkey** is once again pursuing a policy that would remove from the reimbursement list products that are not produced in Turkey.

---

<sup>42</sup> T.F. Goss, E.H. Picard, and A. Tarab, *Recognizing the Value in Oncology Innovation*. Boston Healthcare Associates, Inc., June 2012, available at [http://www.phrma.org/sites/default/files/flash/phrma\\_innovation\\_oncology.pdf](http://www.phrma.org/sites/default/files/flash/phrma_innovation_oncology.pdf) (last visited Oct. 27, 2016).

**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 EAEU manufacturers for a particular class of medicine. **India** has proposed an amendment to its Patent Rules that would provide for expedited examination of patent applications only in cases where the patent applicant, her assignee or licensee is manufacturing or will manufacture the invention for which the patent was filed in India.

- *Mandatory technology transfer.* In 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. 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.

### ***B. Practices that deny fair and equitable market access***

PhRMA members increasingly encounter acts, policies and practices abroad that deny fair and equitable market access. These barriers undermine the ability of biopharmaceutical innovators in the United States to bring new medicines to patients around the world and to invest in future treatments and cures. They delay access or reduce the availability of new medicines in key countries, contribute to an unpredictable business environment, and threaten U.S. exports and jobs. Some examples of the most serious barriers that prevent access to innovative medicines include:

- *Import barriers.* High tariffs and taxes limit access to new treatments in key overseas markets. The value of biopharmaceutical trade with countries outside the WTO pharmaceutical zero-for-zero initiative increased at a combined annual growth rate of more than 20 percent between 2006 and 2013. This means that a larger proportion of medicines distributed around the world are potentially subject

to tariffs. In **India**, basic import duties on biopharmaceutical products and active ingredients average about ten percent, but additional duties and assessments can raise the effective import duty to as high as 20 percent. Federal and state taxes on medicines in **Brazil** can add 38 percent to the price of medicines – the highest tax burden on medicines in the world. Other countries that maintain high tariffs and taxes on imported medicines include **Argentina**, **Russia** and **Thailand**.

- *Regulatory approval delays.* The process of approving a medicine in **China** takes much longer than international practice and a policy regarding the acceptance of multi-regional clinical trial data is further extending this timeline. PhRMA is encouraged by commitments in the 2014 JCCT and by some aspects of the 2015 State Council Drug Reform Opinion to reduce the drug application backlogs and streamline the review and approval system. Accelerating the regulatory approval process will improve the efficiency of global drug development and reduce the time it takes for new medicines to reach Chinese patients.
- *Lack of transparency and due process.* Lack of transparency, due process, and delayed reimbursement decisions are widespread across the world. In **Australia**, the government continues to make significant policy changes, particularly in relation to the Pharmaceutical Benefits Scheme (PBS) – often without adequate consultation with the industry. In **Mexico**, it takes 1,500 days on average for patients to access innovative medicines, compared to 230 days in other countries.<sup>43</sup> These excessive delays are compounded by consolidated procurement processes that lack transparency and are applied inconsistently. In **Turkey**, reimbursement decision criteria are not clearly defined, the process is non-transparent, and unpredictable delays in decision-making produce lengthy timelines that significantly postpone patient access to innovative medicines.

PhRMA members appreciate steps USTR and other federal agencies have taken 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. Further action is needed to address and resolve existing barriers and ensure patients have faster access to new treatments and cures.

### ***C. Inadequate or Ineffective Intellectual Property Protections***

Strong intellectual property protection and enforcement provide innovators with the necessary incentives to incur the financial risk involved in researching and developing innovative medicines. Patents promote competition and greater treatment options. In exchange for the limited period of protection patents provide, innovators

---

<sup>43</sup> 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://efpia.eu/documents/33/64/Market-Access-Delays> (last visited Oct. 27, 2016).

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.<sup>44</sup>

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.

TRIPS entered into force in 1994 and 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,<sup>45</sup> 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 not only fully and effectively implementing, but also in reiterating and enforcing, TRIPS minimum standards.

Through WTO accessions and regional and bilateral trade agreements, the United States and other countries have given effect to and built on the global minimum standards of protection international rules provide. U.S. trade agreements have helped to drive and sustain biopharmaceutical innovation by eliminating restrictive patentability criteria, addressing unreasonable patent examination and marketing approval delays, promoting the early and effective resolution of patent disputes and protecting regulatory test data. They have established rules and principles that promote fair, transparent, reasonable and non-discriminatory market access for innovative medicines and other health technologies.

Despite these achievements, 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

---

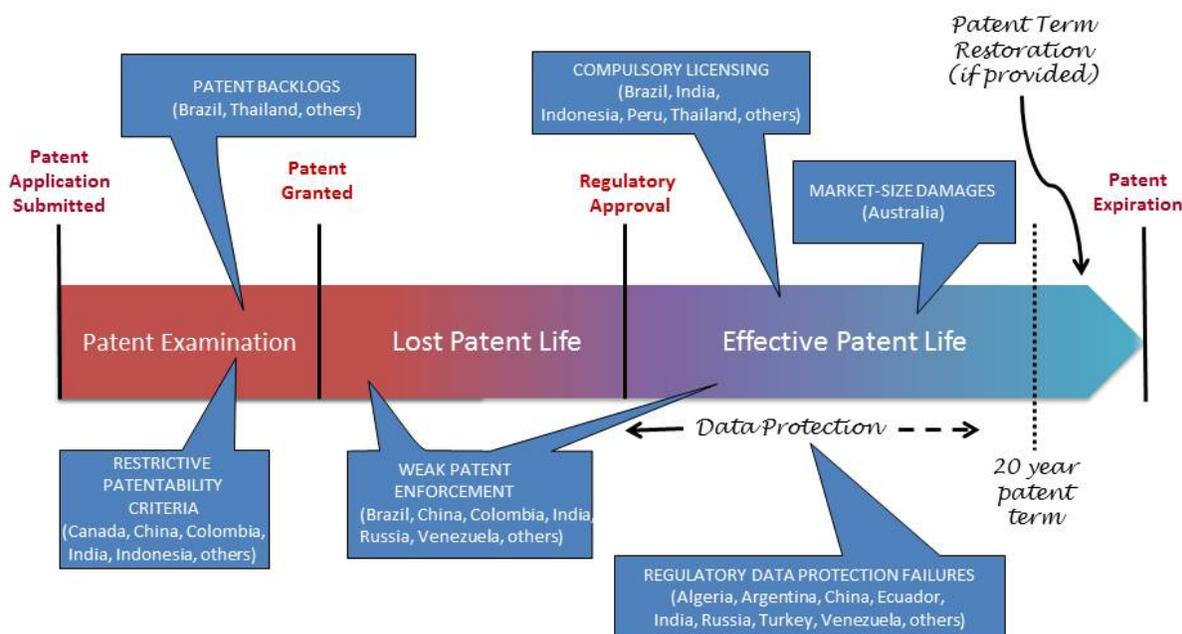
<sup>44</sup> International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), *The New Frontiers of Biopharmaceutical Innovation, 2012*, available at [http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA\\_New\\_Frontiers\\_Biopharma\\_Innovation\\_2012\\_Web.pdf](http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf) (last visited Oct. 27, 2016).

<sup>45</sup> Currently 164 Member States.

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.

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

**Figure 3: Biopharmaceutical intellectual property challenges**



### Patent Backlogs

Long patent examination and approval backlogs harm domestic and overseas inventors in every economic sector. Backlogs undermine incentives to innovate and prevent 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. For biopharmaceutical companies, patent backlogs can postpone the introduction of new medicines. 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. 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. In 2015, India granted one patent based on an application filed 19 years earlier.<sup>46</sup> In Brazil, the patent backlog challenge is compounded by an unnecessary dual examination process for biopharmaceutical patent applications. The Brazilian Health Surveillance Agency (ANVISA) must review all patent applications for new medicines, in addition to the formal patent examination process conducted by the Brazilian Patent Office.

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 Australia, China, the European Union, Japan, Korea, Mexico and elsewhere are succeeding in reducing patent examination delays. Further work is needed to consolidate these gains and extend effective models to other countries.

### *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.<sup>47</sup> 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 treatments that can improve health outcomes<sup>48</sup> and reduce costs<sup>49</sup> by making

---

<sup>46</sup> 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. 27, 2016).

<sup>47</sup> See, generally, TRIPS Article 27.1.

<sup>48</sup> 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

it easier for patients to take medicines and 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:

- *Heightened patent utility requirements.* Based on a unique legal theory found nowhere else in the world, courts in **Canada** have invalidated 25 patents on innovative medicines over the last decade. That legal theory – known as the “promise utility doctrine” – imposes a heightened and unworkable standard for determining the utility of biopharmaceutical products. The promise utility doctrine requires not only that the invention be useful, but that data available *at the time the patent application is filed* prove that the invention serves whatever “promise” a court infers *post hoc* to have been made in the patent’s specification. As a result, the judicially imposed doctrine places innovators in the biopharmaceutical industry in an untenable situation. If a drug developer aims to meet Canada’s enhanced utility test, which may include carrying out long-term clinical trials *before* filing a patent application so that data proving fulfillment of the court-chosen “promise” are more likely to be in hand, it must delay patent filings. Such significant delays would increase the risk of patent refusal and patent invalidity in numerous countries on the basis of an earlier patent filing, intervening publication of additional prior art, or the legally mandated disclosures that attend clinical trials. Even then, because the “promise” Canadian courts will perceive is difficult to identify in advance, delaying the patent application provides no assurance of ultimate patent protection.
- *Patentability restrictions and additional patentability criteria.* **Argentina** issued regulations in 2012 that prevent biopharmaceutical innovators from securing patents on certain types of inventions, including new dosage forms and

---

patient must take their medicine each day. The average adherence rate for treatments taken once daily is nearly 80 percent, compared to about 50 percent for medicines that must be taken four times a day. Patient adherence to prescribed courses of treatment leads to better health outcomes and is particularly important for the management of chronic, non-communicable diseases like diabetes, heart disease and cancer. According to the WHO, “[a]dherence to therapies is a primary determinant of treatment success”. See Shrank, 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. 27, 2016).

<sup>49</sup> Encouraging patients to take their medicines consistently and as prescribed can lower overall health care costs. The cost of non-adherence has been estimated at \$100 billion to \$300 billion annually, including the costs of avoidable hospitalizations, nursing home admissions and premature deaths. Making patents available for incremental improvements and new indications can also drive price competition for medicines by encouraging the development of alternative treatments – leading to multiple drugs in a single therapeutic class and increasing the range of options for patients and healthcare providers. See Osterberg, Lars and Terrence Blaschke, “Adherence to Medication,” *New England Journal of Medicine*, Aug. 2005, available at <http://www.nejm.org/doi/full/10.1056/NEJMra050100> (last visited Oct. 27, 2016); 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](http://journals.lww.com/lww-medicalcare/Abstract/2004/03000/Variations_in_Patients__Adherence_to_Medical.2.aspx) (last visited Oct. 27, 2016); 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.

combinations. In the **Philippines**, a new law limited the patentability of new forms and uses. **India's** Patent Law prohibits patents on known substances, unless applicants can demonstrate they meet an additional "enhanced therapeutic efficacy" test. **Indonesia** has passed new patent legislation that imposes restrictions similar to those found in Indian law.

- *Restrictions on post-filing submissions.* Unlike patent offices in major markets, **China's** State Intellectual Property Office does not consistently accept data generated after a patent is filed during patent prosecution to describe inventions or satisfy inventive step requirements. This practice has caused significant uncertainty about the ability to obtain and maintain biopharmaceutical patents in China and caused denials of patents on new medicines in that country that received patents in other jurisdictions. China continues to restrict post-filing data despite a December 2013 commitment in the U.S.-China Joint Commission on Commerce and Trade (JCCT) to allow patent applicants to submit additional data after filing patent applications.

Restrictive patentability criteria in many of these countries and others appear contrary to WTO rules, which require WTO Members to make patents available for inventions that are new, involve an inventive step and are capable of industrial application. These laws also appear to apply solely to pharmaceutical products, either expressly by law or in a *de facto* manner as applied. This is not consistent with the obligations of WTO Members to make patents available without discrimination as to the field of technology. PhRMA members appreciate steps USTR and other federal agencies have taken to address restrictive patentability criteria and look forward to continuing to work closely with these agencies to secure progress and real results. Further action is needed to resolve these challenges in particular countries and to prevent others from adopting similar practices.

#### *Weak Patent Enforcement*

To continue to invest in the research and development of new medicines, biopharmaceutical innovators must be able to effectively enforce patents on their inventions. Mechanisms such as patent linkage that provide for the early resolutions 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.

PhRMA appreciates steps the United States and other economies around the world have taken to promote effective patent enforcement, including by providing for early resolution mechanisms in trade agreements and encouraging the creation of specialized intellectual property courts. We are closely following work in **Taiwan** to establish early resolution mechanisms and look forward to positive results there and

elsewhere. Early resolution mechanisms are sorely needed in **China, India, Russia** and other countries where innovators are not notified of marketing approval applications filed for potentially infringing products and generally are unable to secure provisional enforcement measures, such as stays, preliminary injunctions or interlocutory injunctions, to prevent the sale of such products.

### *Market-Size Damages*

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

**Australia’s** Department of Health is seeking damages from biopharmaceutical innovators that pursue 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.

Australia’s market-size damages policy unfairly tips the scales in commercial patent disputes encouraging competitors to launch at risk and discouraging innovators from enforcing their patents. It 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 additional, unquantifiable and significant compensation claims that were not agreed at the time provisional enforcement measures were granted. The size of these additional claims equates legitimate patent enforcement with patent abuse.

Laws or policies that allow 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. They appear to be inconsistent with WTO intellectual property rules, including with respect to provisional measures. PhRMA members urge USTR and other federal agencies to prioritize actions to address and resolve this challenge in Australia.

### *Compulsory Licensing*

Biopharmaceutical innovators support strong national health systems and timely access to quality, safe and effective medicines for patients who need them. Patents drive and enable the research and development that delivers new treatments and cures. These limited and temporary intellectual property rights are not a barrier to access to

medicines – particularly when governments and the private sector partner to improve health outcomes.

Some governments, including **Ecuador**, **India** and **Indonesia**, have issued compulsory licenses (CLs) that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder. PhRMA commends **Ecuador** for reevaluating its position and revoking the ten CLs issued in that country since 2010. 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 the 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<sup>50</sup> or speed access<sup>51</sup> in the short-term, or provide sustainable or comprehensive solutions to longer-term challenges. It does not address systemic barriers to access – from weak healthcare delivery systems to low national healthcare funding and high taxes and tariffs on medicines. Compulsory licensing is particularly ineffective relative to the many alternatives available. Biopharmaceutical innovators support different tools and programs that make medicines available to patients who could not otherwise afford them, including drug donation and differential pricing programs, voluntary licensing and non-assert declarations.<sup>52</sup> In sub-Saharan Africa, for example, the majority of antiretrovirals are manufactured under voluntary licenses to local generic drug companies.<sup>53</sup>

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. In 2013, for example, 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.<sup>54</sup>

---

<sup>50</sup> Beall, Reed 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. 27, 2016).

<sup>51</sup> 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, Eric and Kamal 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](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. 27, 2016).

<sup>52</sup> IFPMA Policy Position, *Voluntary Licenses and Non-Assert Declarations*, available at <http://www.ifpma.org/resource-centre/ifpma-position-on-voluntary-licenses-and-non-assert-declarations/> (last visited Oct. 27, 2016).

<sup>53</sup> Chien, Colleen, "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. 27, 2016).

<sup>54</sup> Chatterjee, P., "India's First Compulsory License Upheld, But Legal Fights Likely to Continue," Intellectual Property Watch, Apr. 3, 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. 27, 2016).

Others, such as Colombia, are using mandatory price reductions beyond those already provided for under their existing pricing regimes as an alternative approach to issuing a compulsory license. Earlier this year Colombia issued a declaration of public interest (DPI) – typically a precursor to issuing a compulsory license – in order to secure a substantial mandatory price reduction on an innovative leukemia medicine in order to render the prices for that medicine commensurate with generic prices, *i.e.*, as if the patent did not exist. At no point was it suggested let alone demonstrated that the DPI was needed due to a lack of patient access.

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

### *Regulatory Data Protection Failures*

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

RDP is a carefully balanced mechanism that improves access to medicines. 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.<sup>55</sup> 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 91 percent of all prescriptions filled in the United States.<sup>56</sup>

RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Derived from 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, Congress included provisions in the Affordable Care Act providing 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

---

<sup>55</sup> 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.

<sup>56</sup> PhRMA analysis based on IMS Health data. IMS National Prescription Audit™. Danbury, CT: IMS Health; 2016.

biopharmaceutical innovators and the associated global scientific ecosystem are able to sustainably pursue groundbreaking biomedical research.<sup>57</sup>

Unfortunately, many U.S. trading partners do not provide adequate, if any, RDP. This is clearly contrary to WTO rules, which require parties to protect regulatory test data submitted as a condition of obtaining marketing approval against both disclosure and unfair commercial use. Examples described further in the country profiles below include **Algeria, Argentina, Ecuador, Egypt, India and Turkey**. Other countries, such as **Malaysia and Peru** provide RDP for small-molecule treatments, but not for biologics. In **Chile** and some other countries, RDP is not made available to biopharmaceutical innovations related to new uses, formulations, composition, or dosage forms. **Canada** passed legislation in 2014 that gives the Health Minister broad discretion to share undisclosed test data without safeguards to protect against unfair commercial use.

### **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. Secure strong commitments in global, regional and bilateral negotiations***

Global, regional and bilateral trade and investment negotiations provide critical opportunities to build on the existing foundation of international rules and to secure commitments necessary to drive and sustain 21<sup>st</sup> Century biopharmaceutical innovation. 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, reducing unnecessary regulatory barriers and promoting transparent, timely and predictable medicines pricing and reimbursement processes can promote biopharmaceutical innovation and improve market access.

PhRMA members are disappointed that the Trans-Pacific Partnership (TPP) negotiations concluded last year failed to secure the U.S. standard of twelve years of data protection for biologic medicines, which represent the next wave of innovation in the biopharmaceutical industry. This term of protection was the result of a long debate

---

<sup>57</sup> See, for example, Grabowski, H. et al., "Data exclusivity for biologics," *Nature Reviews – Drug Discovery*, January 2011, available at <https://fds.duke.edu/db/attachment/1592> (last visited Oct. 27, 2016).

in Congress, which determined that twelve years captured the appropriate balance that stimulated research but gave access to biosimilars in a timely manner. PhRMA will continue working with USTR and other federal agencies and with Members of Congress to address this issue and thereby ensure the TPP is not a missed opportunity to encourage innovation that can lead to more important, life-saving medicines that improve the lives of patients.

Ongoing Transatlantic Trade and Investment Partnership (T-TIP) negotiations between the United States and European Union provide a vital chance to further reduce unnecessary regulatory barriers, promote fair and transparent market access and set a global standard for strong intellectual property protection and enforcement. The United States and the European Union are already home to most of the world's biopharmaceutical research and development,<sup>58</sup> and a comprehensive and high-standard T-TIP could further strengthen an already vibrant transatlantic life sciences ecosystem – improving collaboration and boosting two-way trade in biopharmaceuticals that is already valued at more than \$100 billion.<sup>59</sup>

### ***B. Enforce and defend global, regional and bilateral commitments***

The hard-gained protections and commitments secured in trade agreements are only meaningful if implemented by our trading partners. Too often, however, FTA obligations are honored in the breach. While bilateral engagement should always be the first response to any trade barrier, protracted refusal to implement trade obligations must be met with stronger consequences. USTR and other federal agencies should leverage all available tools to ensure America's trading partners live up to their obligations in global, regional and bilateral trade and investment agreements.

PhRMA members appreciate steps the Administration has taken to monitor implementation of agreements and to strengthen enforcement coordination and capacity, including through creation of the Office of the Intellectual Property Enforcement Coordinator and the Interagency Trade Enforcement Center. They welcome and value the actions USTR and other federal agencies have taken to address challenges and promote compliance through timely and effective bilateral engagement.

Stepping up enforcement activity in the months ahead will be critical to address longstanding intellectual property challenges in many countries that are U.S. trade and

---

<sup>58</sup> See EFPIA, *The Pharmaceutical Industry in Figures, Key Data 2014*, available at [http://www.efpia.eu/uploads/Figures\\_2014\\_Final.pdf](http://www.efpia.eu/uploads/Figures_2014_Final.pdf) (last visited Oct. 27, 2016); and Battelle Technology Partnership Practice, *The Economic Impact of the U.S. Biopharmaceutical Industry*, Battelle Memorial Institute, July 2013, available at <http://phrma.org/sites/default/files/pdf/The-Economic-Impact-of-the-US-Biopharmaceutical-Industry.pdf> (last visited Oct. 27, 2016).

<sup>59</sup> European Commission, *Transatlantic Trade and Investment Partnership: The Economic Analysis Explained*, Sept. 2013, available at [http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc\\_151787.pdf](http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151787.pdf) (last visited Oct. 27, 2016); and PhRMA and EFPIA, *The EU—U.S. Transatlantic Trade and Investment Partnership: Towards better health outcomes for patients and economic growth*, available at <http://www.phrma.org/sites/default/files/pdf/EFPIA-TTIP-Brochure.pdf> (last visited Oct. 27, 2016).

investment agreement partners. These agreements 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. **Chile, Peru** and other U.S. trading partners fail to adequately comply with some or all of these obligations.<sup>60</sup> USTR and other federal agencies should consider a process to systematically review compliance with trade and investment agreements and take steps necessary to ensure agreed rules are followed.

The Special 301 Report is an important tool to identify and prioritize acts, policies and practices in these and other overseas markets that are harming America's creative and innovative industries by denying adequate and effective intellectual property protection and fair and equitable market access. PhRMA members urge USTR and other federal agencies to build on this year's report by developing action plans to resolve challenges in Priority Watch List markets. Those plans should consider all available tools and leverage to deliver real results, including diplomatic engagement, trade preference programs and global, regional and bilateral trade and investment agreements.

Where necessary, USTR should consider bringing dispute settlement cases to secure compliance with trade and investment agreement commitments.

### ***C. Ensure transparency and due process of pricing and reimbursement***

As noted above, the biopharmaceutical industry is unique in that most foreign governments, as sole or primary healthcare providers, impose burdensome price controls and regulations on the sector. As a result, market access for pharmaceuticals is not only dependent on manufacturers meeting strict regulatory approval standards, but also in 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 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 of appeal to an independent, objective court or administrative body. In particular, proposed laws, regulations and procedures concerning how medicines are approved, priced and reimbursed should be:

---

<sup>60</sup> For example, 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. Specifically, 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." Similarly, there remain a number of deficiencies in Chile's RDP regime that appear to be inconsistent with Article 17.10.1 of the U.S.-Chile FTA. See separate Peru chapter for examples of commitments contained in the U.S.-Peru Trade Promotion Agreement that are yet to be fully implemented.

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

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

- Based on fair, reasonable, consistent and non-discriminatory procedures, rules and criteria that are fully disclosed to applicants.
- Completed within a reasonable, specified time. 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.

In short, it is essential that decisions whether to approve and/or reimburse a new medicine are made in a reasonable, objective and impartial manner.

#### ***D. Combat the worldwide proliferation of counterfeit medicines***

PhRMA members view counterfeit medicines as a critical public health and safety concern threatening patients worldwide. At best, counterfeit medicines have no effect on patients.<sup>61</sup> At worst, they may contribute to drug-resistant forms of tuberculosis and other serious diseases and contain impurities or toxins that can cause harm or even

---

<sup>61</sup> Testing reported last year in the *Lancet* found one-third of anti-malarial medicines in sub-Saharan Africa and South East Asia lacked active ingredients. See Guarvika, M.L.N., et al., "Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa," *The Lancet*, June 2012, available at <http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2812%2970064-6/fulltext> (last visited Oct. 27, 2016).

death.<sup>62</sup> This challenge is exacerbated by the ease with which counterfeiters can offer fake medicines over the Internet and ship them by mail to patients and consumers worldwide.<sup>63</sup>

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. But in too many countries, customs and other law enforcement officials are not able to seize counterfeit medicines, particularly goods in transit, goods in free trade zones and goods offered for sale on the Internet. In those countries and others, violations of limited laws on the books often are not effectively enforced or do not come with sufficient, deterrent penalties.<sup>64</sup>

According to the WHO, regions where protection and enforcement systems are weakest also see the highest incidence of counterfeit medicines. The manufacture of counterfeit medicines and active pharmaceutical ingredients is especially prevalent in countries like **Brazil, China, India, and Russia** that have drug production capacity, weak regulatory oversight and often ineffective intellectual property protection and enforcement regimes. Illegitimate and often dangerous products manufactured in these and other countries are not only sold domestically, but also exported around the world.<sup>65</sup>

To combat the global proliferation of counterfeit medicines and active pharmaceutical ingredients, PhRMA supports strengthening efforts 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.

---

<sup>62</sup> An International Policy Network study found that fake tuberculosis and malaria drugs kill 700,000 people a year in developing countries. See Harris, J., et al., "Keeping It Real," *Health Issues*, International Policy Network, May 2009.

<sup>63</sup> Institute of Medicine (IOM), *Countering the Problem of Falsified and Substandard Drugs*, Feb. 2013, available at [https://iom.nationalacademies.org/~media/Files/Report%20Files/2013/Substandard-and-Falsified-Drugs/CounteringtheProblemofFalsifiedandSubstandardDrugs\\_RB.pdf](https://iom.nationalacademies.org/~media/Files/Report%20Files/2013/Substandard-and-Falsified-Drugs/CounteringtheProblemofFalsifiedandSubstandardDrugs_RB.pdf) (last visited Oct. 27, 2016). The IOM notes that "because the internet facilitates easy international sales, online drug stores have spread the problem of falsified and substandard drugs...."

<sup>64</sup> *Id.* (noting that "unscrupulous manufacturers and criminal cartels take advantage of the comparatively weak drug regulatory systems in these countries, knowing that the regulators are poorly equipped for surveillance or enforcement").

<sup>65</sup> See, generally, *Pharmaceutical Security Institute Analysis* available at <http://psi-inc.org/index.cfm> (last visited Oct. 27, 2016).

### ***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 of global, regional and bilateral commitments and support training of regulators, law enforcement officials, judges and other court personnel overseas to enforce those commitments.

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

All this provides a valuable foundation on which to build in the coming year and beyond. Fostering and strengthening coalitions that support innovation will be particularly critical in international organizations, such as the WHO, the World Intellectual Property Organization (WIPO), the WTO and United Nations funds and programs. In these forums and others – and despite the bounds of their respective mandates – discussions increasingly are focused on limitations and exceptions to intellectual property rights. This is even the case at WIPO, an organization that was created to “encourage creative activity” and to “promote the protection of intellectual property throughout the world.”<sup>66</sup> The United States must remain vigilant in these organizations and work with other like-minded countries to advocate for robust intellectual property protection and enforcement.

---

<sup>66</sup> See, generally, Convention Establishing the World Intellectual Property Organization, July 14, 1967, available at [http://www.wipo.int/treaties/en/text.jsp?file\\_id=283854](http://www.wipo.int/treaties/en/text.jsp?file_id=283854) (last visited Oct. 27, 2016).

## ALGERIA

PhRMA and its member companies operating in Algeria believe that Algeria has the potential to foster investment in pharmaceutical innovation and address the unmet medical needs of the country. However, significant market access and intellectual property barriers remain. PhRMA noted some success in collaborating with the prior government in place until mid-2012, with that government publicly stating its support for a new strategy that better integrates the innovative pharmaceutical sector into Algeria's economy and healthcare system. Subsequent Ministers have reaffirmed that commitment. PhRMA's member companies are hopeful for a similarly cooperative dialogue with the current government.

### **Key Issues of Concern:**

- **Import restrictions and forced localization:** Algeria prohibits imports of virtually all pharmaceutical products that compete with similar products that are manufactured domestically. Pharmaceutical products and active pharmaceutical ingredients (API) that are not locally manufactured are subject to annual import quotas. Similarly, foreign companies are prohibited from selling to wholesalers, and therefore must establish separate distribution channels in Algeria.
- **Market access barriers:** Under Algeria's pricing system, some patented medicines with no generic equivalent on the market are nonetheless referenced against generic products deemed to be in the same therapeutic class. The resulting price does not recognize the value of innovative products, nor does it reward the significant investment involved in developing new medicines, or encourage the development of tomorrow's new cures.
- **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).

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<sup>67</sup> stipulating that, effective January 2009, the importation of pharmaceutical products that compete with similar products that are being manufactured locally is prohibited. This decision

---

<sup>67</sup> The decision was published in November 2008 under the name "Arrêté du 30 novembre 2008 relatif à l'interdiction des produits pharmaceutiques et dispositifs médicaux destinés à la médecine humaine fabriqué en Algérie."

was essentially a reinstatement of a previous ministerial decree<sup>68</sup> that was suspended as part of the WTO accession process. Subsequently, the Ministry of Health (MOH) published lists of such products comprising hundreds of branded medicines, and this import policy continues to be 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 presence of our member companies in Algeria.

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,<sup>69</sup> further harming Algerian patients. During discussions that started in 2011 and continued in 2012, Government 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. This decision applies prospectively, not to companies engaged in foreign trade prior to December 2008. Despite the lack of success in attracting new investment, the new government has recently confirmed that this law will continue to be enforced for the foreseeable future.

Starting in 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 have to invest also in a distribution infrastructure. While this circular has never been applied, the uncertainty of the regulation continues to concern PhRMA members.

---

<sup>68</sup> Instruction #5 for the Generalization of Generics (Sept. 2003).

<sup>69</sup> Veille Media, "Pénurie de médicaments: le Snapo va interpeller le ministre de la Santé" (May 12, 2011).

## 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 practice is to block imports temporarily as a cost-containment tool. The unintended consequence, however, is that it leads to shortages in the market, to the detriment of Algerian patients.

## Cumbersome and Slow Regulatory System

Despite significant improvements in the MOH’s registration process in 2013, the registration process remains slow and 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 neighboring peer countries. For example, all registration dossiers must be pre-authorized prior to acceptance for review, but there is no transparent process or timeline for completing this preliminary step of the process. After submission to the MOH, registration dossiers are on hold pending National Laboratory results, which causes further delay and complexity in the registration process.

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. But the CRM reimbursement process is entirely separate and the MOH marketing approval price is rarely accepted in the CRM (MOH is member of the CRM) process. 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.

Finally, since June 2010, pharmaceutical companies have noticed lengthy delays of many months in approving variations for imported products already available on the market. The previous government had begun to recognize the negative impact that unnecessary delays have on patients and the business climate, but the backlog continues.

### Industry Association License

PhRMA's member companies have been trying for many years to establish a local pharmaceutical association to engage in public policy advocacy on behalf of the innovative medicines sector. In late 2015, there were signs that the Algerian Government would permit the establishment of a local innovative pharmaceutical association. PhRMA member companies look forward to the working with the Government on securing the legal approval for such an association.

### Other Market Access Barriers

The Algerian Government utilizes international reference pricing (IRP) to determine the government price level of medicines. As a general matter, IRP is a sub-optimal tool for setting drug prices that discourages R&D in new medicines for patients. Instead of recognizing the value that innovative medicines can provide for patients in a specific country, IRP imports prices from other countries that typically have different disease burdens, indications, willingness (preferences) and ability (income) to pay, and market structures. In short, IRP as a policy is not consistent with Algeria's goal of promoting a local innovative pharmaceutical industry. In August 2015, the Algerian Government issued a new procedure for determining drug prices. Key weaknesses in Algeria's new pricing procedure and the IRP model include:

- The new pricing procedure reference a list of countries including Greece and Turkey. Neither Greece nor Turkey are appropriate reference countries. 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 of these countries do not reflect the true value of innovative medicines and certainly are not consistent with a country seeking to encourage local R&D. As such, Turkey and Greece should be removed from Algeria's basket of reference countries.
- To ensure 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.*, follow 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 (MA) renewal process. While the industry commends Algeria for providing a process for allowing manufacturers to seek adjustments during the MA renewal process to account for changes in the reference countries, it is not reasonable or fair 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.

## **Intellectual Property Protection**

### Weak Patent Enforcement

Marketing approval authorities in Algeria improperly interpret current laws and regulations by granting marketing approval to generic medicine manufacturers of copies of patent protected products while the original patent is still in effect. The absence of effective judicial remedies for preventing the infringement of basic patent rights, including the lack of injunctive relief that could prevent irreparable harm prior to the resolution of the case in court, puts the originator in an untenable position with no possibility to defend its 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.

### Transition from Administrative Exclusivity

Pharmaceutical products were not eligible for patents in Algeria until the promulgation of Ordinance No. 03-07 on July 19, 2003. Before that date, in a good faith effort, Algerian authorities would not authorize the marketing of generic forms of pharmaceutical products covered by unexpired patents in their country of origin. In other words, Algeria provided *de facto* administrative exclusive marketing rights (EMR) to pharmaceutical inventions *in lieu* of patents. PhRMA members relied on the protection afforded by these rights.

While the 2003 Ordinance extended patent protection to pharmaceutical products, it unfortunately did not include transitional provisions to require the authorities to continue providing the EMR to pharmaceutical products that could not obtain patent protection under the Ordinance because of prior publications or sales. Accordingly, in 2005, Algerian health authorities abandoned the practice of providing *de facto* exclusive

marketing rights to pharmaceutical products that could not benefit from the Ordinance, and started to approve the marketing of copies of products still covered by patents in their country of origin. Thus, PhRMA members lost the EMR upon which they had relied because of the lack of clear transitional provisions.

## ARGENTINA

PhRMA and its member companies operating in Argentina are concerned about significant market access barriers and intellectual property (IP) issues. New regulations have been introduced which clearly discriminate against foreign products. Patentability restrictions, the patent application backlog, and the lack of regulatory data protection (RDP) remain in place.

### Key Issues of Concern:

- **Discriminatory Reimbursement Policies:** On October 1, 2015, the Ministry of Health and the Secretary of Commerce issued a Joint Resolution establishing a “preferential” reimbursement system for national generics and biosimilar products, to the potential detriment of manufacturers producing medicines outside Argentina.
- **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 Industry and the Argentina Patent Office (Instituto Nacional de la Propiedad Industrial or INPI) established guidelines that significantly limit the type of pharmaceutical inventions that can be patented. These guidelines appear contrary to Argentina’s obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and have led to the rejection of many pharmaceutical patent applications.
- **Regulatory data protection failures:** Argentina does not provide protection for regulatory test data, as required under TRIPS. Specifically, Law 24,766 permits Argentine officials to rely on data submitted by originators to approve requests by competitors to market similar products.

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

### **Market Access Barriers**

#### 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 are undefined, but on its face the new reimbursement system appears to be inconsistent 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.

## **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 (Nº 118/2012, 546/2012 and 107/2012), issued jointly by the Ministries of Health and Industry and INPI sets out Guidelines for Patentability Examination of Patent Applications on Chemical and Pharmaceutical Inventions. It expressly states that pharmaceutical patents are not available for compositions, dosages, salts, esters and ethers, polymorphs, analogous processes, active metabolites and pro-drugs, enantiomers, selection patents and Markush-type claims.

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

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

On October 5, 2015, INPI issued a new Resolution Nro. 283/2015 that further burdens biopharmaceutical innovation. This Resolution regulates patent filings on living matter and natural substances, including biologics. It burdens the patentability process on biologics, among others, by adding more requirements and formalities. This Resolution contradicts Law 24,481, on Patents, regarding living matter because Law 24,481 excludes patentability of all preexisting living matter, while this Resolution bans patentability of all living matter.

### 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.

Patent application delays are particularly acute in Argentina, where pharmaceutical, chemical and biotech innovators must wait eight to nine years, on average, for patents to be granted. According to some estimates, the overall patent backlog is approximately 21,000 applications. Argentina's patent law does not provide sufficient patent term adjustment to compensate fully for unwarranted delays in the examination of patent applications.

To address this challenge, 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 140 Contracting Parties. Accession to the PCT could allow Argentina to reduce its current patent application backlog and use the PCT system to reduce the review period for future patent applications.

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

## 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.<sup>70</sup>

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

Argentina was among the countries that crafted that provision, but has so far failed to provide protection of test and other data in a manner consistent with its international obligations. Indeed, Law No. 24,766 allows Argentine officials to rely on data submitted by innovators in other markets to approve requests by competitors to market similar products in Argentina. The Law provides no period of protection against reliance and does not define “dishonest” use.

---

<sup>70</sup> DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016).

## AUSTRALIA

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

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

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

### **Key Issues of Concern:**

- **Difficulties in listing new medicines on the PBS:** Companies are facing increased uncertainty in the listing of new medicines on the PBS. Navigation through the Regulatory framework of Market Authorisation and Reimbursement remains complex and reiterative.
- **Disincentives to improve products:** The current interpretations of sections 99ACB and 99ACD of Australia's *National Health Act 1953* by the Australian Government are inconsistent with the original intent of the legislation, and have led to instances of Australian patients being unable to access improvements in medicines. Whilst discussions continue through the AMWG, there is little progress towards a solution.
- **Biosimilars:** There have been significant recent developments regarding the introduction of biosimilar medicines into the Australian market. However, coordinated policy and processes to support the evolving market appear to be missing. Australia needs to develop a considered, consistent and comprehensive biosimilars policy that supports their safe introduction, balanced uptake and appropriate use, as well as builds public and global confidence in a sustainable market.

- **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.
- **Uncompetitive intellectual property regime:** There are a number of weaknesses in Australia's IP regime:
  - The Australian Government has persisted with a policy to seek recovery of damages from innovators in cases where challenges to patents on PBS-listed medicines have been upheld following an initial granting of a temporary injunction. This is exacerbated by the inability to seek injunctions and resolve patent challenges prior to market entry (due to lack of adequate patent holder notification). As this policy change was made without consultation with relevant stakeholders and with retrospective application, it continues to create significant uncertainty for pharmaceutical patent owners in Australia and undermines the rights of patent holders by introducing a strong disincentive to defend their IP.
  - Contrary to its obligations under the AUSFTA, Australia does not provide patent holders with advance notice of potentially patent-infringing products applying for marketing approval and coming to market before loss of exclusivity (LOE).
  - The Australian Government recently commissioned yet another Productivity Commission (Commission) inquiry into Australia's "Intellectual Property Arrangements."<sup>71</sup> The Commission's Draft Inquiry Report 2016 contained a number of draft findings that the industry does not consider appropriate or reasonable. Our local sister association Medicines Australia appeared before the Commission at a pharmaceutical roundtable and its public hearings in June 2016. The Productivity Commission has lodged its report (due September 2016) and industry is awaiting the Australian Government's response.
  - Australia should strengthen its regulatory data protection (RDP) to improve the country's attractiveness as a destination for foreign investment by global pharmaceutical companies and encourage companies to bring new medicines to Australia sooner.

For these reasons, PhRMA requests that the U.S. Government continue to seek assurances from Australia that these issues will be quickly and effectively resolved.

---

<sup>71</sup> See <http://www.pc.gov.au/inquiries/current/intellectual-property#issues> (last visited Oct. 27, 2016).

## Market Access

### Difficulties in Listing New Medicines on the PBS

Prescription medicines accessed via the PBS constitute the vast majority of prescription medicines dispensed in Australia.<sup>72</sup> Accordingly, the conditions for listing medicines on the PBS effectively dictate the conditions of access for the Australian innovator pharmaceutical market. The outcomes and processes in PBS listings are therefore critical to securing market access.

The Australian Government continues to make significant policy changes, particularly in relation to the PBS. Most notably in 2015, the Australian Government introduced the *PBS Access and Sustainability Package (PASP)*<sup>73</sup> following the expiry of the Memorandum of Understanding with the Industry in July 2014. The consultation process for the development of the package of reforms effectively reduced the PBS budget by A\$6.6 billion dollars over 5 years, of which A\$4.2 billion was directly from innovative medicines companies. While some health sector representative groups ultimately supported the reforms (including GBMA, the principal body for the generics industry), the consultation process for the development of the PASP reforms was difficult and relatively one-sided. A lack of transparency and rushed timeframes were also at play.

Of particular concern within the PASP was the requirement that the price of all medicines listed on the PBS be reduced by 5% on their fifth anniversary of listing. This was applied retrospectively this year to all medicines listed on the PBS for five or more years (excluding medicines with generic competition). This arbitrary and broad-based price reduction has been applied to medicines already assessed as cost effective through the rigorous Pharmaceutical Benefits Advisory Committee (PBAC) process. The Australian Government has not provided any explanation on why these reductions were appropriate or necessary, other than citing the general need to save money. It is concerning that these cuts, which disproportionately affect non-Australian companies, were considered ahead of reforms in other parts of the Australian health system which are far less cost-effective than the PBS.

The purpose of the PBS is to provide timely, reliable and affordable access to medicines for all Australians. It is important that, moving forward, the PBS remains fit for purpose as new health technologies become available. There is also a need to ensure a high level of industry confidence in the PBAC processes so that Australian patients can access innovative treatments as soon as possible. While the rate of PBAC's positive listing recommendations has improved somewhat over recent years, many of these "positive" recommendations are now accompanied by onerous conditions such that in

---

<sup>72</sup> 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. 27, 2016).

<sup>73</sup> See <http://www.pbs.gov.au/info/general/pbs-access-sustainability-package> (last visited Oct. 27, 2016).

some instances, sponsors are unable to comply or are having to re-apply for PBAC reconsideration. These cause further delay in patient access to medicines.

### Disincentives to Innovate

Interpretations of sections of Australia's *National Health Act 1953* (the Act) by the Government, which are inconsistent with the intent of the original policy, have recently led to instances of Australian patients being unable to access improvements in the delivery of medicines.

Sections 99ACB and 99ACD of the Act allow for statutory price reductions when generic medicines are made available on the PBS. These provisions were established to create the savings/headroom for new and innovative medicines. However, the Australian Government is currently interpreting Sections 99ACB/D in a way that erodes this foundation by treating new presentations of single brand medicines as generic competitors, even when such products retain patent exclusivity. New presentations of currently available medicines are brought to market for various reasons, including to: introduce an improvement in medication delivery which enhances patient outcomes; reflect a global technology change; or address safety concerns related to the existing presentation. In the current environment, pharmaceutical companies are discouraged from bringing improved presentations to the Australian market because their listing could trigger a 16% statutory price reduction for both the old and new presentations of the medicine despite the product still being on patent.

### Biosimilars

There have been significant, concerning developments regarding the introduction of biosimilar medicines into the Australian market, primarily:

- the Government's decision to await the outcome of the WHO on the introduction of Biological Qualifiers (BQ) for all biological and biosimilar medicines before adopting the approach;
- recent revisions to the Evaluation of Biosimilars Guidelines, which limit the TGA's role to determining "biosimilarity", with no reference to "interchangeability" (*i.e.* effectively shifting responsibility for assessing evidence related to pharmacy level substitution to the PBAC); and
- the PBAC approach to pharmacy-level substitution, which effectively allows pharmacists to dispense a biosimilar in place of its reference originator biologic in the absence of explicit direction from the prescriber or suitable evidence.

Moreover, the current TGA naming policy presents pharmacovigilance and traceability concerns, including ongoing consideration of issues associated with pharmacy-level substitution, data collection, and pharmacist notification of dispensing decisions to the prescribing clinician to enhance traceability and pharmacovigilance.

There also remains selective and limited consultation with Medicines Australia on further uptake drivers and broader policy for biosimilars.

Australia needs to develop a considered, consistent and comprehensive biosimilars policy that supports their safe introduction, balanced uptake and appropriate use, as well as builds public and global confidence in a sustainable market.

### Government-initiated Post-market Reviews of PBS Listed Medicines

Recently announced 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; and Post-market Review of Biological Disease Modifying Anti-Rheumatic Drugs (bDMARDs) to treat Severe Chronic Plaque Psoriasis in 2016.<sup>74</sup>

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 assist in the Quality Use of Medicine, in reality, most reviews have focused on cost, and have resulted in price reductions being imposed, predominantly to on-patent medicines. (Price reductions to medicines have been in the order of 40%). While the new PBS Post-Market Review Framework provides industry and stakeholders with more clarity and certainty around processes, timelines and opportunity for input, the cost focus of post-market reviews continues to be a concern.

## **Intellectual Property Protection**

### Market Size Damages

Since announcing its market size damages policy in 2012, innovative pharmaceutical companies engaged in enforcement proceedings began receiving DOH notices of intent to seek damages caused by delayed PBS price reductions. A significant number of those companies received DOH notices *after* the relevant preliminary injunctions were sought *and granted* to enjoin generic companies from launching their products. In addition, these companies could not have foreseen that Australia would take such action because the Government did not previously claim to be a party to those proceedings.

Australia's preliminary injunction policy effectively circumvents the due process afforded to inventors through the patent and court systems by penalizing inventors who have sought to defend their legitimate patent rights in court, which ultimately proved to be unsuccessful. Indeed, the very same government that has granted the patent, issued a preliminary injunction and may have even upheld the patent in the court of first instance, is then seeking damages even if the patent is ultimately not upheld or found not to be infringed. The precedent set by this policy jeopardizes well-accepted principles of

---

<sup>74</sup> See <http://www.pbs.gov.au/info/browse/reviews> (last visited Oct. 27, 2016).

due process and severely discourages innovators from exercising their IP rights. Moreover, this policy contravenes Australia's obligations under TRIPS.

The Australian Patent Office (APO) requires substantive patent examination; the patentee must show it is entitled to a patent. Because of this burden placed on the patentee, one essential component of a granted patent is the presumption of validity – thus providing inventors with a reasonable expectation that they will be able to exclude others from making, using, or selling the relevant technology. This presumption provides the legal and practical certainty required by inventors to carry out costly R&D activities, and to enjoin others from infringing relevant IP rights. The ability to quickly and efficiently enforce IP is especially critical for pharmaceutical innovators. For this reason, courts often employ provisional enforcement measures, e.g. preliminary injunctions, to ensure that patentees do not encounter irreparable harm during the course of a judicial proceeding.

Similarly, biopharmaceutical innovators are severely disadvantaged if they do not seek preliminary injunctive relief in Australia. If a generic product launches, PBS price reduction mechanisms are triggered, thus significantly lowering the PBS price. However, if a court later determines that the generic company infringed the originator's patent, restoring PBS prices to levels prior to generic market entry is at the discretion of the DOH. In other words, there is no legal mechanism or policy that automatically readjusts the PBS price index after a generic product is introduced and subsequently removed from the market.

### Weak Patent Law Enforcement

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

The AUSFTA provides that when marketing approval is sought by an applicant for a generic product or "product for an approved use," where the product or approved use is claimed by a patent, the Party (here, Australia) should "provide measures in its marketing approval process to prevent" marketing of the generic product or use during the patent term without consent or acquiescence of the patent owner. Further, if Australia permits a third party to request marketing approval for a product or approved use claimed by a patent, it "shall provide for notification to the patent owner of such request and the identity of any such other person."

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

There is a serious impact on originator companies from generic medicines entering 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 whether the product is listed on the PBS or available through private prescription. Notification through the intended listing of a generic on the PBS is not sufficient notification of a generic *requesting* marketing approval as required by the AUSFTA because the PBS is not concerned with approval for sale in the Australian market; this is the role of the TGA. Moreover, there is a subset of medicines on the Australian market that will not be listed on the PBS and therefore patent holders of these medicines will not receive the marketing approval notification envisaged in the AUSFTA.

This lack of notification and the unduly prejudicial penalties that can be imposed on patent holders for seeking to defend their IP (including liability for damages as discussed in detail above) significantly weakens an otherwise equitable IP system in Australia. The Australian Government should implement an effective notification system so that patent holders are able to defend their IP in a timely manner and without causing unnecessary delays to generic market entry.

### Productivity Commission

The Australian Government recently commissioned yet another Productivity Commission (Commission) inquiry into Australia's "Intellectual Property Arrangements."<sup>75</sup> The Commission's Draft Inquiry Report 2016 contained a number of draft findings that the industry does not consider appropriate or reasonable, such as calls to restrict patent term restoration in Australia, to allow manufacture for export during the restored patent term, and to redefine inventive step.<sup>76</sup> Medicines Australia appeared before the Commission at a pharmaceutical roundtable and its public

---

<sup>75</sup> See <http://www.pc.gov.au/inquiries/current/intellectual-property#issues> (last visited Oct. 27, 2016).

<sup>76</sup> In June 2016, PhRMA and a number of its international sister associations submitted comments to the Productivity Commission on these and other concerns with the Commission's draft findings, available at <https://drive.google.com/file/d/0B4k-MZcWF-DeU5HOWt2TURFVXM/view> (last visited Oct. 27, 2016).

hearings in June 2016. The Productivity Commission has lodged its report (due September 2016) and industry is awaiting the Australian Government's response.

### Regulatory Data Protection Failures

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate that they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.<sup>77</sup>

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 such data submitted for regulatory approval from unfair commercial use for a period of time. Indeed, TRIPS Article 39.3 requires each WTO member to protect undisclosed test and other data submitted for marketing approval in that country against disclosure and unfair commercial use.

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

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

---

<sup>77</sup> DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016).

## BRAZIL

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

### Key Issues of Concern:

- **Regressive taxes on medicines:** Combined federal and state taxes add up to 38 percent to the cost of medicines in Brazil – one of the highest tax burden on medicines in the world. The innovative pharmaceutical industry supports a proposal under consideration by the Special Committee in the House (PEC 491/11) to eliminate taxes on certain products including medicines.
- **Productive Development Partnerships (PDPs)<sup>78</sup> and government purchasing:** Brazil has developed a new regulatory framework for the establishment of PDPs. While this framework provides improved transparency around PDPs, Brazil still lacks clear rules regarding the purchasing preferences offered to PDPs.
- **Restrictive patentability criteria and procedures:** Amendments to the Brazilian Patent Law in 1999 added Article 229-C, which has been interpreted to inappropriately permit the health regulatory agency, the Brazilian National Health Surveillance Agency (ANVISA) to review all patent applications for pharmaceuticals products and/or processes, resulting in both: i) application of patentability requirements contradictory and/or additive to those established by Brazilian Patent Law and adopted by the Brazilian Patent Authority (INPI); and ii) duplicative, prolonged patent review processes that contribute to the already existing patent backlog that averages more than ten years.
- **Patent backlogs:** Brazil's patent backlog now stretches to ten years or more, hindering innovation, creating uncertainty and significantly raising investment risk.
- **Patent term adjustment for mailbox patents:** Under Patent Law 9,279/96, Brazil provides 20 years of patent protection from the date of filing or a minimum of ten years from the date of patent grant. However, in September 2013, INPI issued a binding opinion followed by the filing of related lawsuits to entirely invalidate or limit the term of approximately 240 so-called "mailbox patents", *i.e.*, patent applications filed after Brazil acceded to the WTO on January 1, 1995, but before the Patent Law went into effect on May 14, 1997. These lawsuits, primarily affecting pharmaceutical patents, are currently proceeding through the

---

<sup>78</sup> The Brazilian PDPs follow the same principles of regular PPP agreements with adaptations designed to respond the specificities of the local pharmaceutical market.

legal system including the Court of Appeals, but most decisions have upheld INPI's retrospective decision to no longer provide a minimum ten years of post-grant patent protection.

- **Regulatory data protection failures:** Although Brazil applies RDP for veterinary and crop products, the same protection is not given to pharmaceutical 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 38% to the price of medicines in Brazil (one of the highest tax burden on medicines in the world). As such, the innovative pharmaceutical industry supports a proposal under consideration by the Special Committee in the House (PEC 491/11) to eliminate taxes on certain products including medicines.

### Government Purchasing and PDPs

The Brazilian Government issued federal Law 12.349/10 granting preferences for locally manufactured products and services in public tenders. 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.

Our members understand the motivation behind the new public purchase policy and believe they can cooperate to improve Brazilian Government conditions to acquire products and services with high quality standards.

Meanwhile, a new PDP regulation (Portaria 2531/14) was issued in 2014 with participation of the private sector, which on its face appears to provide greater transparency and predictability. Recently, the Brazilian Government announced several PDPs under the new regulation. Even still, it remains unclear what criteria were evaluated in assessing and approving these PDPs and the purchasing preferences that will be extended to an approved PDP.

### Regulatory Burden

All participants in the pharmaceutical industry, innovative and generic alike, face numerous challenges stemming from the deadlines currently enforced by ANVISA. While Brazilian legislation adequately addresses ethics, safety and efficacy standards, it

does not provide a mechanism to ensure that ANVISA has adequate capacity to execute its assigned responsibilities. PhRMA and its members commend ANVISA for hiring 280 new technicians and hopes that this will help the agency to reduce review timelines. Other improvements ANVISA should consider include:

- More predictable processes, allowing companies to be prepared in advance, resulting in shorter “clock stops” and faster approvals; and
- Introduction of an expedited process for line extensions (at least similar to the deadline for new products) providing faster access to post-approval innovations.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria and Procedures

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

This “dual examination” is incompatible with Brazil’s obligations under the “anti-discrimination” provisions of Article 27.1 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In addition, ANVISA does not limit its role to the review of the potential sanitary risk aspects of the subject matter of the patent application but also reviews the patentability requirements. ANVISA lacks sufficient technical expertise on patentability and can apply different patentability review standards than INPI, thus generating uncertainty for patent applicants and undermining incentives for innovation.

In October 2009, the Federal Attorney General (AGU Office) issued an opinion that ANVISA’s role in the examination process is limited to health and safety risks. As a result of that opinion, an inter-ministerial group was created to define the correct implementation of the decision released by the AGU Office. The inter-ministerial group recommended that ANVISA should analyze the patent application prior to INPI and only those applications that receive ANVISA’s approval should be submitted to INPI. The patent applications that do not receive ANVISA’s approval are extinguished without the proper examination by the patent authority (INPI), subject to an appeal to the Brazilian Courts.

A number of lawsuits were filed by patent applicants aiming to (i) compel ANVISA to grant prior consent to patent applications and remit those to INPI and (ii) to compel the Brazilian Patent and Trademark Office to immediately start the patentability analysis of the applications. The Federal Court of Appeals in Rio de Janeiro issued an *en banc* decision limiting ANVISA’s role, as requested by the Plaintiffs.

In 2013, ANVISA enacted a new resolution establishing that patent applications considered strategic and of interest to the Brazilian Government will go through a substantive review of the patentability requirements by ANVISA. While Brazilian authorities argue the new administrative rule and flow bring more efficiency to the process, the unduly burdensome “dual examination” process continues to affect IP right holders. The process may have the effect of denying patentability to innovative treatments that meet urgent public health needs, thereby creating disincentives for the launching of innovative products in Brazil. As a result, the local innovative pharmaceutical industry association, Interfarma, has challenged the resolution in court.

In addition, INPI has started blocking patent applications previously reviewed by ANVISA, even though it has said that ANVISA’s review is supplementary and subsidiary to its own patent examination. This has caused additional patent examination delays and highlighted the challenge presented by ANVISA’s resolution.

PhRMA believes that the function of ANVISA in reviewing the health and safety of pharmaceutical products must be distinct from that of INPI which reviews patent applications and prior art to ensure that legal requirements for patent grant are met. We urge that a proper interpretation of 229-C which recognizes the unique role of ANVISA and INPI be implemented, for example as have been put forward by the Office of the Federal General Attorney (see e.g., Opinion No. 210/PGF/AE/2009).

### Patent Backlogs

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

As of August 2016 (the most recent data available), INPI had a backlog of approximately 220,000 applications and estimated that the average time it took to receive a patent for a pharmaceutical product in 2016 is 11 years. Unfortunately, this is a significant increase from the average time for all patent applications of 5.4 years in 2011. Although former President Dilma Rouseff authorized funding and filled new examiner positions (including in the pharmaceutical and biotech fields) to reduce the backlog, the addition of these new examiners has not mitigated the backlog.

The patent backlog for pharmaceutical patents in particular is further exacerbated by ANVISA’s involvement in the “dual examination” process discussed below. ANVISA takes an average of over a year to send a pharmaceutical patent application back to INPI with its decision on whether a patent can be granted.

### Patent Term Adjustment for Mailbox Patents

In September 2013, INPI issued a binding opinion regarding the patent term for patent applications filed between January 1, 1995 and May 14, 1997 (known as “mailbox patents”). Brazilian Patent Law 9,279/96 Article 40 provides that “Patents will be given a 20-year protection from the date of filing” (caput) and “A minimum of ten-year protection will be given from the date of grant” (paragraph one).<sup>79</sup> Per the binding opinion, however, in the event that a company’s patent was filed in Brazil after the country acceded to the WTO on January 1, 1995, but before the Patent Law came into force on May 14, 1997, the application should not have received the minimum ten years of protection from the date that the patent was granted.

Under Brazil’s Patent Law, approximately 250 mailbox patent applications (the majority on pharmaceuticals) were granted a minimum of ten years patent protection under Paragraph One of Article 40. INPI’s September 2013 opinion has the effect of revoking the granted ten-year minimum terms for those mailbox patents. The opinion, however, is not self-executing. As of early 2015, INPI had filed multiple lawsuits in Federal District Courts against the impacted mailbox patent holders seeking to invalidate their patents. Many of those cases are now before the Court of Appeals, which has upheld INPI’s retrospective decision to no longer provide a minimum ten years of post-grant patent protection.

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

### Regulatory Data Protection Failures

Brazilian law (Law 10.603/02) provides data protection for veterinary and crop 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. While some positive steps have been taken to prevent

---

<sup>79</sup> It should be noted that ABIFINA, a Brazilian association representing national companies with chemical interests, including many generics companies, recently filed a legal action in Brazilian court challenging the constitutionality of Brazil’s guarantee of a minimum patent term of ten years for all patents. The ten-year minimum has been critical for biopharmaceutical innovators, particularly in light of INPI’s notorious patent review delays (discussed below). As such, Interfarma, among others, has successfully petitioned to participate in the legal action as *amicus curiae*.

inappropriate disclosure of these data held by the Government, 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, with limited success. 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.

## CANADA

PhRMA and its member companies operating in Canada are extremely concerned about Canada's intellectual property (IP) and market access environment, which continue to be characterized by significant uncertainty and instability for U.S. innovative biopharmaceutical companies. Canada's IP regime lags behind that of other developed nations in several significant respects.

### Key Issues of Concern:

- **Regulatory Barriers to Patient Access to New Medicines:** Bureaucratic barriers exist in Canada that extend the time between submission to the federal government of newly discovered medicines and vaccines for safety approval, and their ultimate availability through public formularies to benefit Canadian patients. This results in significant delays in access to innovative medicines, while also decreasing the time that innovative companies have to recoup their investments.
- **The Patented Medicine Prices Review Board (PMPRB):** In March 2016, the PMPRB initiated a stakeholder consultation on its Strategic Plan for 2015-2018 that contemplates an expansion of its price regulation mandate. Changes in the methodology employed by the PMPRB in its evaluation of "excessive" pricing may have a serious financial impact on U.S. biopharmaceutical companies operating in Canada, and on the potential availability of new medicines to Canadian patients.
- **Restrictive patentability criteria:** Contrary to the Canadian Patent Act (the Act), Canada's treaty obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the North American Free Trade Agreement (NAFTA), and established international norms, the Canadian judiciary has created a new and heightened standard for patentable utility. This standard – referred to as the "promise doctrine" – has resulted in 28 judicial decisions invalidating biopharmaceutical patents, either solely or in part, for lack of utility since 2005.
- **Weak patent enforcement:** The Canadian Patented Medicines (Notice of Compliance) Regulations include several key deficiencies that weaken Canada's enforcement of patents, including the nature of patent dispute proceedings, lack of effective right of appeal for patent owners, and limitations and inequitable eligibility requirements on the listing of patents in the Patent Register. Recent jurisprudence under the regulations has also resulted in a heightened level of liability for patent owners akin to punitive damages.
- **Lack of patent term restoration:** Canada's IP regime currently provides no form of patent term restoration (PTR). PhRMA member companies believe Canada should support innovation by adopting a PTR system consistent with the U.S. and other developed nations to ameliorate the effects of delays caused by its

regulatory processes, which can significantly erode the duration of the IP rights of innovators.

- **Standard for the disclosure of confidential business information:** In November 2014, Canada enacted legislation to update its Food and Drugs Act (Bill C-17). Provisions in that law granted the Health Minister discretion to disclose a company's confidential business information (CBI) without notice to the owner of the CBI and in accordance with a standard that is both inconsistent with other similar Canadian legislation and Canada's treaty obligations under NAFTA and TRIPS.

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**

### Regulatory Barriers to Patient Access to New Medicines

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

At present, it takes an average of 449 days after Health Canada approval before a patient can access a new medicine through a Canadian public drug plan<sup>80</sup>. This delays access to the benefits of new medicines and vaccines for Canadian citizens, and also erodes the already limited time that innovative companies have to recoup their significant investments in R&D, clinical trials and regulatory approval processes. PhRMA members urge the U.S. Government to engage with the Government of Canada departments and agencies, appealing to them to review their drug evaluation and approval processes with a view to finding efficiencies and reducing duplication in order to improve patient access to new medicines.

### The Patented Medicine Prices Review Board (PMPRB)

The PMPRB is an independent quasi-judicial body, created under the Canadian Patent Act,<sup>81</sup> with a mandate to ensure that prices charged for patented medicines sold in Canada are not excessive. It does so by regulating the "ceiling price" – the maximum allowable price – for a patented medicine according to established policies, regulations and guidelines.

---

<sup>80</sup> <http://innovativemedicines.ca/canadians-facing-delayed-access-to-new-innovative-medicines-report/>

<sup>81</sup> *Patent Act*, R.S.C. 1985, c.P-4, ss.79-103.

In December 2015, the PMPRB released a three-year Strategic Plan that strongly suggests the prices of patented medicines in Canada are too high and need to be regulated downward for all three customer markets: publicly-insured, privately-insured and cash-paying.<sup>82</sup> PMPRB has undertaken a stakeholder consultation regarding its proposition to change pricing guidelines and/or regulations, as well as a proposed expansion of its current mandate from ensuring “*non-excessive*” pricing to ensuring “*affordable*” pricing. These contemplated changes could negatively impact the innovative pharmaceutical industry and the availability of new medicines to Canadian patients.

Specifically, the PMPRB has proposed changes to how price ceilings are determined for patented medicines in Canada on the basis of international comparators. The PMPRB currently exercises its statutory mandate by setting ceiling prices for all patented medicines. Through a variety of mechanisms, such as the Canadian Agency for Drugs and Technologies in Health, the Common Drug Review, the pan-Canadian Pharmaceutical Alliance and Product Listing Agreements, industry and public payers have effectively addressed the affordability of medicines. As a result, any expansion of the PMPRB’s mandate would appear to be both unnecessary and potentially harmful to U.S. innovative biopharmaceutical companies through additional downward pricing pressures.

PhRMA recommends that the U.S. Government urge the Canadian Government to prevent changes to the PMPRB’s mandate that would harm U.S. innovative biopharmaceutical companies and undermine the competitiveness of Canada’s innovative medicines sector. Canada should ensure a fair and impartial consultation of the PMPRB Strategic Plan. Any PMPRB mandate changes should be based on a complete and accurate picture of where and how life science investments are taking place in Canada, and should ensure that the PMPRB’s role is placed in its proper context with the many other price regulating agencies already active in the Canadian pharmaceutical marketplace.

The PMPRB is also required to report to the Federal Minister of Health on pharmaceutical trends and on research and development (R&D) spending by pharmaceutical patentees. Due to the antiquated 1987 tax law formula used to measure R&D spending included in its governing regulations, PMPRB has consistently and systematically underreported the R&D levels of U.S. 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 of issues described above. To the extent that PMPRB should have a mandate to report on R&D spending in Canada, PhRMA members urge the U.S. Government to encourage the Government of Canada to update the regulatory R&D definition in order that the PMPRB can more accurately calculate the significant R&D contributions made by pharmaceutical patentees to the Canadian economy.

---

<sup>82</sup> Patented Medicine Pricing Review Board, “Strategic Plan 2015-2018”, available at [http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/StrategicPlan/Strategic\\_Plan\\_2015-2018\\_en.PDF](http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/StrategicPlan/Strategic_Plan_2015-2018_en.PDF) (last visited Oct. 27, 2016).

## Intellectual Property Protection

### Restrictive Patentability Criteria

PhRMA members are extremely concerned that decisions by the Canadian judiciary have created a new and heightened requirement for patentable utility for pharmaceutical patents that is both inconsistent with common law and practice in other major countries and unpredictable in practice. This heightened standard has done great damage to the patent rights of innovative pharmaceutical companies.<sup>83</sup> While it was once unheard of for a pharmaceutical patent to be judicially invalidated for lack of utility, 28 decisions invalidating pharmaceutical patents, either solely or in part, for lack of utility have been issued since 2005 when the doctrine began to emerge in Canadian Federal Court jurisprudence. It is also inconsistent with Canada's international trade treaty obligations because it: (i) imposes onerous and unjustified patentability criteria, narrowing the scope of inventions that receive patent protection; and (ii) discriminates against innovative pharmaceutical products, as this additional requirement has disproportionately impacted pharmaceutical patents. Furthermore, as a result of mixed and conflicting case law from the Canadian court system on this new and heightened utility requirement, it is unclear precisely what standard must be met by innovators in order to address the issue and safeguard their IP. This issue must be addressed given that it undermines the ability of innovative pharmaceutical companies to enforce and defend their existing patents in the court system, and also limits their ability to obtain new patents from the Canadian Intellectual Property Office, which has incorporated this standard into its patent practice manual.

In Canada, “[w]here the specification does not promise a specific result, no particular level of utility is required; a ‘mere scintilla’ of utility will suffice. However, where the specification sets out an explicit ‘promise’, utility will be measured against that promise. The question is whether the invention does what the patent promises it will

---

<sup>83</sup> See, e.g., *Merck & Co. Inc. v. Apotex Inc.*, 2005 FC 755; *Abbott Labs. v. Canada (Minister of Health)*, 2005 FC 1095; *Abbott Labs. v. Canada (Minister of Health)*, 2005 FC 1332, aff'd 2007 FCA 153; *Aventis Pharma Inc. v. Apotex Inc.*, 2005 FC 1283, aff'd 2006 FCA 64; *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, aff'd 2007 FCA 195; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, aff'd 2009 FCA 97; *Shire Biochem Inc. v. Canada (Minister of Health)*, 2008 FC 538; *Glaxosmithkline Inc. v. Pharmascience Inc.*, 2008 FC 593; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 FC 235; *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676, aff'd 2011 FCA 300; *Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711, aff'd 2010 FCA 204; *Lundbeck Canada Inc. v. Ratiopharm Inc.*, 2009 FC 1102; *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.*, 2010 FC 230; *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714; *Eli Lilly and Co. v. Teva Canada Ltd.*, 2010 FC 915, aff'd 2011 FCA 220; *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, rev'g 2010 FC 447; *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 FC 1288, aff'd 2012 FCA 232; *Pfizer Canada Inc. v. Pharmascience Inc.*, 2013 FC 120; *Novartis Pharms. Canada Inc. v. Teva Canada Limited*, 2013 FC 283; *Alcon Canada Inc. v. Cobalt Pharms. Co.*, 2014 FC 149; *Pharmascience Inc. v. AstraZeneca Canada Inc.*, 2014 FCA 133, rev'g 2012 FC 1189; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638, aff'd 2015 FCA 158; *Eli Lilly Canada Inc. v. Mylan Pharms.*, 2015 FC 125; *Servier Canada Inc. v. Apotex Inc.*, 2015 FC 108; *Gilead Sciences v. Idenix Pharms.*, 2015 FC 1156; *Eli Lilly Canada Inc. v. Hospira*, 2016 FC 47; *Eli Lilly Canada Inc. v. Hospira*, 2016 FC 47; *Allergan Inc. v. Apotex Inc.*, 2016 FC 344.

do.”<sup>84</sup> In other words, pharmaceutical innovators in Canada are being required to “demonstrate” or “soundly predict” the utility of a pharmaceutical as “promised” at the time of filing the patent application, rather than simply show that their inventions have a “scintilla of utility”, in order to be considered patentable. Furthermore, the existence and terms of the “promise” are construed by the court. In *Eli Lilly v. Novopharm*, for example, the Court construed that there was a promise in the patent application and that the promise was the clinical treatment of schizophrenia with a better side-effect profile and activity at lower doses. The Court held that because schizophrenia is a chronic condition, the applicant should have filed studies or evidence showing the efficacy of the medicine *over the long term* at the time of filing the patent application. Such a standard is fundamentally inconsistent with TRIPS and NAFTA, as well as the realities of the R&D timeline for pharmaceuticals. To meet the utility requirement, TRIPS and all other developed countries require only that an invention be “useful” or “capable of industrial application.” It is not reasonable or financially feasible to require pharmaceutical firms to undertake substantial risks and invest substantial resources in clinical drug development before a patent application is even filed. Canada’s “promise doctrine” discourages the investment of significant resources to develop new medicines and, in the long run, negatively affects the patients and families who rely upon our sector for innovations leading to new cures and treatments.

In April 2015, the WTO released a Trade Policy Review (TPR) Secretariat Report on Canada, which noted: “In particular, in a number of cases over the review period, courts have continued to develop the Canadian legal doctrine that the ‘promise of the patent’ . . . has to be demonstrated or soundly predicted on the basis of information disclosed in the patent application at the filing date.”<sup>85</sup> A number of Canada’s trading partners, including the United States, raised issues with Canada’s utility standards in their submissions to the TPR.

In light of the ongoing unpredictability of the promise doctrine case law, PhRMA members urge the U.S. Government to press the Government of Canada to resolve this issue through, for example, clarifying amendments to the Patent Act. The promise doctrine effectively imposes a higher utility standard to the patentability of pharmaceutical inventions than to other inventions. TRIPS requires that there be no discrimination as to the field of technology. Furthermore, this heightened utility standard is fundamentally incompatible with the realities of pharmaceutical development, and is causing significant commercial uncertainty for U.S. pharmaceutical companies operating in Canada.

### Weak Patent Enforcement

In 1993, the Patented Medicines (Notice of Compliance) Regulations (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

---

<sup>84</sup> *Eli Lilly Canada Inc. v. Novopharm*, 2010 FCA 197 at ¶ 76.

<sup>85</sup> See [https://www.wto.org/english/tratop\\_e/tpr\\_e/s314\\_e.pdf](https://www.wto.org/english/tratop_e/tpr_e/s314_e.pdf) at p.104 (last visited Oct. 27, 2016).

“early working” exception. Despite these challenges, PhRMA acknowledges that, in 2015, the Canadian government helped resolve a significant issue related to inappropriate court decisions that prevented the listing of patents relevant to combination inventions, seriously undermining patent enforcement actions relevant to those inventions. However, serious and systemic deficiencies remain with the PM (NOC) Regulations that need to be addressed. There is ample evidence that the PM (NOC) Regulations do not reliably provide “expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements,” as required under the TRIPS Agreement and NAFTA. For example:

#### 1. Proceedings under the PM (NOC) Regulations

With respect to patents that are listed on the Patent Register, when a generic producer files an Abbreviated New Drug Submission seeking marketing approval on the basis of a comparison to an already approved brand-name product, it must address any such listed patents that are relevant. In doing so, the generic producer may make an allegation that patents are not valid or will not be infringed. It must notify the patent owner of any such allegation. The patent owner then has a right to initiate judicial procedures to challenge any such allegation. If procedures are triggered, approval of the generic drug is stayed for a maximum period of up to 24 months pending judicial review.

In the United States, such a challenge to an allegation of non-infringement or patent invalidity proceeds as a full action for infringement on the merits. However, under the Canadian PM (NOC) Regulations, a challenge proceeds by way of summary judicial review aimed only at determining if the allegation is “justified.” As a result of the summary nature of the proceeding, there is no discovery and there may be constraints on obtaining and introducing evidence and cross-examination. This, in combination with various other limitations and shortcomings discussed below, can make it difficult for the patent owner to prove its case.

#### 2. No Effective Right of Appeal in PM (NOC) Proceedings

The restrictive nature of the PM (NOC) regime means that a patent owner, unlike a generic drug producer, does not have an effective right of appeal. This is because the PM (NOC) Regulations provide that a generic product may be approved for marketing (through the issuance of a Notice of Compliance, or “NOC”) following a decision by the Court in the first instance in favor of the generic producer; and because the regulations only allow for the prohibition against the issuance of a NOC and not its revocation, once the NOC issues, an appeal filed by the patent owner becomes moot.<sup>86</sup> The patent owner is then left with no alternative but to start a new proceeding outside of the framework of the PM (NOC) Regulations, *i.e.*, commencing an action for patent infringement once the generic product enters the market, essentially having to restart a case it had already spent up to two years litigating under the Regulations. Moreover,

---

<sup>86</sup> *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

irreparable harm often results by the time the patent owner obtains a favorable decision in such a separate infringement case.

In contrast, a right of appeal is available to the generic under the PM (NOC) Regulations if the patent owner prevails in the first instance. PhRMA member companies ask that the U.S. Government strongly encourage Canadian authorities to rectify this fundamental, discriminatory, and unjustifiable imbalance in legal rights and due process in a way that will ensure there is a meaningful and effective right of appeal for patent owners while maintaining other patent enforcement tools.

While a patent owner may separately choose to proceed later by way of a patent infringement action, and may apply for an interlocutory injunction to maintain its patent rights and to prevent the market entry of the generic product or to seek its withdrawal from the market, these interlocutory injunction motions rarely succeed in Canada even if there is compelling evidence of infringement.

Additionally, it often takes at least two years before an action for patent infringement is tried, and far longer to obtain damages once a generic has been successfully sued for infringement.<sup>87</sup> By then, the innovative company's market share can be almost completely eroded by the marketing of the generic product. Provincial and private payer policies mandating the substitution of generics for brand-name products guarantee rapid market loss.

These various deficiencies frequently result in violations of the patent rights of PhRMA member companies operating in Canada with attendant, and often irreparable, economic losses.

PhRMA understands that the unratified final text of the Comprehensive Economic Trade Agreement (CETA)<sup>88</sup> negotiated between Canada and the European Union contains a commitment to provide all litigants equivalent and effective rights of appeal, but the Canadian government has yet to provide any clarity with respect to how it will implement this commitment. PhRMA therefore will be closely monitoring the implementation of this commitment to ensure that the Government of Canada rectifies these issues through appropriate legislative or regulatory changes. In particular, it is imperative that PhRMA members have meaningful and effective patent protection under either the PM (NOC) Regulations or alternative procedures and remedies without limiting or otherwise prejudicing existing rights under the regulations.

---

<sup>87</sup> For example, on July 16, 2013, the Federal Court released a decision granting the largest award of damages for patent infringement in Canadian history. *Merck & Co., Inc. v. Apotex Inc.* (2013 FC 751) ("Merck"). While the award quantum was widely reported, less reported was the fact that the case dated back to 1993 when Apotex first served a Notice of Allegation in which it undertook not to infringe Merck's patent if it obtained a Notice of Compliance (NOC). This judgment has also been appealed, further delaying any eventual damages award.

<sup>88</sup> See CETA, Final Text as of Sept. 26, 2014, as published by the European Commission, available at [http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc\\_152806.pdf](http://trade.ec.europa.eu/doclib/docs/2014/september/tradoc_152806.pdf) (last visited Oct. 27, 2016).

### 3. 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.

PhRMA members are pleased that the Government of Canada recently amended the PM (NOC) Regulations to address recent jurisprudence which held that an innovator cannot list a patent claiming a single medicinal ingredient of a Fixed Dose Combination (FDC) product on the Patent Register.<sup>89</sup> These judicial interpretations were contrary to Health Canada's long standing policy, as set out in the Health Canada Guidance Document, which explicitly allows for such a practice.<sup>90</sup> These amendments restore certainty with respect to the listing criteria for patents on FDC products, which otherwise would not have been eligible to obtain the benefits of the PM (NOC) Regulations.<sup>91</sup>

### 4. Heightened Level of Liability for Lost Generic Profits

The PM (NOC) Regulations allow an innovator to seek an order preventing a generic manufacturer from obtaining Notice of Compliance, on the basis that the innovator's patent covers the product and is valid. When the innovator seeks such an order, but is ultimately unsuccessful, Section 8 provides the generic manufacturer the right to claim damages in the form of lost profits for the period of time they could have been selling the product, but for the innovator's action.

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

The SCC 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

---

<sup>89</sup> The three decisions from which this issue arose are: *Gilead Sciences Inc. v. Canada (Minister of Health)*, 2012 FCA 254; *ViiV Healthcare ULC v. Teva Canada Ltd. et al.*, 2014 FC 328; and *ViiV Healthcare ULC v. Apotex Inc. et al.*, 2104 FC 893. ViiV has appealed these decisions.

<sup>90</sup> See [http://www.hc-sc.gc.ca/dhp-mpps/alt\\_formats/pdf/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3\\_mbreg3-eng.pdf](http://www.hc-sc.gc.ca/dhp-mpps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/patmedbrev/pmreg3_mbreg3-eng.pdf) (last visited Oct. 27, 2016).

<sup>91</sup> See <http://canadagazette.gc.ca/rp-pr/p2/2015/2015-07-01/html/sor-dors169-eng.php> (last visited Oct. 27, 2016).

reasons of the majority in the Federal Court of Appeal.<sup>92</sup> 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. Therefore PhRMA members request that the U.S. Government urge Canada to implement amendments to the PM (NOC) Regulations to address this issue.

### Lack of Patent Term Restoration

Patent Term Restoration (PTR) provides additional patent life 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. Canada's IP regime includes no form of PTR system.

PhRMA member companies believe Canada should support innovation by adopting PTR to ameliorate the effects of delays caused by its regulatory processes.

PhRMA members urge the U.S. Government to engage with the Government of Canada on this issue, and encourage Canada to join the ranks of other industrialized countries who are champions of IP protection internationally and to provide for PTR measures in Canada. The unratified final CETA text indicates that Canada has agreed to implement a "*sui generis* protection" period of between 2 to 5 years (noting, however, that the Government of Canada has separately stated that it only plans to implement the minimum level of 2 years required by CETA).<sup>93</sup> Steps taken by Canada to implement meaningful protection that is equivalent in duration and effectiveness to the PTR regimes in the U.S. and in other developed nations (*e.g.*, up to 5 years) would constitute an important positive precedent. PhRMA is also concerned that the *sui generis* protection will not grant the full patent protections that PTR is intended to provide, *i.e.*, may be implemented at the expense of other patent rights for innovators. Any implementation of PTR that does not confer full patent rights, *e.g.*, that would provide an exception for "manufacturing for export" or other infringing activities, would not be consistent with the fundamental purpose of restoring patent term lost due to marketing approval delays and should be avoided.

---

<sup>92</sup> *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. 27, 2016).

<sup>93</sup> See <http://international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/understanding-comprendre/technical-technique.aspx?lang=eng#p5> (last visited Oct. 27, 2016).

## Standard for the Disclosure of Confidential Business Information

PhRMA members are concerned with provisions of the recently enacted Bill C-17, An Act to Amend the Food and Drugs Act,<sup>94</sup> which could allow for an unprecedented disclosure of CBI contained in clinical trial and other data submitted by pharmaceutical companies to Health Canada in the course of seeking regulatory approval for medicines. The amendments could significantly impact incentives for drug innovation and are inconsistent with Canada's international treaty obligations.

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

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

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

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

---

<sup>94</sup> See

<http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6676418&File=4> (last visited Oct. 27, 2016).

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.<sup>95</sup> PhRMA and its member companies are pleased that the document provides some reassurances with respect to the administration of Health Canada's new powers under Bill-C17. However, the document is a non-binding guidance as opposed to binding law or regulations, and as such Health Canada has the discretion not to follow its requirements, and it is also potentially vulnerable to future legal challenges.

In September 2015, a pharmaceutical company was subjected to a disclosure by Health Canada of CBI related to its pharmaceutical product, representing the first known usage of the new legislative disclosure powers. Following a request made under the new mechanisms in the *Food and Drugs Act*, approximately 35,000 pages of raw trial data were released, demonstrating the potential prejudice to U.S. innovative biopharmaceutical companies that could result from future CBI disclosures.<sup>96</sup>

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

---

<sup>95</sup> 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. 27, 2016).

<sup>96</sup> 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. 27, 2016); 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. 27, 2016).

## THE PEOPLE'S REPUBLIC OF CHINA

PhRMA and its member companies operating in The People's Republic of China are committed to supporting the government's efforts to build a patient-centered and pro-innovation healthcare system. China is taking important steps to strengthen its regulatory framework and to enhance government reimbursement for innovative medicines. However, we remain concerned about restrictive government pricing policies, delayed government reimbursement, the lengthy and non-transparent regulatory approval process, the lack of effective regulatory data protection and patent enforcement, inconsistent patent examination guidelines, rampant counterfeiting of medicines, and under-regulated active pharmaceutical ingredients.

PhRMA is particularly concerned by the China Food and Drug Administration (CFDA) draft "Announcement Concerning the Undertaking on the Sales Price of Newly Marketed Drugs" ("CFDA Price Commitment") circulated on April 1, 2016. The Price Commitment policy proposal would make price concessions a pre-condition for marketing approval of new drugs, require that the price in China be no higher than price in the drug's country of origin or in select neighboring markets and publish the price after the drug is approved for marketing. Linking regulatory approval with pricing decisions is inconsistent with international, science-based regulatory standards and risks distorting regulatory science decisions with budgetary considerations. Such a fundamental change to China's regulatory framework would discourage the introduction of the newest and most innovative treatments in China, further delaying Chinese patient access and undermining China's goals to integrate into global biopharmaceutical research and development (R&D) system.

PhRMA is encouraged by China's ongoing work to amend the Drug Administration Law (DAL) and Drug Registration Regulation (DRR) as well as update the National Reimbursement Drug List (NRDL), as this provides a critical opportunity to enhance patient access to innovative medicines and address many of the following issues of concern. PhRMA is eager to continue supporting China in this reform effort and urges reforms that strengthen regulatory data protection, patent enforcement and patent examination guidelines, accelerate and simplify the regulatory approval process, and reduce the out-of-pocket cost burden for patients. In addition, PhRMA urges China to establish a comprehensive and sustainable policy framework for government pricing and reimbursement that would include predictable and timely reimbursement decisions for new drugs, systematic and transparent mechanisms for price negotiation linked to reimbursement, and an enhanced role for commercial health insurance.

### **Key Issues of Concern:**

- **Government pricing and reimbursement:** The National Reimbursement Drug List (NRDL) has not been updated since 2009. The lengthy process for updating the NRDL delays market access to innovative pharmaceuticals and prevents their timely availability to patients. PhRMA is encouraged by the recent announcement that the NRDL will be updated by the end of 2016. However,

Chinese patients would best be served by a model that allows new drugs to be reviewed for government reimbursement on a regular, or rolling, basis. In addition, lack of stakeholder engagement in the development of new government pricing policies and procedures has created an uncertain business environment and could reduce the reward for innovation, restrict patient access to high-quality medicines and undermine China's healthcare reform and innovation policy objectives. PhRMA is particularly concerned with the CFDA draft Price Commitment policy proposal.

- **Regulatory approval process:** The process for approving a medicine in China takes much longer than international practice and the CFDA policy regarding the acceptance of multi-regional clinical trial (MRCT) data is further extending this timeline. Accelerating the regulatory approval process will improve the efficiency of global drug development and reduce the time it takes for innovative new medicines to reach Chinese patients. While PhRMA is encouraged by commitments in the 2014 U.S.-China Joint Commission on Commerce and Trade (JCCT) and some aspects of the July 2016 draft amendment to the DRR, we are concerned that CFDA's ongoing drug reform is not fully transparent and some proposed measures are inconsistent with international standards.
- **Restrictive patentability criteria:** In December 2013, China announced that SIPO will "permit patent applicants to file additional data after filing their patent applications, and that the Guidelines are subject to Article 84 of the Law on Legislation, to ensure that pharmaceutical inventions receive patent protection".<sup>97</sup> PhRMA recognizes and welcomes this positive step, but uncertainty remains as to when such data will be accepted. PhRMA is also concerned that the State Intellectual Property Office (SIPO) appears to be imposing new – and unfair or inappropriate – limitations on the use of post-filing data to satisfy inventive step requirements.
- **Weak patent enforcement:** Transparent mechanisms are needed in China to ensure that patents are linked to regulatory approval and to ensure patent disputes are resolved before potentially infringing pharmaceutical products are launched on the market. Neither China's DAL nor the DRR provide an effective mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products and the proposed DRR revisions would eliminate the existing weak mechanism.
- **Regulatory data protection failures:** China committed as part of its accession to the World Trade Organization (WTO) to provide a 6-year period of regulatory data protection (RDP) against unfair commercial use for clinical test and other data submitted to secure approval of products containing a new chemical

---

<sup>97</sup> The White House, Joint Fact Sheet on Strengthening U.S.-China Economic Relations, Dec. 5, 2013, available at <https://www.whitehouse.gov/the-press-office/2013/12/05/joint-fact-sheet-strengthening-us-china-economic-relations> (last visited Oct. 27, 2016).

ingredient. In practice, however, China's RDP system is not effective. Furthermore, the lack of provisions on RDP in the revised draft amendment to the DRR undermines China's WTO obligations and its existing commitment to RDP under the DAL Implementation Regulation. PhRMA is also concerned that the February 2016 CFDA "Chemical Drug Registration Category Work Plan," which defines a "new drug" as a chemical entity that is "new to the world," creates a risk that a drug approved or marketed first outside of China would not be eligible for data protection in China, and may thus potentially impact China's 2012 JCCT RDP commitment.

- **Counterfeit medicines:** China has been implementing national plans to improve drug safety and severely crack down on the production and sale of counterfeit medicines, resulting in several positive and tangible actions on the enforcement front. However, the production, distribution and sale of counterfeit medicines and unregulated APIs remain rampant in China and continue to pose a threat to China and its trading partners. PhRMA looks forward to meaningful implementation of China's commitment made during the sixth meeting of the U.S.-China Strategic and Economic Dialogue (S&ED) in July 2014 related to effective regulatory control of APIs and anti-counterfeiting.

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

#### *Government Reimbursement List*

Once drug approval is achieved in China, patients must often wait an additional six years or more<sup>98</sup> before they receive access through national reimbursement. Over the past twelve years, the Government of China has only undertaken two substantive updates (2004 and 2009) to the NRDL. The lengthy process for updating the NRDL delays market access to innovative pharmaceuticals and prevents their timely

---

<sup>98</sup> IMS Consulting Group, *China Drug Lag and the Impact of Reimbursement Delays* (July 2014).

availability to patients. PhRMA recommends an accelerated update to the NRDL and provincial reimbursement drug list (PRDL) followed by the establishment of a transparent, predictable, and regular reimbursement review – for example, on an annual basis. A regular review would significantly improve patient access to innovative medicines, remove the ambiguity of when a formal update will occur, and provide a more stable business environment.

On September 30, 2016, the Ministry of Human Resources and Social Security (MOHRSS) released a draft “Work Plan for Adjusting National Reimbursement Drug List of National Basic Medical Insurance, Employment Injury Insurance and Maternity Insurance in 2016.” PhRMA is encouraged by the Work Plan’s aim to update the NRDL by the end of 2016 and to establish a regular adjustment mechanism for the NRDL in 2017. We appreciate the opportunity to comment on the draft Work Plan, but are concerned that MOHRSS only provided a 13-day comment period, (which runs afoul of China’s international commitments to provide reasonable consultation periods). Furthermore, the draft Work Plan does not provide sufficient detail in a number of key areas, including the process for generating the list of medicines to be evaluated by consultant experts, the criteria used to evaluate the list, and opportunities for industry to provide input on the evaluations and selections of the medicines.

### *Government Pricing Policies*

China, as part of its WTO accession, committed to apply price controls in a WTO-consistent fashion, taking into account the interests of exporting WTO members, and without having the effect of limiting or impairing China’s market access commitments on goods and services.<sup>99</sup> Notwithstanding that commitment, PhRMA is concerned that reforms to China’s government pricing mechanisms have created an uncertain business environment and could further reduce reward for innovation, restrict patient access to high-quality medicines and undermine China’s healthcare reform and innovation policy objectives.

In particular, PhRMA is concerned by the CFDA draft Price Commitment policy proposal, which would make price concessions a pre-condition for marketing approval of new drugs, require that the price in China be no higher than price in the drug’s country of origin or in select neighboring markets and publish the price after the drug is approved for marketing. Linking regulatory approval with pricing decisions is inconsistent with international, science-based regulatory standards and risks distorting regulatory science decisions with budgetary considerations. Such a fundamental change to China’s regulatory framework would discourage the introduction of the newest and most innovative treatments in China, further delaying Chinese patient access and undermining China’s goals to integrate into global biopharmaceutical research and development (R&D) system.

---

<sup>99</sup> Report of the Working Party on the Accession of China to the World Trade Organization, WT/MIN(01)/3 (Nov. 10, 2001), at para. 64.

PhRMA is also seeking additional detail regarding the National Health and Family Planning Commission (NHFPC) national price negotiation pilot program for patented drugs. PhRMA encourages the Chinese Government to engage innovative pharmaceutical companies to evaluate and implement a transparent and appropriate government pricing policy that recognizes quality-systems, innovation, and the value that our member companies' products bring to patients and China.

### Regulatory Approval Process

China is making significant strides in reforming and strengthening its regulatory framework, but remains an outlier in the drug approval process, with new medicines typically taking four to six years longer to reach the China market than other major markets.<sup>100</sup>

#### *Clinical Trials Applications (CTAs)*

Approval of clinical trial applications in China takes much longer than in other countries and is a major contributor to the lengthy drug approval timeline. A late 2013 policy change regarding the acceptance of MRCT data has further extended the drug approval timeline. This policy change is contrary to CFDA's stated goals to promote innovation and harmonize its regulatory framework with international standards. Overall, the lengthy CTA approval process is impeding patient access to new innovative medicines and is a significant barrier to global drug development.

To help China further integrate into the global innovation network and reduce the time it takes for innovative medicines to reach patients, steps should be taken to shorten the CTA review and approval timeline. Underlying the CTA delay is a misalignment between CFDA human resource capacity and capability. PhRMA recognizes and applauds the important steps CFDA is taking to enhance agency capacity and capability by encouraging investment in additional resources and trained evaluators. Based on PhRMA member company experience in other major markets, there should be specific timelines for reviewing and approving applications. In addition, applications should be evaluated based on a clear set of standardized criteria that applies equally to both local and foreign manufacturers. Clear timelines and criteria for the review and approval of applications would support CFDA goals to enhance efficiency and instill predictability in to the regulatory system,

Specifically, we are encouraged that the 2014 JCCT commitments support the use of MRCT as a viable pathway to drug development in China and the implementation of new measures to reform the Certificate of Pharmaceutical Product (CPP) requirements. We are also encouraged that the draft amendment to the DRR indicates an intent to abolish unnecessary distinctions between foreign and domestic applicants and the use of MRCT versus a purely local trial in China to support marketing

---

<sup>100</sup> Liberti, et al., Center for Innovation in Regulatory Sciences. *Characterizing the Influencers of Submission Lag Time for Medicines in the Emerging Markets* (August, 2012).

applications. These actions would allow for drug development in China to occur simultaneously with global drug development. To ensure accelerated patient access to innovative treatments, China should take immediate steps to implement these important commitments and to explicitly abolish in the DRR the three-submission, three-approval system for MRCT-based registration applications.

### *Drug Approvals Process*

PhRMA welcomes the 2014 JCCT commitments and many recent steps by CFDA to reduce the drug application backlog and streamline the review and approval system for new innovative medicines. PhRMA is eager to support CFDA's drug reform efforts, but is concerned that certain measures are inconsistent with international standards and implementation of those measures is not fully transparent.

To ensure Chinese patients receive timely access to new therapies and Chinese companies have the ability to compete globally, PhRMA recommends that the CFDA bring its regulatory framework into compliance with accepted international standards and adopt science-based, transparent, consistent and predictable policies for evaluating and approving drugs and biologics. PhRMA recommends revisions to the DAL and DRR that accelerate and simplify the drug regulatory approval process, provide the same requirements for locally manufactured and imported products and clearly outline the criteria and timeline for reviewing and approving clinical trial and marketing application processes. PhRMA and its members stand ready and look forward to working closely with the U.S. and Chinese governments to support China's regulatory reform efforts.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

Pursuant to the 2006 patent examination guidelines,<sup>101</sup> SIPO had been requiring a significant amount of biological data to support pharmaceutical patent applications submitted pursuant to Article 26.3 of China's Patent Law. Article 26.3 provides that the application must include a "clear and comprehensive description of the invention or utility model so that a technician in the field of the relevant technology can carry it out."<sup>102</sup> This is similar to provisions in U.S. patent law, the European Patent Convention, and Japanese patent law, as well as the Patent Cooperation Treaty (PCT).<sup>103</sup>

In 2006, however, SIPO's examination guidelines were amended regarding the technical patent disclosure requirement for pharmaceutical compounds (though the Patent Law was not changed), causing examiners to require a significant amount of

---

<sup>101</sup> See Guidelines for Patent Examination, State Intellectual Property Office (2010), Rule 17.

<sup>102</sup> Patent Law of the People's Republic of China (SIPO translation), Article 26, available at [http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119\\_566244.html](http://english.sipo.gov.cn/laws/lawsregulations/201101/t20110119_566244.html) (last visited Oct. 27, 2016).

<sup>103</sup> Patent Cooperation Treaty, 28 U.S.T. 7645 (1970), Art. 28.

experimental data to satisfy Article 26.3. This generally meant that data on the biological activity of the compounds needed to be included in the patent specification as filed. Further, this guideline was being applied to applications filed and even granted before the new standard was adopted. This requirement to disclose experimental data at the time of filing placed a much larger burden on companies than faced in the other IP5 Member States (*i.e.*, the United States, the European Union, Japan, and Korea) and belied the timeline realities of pharmaceutical drug development. Moreover, in contrast with the practices of the U.S. Patent and Trademark Office, Japan Patent Office, and European Patent Office, as well as the standard provided by the PCT (of which China is a member), under these guidelines, SIPO would not accept data generated after the patent application was filed to support patentability during patent prosecution. The adoption and implementation of this 2006 guideline caused concerns about the validity of existing patents granted prior to 2006 and caused denials of patents to medicines that had received patents in other jurisdictions.

It should also be noted that SIPO has been imposing unfair or inappropriate limitations on the use of post-filing data to satisfy inventive step requirements under Article 22.3 of China's Patent Law. In practice, SIPO does not consistently accept experimental data after the filing date of pharmaceutical patent applications that would ordinarily be provided to establish inventive step. In other cases, SIPO may accept experimental data during patent prosecution, but not if the data was created after the filing date. These practices cause significant uncertainty about the ability to obtain and maintain pharmaceutical patents in China when patents have been granted on those same inventions in other jurisdictions.

In December 2013, China committed through the JCCT to change its patent examination guidelines regarding technical patent disclosure requirements for pharmaceutical compounds to allow patent applicants to file additional biological data after filing their applications. This JCCT commitment is a critical step in the right direction, but implementation is essential. China's commitment should be executed publicly in writing, and in a manner that is binding on Chinese patent examiners, patent appellate bodies and the courts. Further, for meaningful implementation, China must ensure that patent applications filed prior to 2006 are not being opposed based on retroactively applied standards, and that patent applications that were adversely affected prior to this commitment are reinstated. The JCCT commitment speaks broadly to the acceptance of post-filing, or supplemental, data, and should, therefore, address the inventive step issue as well. PhRMA appreciates the ongoing technical discussions between the U.S. and Chinese governments on the supplementation of data and welcomes the commitment by both sides in the 2014 JCCT to continue exchanges and engagement on specific cases. Like the 2013 commitment, implementation and follow-through is critically important. Uncertainty remains as to when such data will be accepted. Issuance of new patent examination guidelines with examples would be a good way to resolve this uncertainty.

## Weak Patent Enforcement

If a follow-on company actually begins to market a drug that infringes the innovator's patents, the damage to the innovator may be irreparable even if the innovator later wins its patent litigation. This could undermine the goal of encouraging innovation in China. In fact, CFDA has approved infringing follow-on products, and research-based pharmaceutical companies have not been able to consistently resolve patent disputes prior to 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. Transparent mechanisms are therefore needed in China to ensure that patent issues can be resolved before potentially infringing pharmaceutical products are launched on the market.

Articles 18 and 19 of CFDA's DRR govern the current patent enforcement mechanism, recognizing patents associated with drug registration.<sup>104</sup> The DRR does not provide, however, an effective mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products. For example, the current DRR provisions do not explicitly address the circumstances and processes through which disputes over the patents will be resolved prior to market entry by follow-on products. The regulation states that if an infringement dispute occurs during the application period, it "shall be settled in accordance with relevant laws and regulations on patent."<sup>105</sup> However, the patent laws require there to be sales in the marketplace before an infringement suit can be filed.

PhRMA is very concerned that the July 2016 draft amendment to the DRR eliminates Articles 18 and 19, thereby abolishing China's only (albeit weak) protection against marketing approval for patent-infringing products and seriously undermining incentives for biopharmaceutical innovation in China. This draft amendment takes a significant step backwards in protecting and enforcing patents.

To avoid the unnecessary costs and time of litigating damages claims in patent litigation, to increase market predictability for both innovators and follow-on manufacturers, and following the model of other countries, China – through the DRR and DAL reform processes – should institute mechanisms that ensure the originator manufacturer is notified of relevant information within a set period of time when a follow-on manufacturer's application is filed. China should also enable patent holders to file patent infringement suits before marketing authorization is granted for follow-on products and afford sufficient time for such disputes to be resolved before marketing occurs. This might include a form of automatic postponement of drug registration approval, either pending resolution of the patent dispute or for a fixed period of time.

---

<sup>104</sup> Provisions for Drug Registration (SFDA Order No. 28), Arts. 18 and 19.

<sup>105</sup> Id., Art. 18.

## Regulatory Data Protection Failures

As part of its accession to the WTO in 2001, China committed to provide a six-year period of RDP for undisclosed test or other data submitted to obtain marketing approval for pharmaceuticals in accordance with Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>106</sup> Indeed, China's DAL and DRR, administered by the CFDA, establish a six-year period of protection for test data of products containing a new chemical ingredient against unfair commercial use.<sup>107</sup> In practice, however, China's regulatory environment allows for unfair commercial use of safety and efficacy data generated by PhRMA member companies.

China's RDP system in practice is inconsistent with TRIPS Article 39.3 in several ways. First, certain key concepts such as "new chemical ingredient" and "unfair commercial use" are undefined. This leads to the inconsistent and arbitrary application of the law by CFDA, in addition to confusion and uncertainty for sponsors of marketing approval applications. The term "new chemical ingredient" should be clearly defined in the DAL, DRR, and other relevant laws and regulations to include biologic and chemically synthesized drugs, recognizing the considerable investment by innovative biopharmaceutical companies in developing and proving safety and efficacy of a new product. The July 2016 draft amendment to the DRR takes a step backward in protecting RDP. The lack of provision of RDP for new chemical entities undermines China's international obligations under Article 39.3 of the WTO Agreement on TRIPS to provide RDP and the DAL Implementation Regulation.

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

During the December 2012 JCCT, China "agreed to define new chemical entity in a manner consistent with international research and development practices in order to ensure regulatory data of pharmaceutical products are protected against unfair commercial use and unauthorized disclosure."<sup>108</sup> Following many years of discussion in the JCCT and other venues, this commitment was a positive development. Unfortunately, this commitment remains unfulfilled. Effective implementation of this

---

<sup>106</sup> 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.

<sup>107</sup> 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.

<sup>108</sup> See Fact Sheet: 23<sup>rd</sup> U.S.-China Joint Commission on Commerce and Trade (Dec. 19, 2012, available at <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2012/december/23rd-JCCT> (last visited Oct. 27, 2016)).

commitment is necessary. Although the U.S. Government has actively engaged CFDA to revise the definition of new chemical entity, little progress has been made.

The February 2016 CFDA “Chemical Drug Registration Category Work Plan,” defines a “new drug” as a chemical entity that is “new to the world.” PhRMA is concerned that this revised definition of “new drug” may signal a similar narrowing of thinking with respect to the definition of new chemical ingredient, and therefore, creates a risk that a drug approved or marketed first outside of China may receive weaker or no exclusivity in China. In addition, this revised definition of “new drug” could potentially impact China’s JCCT RDP commitment.

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

#### Anti-Monopoly Law

As one of the three anti-monopoly agencies in China, China NDRC appears to take a leading role in the making and enforcement of IP-related antitrust rules. Currently there seems to be a lack of transparency and clear standards with regard to many related issues. While NDRC issued the draft IP Abuse Antitrust Guidelines (the “draft Guidelines”) on December 31, 2015, NDRC only allowed a very short period of time (20 calendar days) for public comments. Since the draft Guidelines will likely be considered departmental measures, they may be approved without being required to seek public comments for a second time. As currently drafted, the penalty for an IP abuse antitrust violation for a large global company could be significant. We urge NDRC to allow additional opportunities and longer period of time for global industries to provide inputs and comments before finalizing the draft Guidelines.

## Counterfeit Medicines

Pharmaceutical counterfeiting poses global public health risks, exacerbated by rapid growth of online sales of counterfeit medicines and the production and sale of unregulated active pharmaceutical ingredients (API) used to manufacture counterfeit products. China has been stepping up enforcement efforts against counterfeited drugs in recent years, both through legislative reforms and increased police activity. However, online distribution of counterfeit medicines and unregulated API remain the most serious challenges in China.

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

- amending the Criminal Code to ease the burden of proof to prosecute brokers or API suppliers who knowingly deal with illegal APIs;
- empowering CFDA to regulate any party that manufactures API even if that party has not declared an intent to do so;
- empowering CFDA to penalize factors based on *prima facie* evidence of a product as having medicinal use or being an "API" or a "chemical drug substance" without cGMP certification;
- amending the DAL to require adherence to ICH Q7A (*Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*) with meaningful penalties for failure to do so; and
- deepening cooperation with major Internet Service Providers, portal sites, and search engines for earlier identification and tracking of illegitimate API suppliers through B2B websites.

While CFDA plays a critical role in developing future solutions, any significant reform plan will require coordination and consultation among all relevant ministries within the central government. These efforts to crack down on unregulated API must go hand-in-hand with China's current campaign against counterfeit drugs in order to enhance the effectiveness of China's national drug safety plan objectives.

China continued to coordinate joint special enforcement campaigns targeting counterfeit drug crimes.<sup>109</sup> It also appears that China is beginning to spend more efforts

---

<sup>109</sup> See, e.g., "2,000 Arrested in China in Counterfeit Drug Crackdown," Aug. 5, 2012, available at: [http://www.nytimes.com/2012/08/06/world/asia/2000-arrested-in-china-in-crackdown-on-counterfeit-drugs.html?\\_r=0](http://www.nytimes.com/2012/08/06/world/asia/2000-arrested-in-china-in-crackdown-on-counterfeit-drugs.html?_r=0) (last visited Oct. 27, 2016); "China Detains 1,300 People Suspected of Making and

tackling the sale of counterfeits on the Internet. In 2013, CFDA and the State Information Office jointly led a 5-month crackdown campaign with collaboration of several ministries and offices against illegal online sales of drugs. Reportedly, the government also demands major search engines to filter out fake drug posts, which is a significant partnership with the private sector aimed at protecting Chinese patients.<sup>110</sup> 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 to protect 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 cooperation can serve as a best practice for other bilateral and multilateral efforts to reduce the global counterfeit drug trade.

Finally, while we commend China for improvements in customs regulations, which include monitoring and seizure of imports and exports, Chinese Customs authorities rarely exercise their authority to monitor biopharmaceutical exports. Accordingly, PhRMA believes that more resources and support should be targeted to monitoring biopharmaceutical 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.

---

Selling Counterfeit Drugs," Dec. 15, 2013, available at [http://www.huffingtonpost.com/2013/12/16/counterfeit-drugs-china-medicine\\_n\\_4447483.html](http://www.huffingtonpost.com/2013/12/16/counterfeit-drugs-china-medicine_n_4447483.html) (last visited Oct. 27, 2016).

<sup>110</sup> Reportedly, search engines have been required to ensure that qualified websites are listed earlier in the search results, to conduct active searches for illegal online drug sales, to delete false and illegal medical advertising, and to report unqualified websites to the National Internet Information Office and the CFDA. In response, several Internet companies have stepped in to support the fight against counterfeit drugs. One of the most prominent companies, 360, introduced several products to provide users with accurate information on medicines and block false medical information websites, claiming that such sites accounted for 7.9% of all blocked websites or approximately 40,606 websites.

## COLOMBIA

PhRMA member companies face several market access barriers and intellectual property (IP) issues in Colombia, including the issuance on September 18, 2014, of Decree 1782 on sanitary evaluation for biologics, which establishes an unprecedented “third pathway” for approval of non-comparable biologics that is not in line with World Health Organization (WHO) guidelines and practices in the United States and other countries. This is in addition to *ad hoc* and non-transparent market access policies that are often paired with initiatives that undermine innovation.

### Key Issues of Concern:

- **Issuance of a Declaration of Public Interest (DPI) to force a price discount:** On June 14, 2016, the Ministry of Health and Social Protection (MSPS) issued a DPI for the patented medicine Glivec®. In Colombia, a DPI must be made by the MSPS before a compulsory license can be granted. In this case, the MSPS preserved the option of imposing a CL, while recommending a mandatory price reduction to bring the price down to levels as if the patent on Glivec did not exist. PhRMA has strong concerns that the DPI appears inconsistent with Colombia’s market access commitments under the U.S.-Colombia Trade Promotion Agreement (TPA), which incorporates relevant provisions of the General Agreement on Tariffs and Trade (GATT).
- **Increased regulatory barriers under the National Development Plan (NDP):** Colombia’s NDP, which passed into law on May 7, 2015, undermines recent gains Colombia has made to encourage innovation, delays access for Colombians to cutting edge technologies, and is inconsistent with Colombia’s international commitments on IP and trade. Particular concerns include Article 72, which makes price a criterion in the regulatory approval process, and Article 70, which establishes a role for Ministry of Health and Social Security (MHSS) in reviewing pharmaceutical patent applications and elevates the risk of unjustified compulsory licenses. PhRMA supports the creation of sustainable healthcare systems, and believes this can be achieved without creating delays to new medicines and in a manner consistent with Colombia’s international obligations.
- **Substandard biologics regulation:** On September 18, 2014, Colombia issued Decree 1782, which establishes marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia has established an unprecedented “abbreviated” pathway for the registration of non-comparable products, which is inconsistent with 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.
- **Arbitrary and non-transparent market access policies:** Colombia’s international reference pricing methodology could inappropriately be used to set the same price for both the public and private segments of the market, does not

account for different margins in the reference countries, and does not reflect the realities of the Colombian market *vis-à-vis* other jurisdictions.

- **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 and, despite recent improvements, can apply unreasonably restrictive patentability criteria to biologics.
- **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

### Declaration of Public Interest on an Innovative Pharmaceutical Product

On June 14, 2016, the Colombian government issued a DPI for the patented medicine Glivec.<sup>111</sup> A DPI is typically a first step toward issuance of a compulsory license in Colombia, but in this case it was framed as a precursor to a substantial mandatory price reduction designed to render Glivec prices commensurate with prices for generic imatinib. The text of the DPI refers to such a price reduction as an “alternative” to issuing a compulsory license (while still leaving open the possibility of issuing a compulsory license).

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

#### *Consistency with Colombia’s TPA Obligations*

Limiting the price of Glivec to levels equivalent to those of generic forms of imatinib appears to be inconsistent with Colombia’s TPA obligations, which prohibit exceptions that unreasonably conflict with the normal exploitation of the exclusive rights conferred by a patent. Specifically, Article 16.9(3) of the Colombia TPA permits the

---

<sup>111</sup> An innovative leukemia medicine that contains the active ingredient imatinib.

Parties to “provide limited exceptions to the exclusive rights conferred by a patent, provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner”.

The DPI and proposed pricing measures appear to contravene this obligation. Biopharmaceutical patent holders in Colombia have a legitimate right to expect economic returns on their investments at the levels set by the Colombian government under its existing price control systems. Imposing additional price measures that reduce prices to levels equivalent to “that of the competitors before the patent was granted” – as if the patent did not exist – “unreasonably conflict[s] with a normal exploitation of the patent”. The extraordinary measures Colombia is taking through the DPI and the pricing measure will, by design, destroy the value of the patent. Beyond the intellectual property rights concerns, the DPI and pricing measure appear to also be inconsistent with Colombia’s market access commitments under the Colombia TPA, which incorporates relevant provisions of the GATT. In particular, Colombia’s actions would potentially constitute:

- An impermissible import price requirement under Article 2.8(2)(a) of the Colombia TPA and Article XI:1 of the GATT; and
- An internal maximum price giving rise to prejudicial effects on exporting parties that have not been taken sufficiently into account under GATT Article III:9.<sup>112</sup>

#### Article 72 of NDP

Article 72 of the NDP makes significant changes to the registration process for health care products and devices. The globally accepted practice is to base regulatory approval reviews on safety, efficacy, and quality, not price. Article 72 would make price a central criterion of the registration process and prevent technologies from accessing the market to the detriment of Colombian patients. Article 72 also appears contrary to the WTO Technical Barrier to Trade (TBT) Agreement since price is irrelevant to whether medicines and medical devices meet the relevant technical requirements for market authorization, and is more trade restrictive than necessary.

#### Substandard Biologics Regulation

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

---

<sup>112</sup> Given that the concerns raised by Colombia in imposing the DPI have all been budgetary versus health-related, it is difficult to see how Colombia could legitimately claim that the DPI and pricing measure are “necessary to protect human . . . life or health” within the meaning of GATT Article XX.

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

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

Furthermore, per the Decree, a product approved via the “Abbreviated Comparability Pathway” will use the same non-proprietary name as the innovator, despite the fact that any similar biologic product would be a distinct biologic product from that of the originator or other biosimilar products. Assigning identical non-proprietary names to products that are not the same could result in inadvertent substitution of the products, and would make it difficult to quickly trace and attribute adverse events to the correct product.

### Arbitrary and Non-Transparent Market Access Policies

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

The pricing system is highly subjective. For example, it provides that certain price control exceptions may be made for products providing a significant technical benefit over medicines containing the same active ingredient (*i.e.*, regular versus modified release tablets), yet it does not clearly establish the criteria required to grant such exceptions. Furthermore under the pricing system, therapeutic areas deemed to have three or fewer competitors are subject to international reference pricing based on a reference basket of 17 countries.

Finally, the recently approved Statutory Law of Health eliminated the National Pricing Commission, which includes representatives from the Ministry of Trade, Ministry of Health, and one representative of the President, and assigns pricing authority exclusively to the Ministry of Health. PhRMA’s member companies are concerned that this will result in a one-sided approach that does not adequately consider trade and market considerations as well as promotion of innovation.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

PhRMA continues to have concerns about restrictions on the scope of patentable subject matter in Colombia. The Colombian Patent Office (CPO) recently adopted new examination guidelines for granting patents to polymorphs, selection inventions, and pharmaceutical kits that are consistent with its TRIPS obligations. Similarly, the CPO made a number of improvements in terms of granting patents for pharmaceutical processes and biologics. These improvements are welcome, but implementation remains inconsistent and decisions continue to be unpredictable. There have been several recent cases of denials of patents for these types of inventions in first instance decisions.

### *Second Use Patents*

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

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

### 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.

### Dual Patent Examination Under Article 70 of NDP

Article 70 of Colombia's National Development Plan (NDP) undermines IP rights by establishing a role for the MHSS to submit non-binding opinions on pharmaceutical patent applications, which would likely delay and introduce subjectivity into patent reviews. Article 70 additionally expands the scope of MHSS by mandating that on an ongoing basis it review patents relating to health technologies that are susceptible to compulsory licenses. As provisions that appear to apply exclusively to healthcare technologies, they discriminate against pharmaceuticals contrary to TRIPS and the U.S.-Colombia FTA.

## Trademarks

In 2003, INVIMA authorized a copier to use the registered trademark of a U.S. pharmaceutical company (and a member of the local R&D pharmaceutical association) without the trademark owner's authorization. Specifically, the copier was permitted to use the U.S. company's trademark on its product's label in order to show it was the same as the original product (the approved legend is: "[COPIER PRODUCT] is bioequivalent to [ORIGINAL PRODUCT]") and without having to use any disclaimer.

This undermines the basic function of the mark as an indicator of source and origin. It also tarnished the image of the registered trademark and opened the door for copiers to freely take advantage of the innovator's reputation. This unprecedented decision by INVIMA violates Andean Community Trademark Law and Colombia's domestic law. To date, this case has been litigated before the Council of State for more than nine years, and a final decision has not been issued.

## ECUADOR

PhRMA and its member companies welcome recent positive developments in Ecuador, including the revocation of ten compulsory licenses issued since 2010 and the reduction of patent fees to be more in line with international norms. Nonetheless, there remain several areas of concern.

### **Key Issues of Concern:**

- **Detrimental market access policies:** In July 2014, Ecuador issued Decree 400 which establishes regulations for the setting of prices for medicines for human use and consumption. The Decree regulates government pricing for three categories of medications – Regulated, Direct Fixation and Free Pricing. Per Decree 10 issued last October, these new regulations went into effect in April 2016. To date approval decisions have been delayed and there remains uncertainty as to how medicines will be categorized.
- **Proposed new intellectual property (IP) law:** The National Assembly is in the process of developing a new IP regime under a proposed Code of Knowledge (INGENIOS Code). Proposals to date do not address the current IP deficiencies in Ecuador, defeating the purpose of the INGENIOS Code to create an environment in the country that fosters innovation.
- **Restrictive patentability criteria:** The Andean Court of Justice issued several legal opinions obliging Andean Community members, including Ecuador, to refuse recognition of patents for second medical uses. Ecuador has chosen to comply with these opinions in violation of Article 27.1 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and contrary to long-standing precedents. Further, crystalline forms and salts of compounds are improperly considered inherent properties of the compound and not an invention.
- **Regulatory data protection failures:** Ecuador does not sufficiently support and value the rigorous testing and evaluation biopharmaceutical innovators and their partners around the world undertake to demonstrate potential new medicines are safe and effective for patients who need them.

For these reasons, PhRMA requests that the U.S. Government continue a close follow up to the problems described herein until they are effectively resolved.

### **Market Access Barriers**

#### **Detrimental Market Access Policies**

Ecuador has had a government price control system for pharmaceutical products since 1992. In July 2014, Ecuador passed a decree (No. 400) regulating the

establishment of pricing for medicines destined for human use and consumption. Decree 400 creates three price control regulation categories: regulated, direct fixation, and free pricing. In October 2015, Ecuador issued Decree 10 per which the new pricing system became effective as of April 2016.

New medicines deemed to be strategic fall within the first category – regulated – and are subject to price ceilings established by the National Council of Fixation and Revision of Prices of Medications for Human use and consumption (hereinafter the “Council”). To date, approval decisions establishing a ceiling price for medicines falling within this category have been delayed.

The second category – direct fixation – is intended to be applied in exceptional cases and consists of a unilateral determination of prices by the Council, in accordance with Decree 400. This category is used when the sale prices of a medicine has exceeded the ceiling established by the Council for the corresponding market segment, when new and strategic medications are sold that have not been previously subject to the price ceilings set by the Council, and when the holder of the sanitary registration provides false information to the government, *i.e.*, is essentially a punitive category.

All other medicines are subject to free pricing under the third category, with the prices set by the sanitary registration holder notified to the Council, in accordance with the Decree.

This regulation has created uncertainty and unpredictability for pharmaceutical companies, due to, *inter alia*, an unclear definition of the scope of application and the criteria under which the Ministry of Health will categorize drugs as strategic under the first category of the regulation.

Further, in referencing prices of products deemed to be in the same therapeutic area, the pricing system does not adequately account for differences in quality, efficacy or safety, thereby discouraging quality medicines in Ecuador, threatening patient safety and decreasing incentives to bring innovative medicines to the Ecuadorean market.

## **Intellectual Property Protection**

The National Assembly is in the process of developing a new IP regime under a proposed Code on the Social Economy of Knowledge, Creativity and Innovation (INGENIOS Code). The provisions contained in the proposed INGENIOS Code do not address the current IP deficiencies in Ecuador, defeating the purpose of the Code to create an IP environment in the country that fosters innovation.

### 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 medical uses. These decisions are contrary to long-

standing precedents and inconsistent with TRIPS Article 27.1. Andean member countries, including Ecuador, have chosen to honor their Andean Community obligations, while ignoring their TRIPS obligations.

The failure to provide patents for second medical uses adversely affects PhRMA members who dedicate many of their research investments to evaluating additional therapeutic benefits of known molecules (second medical uses) in order to 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.

Furthermore, crystalline forms and salts of compounds are improperly considered inherent properties of the compound and not an invention.

### Regulatory Data Protection Failures

The protection for undisclosed test data or other information submitted to obtain marketing approval of pharmaceutical products remains, in practice, inadequate.

This is because the implementation of RDP in Ecuadorian law prohibits the *release* of undisclosed test or other data except to protect the public interest, but, in practice, *reliance* on such data by a generic manufacturer seeking marketing approval is not considered an act of unfair competition. This renders RDP in Ecuador not only ineffective but also inconsistent with Ecuador's obligations under TRIPS Article 39.3.

### Trademarks

On January 15, 2015, Presidential Decree 522 was enacted, which appears to limit the use of trademarks for any medicine once patents have expired. This measure appears to deny another important form of IP protection that is critical to ensure that innovator companies can distinguish their products from others. A trademark for a medicine designates its source and helps doctors and patients identify the quality, safety, and intrinsic effectiveness of a given product – reputational capital that manufacturers strive to build over time.

Industry had hoped that inter-ministry efforts in late 2015 into early 2016 would remedy the problems with Decree 522. While the Ministries' recommendations were sound, the Decree issued on August 22 disregarded many of these proposals and compounded the existing deficiencies in Decree 522. Specifically, the new Decree (1159) appears to:

- mandate that medicines be registered and marketed solely as generics after the patent expires;
- require the use of the international non-proprietary name on the label and the indication that it is the "reference product" above the name of the manufacturer; and

- prohibit exclusive marketing of generic medicines on the basis of a given brand name.

Decree 1159 was published in Ecuador's Official Gazette on September 19, 2016, and is due to go into force one year later. Industry strongly encourages the U.S. Government to engage with its counterparts in Ecuador to seek a resolution to this issue before the new decree goes into effect.

## EGYPT

PhRMA and its member companies operating in Egypt are concerned about the market access and intellectual property (IP) environment in Egypt. Egypt is one of the most populous countries in the Middle East-Africa region. There is tremendous unmet medical need in the country.

During the past several tumultuous years, PhRMA and its member companies have tried to work in good faith with Egyptian officials to address health and industrial issues. While serious challenges remain, PhRMA notes that, for the most part, Egyptian officials have shown a willingness to meet and discuss issues of concern, and have expressed interest in supporting the innovative biopharmaceutical industry and encouraging investment in the country. PhRMA and its member companies appreciated the government's openness and eagerness in 2015, particularly the Ministry of Health (MOH), to collaborate and engage with our industry on policies and regulations related to regulatory approval, government pricing and reimbursement, patient access to new innovative medicines and IP protections. Unfortunately, the Egyptian Government was less collaborative in 2016, but the industry is hopeful that better relations can resume.

### **Key Issues of Concern:**

- **Discriminatory market access policies:** Although Egypt has not fully implemented Decree 499, which discriminates against foreign manufacturers, industry remains concerned that the discriminatory margins established by that Decree could be restored absent the establishment of a new pricing decree that is transparent and equitable.
- **Weak patent enforcement and regulatory data protection failures:** Egypt lacks regulatory data protection (RDP) and effective patent enforcement, enabling manufacturers to obtain marketing licenses for follow-on products prior to the expiration of the patent on the original product.

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**

#### **Discriminatory Market Access Policies**

In 2012, the MOH issued Decree 499, which discriminates against foreign-made products by offering differential treatment of those products in the supply chain. Specifically, Decree 499 imposed higher distributor and pharmacy margins on imported products as compared with locally produced products (which in turn were deducted from the ex-factory price), thereby discriminating against foreign manufacturers contrary to Egypt's WTO obligations.

PhRMA commends the MOH for not fully implementing that decree, and engaging in new negotiations. It is important that trading partners communicate the need for the new pricing regulations that are transparent and equitable to avoid discrimination between local and foreign manufacturers and their products.

### Regulatory Approval Delays

We are encouraged that in 2015, under challenging circumstances, Egyptian officials recognized that the government and industry should partner to streamline and modernize the existing system for reviewing and approving new medicines. In part, officials realized that unnecessary delays in reviewing and licensing new medicines do not serve the best interests of patients who can benefit from advances in new medical technology. Officials seem sensitive, too, to the fact that outdated, sluggish regulatory systems are disincentives for investment in the sector.

To this end, officials issued a new regulatory decree in June 2015 that would streamline the review process and reduce licensing times to less than 12 months versus the two to three years that this process can take at present. PhRMA and its member companies appreciate the positive approach and collaboration on this new decree.

## **Intellectual Property Protection**

### Weak Patent Enforcement

Egypt does not provide an effective mechanism to ensure that marketing licenses are not granted to companies making products that infringe an originator's patent.

Some officials have opposed putting in place an effective patent enforcement system similar to the process used by the United States or, more recently, the regulation enacted in neighboring Saudi Arabia. In those countries, health officials receiving applications from generics companies are required to check for the existence of a valid patent. If the originator can demonstrate a valid patent, there should be a procedure in place whereby the MOH can either defer the file to a date for examination period closer to the date of the patent expiration and/or specify that the license is valid only after the expiration of the innovator's patent or after a sufficient period to resolve the patent dispute.

In 2013, PhRMA and its member companies became aware of local generics companies obtaining marketing licenses from the MOH and then proceeding to engage in patent infringing acts in the marketplace. However, in 2014, and after engagement by the U.S. Government and the industry, the MOH stopped issuing marketing authorizations for copies of patented products, and the Minister of Health created a committee to examine the possibility of implementing an effective patent enforcement mechanism. Industry submitted comments to the Committee, but as yet no action has been taken. That said, we are not aware of any other instances of generics being granted marketing authorization during the reference product's patent term.

As Egypt is a WTO member, has enacted patent laws, and issues patents through the Patent Bureau, it follows that the MOH should have in place a system whereby it can defer market entry of newly licensed medicines until after the expiration of any applicable patents or at least until after a sufficient period for resolving patent disputes.

#### Regulatory Data Protection Failures

Egypt does not provide RDP, and some officials have consistently opposed enacting regulations that would offer a minimum period of data protection to innovators. RDP would ensure that manufacturers of follow-on products are not obtaining an unfair commercial advantage by relying on data developed at great risk and expense by the innovator company. PhRMA and its member companies have proposed that the Egyptian Government adopt a minimum RDP period calculated from the date of registration in Egypt.

## THE EUROPEAN UNION

PhRMA member companies are facing a variety of government restrictions in the European Union (EU) that undermine the ability of PhRMA member companies to enjoy the full benefits of their patents and that predominantly affect innovative products relative to their generic counterparts. As a result of Europe's on-going economic challenges, EU Member States continue to seek additional cost savings.

PhRMA and its members strongly support and encourage a focused effort by the U.S. Government to leverage the Transatlantic Trade and Investment Partnership (TTIP) negotiations to promote transparent market access processes in the European Union, greater regulatory compatibility, and strong intellectual property protection for the pharmaceutical sector. Of particular interest to PhRMA and its members is the inclusion in the TTIP agreement of similar due process and transparency guarantees that have been included in both the Korea-U.S. Free Trade Agreement (KORUS) and the Korea-EU Free Trade Agreement (KOREU). In addition, PhRMA strongly supports the conclusion of a mutual recognition agreement for good manufacturing principles certification, continued cooperation between the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) at the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), and a commitment to implement and enforce globally leading standards for pharmaceutical intellectual property rights protection.

### Key Issues of Concern:

- **Government price controls:** Among numerous other price controls that are in effect, a number of EU Member States are either basing the price of patent protected innovative products on groups that include the price of generics in the same therapeutic class and/or are using the price of the medicine in countries undergoing heavy fiscal crisis (*e.g.*, Greece and Portugal) to establish the medicines price in their own country. Such practices harm patients and undermine innovation. EU legislation requires transparent processes for such national pricing and reimbursement decisions, but these requirements need to be enforced more rigorously and with broader oversight of national practices.
- **EMA data disclosure policy:** PhRMA and its member companies remain concerned that the European Medicines Agency's (EMA) policies to provide access to companies' regulatory submissions without adequate controls against potential misuse could substantially harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. Failing to protect confidential commercial information contained in regulatory submissions from unfair commercial use would be inconsistent with the EU's treaty obligations contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and would primarily benefit competitors who wish to free-ride off of the investments of innovators.

- **Effective patent enforcement:** The EU and its Member States lack an effective mechanism to allow for sufficient time to resolve legitimate patent disputes before market launch of a follow-on product (e.g., generics or biosimilars). Although follow-on products have several opportunities to challenge existing patents, there is no opportunity for innovator companies to resolve patent disputes in advance of generic or biosimilar launch. In addition, even if an innovator successfully challenges an infringing product in court, they are rarely restored to the position that they would have been in but for the market entry of the patent infringing product. This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

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

Many EU member states are engaging in practices that restrict availability of and limit access to state-of-the-art medicines. Exacerbated further by the economic and financial crisis gripping many countries, such practices harm patients and innovation. Moreover, since the U.S. research-based industry is the world leader in the development of new medicines, PhRMA members and their innovative products disproportionately bear the brunt of these measures as they undermine the financial incentive for privately sponsored research and development. Furthermore, even though EU legislation requires transparent processes in making such national pricing and reimbursement decisions, these requirements need to be enforced more rigorously and broader oversight of national practices should be in place.

### Therapeutic Reference Pricing

The continued use of therapeutic reference pricing as a tool to reduce the price of innovative medicines with active patents is a concern for PhRMA member companies. More specifically, a growing number of countries (e.g., the Czech Republic, Germany, Greece, Poland and Slovenia) base the price of a patented medicine on a group of medicines in the same therapeutic class, including generics”). This *de facto* devalues the worth of the patent, reducing the remuneration a company can receive for an innovative product to the price level of a competing generic medicine.

### International Reference Pricing

International reference pricing (IRP) is a mechanism whereby a government considers the price of a medicine in other countries to establish the price in its own country. Initially used on an informal basis to validate prices paid in countries of similar economic standing, countries that are fiscally strong such as Germany are now formally referencing prices in countries with much weaker economies like Greece and Portugal

(Germany's IRP becomes active if government price negotiations fail following the quick assessment under Germany's AMNOG legislation) and, as such, IRP creates a complexity of pricing relationships between countries and beyond that undermines incentives for price differentiation that could improve access in poorer countries, contributes to supply shortages via parallel trade, and launch delays. Such unintended consequences of IRP are explained in a 2008 OECD study, and others.<sup>113</sup>

## **Intellectual Property Protection**

### EMA Data Disclosure Policy

PhRMA and its member companies are concerned that the EMA's policy (including new policies that entered into force in 2016) to provide access to companies' regulatory submissions may substantially harm patient privacy, the integrity of the regulatory system, and incentives for pharmaceutical research and development. In particular, PhRMA has concerns that the limited access controls to prevent unfair commercial use of this information by the EMA could allow other commercial competitors, including those operating in third countries, to benefit from this information unfairly and jeopardize confidential commercial information that represents much of the value generated through the research and development process. Also, because it is possible that even anonymized patient-level data can lead to re-identification of individual patients,<sup>114</sup> it is imperative that the EMA not release this type of data, less it risk undermining patient willingness to participate in future trials and violating the promise in the individual consent forms to protect personal information. Disclosure of such data also encourages second guessing of the EMA's expert regulatory decisions, thereby undermining patient trust in the safety and effectiveness of approved medicines.

Further, failure to protect confidential commercial information contained in regulatory submissions would be inconsistent with the EU's treaty obligations contained in the TRIPS Agreement. This would harm incentives to invest in biomedical research. The primary beneficiaries of such non-public information are competitors who wish to free-ride off of the investments of the innovators. This is also concerning since, once disclosed in Europe, the regulatory documents could be used by third-party companies to seek approvals in other markets such as Russia, China, and Colombia.

As the EMA seems to gradually expand clinical data sharing, PhRMA requests that the U.S. Government continue to closely monitor the implementation to ensure there is no unfair commercial use in third countries of data disclosed by the regulator in the EU.

---

<sup>113</sup> OECD Health Policy Studies, *Pharmaceutical Pricing Policies in a Global Market*, 2008, p. 18; see also Charles River Associates. *The Implications of International Reference Pricing and Parallel Trade on Social Welfare and Patient Access*. September, 2012 and Garau, M., Towse, A. and Danzon, P. (2011) *Pharmaceutical pricing in Europe: Is differential pricing a win-win solution?* Occasional Paper 11/01. London: Office of Health Economics.

<sup>114</sup> See Gymrek, M. et al., *Identifying Personal Genomes by Surname Inference*, 339 SCIENCE 6117 321-324 (2013).

## Effective Patent Enforcement

When a generic product is launched and remains on the market until infringement is proved in patent litigation, harm may be caused to the patent owner which cannot be compensated through damage awards. This reasoning is often cited by English courts, and some EU courts, for granting pre-trial interim injunctions.<sup>115</sup> Overall, however, interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases.<sup>116</sup> This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

A mechanism to resolve legitimate patent disputes before launch of a follow-on product (e.g., generics or biosimilars) would alleviate this problem. It would also help prevent unnecessary, costly and time-consuming litigation regarding the amount of damages and problems associated with removing an infringing follow-on product from the market.

It is imperative for all pharmaceutical companies, innovative or otherwise, that there are dependable mechanisms in Europe to resolve potential patent infringement issues before follow-on product launch.<sup>117</sup>

Currently there are three mechanisms available to generic companies to “clear the path” of patents that may be obstacles to launch and marketing: 1) file an opposition with the European Patent Office; 2) pursue a revocation/nullity action in individual Member States; or 3) apply for a declaration of non-infringement in individual Member States. The latter is similar to an application for declaratory judgment in the United States.

However, there is no opportunity for innovator companies to resolve patent disputes well in advance of generic or biosimilar launch. This is because, in most EU Member States, it is not possible to bring patent infringement proceedings until just before or just after launch of the third party product, which often makes resolution of disputes before actual launch impossible. In addition, resolving these disputes in this manner is often lengthy, expensive, and can result in significant market loss, even if the end ruling favors the innovator patent owner.

There is thus an unjustifiable and commercially significant imbalance between the rights of innovator patent owners and generics to resolve patent issues before product launch in most EU Member States.

---

<sup>115</sup> See, e.g., *Leo Pharma v. Sandoz*, [2008] EWHC 541 and *Novartis v. Dexcel-Pharma*, [2008] FSR 31.

<sup>116</sup> DG Competition, European Commission, “Pharmaceutical Sector Inquiry Final Report,” para. 641 (Jul. 8, 2009).

<sup>117</sup> EFPIA, Submission to the European Commission in Relation to the Pharmaceutical Sector Inquiry (June 13, 2008).

Further, in many cases, PhRMA member companies have experienced EU Member States reimbursing infringing products, or approving prices for their purchase by government procurement agencies without regard to whether or not the products infringe third party patents.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) has proposed adoption of an “early resolution” mechanism to the European Commission and PhRMA supports this approach in Europe, including through negotiation and implementation of TTIP.

### SPC Review

PhRMA is also interested in the current review of the Supplementary Protection Certificate (SPC) in Europe and concerned about proposals made that might “recalibrate the existing EU SPC rules”<sup>118</sup> and/or weaken the exclusive rights conferred under an SPC. SPC’s are a critical part of the European IP system that restore effective patent term to compensate for the time incurred during the regulatory review period that may “make[] the period of effective protection under the patent insufficient to cover the investment put into that research.”<sup>119</sup> Effective SPC protection, conferring the same legal protections as those available during the regular patent term, must be retained in order to ensure the ability of the system to continue to meet its policy objectives.

---

<sup>118</sup> See “Call for tenders: Study on the legal aspects of the supplementary protection certificates in the EU” (June 9, 2016), available at [http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item\\_id=8847](http://ec.europa.eu/growth/tools-databases/newsroom/cf/itemdetail.cfm?item_id=8847) (last visited Oct. 27, 2016)

<sup>119</sup> See EC Regulation No. 469/2009 concerning the supplementary protection certificate for medicinal products (May 6, 2009) at Recital 4.

## INDIA

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

Pharmaceutical innovators saw positive signs and statements from the Indian Government in 2016; however, translating these positive statements into concrete progress and real policy change has remained a challenge. Despite important announcements to expand healthcare programs, the Indian Government has not increased investment in this critical area, leaving public healthcare spending at a very low level of approximately 1% of GDP. A slow and piecemeal approach to clinical trials reform does not demonstrate a consistent and transparent environment for investment in clinical research and drug development. There are delays and cumbersome procedures which prevent India from becoming a part of a global clinical trial program and thereby limit patient access to innovative medicines in India. Data from the Indian drug regulator shows that since 2011, when a total of 41 new medicines were approved, the number has dropped significantly to only 11 new medicines in 2015.<sup>120</sup>

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 the U.S. and Indian Governments to improve access to medicines, and healthcare overall, by removing market access barriers and fostering legal and regulatory certainty for the protection of IP in India.

### **Key Issues of Concern:**

- **High tariffs and taxes on medicines:** Medicines in India face high effective import duties for active ingredients and finished products. The basic import duties for pharmaceutical products average about 10 percent, and additional duties and assessments bring the effective import duty to approximately 20 percent.
- **Discriminatory and non-transparent market access policies:** The threat of an existing recommendation for strict price controls on patented medicines represents an effort to significantly reduce the benefits of patent protection and create an unviable government pricing framework and business environment for medicines in India. In addition, the National Pharmaceutical Pricing Authority (NPPA) is revising price controls on medicines for which prices were already

---

<sup>120</sup> Indian Express, "New drug launches take a hit in India amid tight USFDA scrutiny," October 26, 2015, available at <http://indianexpress.com/article/business/business-others/new-drug-launches-take-a-hit-in-india-amid-tight-usfda-scrutiny/> (last visited Oct. 27, 2016)

fixed under the Drug Price Control Order (DPCO) 2013. The DPCO 2013 discriminates against foreign pharmaceutical companies by exempting new medicines developed through indigenous research from price controls. These pricing decisions, as well as the broad authority granted to NPPA under this provision, do not adhere to the need for transparency, predictability, and trust in the decision-making process, which hinders industry's ability to further invest in India.

- **Burdensome environment for clinical research:** While the Government is keen to reinvigorate clinical research in India, ambiguities in the Indian regulatory space prevail. In particular, the definition of “trial related injury” is not well defined, and the determination of local clinical trials requirements is highly subjective and perpetuates a burdensome environment for clinical research that undermines the availability of new treatments and vaccines for Indian patients.
- **Unpredictable IP environment:** India's legal and regulatory systems pose procedural and substantive barriers at every step of the patent process, ranging from impermissible hurdles to patentability posed by Section 3(d) of India's Patents Act, narrow patentability standards applied in pre-grant and post-grant opposition proceedings, to onerous patent application disclosure requirements that disproportionately affect foreign patent applicants. Not only is this a concern in the Indian market, but also in other emerging markets that may see India as a model to be emulated. Products have faced issues due to the continued denial of applications 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 IP environment in India. .
- **Regulatory data protection failures:** The Indian Regulatory Authority relies on test data submitted by originators to seek approval in India and/or another country when granting marketing approval to follow-on pharmaceutical products. This reliance results in unfair commercial use prohibited by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and discourages the development of new medicines that could meet unmet medical needs.

The innovative biopharmaceutical industry greatly appreciates the efforts to address these concerns at the highest levels of the U.S. Government. The continued attention to the market access and legal and regulatory barriers in India has sent a strong signal of the importance of these issues to the bilateral relationship and has been critical to preventing further deterioration of the policy environment. However, there remains significant unpredictability in market access and IP protection in India as there has yet to be meaningful policy change to address the challenges. 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 effective import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10 percent, additional duties and assessments are imposed that bring the effective import duty total to approximately 20 percent. In fact, India collects more in taxes on pharmaceuticals than it spends on medicines. Broad analysis indicates total annual Government expenditure on drugs in India at around \$1.15B<sup>121</sup> in comparison to the \$1.22B<sup>122</sup> it receives in taxation of pharmaceuticals. 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 the 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.<sup>123</sup>

The Constitution Amendment Bill for Goods and Services Tax (GST) was recently passed in the Parliament and is expected to be implemented by April 2017, replacing all the indirect taxes levied on goods and services by the Centre and States. GST is expected to significantly reduce layers and complexity in the indirect tax system and develop a common Indian market. Proposals to exempt certain life-saving drugs from excise and customs duties should be expanded to all medicines.<sup>124</sup>

### Discriminatory and Non-Transparent Market Access Policies

PhRMA's members are concerned about the general lack of access to health care in India. The Indian government circulated a draft National Health Policy<sup>125</sup> early in 2015 that called for greater access to healthcare for low-income patients. While the National Health Policy has yet to be finalized, the Indian Government has expanded coverage in existing health schemes. Prime Minister Modi announced a new scheme to

---

<sup>121</sup> High Level Expert Group (HLEG) report on Universal Healthcare Coverage for India 2011, Instituted by Planning Commission of India.

<sup>122</sup> Includes domestic tax (VAT and excise duty) and import taxes; based on broad analysis of 2011 data representative at National level – state level data not investigated. Source: Indian Department of Pharmaceuticals Annual Report 2012, HLEG report on Universal Healthcare Coverage for India 2011.

<sup>123</sup> See, e.g., Business Standard, "Puzzle in Wednesday order on duty exemption," Feb. 19, 2016, available at [http://www.business-standard.com/article/companies/puzzle-in-wednesday-order-on-duty-exemption-116021800993\\_1.html](http://www.business-standard.com/article/companies/puzzle-in-wednesday-order-on-duty-exemption-116021800993_1.html) (last visited Oct. 27, 2016).

<sup>124</sup> Hindu Business Line, "GST: The right prescription," Aug. 5, 2016, available at <http://www.thehindubusinessline.com/specials/pulse/gst-the-right-prescription/article8949378.ece> (last visited Oct. 27, 2016).

<sup>125</sup> "National Health Policy 2015 Draft." Ministry of Health & Family Welfare. Dec. 2014.

increase health coverage for low-income families<sup>126</sup> and the Employees' State Insurance Corporation (ESIC) has announced a raise to the threshold limit for mandatory coverage for organized-sector workers.<sup>127</sup> Still, coverage is typically limited to hospital care and does not cover outpatient care or medicines.

India has insufficient numbers of qualified healthcare personnel, inadequate and poorly equipped healthcare facilities, and most importantly lacks a comprehensive system of healthcare financing which would pool financial risk through insurance and help to share the cost burdens.<sup>128</sup> Still, government spending on healthcare remains at about 1% of GDP, one of the lowest levels of expenditure in the world.<sup>129</sup> In the absence of increased resources and reform, high out-of-pocket spending on healthcare and pressure on the cost of medicines persist. Despite decades of government price controls in India, the objective of which has been to improve access to medicines, essential medicines are still not easily accessible; for example, essential medicines may only be available at government pharmacies 20 percent of the time.<sup>130</sup> 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.<sup>131</sup>

Expansion of price controls to a larger range of medicines will not substantially improve access to medicines in India because lack of access is more a function of insufficient healthcare financing systems, poor access to physicians, and inadequate healthcare facilities.<sup>132</sup> For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.<sup>133</sup> A recent study by IMS – “Analyzing the Impact of Price Controls on Access to Medicines” found that price controls are neither an effective nor a sustainable strategy for improving access to medicines. The study further found that the primary beneficiaries of price controls have

---

<sup>126</sup> Indian Express, “Narendra Modi’s speech on Independence Day 2016: Here’s the full text,” Aug. 15, 2016, available at <http://indianexpress.com/article/india/india-news-india/pm-narendra-modis-speech-on-independence-day-2016-here-is-the-full-text/> (last visited Oct. 27, 2016).

<sup>127</sup> Financial Express, “Employees State Insurance Corp hikes wage threshold job coverage to Rs 21,000,” Sept. 7, 2016, available at <http://www.financialexpress.com/economy/employees-state-insurance-corp-hikes-wage-threshold-job-coverage-to-rs-21000/369504/> (last visited Oct. 27, 2016).

<sup>128</sup> “Health Systems Financing: The Path to Universal Coverage,” *The World Health Report*, World Health Organization, 2010.

<sup>129</sup> “National Health Policy 2015 Draft.” Ministry of Health & Family Welfare. Dec. 2014.

<sup>130</sup> “Health workforce, infrastructure, essential medicines”, World Health Statistics 2013, The World Health Organization.

<sup>131</sup> Analysis based on IMS MIDAS Data.

<sup>132</sup> “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. 27, 2016).

<sup>133</sup> “India Turns to Mobile Phones in Bid to Improve Vaccination Rate,” *India Real Time/Wall Street Journal*, Aug. 4, 2011. Patra, Nilanjan, “When Will They Ever Learn?: The Great Indian Experience of Universal Immunisation Programme”, Dec. 2009, available at [http://www.isid.ac.in/~pu/conference/dec\\_09\\_conf/Papers/NilanjanPatra.pdf](http://www.isid.ac.in/~pu/conference/dec_09_conf/Papers/NilanjanPatra.pdf) (last visited Oct. 27, 2016).

been high-income patients, rather than the intended low-income population.<sup>134</sup> 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.<sup>135</sup>

In 2014, an Inter-Ministerial Committee was constituted to suggest a methodology to be applied to pricing of patented medicines before their marketing in India,<sup>136</sup> but a decision by the Committee has yet to be taken. A Department of Pharmaceuticals (DoP) Committee on Price Negotiation for Patented Drugs report in February 2013 recommended an international reference pricing scheme with a purchasing power parity adjustment for government procured patented medicines, with those patented medicines to be provided through health insurance. The Committee also considered whether the price negotiation of a patented medicine should be linked with its marketing approval in India, whereby the price of the patented medicine would be negotiated between the government and the manufacturer *before* the patented medicine is authorized for sale in India. PhRMA members are highly concerned that the threat of the existing recommendation represents a potential effort to significantly reduce the benefits of patent protection, which will *de facto* discriminate against importers, and will create an unviable government pricing framework and business environment for innovative pharmaceutical companies.

DPCO 2013 sought to establish price stability by setting ceiling prices for medicines listed on Schedule I every five years. Despite doing so in 2013, the NPPA announced in June 2016, per Paragraph 18 of the DPCO, that it was going to set new ceiling prices for all medicines, including those for which a ceiling price had already been set only three years prior. Transparency and predictability are paramount to a robust environment for business investment. These pricing decisions, as well as the broad authority granted to NPPA under this provision, do not respect the need for transparency, predictability, and trust in the decision-making process, and ultimately impact patient access to medicines. Furthermore, frequent repricing imposes an unnecessary administrative burden, due to the need to recall and re-label medicines to reflect the new price, and in turn can result in product shortages.

Finally, Paragraph 32 of the DPCO 2013 exempts from the pricing formula, for a period of five years, new medicines developed through indigenous research and development that obtain a product patent, are produced through a new process, or involve a new delivery system. This section creates an un-level playing field that favors local Indian companies and discriminates against foreign pharmaceutical companies.

---

<sup>134</sup> IMS, "Assessing the Impact of Price Control Measures on Access to Medicines in India." June 2015.

<sup>135</sup> "Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation," U.S. Dept. of Commerce, Int'l Trade Administration, Dec.. 2004. Vernon, John, "Drug Research and Price Controls," *Regulation*, Winter 2002-2003.

<sup>136</sup> 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.

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

### Burdensome Environment for Clinical Research & Drug Approval

India has many of the components of an effective regulatory system, such as institutional capacity across central and state regulators and a robust technical framework. India also has several components to support a broader ecosystem for clinical research and drug development, such as the presence of a highly skilled workforce of qualified scientists, hundreds of medical colleges, and a large and diverse patient pool. Still, India faces the consequences of an unpredictable regulatory environment as clinical trials falter<sup>137</sup> and new medicines face significant launch delays.<sup>138</sup>

We welcome the fact that the MOH and the Central Drugs Standard Control Organization (CDSCO) have undertaken regulatory reform efforts with the goal of strengthening the regulatory regime and reinvigorating clinical research. Strong, transparent and predictable regulatory frameworks are essential to protecting patients as well as to promoting globally-competitive innovative and generic pharmaceutical industries. This year the Indian Government announced its intention to revise the Drugs & Cosmetics Act and Rules “to make it easier for companies to do business while ensuring the safety and efficacy of medicines.”<sup>139</sup> In the meantime, inconsistencies and ambiguities continue to prevail in the Indian regulatory space resulting in lack of clarity and burdensome approval process for trial sponsors. In particular, the Indian regulatory system exhibits slow approval times, ambiguities in the definition of “trial related injury” and a lack of an appeals mechanism in decisions about causation. The piecemeal approach to reform continues to reinforce the unpredictability of the clinical trials regime and the slow resurgence of trials, especially in the presence of global multiregional trials. As a result, clinical trial investment in India has decreased significantly since

---

<sup>137</sup> Scrip, “Industry Sponsored Trials Fall Sharply In Challenging Indian Environment,” Sept. 8, 2016, available at <https://scrip.pharmamedtechbi.com/SC097232/Industry-Sponsored-Trials-Fall-Sharply-In-Challenging-Indian-Environment> (last visited Oct. 27, 2016); Asia Sentinel “Southeast Asia Steals Indian Pharma,” July 14, 2014, available at <http://www.asiasentinel.com/econ-business/southeast-asia-steals-indian-pharma/> (last visited Oct. 27, 2016).

<sup>138</sup> Ernst R. Berndt and Iain M. Cockburn. The Hidden Cost of Low Prices: Limited Access to New Drugs in India. *Health Affairs*, 33, no.9 (2014): 1567-1575.

<sup>139</sup> Reuters, “India to revise drugs law, draft new rules for medical devices,” June 22, 2016, available at <http://in.reuters.com/article/us-india-drug-lawmaking-idINKCN0Z8190> (last visited Oct. 27, 2016).

2010.<sup>140</sup> Such uncertainty in the regulatory process for clinical trials threatens the overall clinical research environment in India, as well as the availability of new treatments and vaccines for Indian patents.

The Indian Government, as per the notice issued on August 4, 2016, has taken several measures to improve the clinical trial environment, such as removal of restrictions on the number of trials that may be conducted by an investigator at a given point of time, the minimum number of beds at the clinical trial site, and the need to obtain an objection certificate from the DCGI in case of addition or deletion of new clinical trial site or investigator.<sup>141</sup>

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

As a result, there is great uncertainty relating to future costs and liabilities associated with conducting trials in India, resulting in many sponsors not launching trials in India until these uncertainties have been resolved. Research shows that if India were to address outstanding concerns with clinical trials regulations, India could see an increase in the number of new clinical trials per year to above 800 and add over \$600 million in economic gains.<sup>142</sup> Greater clarity and predictability are needed for administrative procedures of drug registration applications and drug review standards and procedures in order to make the latest research products available in India.

## **Intellectual Property Protection**

India announced the new National Intellectual Property Rights (IPR) Policy in May 2016.<sup>143</sup> India's National IPR Policy recognizes the tremendous economic and

---

<sup>140</sup> Scrip, "Industry Sponsored Trials Fall Sharply In Challenging Indian Environment," Sept. 8, 2016, available at <https://scrip.pharmamedtechbi.com/SC097232/Industry-Sponsored-Trials-Fall-Sharply-In-Challenging-Indian-Environment> (last visited Oct. 27, 2016)

<sup>141</sup> CDSCO Notice, Aug. 4, 2016, available at <http://www.cdsc0.nic.in/writereaddata/NOTICE%20DATED%204th%20August%202016.pdf> (last visited Oct. 27, 2016)

<sup>142</sup> Pugatch Consilium, "Quantifying the Economic Gains of Strengthening India's Clinical Research Policy Environment." Sept. 2015, available at <http://www.pugatch-consilium.com/reports/Quantifying%20the%20Economic%20Gains%20from%20Strengthening%20the%20Clinical%20Research%20Policy%20Environment%20in%20India.pdf> (last visited Oct. 27, 2016).

<sup>143</sup> Department of Industrial Policy and Promotion, "National Intellectual Property Rights Policy," May 12, 2016, available at

socio-cultural benefits that a strong IP regime could bring to India through economic growth, employment, and a vibrant R&D environment. The policy also puts forward important administrative and procedural improvements. However, it should be strengthened to accelerate the reforms needed to foster medical innovation and enhance India's global competitiveness. For example, while the policy focuses on government, open source R&D, Corporate Social Responsibility credits, tax breaks, loan guarantees for start-ups, support systems for Micro-, Small- and Medium-sized Enterprises and other mechanisms to encourage innovation in India, it is also important to incentivize the private sector and scientific institutions by providing effective and meaningful IP protection and enforcement mechanisms. Implementation of the policy should include a consultative process with relevant stakeholders and meaningful reforms to India's IP policies that lead to improvements in intellectual property protection and enforcement for medicines.

### Restrictive Patentability Criteria

TRIPS requires that an invention which is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. Section 3(d) of the Indian Patents Act as amended by the Patents (Amendment) Act 2005 adds an impermissible hurdle to patentability by adding a fourth substantive criteria of "enhanced efficacy" to the TRIPS requirements. Moreover, this additional hurdle appears to be applied only to pharmaceuticals. Under this provision, salts, esters, ethers, polymorphs, and other derivatives of known substances are presumed to be the same substance as the original chemical entity and thus not patentable, unless it can be shown that they differ significantly in properties with regard to efficacy.

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 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 principle provided by TRIPS Article 27.<sup>144</sup> From a policy perspective, Section 3(d) undermines incentives for biopharmaceutical innovation by preventing patentability for improvements which do not relate to efficacy, for example an invention relating to the improved safety of a product.

---

[http://dipp.gov.in/English/Schemes/Intellectual\\_Property\\_Rights/National\\_IPR\\_Policy\\_08.08.2016.pdf](http://dipp.gov.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf)  
(last visited Oct. 27, 2016)

<sup>144</sup> The additional patentability hurdle imposed by section 3(d) was recently reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014.

Other examples of the overly restrictive standards for patentability in India are the recent patent revocations using “hindsight” analyses made during pre- and post-grant oppositions citing a lack of inventiveness concluding that the patent applications are based on “old science” or failed to demonstrate an inventive step.

### Weak Patent Enforcement

Indian law permits state drug regulatory authorities to grant marketing approval for a generic version of a medicine four years after the original product was first approved.<sup>145</sup> 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 authorization from the 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 should close this regulatory loophole in order to provide effective patent protection and enforcement for pharmaceutical patent holders.

Moreover, India does not provide mechanisms for notification or resolution of patent disputes prior to marketing approval of third party products. Such mechanisms are needed to prevent the marketing of patent infringing products and resolve disputes in a timely manner.

In recent examples, the patent holder waited two and a half years before the Court provided injunctive relief.<sup>146</sup> In another example, the patent holder waited seven years before receiving a Court decision upholding its patent. The Court ultimately did not grant an injunction because by the time the decision was issued the patent was close to expiration.<sup>147</sup> The new Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Bill provides for the creation of commercial divisions 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

---

<sup>145</sup> Rule 122E of the Drugs and Cosmetics Rules states that a new drug shall continue to be considered as new drug for a period of four years from the date of its first approval or its inclusion in the Indian Pharmacopoeia, whichever is earlier. The Drugs and Cosmetics Act goes on to specify that “Where an application under this Rule is for the manufacture of drug formulations falling under the purview of new drug as defined in rule 122-E, such application shall also be accompanied with approval, in writing in favor of the applicant, from the licensing authority.” Thus, to obtain a manufacturing license for a new drug, the Central Drug Regulatory must provide written approval. In the case of drugs which do not meet the definition of a new drug, an “Application for grant and renewal of license to manufacture for sale or distribution of drugs shall be made to the licensing authority appointed by the State Government.” See Ministry of Health and Family Welfare, “The Drugs and Cosmetics Rules, 1945 (As amended up to the 30<sup>th</sup> June, 2005)”, available at <http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf> (last visited Oct. 14, 2016).

<sup>146</sup> Times of India, “Delhi high court restrain Glenmark from selling anti-diabetes drugs” Oct. 7, 2015, available at <http://timesofindia.indiatimes.com/business/india-business/Delhi-high-court-restrain-Glenmark-from-selling-anti-diabetes-drugs/articleshow/49262612.cms> (last visited Oct 27, 2016).

<sup>147</sup> Times of India, “Cipla infringing Roche’s cancer drug patent: HC” Nov. 28, 2015, available at <http://timesofindia.indiatimes.com/business/india-business/Cipla-infringing-Roches-cancer-drug-patent-HC/articleshow/49956000.cms> (last visited Oct. 27, 2016).

is a promising development, these courts are now overburdened with cases and will require a significant amount of technical expertise and commitment of resources to be properly implemented. While the draft National IPR Policy proposed to establish specialized patent benches at the High Court level and designate an IP court at the district level, the final National IPR Policy did not include this provision.<sup>148</sup>

### Compulsory Licensing

The Indian Government appears to have taken a more measured and cautious approach in responding to recent CL cases. We are encouraged by this trend. Still, the grounds for issuing a CL under the provisions are broad, vague and appear to include criteria that are not clearly related to legitimate health emergencies. The Ministry of Health (MOH) continues to entertain potential recommendations to impose CLs on certain anti-cancer medicines under the special provisions of Section 92 of India's Patents Act, which would make it even more difficult for patent owners to defend their patents. Moreover, Indian pharmaceutical companies continue to make requests for voluntary licenses under Section 84(6)(iv) of the Patent Act as a strategy and subsequently seek a CL by using it as a commercial tool under the guise of better access to medicines, rather than a measure of last resort. A market with ongoing threats of CLs perpetuates an unreliable environment for patent protection and investment.

The research-based pharmaceutical industry believes that the findings on the working requirements in the CL decision for a patented anti-cancer medicine in March 2012 contravene India's obligations under the TRIPS Agreement (as well as the General Agreement on Tariffs and Trade and the WTO Agreement on Trade-related Investment Measures), which prohibit WTO members from discriminating based on whether products are imported or locally produced. The Bombay High Court further interpreted the working requirement to specify that satisfaction of the working requirement "would need to be decided on a case to case basis" and that "the patent holder would nevertheless have to satisfy the authorities under the Act as to why the patented invention was not being manufactured in India."<sup>149</sup> The Indian Supreme Court refused to hear the appeal arising out of the Bombay High Court judgment thereby perpetuating the ambiguity of the CL criterion and terms of use.

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

---

<sup>148</sup> Department of Industrial Policy and Promotion, Press Release, Oct. 22, 2014, available at [http://dipp.nic.in/English/acts\\_rules/Press\\_Release/ipr\\_PressRelease\\_24October2014.pdf](http://dipp.nic.in/English/acts_rules/Press_Release/ipr_PressRelease_24October2014.pdf) (last visited Oct. 27, 2016); "National Intellectual Property Rights Policy," May 12, 2016, available at [http://dipp.gov.in/English/Schemes/Intellectual\\_Property\\_Rights/National\\_IPR\\_Policy\\_08.08.2016.pdf](http://dipp.gov.in/English/Schemes/Intellectual_Property_Rights/National_IPR_Policy_08.08.2016.pdf) (last visited Oct. 27, 2016).

<sup>149</sup> *Bayer v. Union of India*, Writ Petition No. 1323 of 2013.

by other governments, both developed and developing.<sup>150</sup> These are misunderstandings and do not justify widespread use of compulsory licensing.

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

### Administrative Burdens

Section 8 of the Patents Act sets forth overly burdensome requirements that effectively target foreign patent applicants in a discriminatory manner since foreign applicants are more likely to have filed patent applications for the same invention 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 same foreign patent applications if that information is requested. These additional patent application processing requirements have been interpreted in a manner that creates heightened and unduly burdensome patent application procedures that mainly impact foreign patent applicants – those most likely to have patent applications pending in other jurisdictions. Further, Section 8 was enacted in 1970 when the information was only available from the applicant; much of the information sought is now publicly available on patent office websites in most major countries. For example, through the Global Dossier Initiative of five major patent offices (the U.S. Patent and Trademark Office, the European Patent Office, the State Intellectual Property Office of China, the Japanese Patent Office, and the Korean Intellectual Property Office), the current file histories from each of these offices are accessible at one website. Thus, accurate information about counterpart foreign applications is easily available to the Indian Patent Office Examiners.

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

Additionally, recent requests pursuant to Section 8(2) for the translation of foreign search and/or examination reports are not only unduly burdensome but costly as well. In practice, attorneys routinely receive informal translations of foreign search and/or examination reports intermingled with local attorney advice and counsel (information

---

<sup>150</sup> See, e.g., <http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws> (last visited Oct. 27, 2016). These allegations of wide-spread use of CLs in the U.S. and the premise that CLs can resolve access problems in India have been refuted by OPPI and PhRMA.

subject to attorney-client privilege). Moreover, translations of the search and/or examination reports may not yet be available at the time of the Section 8(2) request.

Moreover, the remedy for failure to comply with Sections 8(1) and 8(2) is extreme compared to other countries with similar (but less onerous) administrative requirements. In India, the failure to disclose under Section 8 can be treated as a strict liability offense that by itself can invalidate a patent (although a recent court decision indicates some flexibility for mere clerical errors). This is in contrast to a requirement that the failure to disclose be material and/or intentional as in the U.S. or Israel. Thus, India's disclosure requirement and remedy are each more burdensome as compared to other jurisdictions, thereby creating a barrier to patentability that has an unfairly greater effect on foreign patent applicants, and, in some instances resulted in India revoking patents on the grounds of non-compliance with this particular provision.<sup>151</sup>

### Regulatory Data Protection Failures

Contrary to its TRIPS Article 39.3 obligation, India fails to ensure that there is no unfair commercial use of the regulatory data submitted by another party in securing marketing approval in India or in a third country. Rather, when a pharmaceutical product has been previously approved by a Regulatory Authority in India or in another country, India requires only limited clinical data (in some cases involving as few as 16 Indian patients). This is in lieu of requiring submission of the entire dossier for review by India's Regulatory Authority. Moreover, in some instances when an applicant seeks approval for a drug that has already been approved abroad, Indian authorities waive the requirement to submit even this data.<sup>152</sup> In those circumstances, any subsequent approval of the drug in India is based entirely on the prior approval of the drug in a third country.

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

---

<sup>151</sup> See, e.g., *Ajantha Pharma Limited v. Allergan*, Intellectual Property Appellate Board (2013).

<sup>152</sup> See Rules 122A and B of the Ministry of Health and Family Welfare, "The Drugs and Cosmetics Rules, 1945 (As amended up to the 30<sup>th</sup> June, 2005)", available at <http://www.cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf> (last visited Oct. 27, 2016).

## INDONESIA

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

### Key Issues of Concern:

- **Registration delays:** PhRMA member companies continue to face burdensome regulatory delays in the registration process of new products, in contravention of Indonesia's own regulations. We understand that efforts to achieve stronger conformance with international best practices are being made with respect to regulatory timelines and processes as part of the ASEAN Pharmaceutical Regulatory Harmonization. We encourage the Indonesian Government to also make efforts to achieve stronger conformance with international best practices with respect to regulatory data protection and bioequivalence requirements.
- **Forced localization requirements:** The local manufacturing and technology transfer requirements of Decree 1010 are discriminatory, are implemented inconsistently, and raise national treatment concerns under Article III of the General Agreement on Tariffs and Trade (1994) that will have lasting implications for market access and patient health in Indonesia. To prevent import restrictions on innovative medicines, it is imperative that a solution is reached to allow all legitimate high quality pharmaceuticals to be traded, sold and distributed, regardless of origin.
- **Non-transparent policies:** The selection criteria for new molecules to be listed on the Indonesian National Formulary (FORNAS) remains unclear. There is a lack of clarity over how products are selected for the formulary and whether these products will stay on the formulary. The pharmaceutical industry urges the Indonesian government to work with stakeholders to develop a methodology that explains the formulary selection process. In addition, decisions regarding approvals should be based on science and efficacy of a new medicine and the process should be clearly defined.
- **Restrictive patentability criteria:** Recent amendments to the Patent Law preclude patents on new uses (indications) and establish an additional patentability criteria of "increased meaningful benefit" for certain forms of innovation, such as new salts or new dosage forms. These restrictions are bad policy because they undermine support for important innovations and appear to conflict with existing international obligations by imposing additional or heightened patentability criteria that discriminate against particular classes of technology. We are also concerned by amendments to the Patent Law that would impose new patent disclosure requirements regarding the source and origin of

genetic resources. Such requirements introduce uncertainties into the patent system that inhibit innovation in relevant technologies and undermine the potential of benefit-sharing.

- **Compulsory licensing:** In recent years (2004, 2007, and 2012), Indonesia has issued “government use”-type compulsory licenses (CLs) on nine patented pharmaceutical products, despite concerns raised by the affected PhRMA member companies. PhRMA is troubled by Indonesia’s decision to issue these licenses, which were promulgated without attempts to engage with the affected PhRMA member companies to find more sustainable and long-term solutions and in a manner that appears inconsistent with Indonesia’s international obligations. PhRMA is also concerned by the recent passage of the Patent Law, which includes provisions that discourage voluntary licensing between private parties and promote compulsory licensing on grounds that are vague or appear to be inconsistent with Indonesia’s international obligations. PhRMA member companies are prepared to work collaboratively with Indonesian authorities to find solutions that benefit patients in Indonesia while maintaining adequate and effective IP protection.

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**

### Registration Delays

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

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

### Negative Investment List (NIL)

In 2014, the Government of Indonesia amended the NIL to increase the percentage of foreign ownership allowed in pharmaceutical firms designated as manufacturers from 75 percent to 85 percent. Many multinational research-based

pharmaceutical companies are currently classified as distributors, or “PBF” enterprises, and many are 100 percent foreign-owned as permitted under the grandfather clause in the NIL. At present, the NIL limits any PBF enterprise to be 67 percent foreign-owned and multinational pharmaceutical companies’ investment is capped to 85 percent foreign owned (subject to a “grandfather clause” for existing investments).<sup>153</sup> These requirements limit Indonesia’s ability to attract foreign investments in the pharmaceutical sector and hence limit the competitiveness of Indonesia’s domestic pharmaceutical industry vis-à-vis its peers in the region. The MOH and Indonesia Investment Coordinating Board (BKPM) have expressed some support for eliminating these limitations in the NIL to allow 100 percent foreign-owned companies in Indonesia.

### Forced Localization Requirements

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

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

Rather than amend Decree 1010 to mitigate damaging provisions, the MOH created Decree 1799 on December 16, 2010, altering the definition of local manufacturing and introducing the concept of partial manufacture. PhRMA’s member companies have sought clarification on several vague and conflicting provisions of Decree 1799 since its release. Furthermore, in July 2011, BPOM released a draft of the Brown Book containing implementation guidelines for several Decree 1010 and 1799 provisions. Final revisions to the Brown Book were released on September 14, 2011,

---

<sup>153</sup> However, there are no restrictions on foreign ownership of raw material production.

following BPOM's review of stakeholder comments; some of the provisions in the revised Brown Book provided leeway for PhRMA's member companies to comply with the requirement to locally manufacture imported products within five years of patent expiration. While PhRMA's member companies acknowledge the initial steps taken by BPOM to engage in consultations, key concerns remain unresolved and several provisions of Decree 1010 and 1799 still require further clarification.

In short, PhRMA's member companies are concerned about the discrimination of Decree 1010 as well as the lasting implications to market access, IP protection, and patient health if unresolved.

### Non-Transparent Policies

The Indonesian Government's policies and regulations are regularly developed and implemented without providing multinational companies an opportunity for consultation or a clear and transparent sense of the process whereby they will be implemented. This lack of transparency is an underlying concern in each of the issues specified above, and significantly contributes to the uncertainty PhRMA's member companies face regarding investment and IP protections in the market. Another example of this is the selection criteria for new molecules to be listed on the Indonesian National Formulary (FORNAS). There is a lack of clarity regarding how products are selected for the formulary and whether these products will stay on the formulary. The innovative pharmaceutical industry urges the Indonesian government to work with stakeholders to develop a methodology that explains the formulary selection process. In addition, decisions regarding approvals should be based on science and efficacy of a new medicine. The Indonesian Government should extend access to its formal consultation process to incorporate input from stakeholders on government policies and regulations to the multinational private sector.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

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

TRIPS requires that an invention which is new, involves an inventive step, and is capable of industrial application, be entitled to patent protection. The revised Patent law adds an impermissible hurdle to patentability by adding a fourth substantive criteria of "increased meaningful benefit" to the World Trade Organization Agreement on Trade-

Related Aspects of Intellectual Property Rights (TRIPS) requirements. Moreover, this additional hurdle appears to be applied only to chemicals.

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

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to secure patents on *all* inventions that are new, involve an inventive step and are capable of industrial application. Restrictions that narrow patentability prevent innovators from building on prior knowledge to develop valuable new and improved treatments that can improve health outcomes and reduce costs by making it easier for patients to take medicines and improving patient adherence to prescribed therapies.

#### Burdensome and Vague Disclosure Obligations

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

#### Compulsory Licensing

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

The recently amended Patent Law creates further uncertainty in this area by discouraging voluntary licensing agreements between private parties and by promoting compulsory licensing on grounds that are vague or appear to be inconsistent with

Indonesia's international obligations. In particular, the Draft Patent Law unnecessarily requires disclosure of private licensing agreements and allows compulsory licensing if a patented product is not being manufactured in Indonesia. Requiring disclosure of private agreement terms would discourage entry into such agreements to the detriment of Indonesia. The local manufacturing requirement would also appear to contravene Indonesia's national treatment obligations under which it is clear that "local working" requirements may be met through importation.

Indonesia should make clear in its law that any compulsory licensing action needs to be taken on a patent-by-patent basis with full consideration of particular circumstances in each case. CLs should only be used in extraordinary circumstances as a last resort rather than standard government practice. As a general matter, CLs are not a sustainable or effective way to address healthcare needs. Voluntary arrangements independently undertaken by member companies better ensure that current and future patients have access to innovative medicines. PhRMA member companies are willing to work with Indonesian authorities to find solutions that benefit patients in Indonesia, while maintaining adequate and effective IP protections that are essential to sustain research toward the next generation of treatments.

### **Counterfeit Medicines**

Although PhRMA's member companies welcome Indonesia's ongoing efforts to promote the use of safe medicines, there is an urgent need to expand national enforcement efforts. Although new leadership at BPOM have focused their efforts on combatting counterfeit food and medicine products, the budget and resources for this effort remain inadequate. Increasing and especially enforcing the penalties for criminals caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as unsafe medicines will greatly assist Indonesia's efforts to reduce the harmful impact of counterfeit medicines.

Research conducted by Masyarakat Indonesia Anti-Pemalsuan (MIAP), Indonesia's anti-counterfeiting society, suggests that losses incurred by the state as a result of counterfeiting practices continue to rise each year. Greater collaboration and government initiatives, such as a nationwide campaign and devoted budget to combat counterfeit products, should be intensified to ensure the health and safety of the Indonesian people.

## JAPAN

Over the past half-decade, Japan has made important reforms in the areas of drug pricing, drug evaluation and approval, and vaccine policy that have made the system more transparent and more conducive to innovative biomedical research and development. These changes have increased patient access to life-saving medicines and reduced regulatory delays in the introduction of new drugs. Nevertheless, PhRMA's member companies continue to face several market access barriers in Japan.

### Key Issues of Concern:

- **Government pricing policies:** To continue in the positive direction described above, Japan should take further actions to ensure patients have prompt access to the newest drugs, increase incentives for research and development, make the innovation price maintenance scheme (now in its fourth two-year pilot stage) a regular part of the pricing and reimbursement system, and eliminate the premium ceiling. Proposals to change the biennial price revision process to an annual one should be rejected. Current market expansion repricing policies and new proposals to curb spending for “high-priced drugs” punish the most successful and highly regarded drugs in the Japanese market and discourage innovation. These practices should be eliminated, or, at a minimum, should not be applied to comparator priced products.

In addition, the Chuikyo suddenly decided in December 2015 to implement a new, *ad hoc* price cutting mechanism (the “huge seller repricing program”), which went into effect in April 2016. The Ministry of Health, Labour and Welfare (MHLW) is also developing new “optimal use guidelines” on a trial basis for targeted drugs with an eye toward launching the system more broadly in 2017. The imposition of these new programs on top of the myriad existing pricing and reimbursement rules is of serious concern to the industry. Stakeholder involvement in these programs has been limited, and many details on how the optimal use guidelines will affect the health insurance system and drug prices remain unclear. Similarly, proposals made in the Chuikyo to increase the time between drug approval and drug price listing should be rejected.

- **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, further flexible approaches are needed in the approval and regulatory process to promote simultaneous global development, including Japanese sample size for multi-regional clinical trials and long-term clinical studies.
- **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.

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**

### Pharmaceutical Pricing and Reimbursement

The Japanese pharmaceutical market accounts for ten percent of the global market. However, the global and Japanese drug development environment has become more challenging and risky for both foreign and Japanese firms with a declining success rate of new drug development, longer development times, and a significant increase in development costs.

The introduction of the price maintenance premium 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, and ensuring that Japanese patients have timely access to the world's newest and most innovative drugs. This system has demonstrably led to increased R&D, applications and approvals for new drugs and indications. However, the net benefit of the price maintenance premium has been somewhat reduced by the 80 percent ceiling on the innovation premium under certain circumstances and the continued use of the market expansion and other re-pricing rules.

Investment in drug innovation is a long-term endeavor, such that any unpredictability in the implementation of the price premium mechanism could lead to slower development of new drugs. Therefore, the top public policy priority of PhRMA's member companies is that the price maintenance premium be made a permanent part of the government's pricing and reimbursement system.

Sudden changes such as "huge seller repricing" and "optimal use guidelines" reduce the predictability and transparency of the drug pricing system in Japan and go against the Japanese government's stated goal to promote R&D investment in Japan. Reform of the pricing system should be based on a longer-term perspective and should avoid reactive short-term, *ad hoc* re-pricing mechanisms. The huge seller repricing program should not be extended any further and the effect of optimal use guidelines on the health insurance system should be strictly limited so that patients' early access to innovative drugs is ensured.

Another issue of serious concern is the continuing effort by some in the Japanese government to change the current biennial price revision system into an annual revision system.

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

1. The Repricing for Market Expansion Rule: The repricing for market expansion rule was introduced decades ago to address significant market changes since the initial drug price was established. However, over time, the rule has transitioned into a cost containment measure directed at innovative medicines without any clear rationale. Given the significant efforts made over the past decade by the Japanese Government to encourage the development and entry of innovative drugs for Japanese patients, this anti-innovation policy should be eliminated or, at a minimum, be applied in a manner that is consistent with the original intention of the repricing system. Specifically, to promote and reward innovation, market expansion repricing should not be applied to comparator priced products.
2. The Foreign Price Adjustment (FPA) Rule: The FPA rule was introduced as a mechanism to prevent and correct large price discrepancies arising between Japanese and foreign pharmaceutical prices. It has been amended several times over the past decade, and each change has further restricted its application. The FPA rule should be revised to its original intent, eliminating changes that exclude the highest reference price and other limitations on its application, and no new provisions should be enacted that would increase unfairness in its use. The current FPA rule, as amended, also is counter to the government's successful policy to eliminate the drug lag.
3. Application of the Innovation and Usefulness Premiums: Under the comparator pricing method of new drugs, certain premiums may be granted where the drug shows greater innovation or usefulness than its comparator. PhRMA welcomes recent increases in the range of allowable premiums. However, as it is being applied, most new drugs eligible for the price premium still receive no, or relatively low, premiums. PhRMA's members continue to support full use of the sliding scale in the application of premiums, and clearer guidelines would increase transparency and utilization of the sliding scale.
4. Relaxation of 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 approval. 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.
5. Health Technology Assessment (HTA): Discussions are being held at Chuikyo on the introduction of a more elaborate HTA system. PhRMA agrees that appropriate HTA has the potential to assist governments in making informed decisions about allocating resources. However, poor 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. The current discussions appear to favor a cost-utility approach which is likely to require greater stakeholder input on issues including equity considerations and cultural challenges to deriving health state preferences. Alternative technical approaches may need to be explored.

An HTA framework already exists in Japan in all three segments of medical technology, including procedures, drugs and medical devices. Specifically, during the reimbursement process it is necessary to demonstrate the effectiveness of a procedure, drug or device as compared to existing therapies. Superior effectiveness is able to be recognized and rewarded under the price premium process. Since this HTA framework is already in place, PhRMA's view is that enhancements could be made that will improve the framework and ensure that it meets the goals of providing patients with the best and most appropriate healthcare. PhRMA believes, however, that four key principles must be followed in guiding any efforts to enhance HTA.

- First, patients' access to various treatment options should be maintained at the current level. There should be no delay or restrictions in patient access to new health technologies in the areas of pharmaceuticals, medical devices, and medical procedures.
- Second, appropriate assessment of the holistic value of treatment options should be conducted. The assessment of value should take a broad perspective and should include not only the direct benefits of treatment but also the impact on patient quality of life, the social and economic benefits of health technologies, and economic productivity of the patient. Appropriate methods must be developed for this assessment.
- Third, the burden associated with enhancement of HTA should be minimized. Additional data collection should be kept to a minimum, and expansion of the bureaucracy structure should be avoided.
- Fourth, innovation should be rewarded appropriately based on the assessment for the further benefit of patients. In particular, policies related to re-pricing for market expansion should be assessed as to their impact on patient health and social and economic benefits.

It is vital that healthcare policy be viewed not in terms of cost, but in terms of its impact as a social and human investment on the national economy and the livelihood of the population.

## 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 Japanese sample size for multi-regional clinical trials and long-term clinical studies.
- PhRMA encourages harmonization of the following CMC data points:
  - Requirement to provide detailed description in the application form about manufacturing and manufacturing control;
  - Bio-equivalency (BE) data requirements for drug products under development; and
  - CMC data requirements for biological products.
- The industry appreciates the continuing efforts of the PMDA to report metrics on the number of simultaneous global development protocols and consultations. The commitment of PMDA to transition to using the 80 percent level rather than the median in reporting progress is a welcome development.
- 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 becoming a worldwide issue. In the U.S., the Generating Antibiotic Incentives Now (GAIN) Act is being implemented to provide incentives such as an exclusivity period and fast track approval for new drugs against drug-resistant pathogens. The gap in drug development in this area between the U.S. and Japan may lead to a future drug lag in this area. PhRMA encourages the Japanese government to consider measures to promote drug development in this area.

## 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 Expert 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 Plan (RMP)

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 Plan. The RMP went into effect on April 1, 2013. Global standardization of risk minimization measures is critical. PhRMA looks forward to continuing to engage collaboratively with academia and regulatory authorities on the implementation of this 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 healthcare 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

PhRMA welcomes the creation of the "Sakigake" program which will encourage the early evaluation and approval of important new drugs. PhRMA requests that this program apply equally to Japanese and foreign pharmaceutical companies without discrimination based on company nationality or country of manufacture.

## 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 National Vaccine Plan and adoption of six vaccines into the national immunization program (NIP). PhRMA applauds the government for these efforts, as well as for co-hosting six annual, high-level, important, and very successful Vaccine Policy Exchanges with the U.S. Department of Commerce, the U.S. Department of Health and Human Services, and the U.S. Centers for Disease Control and Prevention (CDC). However, outstanding issues continue to require attention:

- 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 an 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.
- It is critical that decisions related to vaccines be based on science. This is especially important in any evaluation of adverse events and attendant actions.
- The current recommendation (and reimbursement) 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.
- PhRMA welcomes 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 this and urges that the Committee on Immunizations be given the maximum possible responsibility and autonomy to make recommendations based on scientific evidence. A priority should be full execution of the National Vaccine Plan.
- 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.

- While stable supply of vaccines is critical for immunization programs, disruptions can occur given that vaccines are biological products and the production processes are complex and take a long time. As such it is critical to establish stockpile programs based on foreign best practices, to ensure reliable vaccine supplies during any disruptions.

## JORDAN

PhRMA and its member companies operating in Jordan are encouraged by recent developments and changes in how the Health Authorities and other government entities consider the opinions and feedback they receive from industry. Most recently, the Jordanian Food and Drug Administration (JFDA) conducted several workshops with innovative biopharmaceutical manufacturers to tackle many of the market access and regulatory issues currently impacting patient access to medicines in Jordan. However, this reform process will be lengthy and requires continued, transparent engagement between the Jordanian Government and innovative biopharmaceutical companies, in order to advance human health, and strengthen Jordan's competitiveness in the innovative medicines sector.

### Key Issues of Concern:

- **Local preference in government tenders:** Jordan's public procurement tenders provide preferential treatment to locally-produced generic products.
- **Innovative industry representation:** Although, the innovative biopharmaceutical industry is not represented at the Higher Council for Drugs, the chief decision-making body governing the medicines sector, the JFDA is engaged in separate consultations with PhRMA and is considering whether to include an industry representative as an observer to the Council. This is the first year where JFDA has assigned a member from the local area working group (LAWG) to be part of their scientific committee, which is a positive step. In addition, the LAWG was invited to provide input and recommendations on the new intellectual property strategy in Jordan.
- **Burdensome regulatory and pricing policies:** Jordan's regulatory and government pricing policies delay market access for novel medicines and vaccines, and deprive patients of access to promising new treatments that save, improve and extend life.
- **Regulatory data protection (RDP):** Jordan has significantly improved its RDP regime, consistent with its obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the U.S.-Jordan Free Trade Agreement (FTA). Nonetheless, industry continues to face challenges in meeting the requirement that marketing approval applications be filed in Jordan within 18 months of first global approval in order to qualify for RDP, particularly given the pharmacovigilance and other regulatory requirements established by the JFDA.

PhRMA requests that the U.S. Government continue to support industry actions with the JFDA to ensure that the problems described herein are quickly and effectively resolved.

## **Market Access Barriers**

### Local Preference in Government Tenders

Tenders of the Joint Procurement Procedures of Drugs (JPD) are designed to favor locally-produced generic drugs, which restricts Jordanian patients' access to innovative medicines. Per Article 52 (I) of the JPD, locally-produced generic products are rewarded a 15 percent price benefit (increased in 2014 from 10%) over innovative foreign products when considering tenders. Industry encourages the U.S. Government to seek the elimination of these discriminatory preferences, particularly through ongoing discussions with their counterparts in Jordan on Jordan acceding to the WTO Government Procurement Agreement.

### Denial of Representation at the Higher Council for Drugs

Despite representing more than 50 percent of the Jordanian pharmaceutical sector, the innovative pharmaceutical industry is denied representation at the Higher Council for Drugs at the Jordanian Food and Drug Administration (JFDA), while the drug owner association and local industry participate in the process. The issues considered by the Council thus do not address adequately, transparently or fairly the concerns of all stakeholders.

In a positive development, JFDA is engaged in separate consultations with PhRMA and is considering whether to include an industry representative as an observer to the Council. Further, the Jordan LAWG was invited by the JFDA's Scientific Committee to participate in their first conference for the Middle East and North America region, as well as to an IP roundtable conducted by the Ministry of Industry and Trade to establish an IP strategy for Jordan. Industry welcomes this increased engagement and is organizing several workshops on key issues identified by JFDA as priorities and areas for collaboration.

### Burdensome Regulatory and Pricing Policies

Jordan currently has in place burdensome regulatory policies. Jordan's FDA mandates that prior to accepting the registration file of a new product, the product must be marketed for at least one year in a reference country. This policy ignores the fact that the products have already undergone significant pre-market safety testing and continue to be subjected to post-approval surveillance efforts. As a result, the policy creates unnecessary obstacles to trade in violation of Article 2.2 of the WTO Technical Barriers to Trade Agreement.

Furthermore, the Jordanian Government sets pharmaceutical prices at the median of 16 EU reference countries, or the lowest price paid either in Saudi Arabia or in the country of origin of any active pharmaceutical ingredient. Prices are frequently revised by JFDA upon any variation/ regulatory activity considered to be a "major variation". These government price alignments are too frequent, and are an

administrative and operational burden on the industry and JFDA. While industry welcomes some improvements in 2016 (reducing the frequency of re-pricing), PhRMA recommends that JFDA review the definitions for major or minor variations, and thereby reduce the number of events triggering price revisions.

## **Intellectual Property Protection**

### Regulatory Data Protection

Industry has worked closely with the Jordan health authorities to improve the provision of RDP in Jordan, consistent with Jordan's international obligations under TRIPS and the U.S. Jordan Free Trade Agreement (FTA). In particular, Jordan now provides: (1) RDP from the date of marketing authorization in Jordan (rather than the date of the marketing application); and (2) three-years of RDP for newly approved indications, consistent with Article 4(22) of the FTA. PhRMA and its members commend Jordan for these improvements.

Jordan continues, however, to require that marketing authorization applications for new medicines 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. Meeting the 18-month deadline to file is complicated by a complex series of regulatory requirements established by the JFDA, and the one-year delay that is legally required to monitor the usage of the new drug in a larger population (pharmacovigilance). 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 (CPP) application and the one year of pharmacovigilance and other technical requirements).

## KOREA

PhRMA and its member companies remain concerned with several market access and intellectual property issues in Korea. As one of the largest and fastest growing pharmaceutical markets in the world, Korea's efforts to reform its healthcare system are ongoing.

### **Key Issues of Concern:**

- **Discriminatory market access policies:** The current government pricing mechanism sets prices for new medicines considering the weighted average price for pharmaceuticals – including generics – within the same therapeutic class. This policy means that the government pricing system significantly undervalues medicines. Consistent with the South Korea-U.S. Free Trade Agreement (KORUS), the MOHW should improve its government pricing policies, for example, by not using off-patent or generic prices in the calculation of prices for new, patented products, so that prices for new medicines appropriately reward innovation and encourage investment in the new medicines needed by the people of Korea.
- **Patent enforcement concerns:** While Korea has implemented a patent enforcement 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; the lack of clarity regarding how the criteria for seeking and being granted a stay will be applied; and the limited period of only nine months for a sales stay. Furthermore, the patent enforcement mechanism should be based on the patents as granted by the Korean Intellectual Property Office (KIPO) and uncertainties (including the MFDS's redrafting of claims) should be removed from the patent enforcement system.

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**

#### **Transparency and Predictability in Government Policy-making**

Since 2010, MOHW has repeatedly changed its pharmaceutical pricing and reimbursement policies without considering the long-term implications for innovation and market predictability, and in some cases disproportionately targeting innovative pharmaceutical companies. In spite of significant input from the pharmaceutical industry regarding the need to appropriately value innovative medicines following the 2012 global price cut, little progress has been made and subsequent consultation processes have proven perfunctory in most cases. In 2016, the government-industry consultation body met with the agenda of improving the pricing and reimbursement (P&R) system.

Some areas such as actual transaction price (ATP) and the pricing of biologics have shown progress, but there remains a lack of predictability and transparency in new drug P&R guidelines for the innovative pharmaceutical industry. This lack of predictability and transparency results in an uncertain business environment for the innovative pharmaceutical industry.

Also, there are still repetitive and excessive price control mechanisms working in the market after reimbursement listing, such as price reductions due to ATP, Price-Volume Agreements (PVA), listing of first generic at LOE, and adding new indications or expanding reimbursement scope.

Separately, the Risk Sharing Agreement (RSA) system should be expanded to provide an alternative pathway for reimbursement listing to enhance patient access to innovative medicines regardless of disease area and without the need to submit unrealistic pharmaco-economic or statistical data. Currently the RSA is limited to rare or cancer disease areas only and dependent on mandatory submission of pharmaco-economic data.

Government price cuts have significantly impacted incentives for further investments in pharmaceutical innovation, by creating an unpredictable operating environment for innovative pharmaceutical companies that rely on long-term planning to make the vital investments necessary for the development of new medicines. These measures have significant impacts in other markets around the world given the number of countries that directly or indirectly reference Korean prices.

### Recent Reform Measures

In Korea, prices of new medicines are based on the weighted average price within the therapeutic class, which includes prices of off-patent and generic drugs. As a result, government measures that lower existing medicine prices impact new drug pricing. In other words, by instituting drastic price reductions on the off-patent and generic market, and then basing new drug prices on the prices of these now heavily-discounted medicines, the government inappropriately depresses the prices of innovative medicines.

Since the Positive Listing System (PLS) was introduced in 2007, the reimbursement prices of new drugs have reached new lows, less than half of the average OECD price for new drugs.<sup>1</sup> In turn, these unsustainably low prices for existing drug prices are referenced in setting prices for new medicines in Korea. Despite these low prices, during 2009-2014, only 29%<sup>2</sup> of oncology drugs were listed for reimbursement. It is difficult for a new drug to be listed under Korea's pharmaco-economic (PE) evaluation given the current the comparator selection criteria, which inappropriately reference generics. As a consequence, the ratio of medicines listed under PE evaluation has been significantly lower in recent years, with only 12.9% (26/201)<sup>3</sup> listed since 2007.

Effective May 29, 2015, MOHW implemented new listing processes that exempts certain new drugs from completing a pharmaco-economic (PE) evaluation and provides for fast-track pricing decisions. However, the PE exemption criteria are too narrow to be applicable for most new medicines. An effective dialogue with stakeholders, including the research-based biopharmaceutical industry, on valuing innovation will support MOHW's intention to promote greater pharmaceutical R&D in Korea and improve the global competitiveness of the Korean biopharmaceutical industry in the future.

On July 7, 2016, MOHW announced a "Plan of Improving Drug Pricing System", which would grant price and other preferences for all locally-developed new medicines, but not for imported innovative medicines. As such, this proposed plan appears to be inconsistent with Korea's national treatment obligations under the General Agreement on Tariffs and Trade and KORUS. PhRMA, in close coordination with its local sister association KRPIA, will continue to closely monitor implementation of this new preferential drug pricing system.

#### Independent Review Mechanism (IRM)

Under Article 5.3(5)(e) of the U.S.-Korea Free Trade Agreement and the side letter thereto, Korea agreed to "make available an independent review process that may be invoked at the request of an applicant directly affected by a [pricing/reimbursement] recommendation or determination." The Korean Government has taken the position, however, that reimbursed prices negotiated with pharmaceutical companies should not be subject to the IRM because the National Health Insurance Service (NHIS) does not make "determinations" and merely negotiates the final price at which a company will be reimbursed. However, this interpretation totally negates the original purpose of the IRM, which we believe should apply to the negotiation process for prices of all reimbursed drugs, particularly patented medicines.

#### Ethical Business Practices (EBP) Reform

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

## Intellectual Property Protection

### Patent Enforcement

Consistent with its IP obligations under KORUS,<sup>154</sup> effective March 15, 2015, Korea has implemented the framework of an effective patent enforcement system. Key issues that PhRMA continues to monitor include:

- The discretion afforded to MFDS to determine whether to list a patent in the Green List or to permit a change to the patent listing.
- The sales stay of the potentially infringing product is not automatic; rather the patent holder must seek a stay. It is not clear how MFDS will apply the criteria set forth in the new regulation to determine whether to grant a stay. To date, however, stay sales have been granted as long as the applicant meets the basic formalities.
- Korean law only provides for a nine-month sales stay. It is unclear whether this will be an adequate period of time to resolve a patent dispute (consistent with Article 18.9(5)(b) of KORUS) before an infringing product is allowed to enter a market or whether injunctive relief will remain available through Korea's courts.

---

<sup>154</sup> See U.S.-Korea Free Trade Agreement, Art. 18.9, para. 5.

## MALAYSIA

PhRMA and its member companies operating in Malaysia hope to continue our engagement with the Government of Malaysia as it looks to improve the regulatory and intellectual property environment for the research-based pharmaceutical industry.

### Key Issues of Concern:

- **Listing pharmaceuticals on the national formulary:** Effective 2016, Malaysia adopted a new process for listing products on the Ministry of Health (MOH) Formulary. While this is a welcome development, PhRMA and its members are concerned that the final guidelines require one year of post-marketing surveillance data prior to listing and that there is no mechanism to ensure that patients who benefited from the medicines during local clinical trials maintain access during this period. In addition, if a product is not approved for listing on the Formulary, the applicant should be provided a rationale for that decision so that it can better understand the criteria for listing and to determine if it may negotiate an alternative access scheme with the government.
- **National tenders:** Recently, there have been extraordinary delays in call and award of tenders ranging from 6-8 months for innovative medicines in Malaysia. The industry is concerned that the delays could adversely affect patient access to medicines in Malaysia. Prompt actions are required to ensure the root cause of the delays are identified and remedial actions are taken to ensure continued access to medicines without any interruptions.
- **Preferential treatment of local manufacturers:** The Government of Malaysia indirectly discourages an open and competitive marketplace for international pharmaceutical compounds through procurement preferences for locally manufactured products. For example, the Government of Malaysia has recently announced that it will grant three-year procurement contracts to companies who move production of imported products to Malaysia (with the potential for a two-year extension if those locally produced products are exported).
- **Intellectual property protection:** Malaysia does not have an effective patent enforcement system that provides for the early resolution of patent disputes before marketing approval is granted to infringing follow-on products during the patent term. In addition, its regulatory data protection (RDP) system fails to provide (1) any protection for biologics; and (2) effective protection for a sufficient period of time for chemically synthesized drugs from the date of marketing approval in Malaysia.
- **Counterfeit medicines:** There is great need for deterrent criminal penalties for those caught manufacturing, supplying, or selling counterfeit pharmaceuticals as well as closer coordination between the U.S. and Malaysian Governments on anti-counterfeiting initiatives. While the industry welcomes the proposed

enhanced penalties for counterfeiting of medicines contained in the Pharmacy Bill, action is required to advance this stalled legislation (pending for the last five years).

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**

### Listing Pharmaceuticals on the National Formulary

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

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

### National Tenders

Recently, there have been extraordinary delays in call and award of tenders ranging from 6-8 months for innovative medicines in Malaysia. The industry is concerned that the delays could adversely affect patient access to medicines in Malaysia. Prompt actions are required to ensure the root cause of the delays are identified and remedial actions are taken to ensure continued access to medicines without any interruptions.

### Preferential Treatment of Local Manufacturers

Malaysia's National Medicines Policy (MNMP/DUNas), which prioritizes the medium and long-term goals set by the Government for the pharmaceutical sector, endorses potential price controls, generic drugs substitution, and preferences for generics and local manufacturers by promoting national self-reliance for drugs listed on the National Essential Medicine List (NEML). PhRMA member companies submit that the Government of Malaysia should eliminate discriminatory preferences for locally

manufactured pharmaceuticals. This preferential treatment discourages an open and competitive marketplace in Malaysia.

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

### Regulatory Approval Process

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

Further, the recent introduction of the Quest system for dossier submissions has created significant administrative hurdles in the processing of biopharmaceutical industry regulatory submissions and threatens to delay patient access to new medicines in Malaysia. Although additional resources have been allocated to develop the Quest system, full deployment which was initially expected before the first quarter of 2016 has been delayed. In the interim, a moratorium on submissions and a manual process with set limitations have been established.

### Halal Pharmaceutical Guidelines

In April 2011, The Department of Standards Malaysia, under the Ministry of Science, Technology and Innovation (MOSTI), launched "Halal Pharmaceuticals: General Guidelines". These guidelines were developed by Standard Malaysia's Technical Committee on Halal Food and Islamic Consumer Goods under the authority of the Industry Standards Committee on Halal Standards (ISC I), comprising representatives from a diverse set of Malaysian government, academic, and domestic pharmaceutical stakeholders.

As a general matter, PhRMA's member companies are strongly supportive of the religious and cultural sensitivities of all Malaysians and believe these guidelines should remain voluntary. PhRMA's members are concerned, however, by certain policy decisions that may indicate that these voluntary guidelines could be made mandatory. For example, in 2013, MoH indicated that halal logos could be affixed to over the-counter medicines (albeit affirming that halal logos should not be affixed on other medicines). Similarly, questions in the government tender process concerning porcine content and whether the product has a halal certification, suggest that there may be preferential treatment for halal products in government procurement contracts.

## **Intellectual Property Protection**

### Effective Patent Enforcement

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

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

### Regulatory Data Protection (RDP)

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.<sup>155</sup>

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

---

<sup>155</sup> DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016).

for a period of time. TRIPS Article 39.3 requires WTO members, including Malaysia, to protect proprietary test data submitted to market authorizing bodies, including the MoH, “against unfair commercial use” and against “disclosure.”

The stated objective of Malaysia’s Directive (11) dlm. BPFK/PPP/01/03 Jilid 1 is “to protect the undisclosed, unpublished and non-public domain pharmaceutical test data ... for the purpose of scientific assessment in consideration of the quality, safety, and efficacy of any new drug product....”<sup>156</sup>

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....<sup>157</sup>

As such, Malaysia requires the marketing authorization application of the new medicine to be filed within 18 months from the first worldwide regulatory approval in order to be considered as a “new chemical entity” and, thus, eligible for RDP in Malaysia. If the 18 month deadline is not met, the product loses data protection, allowing a follow-on molecule to be approved based on the originator’s regulatory data during what should have been the data protection period. It is challenging – if not impossible – to meet the 18-month application requirement if the first worldwide registration was not in the EU or the United States (both are relied upon for the Certificate of Pharmaceutical Product (CPP) application).

In addition to this inappropriate time restriction on products eligible for RDP in Malaysia, the actual term of the protection in Malaysia is measured from the date of first approval in the world. Thus if a new chemical entity is registered in Malaysia one year after first approval in the world, Malaysia only provides four years of RDP. Indeed, the only instance in which an innovator can receive the full five years of RDP in Malaysia is if they seek marketing approval in Malaysia first.

This interpretation of RDP improperly penalizes innovators for first seeking marketing approval in other countries. As in other markets that seek to promote research and development into innovative medicines, Malaysia should measure the term of the RDP protection from the time that the new molecule is approved in Malaysia.

---

<sup>156</sup> See paragraph 1.2 of Directive BPFK/PPP/01/037.

<sup>157</sup> Id.

Finally, Malaysia fails to provide any RDP for biologics. Made from living organisms, biologics are complex and challenging to manufacture and may not be protected adequately by patents alone. Unlike generic versions of traditional chemically-synthesized compounds, biosimilars are not identical to the original innovative medicine and there is greater uncertainty about whether an innovator's patent right will cover a biosimilar version. Without the certainty of a substantial period of exclusivity, innovators will not have the incentives needed to conduct the expensive, risky and time-consuming work to discover and bring new biologics to market.

### Patent and Trademark Laws

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

### **Counterfeit Medicines**

The counterfeiting of pharmaceutical products poses a serious threat to the health and safety of Malaysia's citizens. PhRMA member companies strongly support enhanced coordination between the U.S. and Malaysian Governments on anti-counterfeit initiatives, including training for regulatory and security officials. The addition of new resources and heightened enforcement capabilities for Malaysia's intellectual property court system would serve as a strong compliment to these initiatives. Increasing the penalties for criminals caught manufacturing, supplying, or selling counterfeits will also help Malaysia achieve world class status as a hub for advanced health innovations and healthcare delivery. While the industry welcomes the proposed enhanced penalties for counterfeiting of medicines contained in the Pharmacy Bill, action is required to advance this stalled legislation.

## MEXICO

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

### Key Issues of Concern:

- **Market access delays:** Despite recent improvements to the marketing approval process for pharmaceutical products by the Federal National Commission for Protection against Health Risks (COFEPRIS), significant barriers to the public market for medicines remain due to the lengthy, non-transparent, and unpredictable sanitary registration release process.
- **Weak patent enforcement and regulatory data protection failures:** Mexico's health regulatory agency (COFEPRIS) and the Mexican Patent Office (IMPI) have committed to improve the application of Mexico's 2003 Linkage Decree and to provide protection for data generated to obtain marketing approval for pharmaceutical products. Despite these commitments, the application of Mexico's patent linkage system continues to be distorted. For example, it is not clear how COFEPRIS reviews the Gazette listing during the regulatory approval process. In addition, although courts have consistently ruled that patents for medical uses may be listed, the Mexican Patent Office (IMPI) continues to deny such listings. Implementation of substantive regulatory data protection (RDP), including provision of RDP for biologics, is still pending.
- **Inadequate biosimilars regulation:** Recent additions (2011) and updates to the regulations covering approval of non-innovative biologics (biosimilars) lack clarity.

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

Key market access issues in Mexico concern the excessive times taken for formulary inclusion and the 5-year registration renewal process. Both significantly exceed stated time frames. COFEPRIS, under the leadership of Julio Sanchez y Tepoz, has made important improvements in the approval process despite limited resources and cost-containment pressures. Industry applauds Commissioner Sanchez y Tepoz's efforts to improve the efficiency and technical capability of COFEPRIS.

Following COFEPRIS approval, there remain significant barriers for patients, primarily those covered by public institutions, in accessing life-saving and enhancing

interventions. This additional delay is caused by the lengthy, non-transparent, and uncertain reimbursement system used in Mexico.

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

Accordingly, reimbursement delays add, on average, over two years to the access process, if made available at all in the public sector. On average, it takes 1,500 days for Mexican patients to access innovative medicines.<sup>158</sup>

## **Intellectual Property Protection**

### Weak Patent Enforcement

To ensure adequate and effective protection of IP rights for the research-based biopharmaceutical sector, mechanisms that provide for the early resolution of patent disputes before an infringing product is allowed to enter the market are critical.

Mexico's Linkage Decree of 2003 constituted important progress toward an early resolution mechanism and the full recognition of pharmaceutical patent rights in Mexico. However, the decree is not being implemented in a comprehensive and consistent manner. For example, the publication in the Official Gazette of formulation 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, it is unclear whether and how COFEPRIS consults the Official Gazette and with the Patent Office to verify that there is no patent infringement, including for formulation patents, before issuing marketing authorizations.

---

<sup>158</sup> AMIIF "Access 2015" report.

Both of Mexico's North America Free Trade Agreement (NAFTA) partners provide patent enforcement systems for product, formulation and use patents. It is therefore inappropriate for Mexico to not provide effective patent enforcement for use patents. Furthermore, effective patent enforcement mechanisms inherently prevent the marketing of follow-on products when such marketing would infringe valid patent rights.

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.

Unfortunately, PhRMA member companies generally are unable to remove patent infringing products from the Mexican marketplace. Obtaining effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains the rare exception rather than the norm. Although injunctions may be initially granted subject to the payment of a bond, counter-bonds, or in some proceedings mere applications, may be submitted by the alleged infringer to lift the injunction. The failure to provide effective patent enforcement mechanisms is inconsistent with Mexico's commitments under NAFTA and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

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

### Regulatory Data Protection Failures

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.<sup>159</sup>

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. 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.

---

<sup>159</sup> DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016).

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

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

In June 2012, COFEPRIS issued guidelines to implement RDP for a maximum period of five years – an important step toward fulfilling Mexico's obligations under TRIPS and NAFTA. PhRMA members initially welcomed this decision as an important confirmation of Mexico's obligations and its intention to fully implement the NAFTA provisions.

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

#### Potential Abuse of the "Bolar" Exemption

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

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

## 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 Pharmaceutical Management Agency (PHARMAC) as well as broader intellectual property protections. PHARMAC continues to impose stringent cost containment strategies,<sup>160</sup> and operates in a non-transparent manner, creating an unfavorable environment for innovative medicines.

### Key Issues of Concern:

- **Government pricing and reimbursement:** PHARMAC's reimbursement decisions severely limit New Zealand patient access to new medicines, and funding for new medicines is significantly delayed. In anticipation of meeting its Trans-Pacific Partnership (TPP) obligations, New Zealand is currently undertaking a consultation to determine whether PHARMAC meets the transparency and due process obligations included in Chapter 26 and the industry specific provisions in Annex 26-A of the TPP. Based on the current consultation documentation, it appears that the New Zealand Government has taken a liberal interpretation of the transparency obligations.
- **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 released a guideline on Government procurement including principles that PhRMA member companies would strongly support if applied to PHARMAC.
- **Amendments to the Patents Act 2013:** To meet its TPP obligations, New Zealand has initiated legislative changes to a number of Acts (including the Patents Act 2013). While clauses to provide patent term adjustment to account for delays in patent processing have been included, it is disappointing that the provisions for pharmaceutical patent term restoration to account for the time taken to secure marketing approval cap the maximum restored term to two years. This does not reflect best practices in other markets, including the United States and Japan.

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

---

<sup>160</sup> 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).

## Market Access Barriers

### Government Pricing and Reimbursement

Though not explicitly stated, PHARMAC's reimbursement decisions suggest a pharmaceutical 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. A recent study found that between 2009-2014, 88% of new medicines available in Australia were *not* available in New Zealand. Almost 10% of these medicines are for diseases with no current treatment available in New Zealand. In 2014, Australia listed 17 new medicines on the Pharmaceutical Benefit Scheme (PBS), and New Zealand just listed one. The data also showed that the timeliness of the listing in New Zealand was slower than in Australia, taking two years longer, on average, for PHARMAC to fund the same medicines compared to Australia.<sup>161</sup>

Ongoing monitoring of PHARMAC and the Pharmaceutical Schedule listing trends by innovative pharmaceutical industry association, Medicines New Zealand, continues to show the lag in patient access in New Zealand. In March 2016, updated analysis showed that there were 81 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 diabetes, metastatic breast cancer and rheumatoid arthritis. Some of these medicines have been on the list for up to twelve years, and the average waiting time is nearly three years.<sup>162</sup>

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 and to citizens of other OECD countries.

---

<sup>161</sup> 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).

<sup>162</sup> Medicines New Zealand, Evidence of a Waiting List PPT, available at <http://www.medicinesnz.co.nz/assets/Documents/Evidence-of-a-waiting-list2.pdf> (last visited Oct. 27, 2016).

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 imperative. 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 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 there has been little to no growth (a total of 9.5 percent over the last 10 years) and savings from year to year are not accrued into the following year’s budget.
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 in New Zealand. 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.

## Consultation on Transparency and Due Process in Innovative Pharmaceutical Procurement and Reimbursement

As part of meeting its TPP obligations, New Zealand is currently undertaking a consultation<sup>163</sup> to determine whether PHARMAC meets the transparency and due process obligations included in Chapter 26 and the industry specific provisions in Annex 26-A of the TPP. Based on the current consultation documentation, PhRMA and its members are concerned that the current proposals being considered will not provide the meaningful timelines, due process and independent review required to ensure that New Zealand patients and their healthcare professionals gain timely access to innovative medicines.

### 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 PHARMAC's funding by setting ongoing three-year funding rather than year-to-year funding.
- Develop an action agenda for the industry on public policy issues 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 Ministry of Business, Innovation and Employment released a guideline on Government procurement. Among other recommendations, the guideline includes the following principles:

---

<sup>163</sup> See *PHARMAC's Implementation of the Trans-Pacific Partnership (TPP) provisions and other Amendments to Application Processes* (Sept. 5, 2016), available at <https://www.pharmac.govt.nz/news/consultation-2016-09-05-tpp-implementation/> (last visited Oct. 27, 2016).

- Be accountable, transparent and reasonable;
- Make sure everyone involved in the process acts responsibly, lawfully and with integrity;
- Stay impartial – identify and manage conflicts of interest; and
- Protect suppliers' commercially sensitive information and intellectual property.

These are the exact 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

PhRMA and its members are glad to see that legislation introduced into the New Zealand Parliament in order to meet certain TPP obligations provides for patent term adjustments to compensate for unreasonable delays in the processing of patent applications. However, the proposed legislative changes to the Patent Act 2013 to restore a portion of the patent term lost during the marketing approval process, unreasonably cap the extension at two years, regardless how long Medsafe takes to review the marketing application. This does not reflect international best practices, including in the United States and Japan, and does not provide the necessary incentives for Medsafe to conduct its review process in a timely manner.

## PERU

PhRMA and its member companies operating in Peru are concerned about market access barriers and weakness of certain intellectual property (IP) protections and the state of several discriminatory regulatory requirements that favor local producers in Peru.

The U.S.-Peru Trade Promotion Agreement (USPTPA), which was signed in 2006 and amended in 2007, obligates Peru to protect pharmaceutical products' safety and efficacy data, provide a pre-launch legal system that will provide patent holders with sufficient time and opportunity to resolve patent disputes prior to the marketing of an infringing product, and establish a stronger IP framework. Peru has failed to adequately comply with these obligations. Although PhRMA and its member companies do not consider the USPTPA a model for future trade agreements, PhRMA has monitored implementation of the USPTPA, and has been closely monitoring the enforcement of the implementation regulations since its entry into force in February 2009.

### **Key Issues of Concern:**

- **Regulatory barriers, processing delays and duplicative testing requirements:** Peru has introduced a number of measures to help ensure the quality, safety and efficacy of pharmaceuticals. However, implementation of these measures has been delayed and a number of these regulations are applied by the Health Authority in an impractical way in that they request additional documents that may not be issued in the country of manufacture, or impose excessive administrative burdens that serve no purpose other than delaying the marketing approval process and patient access to medicines. In general, capabilities of the Peruvian Health Authority (PHA) need to be increased as a way to reduce current uncertainty and unpredictability.
- **Weak patent enforcement:** Peru does not provide patent holders with sufficient time and opportunity to seek injunctive relief prior to the marketing of an infringing product. This is contrary to Peru's trade agreement obligations and creates significant uncertainty for innovators, their competitors and patients alike.
- **Compulsory licensing:** In January 2014, the Ministry of Health (MOH) received a petition to issue a compulsory license (CL) on a patented medicine. The MOH did not permit the manufacturer or the local innovative industry association to participate in the petition review process, raising significant due process concerns.
- **Regulatory data protection failures:** Peru does not sufficiently support and value the rigorous testing and evaluation biopharmaceutical innovators and their partners around the world undertake to demonstrate potential new medicines are safe and effective for patients who need them. Contrary to Peru's commitments in bilateral and global trade negotiations, the PHA provides an insufficient period

of regulatory data protection (RDP) and has failed entirely to provide RDP for biologic 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**

### Regulatory Barriers

Peru has introduced a number of measures to help ensure the quality, safety and efficacy of pharmaceuticals. However, implementation of these measures has been delayed and a number of these regulations are applied by the Health Authority in an impractical way in that they request additional documents that may not be issued in the country of manufacture, or impose excessive administrative burdens that serve no purpose other than delaying the marketing approval process and patient access to medicines.

### Processing Delays

To date, the PHA's implementation of regulations still unduly focuses on administrative details and formatting, with less emphasis on the substance of the application, *i.e.*, whether science supports granting a product marketing approval. For example, failure to provide documentation in the exact format required by the PHA is a basis for delaying or even refusing marketing approval. These regulatory measures and delays present unnecessary trade barriers and may have a negative impact on individual companies' plans to bring products to market in Peru. In general, the capabilities of the PHA need to be increased in order to reduce current uncertainty and unpredictability.

### Duplicative Testing

The PHA's regulations include numerous provisions that create unnecessary confusion and market access barriers. Article 45 of Law 29459 provides that: (1) the first batch of any pharmaceutical product after registration or renewal must undergo complete quality testing in Peru (even if quality testing has already been performed at the manufacturing facility overseas); and (2) subsequent quality testing on further batches may be performed outside of Peru as long as the laboratory conducting that testing has been certified by the PHA. However, these certifications have been delayed and at the current rate, the processing time and backlog are expected to grow.

In addition, regulations provide that the PHA will accept quality testing of manufacturers certified by health authorities of high sanitary vigilance countries, such as the United States, in Good Laboratory Practices (GLP) or Good Manufacturing Practices (GMP), provided the GMP covers GLP and the authority so states.

Unfortunately, local generic manufacturers are trying to capitalize on this uncertainty by pressing authorities to request local duplicative testing of all batches of all pharmaceutical products. The former Peruvian Minister of Commerce has supported this pressure through a letter to the Minister of Health.

Bill 995/2011-CR (“Bill 995”), which was approved by the Health Committee of the Congress in June 2012, would make it mandatory for a pharmaceutical products’ importer to conduct duplicative testing in Peru of every batch of imported pharmaceutical products. Further, Article 5 of Bill 995 would require all technical information relied upon in a sanitary registration application to “be extracted from internationally recognized bibliographical sources, freely accessible to the public...” Public disclosure of these data as a precondition of obtaining a sanitary registration would be an inappropriate circumvention of Article 16.10.2 of the USPTPA, and violate Peru’s broader international obligations under Article 39 of the WTO TRIPS Agreement and the Technical Barriers to Trade Agreement.

In short, the bill, if approved, would impose a disproportionate burden on U.S. and international pharmaceutical companies, thereby creating a significant trade barrier for imported medicines and a profitable but artificial industry for local laboratories. Currently, the Plenary Session of the Congress has submitted the bill back to the Health Committee for further analysis. After four years, the bill is still pending and remains a threat.

### Clinical Investigation Standards

The National Health Institute (INS) is working on measures to increase sanctions and impose clinical authorization requirements that are not in line with international standards. This has created significant uncertainty regarding ongoing clinical studies and could discourage future investment and clinical trials in Peru.

## **Intellectual Property Protection**

### Weak Patent Enforcement

To ensure adequate and effective protection of IP 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. Such mechanisms prevent the grant of marketing approval for any product known by regulatory entities to be covered by a patent until expiration of the patent. An effective early resolution mechanism provides a procedural gate or safeguard. It ensures drug regulatory entities do not inadvertently contribute to infringement of patent rights granted by another government entity by providing marketing authorization to a competitor of the innovative firm.

Another critical tool to protect against irreparable harm from the loss of IP is the ability to seek injunctive relief (or equivalent procedural measures) to prevent the sale of an infringing product during expeditious adjudication of patent disputes.

Article 16.10.3 of the USPTPA requires Peru to provide patent holders with sufficient time and opportunity to resolve patent disputes prior to the marketing of an allegedly infringing product if a sanitary registration is requested by an unauthorized manufacturer of a patented product. In response, the Peruvian Government indicated that it would provide notice of sanitary registration applications on the PHA website so that patent holders have notice of an intention to commercialize a potentially infringing product. In reality, the web page of the PHA is never updated, and this notice alone is not adequate to provide the ability to seek and obtain a remedy before the marketing of the infringing product.

Further, the Peruvian patent enforcement system is ineffective in that it does not provide for timely resolution of patent disputes. The Peruvian system for enforcing patents is a two-step, sequential process: (1) an administrative process for determining infringement by the Institute for Defense of Competition and Intellectual Property (INDECOPI) that takes two years on average; and (2) a judicial action in a civil court to recover damages, which can commence only after the administrative process is exhausted. This judicial action takes four years on average, a duration which discourages patent owners from enforcing their patents.

### Compulsory Licensing

In January 2014, the MOH received a petition to issue a CL on a patented medicine. Although MOH has initiated a process to review the petition, to date neither the manufacturer nor the local innovative pharmaceutical industry association have been permitted to participate in that review. Moreover, neither MOH nor the Ministry of Commerce have responded to correspondence from the manufacturer or local industry association. Any technical analysis being undertaken is being done without consulting the manufacturer, raising significant due process concerns.

### 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.<sup>164</sup>

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

---

<sup>164</sup> DiMasi JA, Grabowski HG, Hansen RW; Tufts Center for the Study of Drug Development. Innovation in the pharmaceutical industry: new estimates of R&D costs. In: Briefing: Cost of Developing a New Drug, available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited Oct. 27, 2016).

the world protect such data submitted for regulatory approval from unfair commercial use for a period of time. TRIPS Article 39.3 requires each WTO member to protect undisclosed test and other data submitted for marketing approval in that country against both disclosure and unfair commercial use.

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

Since 2009, Peru has granted RDP for a very limited period of time (40 months, on average). Further, PHA has refused to grant RDP to biologic products. This action is inconsistent with Peru's obligations under TRIPS, the USPTPA, and national law.

Legislation pending before the Peruvian Congress would further undermine protection of undisclosed information. Bill 995 would require public disclosure of confidential data as a precondition of obtaining a sanitary registration (by virtue of the obligation to use internationally recognized bibliographic sources freely accessible to the public), in apparent violation of Peru's trade agreement obligations.

To appropriately support and value the rigorous testing and evaluation of potential new medicines, the Government of Peru should refrain from granting sanitary registrations to third party follow-on versions of any kind of innovative pharmaceutical products, regardless if they are synthesized or biotechnologically derived pharmaceutical products, for a sufficient period of time, unless the applicants for such versions base their applications on their own clinical data.

### 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 Peru, have chosen to honor their Andean Community obligations, while ignoring their TRIPS obligations.

The failure to provide patents for second uses adversely affects PhRMA members who dedicate many of their research investments to evaluating additional therapeutic benefits of known molecules in order to 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.

## ROMANIA

PhRMA's member companies face several market access barriers and intellectual property issues in Romania, including reference pricing, inadequate healthcare funding mechanisms and significant delays in the reimbursement process.

### **Key Issues of Concern:**

- **Unpredictable, burdensome clawback tax:** Since 2009, the innovative pharmaceutical industry has been the target of numerous misguided “clawback” tax regimes intended to increase revenue or control expenditure. The latest version of the clawback, in effect a payback system, was implemented on October 1, 2011, and requires medicine producers to cover the entire reimbursed medicine budget deficit (the difference between the medicines budget allocated by the government and the real market consumption), including wholesale and retail margins.
- **Unpredictable, non-transparent, and delayed reimbursement processes:** The Health Technology Assessment (HTA) process introduced in 2014 represented a step forward in improving transparency of the assessment process of new medicines, implementing objective, quantifiable criteria and timelines for assessment. However, the process for updating the reimbursement list remains unpredictable and arbitrary. The last two years have seen partial updates of the reimbursement list, occurring around election times or amid strong public pressure, and only for therapeutic areas chosen by the Government as a priority. In addition, administrative hurdles are hampering effective access to approved medicines for reimbursement. PhRMA and its members operating in Romania support a transparent and predictable reimbursement process that rewards innovation and encourages development of future treatments.
- **Weak patent enforcement:** There is no opportunity for innovator companies to resolve patent disputes in advance of the generic or biosimilar launch. Patent infringement proceedings may not be initiated until just before or just after launch of the third party product, which often makes resolution of disputes before actual launch impossible. Interim injunctions to prevent potentially infringing products from remaining on the market until trial are granted in less than half the relevant cases. This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

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**

### Clawback Tax

In September 2009, the Romanian Government implemented a “Clawback Tax”, as a temporary measure to raise more revenue in the context of the financial crisis. More recently, Romania has been enjoying rapid growth, this year being the fastest growing economy in Europe. However, this “temporary” measure remains in effect. The clawback tax mechanism acts as an “expropriatory tax”, whereby quarterly deficits (15.62% in Q2 2016) in the medicines budget are allocated among pharmaceutical companies. In addition, pharma companies are taxed also on the incomes of other actors in the supply chain (e.g., on wholesale and pharmacy margins). Unfortunately the medicine budget is set by the Government in a non-transparent and unpredictable manner and has ultimately resulted in more than 200 lawsuits between the affected companies and the government.

Based on recent proposals, PhRMA’s members are concerned that the Parliament plans to further reform the clawback tax regime in a way that would disproportionately shift the burden of the clawback tax to the innovative sector.

The innovative biopharmaceutical industry in Romania is ready to be a strong partner with the Romanian Government in order to find a viable solution to remedy its inadequate health spending and inefficient allocation of healthcare resources.

### Unpredictable, Non-Transparent and Delayed Reimbursement System

The Romanian reimbursement system imposes myriad administrative barriers on the reimbursement of innovative medicines, adversely impacting market access and incentives for further innovation.

In 2014, Romania introduced a “light” health technology assessment (HTA) system that adds objective, quantifiable criteria and timelines in the assessment of new medicines, but does not consider the efficacy of the drug when producing its assessments, instead relying almost exclusively on cost.

Reimbursement, however, can be subject to arbitrary criteria and even products that meet the reimbursement criteria are subject to lengthy listing delays. As a further cost containment measure, the payer has introduced cost-volume agreements for reimbursing medicines. Further, for medicines addressing the same indication, only one winner is attributed, based on the largest discount offered, discouraging further investments by the losing company and reducing physician choice to prescribe the medicine best suited for their patients.

The lengthy process to approve reimbursement (demonstrated to be the longest in the European Union)<sup>165</sup> results in delays in getting medicines to Romanian patients and significantly shortens the period for the innovator to recoup its investment before the first generic/biosimilar enters the market.

To sustain innovation, the government should seek to improve the reimbursement system by making it more transparent, more predictable, and more regular in its timing, in accordance with the EU Transparency Directive, which sets specific deadlines for reimbursement decisions (90 days).

## **Intellectual Property Protection**

### Weak Patent Enforcement

There is no opportunity for innovator companies to resolve patent disputes in advance of the generic or biosimilar launch. Patent infringement proceedings may not be initiated until just before or just after launch of the third party product, which often makes resolution of disputes before actual launch impossible. In addition, resolving these disputes in this manner is often lengthy, expensive, and can result in significant market loss, even if the end ruling favors the company that produced the original molecule.

When a generic product is launched and remains on the market until infringement is proved in patent litigation, harm may be caused to the patent owner which cannot be compensated through damage awards. Overall, however, interim injunctions to prevent accused products from remaining on the market until trial are granted in less than half the relevant cases. This failure to provide effective remedies fundamentally undermines the exclusive rights conferred by a patent.

---

<sup>165</sup> European Federation of Pharmaceutical Industries and Associations (EFPIA) *Patients' W.A.I.T. Indicator Report*, available at <http://efpia.eu/documents/33/64/Market-Access-Delays> (last visited Oct. 27, 2016).

## RUSSIA

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

### Key Issues of Concern:

- **Discriminatory public procurement:** Despite statements expressing support for accession to the WTO Agreement on Government Procurement (GPA), Russia continues discriminatory practices in its government procurement system. Russia has adopted a regulation that bans foreign participation in tenders in cases where two or more companies from the Eurasian Economic Union (EAEU)<sup>166</sup> have bid to supply medicines included on Essential Drugs List. Moreover, Russia has maintained its policy of providing locally made pharmaceuticals a 15% price preference in government procurement tenders.
- **Compulsory licensing and restrictive patentability criteria:** Notwithstanding the Russian Government's goal to stimulate the development of an innovative pharmaceutical industry in Russia (as described in the *Pharma 2020 Strategy*),<sup>167</sup> Russia's Federal Anti-monopoly Service (FAS) continues to express strong support for expanded use of compulsory licenses and expressed its intent to adopt restrictive patentability criteria for pharmaceuticals.
- **Regulatory data protection failures:** On August 22, 2012, Russia officially acceded to the World Trade Organization (WTO). Russia's commitments on regulatory data protection (RDP), embedded in the Law on the Circulation of Medicines, are an integral part of Russia's WTO obligations and came into force on the date of Russia's WTO accession. However, revisions to these protections were included in amendments to the Law on the Circulation of Medicines<sup>168</sup> that entered into force in 2016. PhRMA and its member companies are concerned that some of the new provisions of the Law on the Circulation of Medicines weaken RDP protection for innovative medicines in Russia. Russian court rulings in 2016, not upholding RDP protections, also demonstrate a worrying trend.
- **Weak patent enforcement:** Currently, there is no mechanism in place to provide patent holders with the opportunity to resolve patent disputes prior to the launch of a follow-on product. The Russian courts are also reluctant to issue court injunctions in patent infringement cases related to pharmaceuticals. This has led

---

<sup>166</sup> Includes, Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia.

<sup>167</sup> Strategy for Developing the Russian Pharmaceutical Industry until 2020, approved by the Order of the Ministry of Industry and Trade, dated 23 October 2009, No. 956.

<sup>168</sup> Federal Law No. 61-FZ dated 12 April 2010 "On the Circulation of Medicines". Relevant amendments were introduced by Federal Law No. 429-FZ dated 22 December 2014.

to the approval and marketing of follow-on products, despite the fact that a patent for the original drug is still in force.

- **Parallel imports initiatives:** Regulations are under development to allow for the parallel import in the EAEU of pharmaceuticals. Although this process does not have any clear deadlines, the Eurasian Economic Commission (EEC) continues to see the parallel importation of pharmaceuticals as a worthy policy objective.

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

Russia indicated that, sometime in fall 2016, it would formally submit its application to join the GPA. Notwithstanding this commitment, however, Russia continues discriminatory practices in its government procurement system.

On November 30, 2015, the Russian Government adopted Resolution No. 1289 “On Restrictions and Conditions of Access of Foreign Essential Medicines to State and Municipal Tenders”, which codifies the so-called “three’s a crowd” approach in relation to medicines included on the Essential Drugs List (EDL). According to Resolution No. 1289, if two or more EAEU pharmaceutical manufacturers bid on a tender for an EDL product, any foreign bid for that same tender must be rejected. Medicines not falling within Resolution No. 1289, remain subject to the tender preferences established by the Ministry of Economic Development (MoED), where local companies receive a 15 percent price preferences.

The Russian Government has also taken a number of steps to isolate certain segments of the pharmaceutical market for sole-supply contracts given to Russian companies. For example, in 2015, the National Immunobiological Company (NIB) announced its intention to become the sole supplier of TB, HIV and hepatitis products. In June of that same year, it was appointed as the sole supplier of certain local vaccines for 2015-2017. Then on June 15, 2016, the Russian Government signed Decree No. 1216-r and appointed NIB as the sole supplier of blood products for state needs in 2016-2017.

A number of other measures aimed at supporting local manufacturers are under development and implementation in Russia. For instance, on June 17, 2016, the Russian Government signed Resolution No. 548 and approved the Rules for Provision of Federal Subsidies for Partial Reimbursement of Costs Related to Patenting of Russian Inventions Abroad.

Some of these measures (e.g., the practice of appointment of a sole supplier under governmental decision) may discriminate against U.S. firms and limit a patient's access to certain medicines.

## Eurasian Economic Union

The EAEU, comprised of Russia, Belarus, Kazakhstan, Armenia, and Kyrgyzstan entered into force on January 1, 2015. The treaties establishing the Eurasian Customs Union and the Single Economic Space were terminated by the agreement establishing the EAEU, which incorporated both into its legal framework. The EAEU envisages the gradual integration of the former Soviet countries' economies, establishing free trade, unbarred financial interaction and unhindered labor migration. Although the EAEU is just coming into effect, the first sector which it plans to integrate is the pharmaceutical sector through creation of a single pharmaceutical market. The EAEU Agreement on Common Principles and Rules of Drug Circulation in the EAEU was executed in the city of Minsk on December 23, 2014.

On August 12, 2016, the EAEU Intergovernmental Council approved the second-level documents, necessary to set up a common pharmaceutical market in the EAEU.<sup>169</sup> While it is yet unknown when the common market will start operating, the innovative pharmaceutical industry stands ready to work with the Government to ensure that there is a robust regulatory review system and continued patient access throughout the EAEU.

## Orphan Drugs Legislation

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

## Biologic and Biosimilar products in Russia

The Law on the Circulation of Medicines sets forth the basic regulations for biologics and biosimilars. Although PhRMA's members welcome Russia's actions to better regulate biologics and biosimilars, there remain some concerns regarding implementation of the relevant framework amendments (including assessment guidelines for biosimilar drugs, determining the interchangeability of biologic drugs, etc.). PhRMA's members are hopeful that these issues will also be resolved under the EAEU regulatory framework.

---

<sup>169</sup> See <http://www.eurasiancommission.org/en/nae/news/Pages/2016-08-12-1.aspx> (last visited Oct. 27, 2016).

## **Intellectual Property Protection**

### Compulsory Licensing

PhRMA and its member companies are concerned about ongoing FAS proposals, including in the draft “Roadmap for Development of Competition in the Healthcare Sector” released on May 27, 2016, to expand the use of compulsory licenses (CLs) in Russia. Under these proposals, FAS suggests that Russia could address access and pricing concerns under the guise of antitrust enforcement, for which adequate mechanisms already exist. These proposals are contrary to positive statements made by others in the Government, including the Deputy Prime Minister Arcady Dvorkovich, who sent a letter to the Russian President in April 2016 rejecting the expanded use of CLs.

### Restrictive Patentability Criteria

On May 27, 2016, FAS published on its official web-site, the draft Roadmap for Development of Competition in the Healthcare Sector. This document, *inter alia*, 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, new dosage forms and manufacturing methods). PhRMA and its members are concerned that these amendments could inappropriately restrict the availability of patents for innovative medicines in Russia, and thus undermine incentives to innovate.

### Regulatory Data Protection Failures

Weaknesses in Russia’s judicial system are particularly concerning to PhRMA members in light of amendments to Russia’s Law on the Circulation of Medicines passed in 2014. Specifically, beginning in 2016, a registration application is allowed for follow-on medicines four years after the granting of marketing authorization for a reference small molecule drug and three years after marketing authorization of a reference biologic medicine. The inability of PhRMA members to seek effective and efficient court rulings could lead to the granting of marketing authorization of infringing follow-on products during the regulatory data protection term.

As part of its accession to the WTO in August 2012, Russia committed to provide a six-year period of RDP for undisclosed information 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):

The representative of the Russian Federation confirmed that the Russian Federation had enacted legislation and would adopt regulations on the protection of undisclosed information and test data, in compliance with Article 39.3 of the WTO TRIPS Agreement, providing that undisclosed information submitted to obtain marketing approval, *i.e.*, registration of pharmaceutical products, would provide for a period of at least six years of

protection against unfair commercial use starting from the date of grant of marketing approval in the Russian Federation. During this period of protection against unfair commercial use, no person or entity (public or private), other than the person or entity who submitted such undisclosed data, could without the explicit consent of the person or entity who submitted such undisclosed data rely, directly or indirectly, on such data in support of an application for product approval/registration. Notice of subsequent applications for registration would be provided in accord with established procedures. During the six year period, any subsequent application for marketing approval or registration would not be granted, unless the subsequent applicant submitted his own data (or data used with the authorization of the right-holder) meeting the same requirements as the first applicant, and products registered without submission of such data would be removed from the market until requirements were met. Further, he confirmed that the Russian Federation would protect such data against any disclosure, except where necessary to protect the public or unless steps were taken to ensure that the data were protected against unfair commercial use.<sup>170</sup>

Russia's commitment to six years of RDP was initially embedded in Article 18.6 of the Law on the Circulation of Medicines, as passed in 2010:

The results of the nonclinical trials of medicinal products and clinical trials of medicinal products submitted by the applicant for state registration of the medicinal products shall not be obtained, disclosed, used for commercial purposes and for purposes of state registration without applicant's permission within six years from the date of the state registration of the medicinal product.

Violation of the prohibition specified by this Clause shall entail the responsibility in accordance with the legislation of the Russian Federation.

The circulation of medicines in the Russian Federation registered with violation of this Clause shall be prohibited.<sup>171</sup>

The enactment of data protection legislation in Russia was a positive step towards fulfilling Russia's obligations, according to the TRIPS Article 39.3, and creating a supportive environment for pharmaceutical innovations in Russia.

However, PhRMA members have significant concerns related to recent court decisions, holding that Article 18.6 of the Law on the Circulation of Medicines does not prevent a follow-on manufacturer from indirectly relying on the innovator's approval, *i.e.*,

---

<sup>170</sup> 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.

<sup>171</sup> Federal Law No. 61-FZ, "Law on the Circulation of Medicines" (Apr. 12, 2010).

relying on the data reported in scientific journals following approval of the innovative product, in seeking marketing approval for its own follow-on product during the RDP term. PhRMA and its member companies are concerned that these trends call into question Russia's commitment to uphold the requirements of TRIPS Article 39.3.

### Weak Patent Enforcement

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

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

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

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

Predictable and effective patent enforcement procedures are especially important in connection with the creation of the common Eurasian Economic Union (EAEU) market for medicines. PhRMA and its member companies are concerned that the EAEU's regulatory framework creates a common pharmaceutical market does not provide robust patent protection for innovative medicines.

### Parallel Imports

Currently, parallel imports (PI) are prohibited from countries outside the EAEU under the EAEU Treaty. However, in 2015, the possibility of authorizing parallel imports from outside the EAEU for certain product groups was actively discussed by the EEC. Subsequently on April 13, 2016, the EAEU Interstate Council adopted a specific Resolution, directly assigning work on the Protocol Amending the EAEU Treaty to the EEC. PhRMA and its member companies are concerned that the Treaty could be amended to allow for parallel imports in certain industries (e.g., in the pharmaceutical and medical devices sectors), which may create unreasonable risks for patients.

## SINGAPORE

PhRMA's member companies face several market access barriers in Singapore. Singapore serves as a strong model for protecting and creating innovation in the research-based pharmaceutical sector. With continued collaboration between PhRMA member companies and the Government of Singapore, and with U.S. Government support, we are confident we can resolve outstanding issues and strengthen the country's global leadership position.

### Key Issues of Concern:

- **Listing process transparency for government subsidy program:** There are additional steps the Ministry of Health (MoH) can take to improve transparency and speed in the listing process for both listing in hospital formularies and for government subsidy program (e.g., Standard Drug List (SDL), Medical Assistance Fund (MAF)) including publication of the annual review timeline and the criteria for evaluation/inclusion of medicines as well as making an updated list of medicines regularly available.
- **Non-publication of tender prices:** PhRMA's member companies urge Singapore to adopt the standard practice of publishing details of tenders, including the names of successful tenderers.
- **Package inserts:** Singapore-specific requirements on package inserts for pharmaceutical products are costly, burdensome, and unnecessary. Singapore should remove these specific requirements and align package insert approval with the dossier application.
- **Intellectual property protection:** Singapore generally maintains a strong intellectual property protection and enforcement system. However, further improvements to the manner in which Singapore provides patent term restoration, as well as its data protection regime would support that 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**

#### Listing Process Transparency for Government Subsidy Program

While PhRMA's member companies are pleased that an annual review of the government subsidy program is in place to ensure it keeps pace with medical developments, there are additional steps the MoH could take to improve transparency in the listing process for hospital formulary listing and government funding of medicines. These include: (1) publication of the annual review timeline and criteria for

evaluation/inclusion of medicines; and (2) making an updated list of medicines regularly available. Both items should be published on the MoH website. PhRMA's member companies believe this enhanced transparency will remove ambiguities and lead to well-informed decision-making.

### Non-Publication of Tender Prices

The MoH Group Procurement Office (GPO) does not publish details of tenders, including the names of successful bidders. PhRMA's member companies urge the GPO to adopt this standard practice, as it will encourage able companies to participate in the procurement process. Patients will serve as the ultimate beneficiaries of such transparency

### Package Inserts

Singapore-specific requirements on package inserts for pharmaceutical products are costly, burdensome, and unnecessary. PhRMA recommends that the Health Sciences Authority (HSA) eliminate Singapore-specific requirements for package inserts, particularly because adjustments following HSA review often result in strict labeling requirements relative to other countries. The end result is an overly-conservative package insert, particularly where existing data supports the broader labeling used in reference countries.

Additionally, there is a misalignment between how package inserts are used and administered. For example, in most cases, healthcare providers remove pack inserts and dispense medicines without the insert. In addition, in the public sector, hospitals remove package inserts to align medication dispensing with their in-hospital dispensing systems. PhRMA's member companies recommend that Singapore align package insert approval with the dossier application, which is supported by the reference agency approval letter.

### **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. To fully realize this goal, and in keeping with the U.S.-Singapore Free Trade Agreement, Singapore should adjust its patent term restoration mechanism to compensate the patent holder for the time invested in conducting clinical trials either in Singapore or in any other market when such data is a condition of obtaining marketing approval in Singapore.

In addition, 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.

## TAIWAN

PhRMA and its member companies operating in Taiwan value the positive response during the recent discussions with the Government of Taiwan on health policy reform measures designed to bring stability and predictability to the Taiwan pharmaceutical market. Some concerns remain, however, and PhRMA appreciates the willingness and commitment of the Government of Taiwan to continue its dialogue with PhRMA 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 Taiwanese Government to continue developing sound intellectual property (IP) protections and drug pricing policies with stakeholder involvement.

PhRMA particularly appreciates the recent positive engagement from the Government of Taiwan on ways to address the innovative biopharmaceutical industry's concerns regarding certain IP protections. Specifically, the Government has recently expressed a willingness to work with the biopharmaceutical industry to enhance the current regulatory data protection (RDP) and effective patent enforcement mechanisms. PhRMA welcomes the Government's renewed engagement, and looks forward to working with the Government toward the enhancement of biopharmaceutical market access and IP in Taiwan.

### Key Issues of Concern:

- **New government drug pricing and reimbursement mechanism:** The second generation of National Health Insurance (2G NHI), which was implemented in January 2013, has made the process of new drug reimbursement review and decision making much more complicated due to the newly added Pharmaceutical Benefit & Reimbursement Scheme (PBRS) Joint meeting. As a result, the average prices and approval rate for new medicines continue to be low and do not adequately reflect or reward the value of those innovative medicines. Furthermore, the new government pricing and reimbursement system fails to recognize all forms of pharmaceutical innovation.
- **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, however, these protections should be available to all drugs granted patent protection by the Taiwan IP Office during their patent term, as well as those still subject to regulatory data protection. PhRMA recognizes the efforts of the 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 good quality innovative pharmaceuticals. Any regulations on drug expenditure should fairly recognize the value of innovative medicines.

- **MOHW medical center accreditation:** In September 2015, the MOHW announced that a criterion to be considered in accrediting new medical centers is whether they purchase locally developed and produced drugs and medical devices. This regulation appears inconsistent with Taiwan's national treatment obligations and imposes unnecessary obstacles to trade contrary to the World Trade Organization (WTO) Technical Barriers to Trade (TBT) Agreement.
- **Intellectual property protection:** Taiwan lacks adequate systems for effective patent enforcement and RDP, which discourages investment in innovative medicines for Taiwanese patients and intellectual property rights including all types of patent and data protection afforded by the Taiwan Intellectual Property Office (TIPO) and Taiwan Food & Drug Administration (TFDA), respectively.

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**

### Reward for Innovation

Over the past two years, the industry has had a constructive dialogue with the Government on how to smoothly transition from the First Generation to the Second Generation of NHI in terms of new drug pricing and reimbursement processes. After 3.5 years of observation and evaluation, and despite efforts from National Health Insurance Administration (NHIA), the outcome is disappointing. According to PBRs expert analysis, average drug prices in Taiwan continue to be low, around 53% of the A10-country median price. The percentage of new medicines approved for government reimbursement is also low: 62% for all drugs and 42% for cancer drugs. Government reimbursement assessment and review is lengthy, taking 414 days for general new drugs and 714 days for cancer drugs. In short, the new system does not reflect or value innovation and adversely impacts patients' access to new and innovative medicines.

PhRMA and its member companies continue to discuss with Ministry of Health and Welfare (MOHW) and NHIA the following issues to improve the pricing and reimbursement policies and regulations:

- *Government pricing and reimbursement:* A key factor suppressing new-drug prices is that most new drug prices are determined based on those of reference drugs in Taiwan, many of which have gone through several annual price cuts and now stand at new lows. Too often new uses are not approved by the PBRs, even where the manufacturer has demonstrated increased efficacy and/or safety. We urge NHIA to revise the appropriate regulations so that the pricing system better reflects pricing methodologies in other advanced economies, allows companies to recoup the significant investment required to develop a new medicine, and rewards innovation.

- *Increase budget for new drugs*: Under the current structure, most new drugs/indications are either rejected or experience delays in inclusion in the formulary due to insufficient budget allocation. We urge MOHW/NHIA to establish a prospective and advanced mechanism to ensure that the medicines budget accounts for future introduction of new drugs.
- *Drug Expenditure Targets (DET)*: Under the price adjustment scheme instituted in October 2013, the government implemented a two-year pilot program designed to maintain national spending targets that ultimately allowed only compound and combination patented products some protection from price cuts. In order to encourage innovation, however, these protections should be available to all drugs granted patent protection by the Taiwan IP Office during their patent term, as well as those still subject to regulatory data protection. We encourage the continued piloting of DET to further improve the methodologies and implementation of the program. 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 to meet Taiwan's unmet needs, and ensuring that Taiwanese patients have access to innovative drugs, PhRMA strongly recommends that the U.S. Government encourage Taiwan's Government to implement a fair and reasonable price adjustment policy under DET. DET should continue to be piloted to allow more flexibility for improvement and adjustments before a permanent decision is made. Furthermore, PhRMA asks the U.S. Government to encourage their counterparts in the Taiwanese Government to engage in renewed consultation with the innovative pharmaceutical 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.

#### MOHW medical center accreditation

In September 2015, the MOHW announced that a criterion to be considered in accrediting new medical centers is whether they purchase locally developed and produced drugs and medical devices. This regulation appears inconsistent with Taiwan's national treatment obligations under Article III:4 of the General Agreement on Tariffs and Trade and the parallel obligations in Article IV of the WTO Agreement on Government Procurement. In addition, this regulation appears to impose unnecessary obstacles to trade contrary to Article 2.2 of the TBT Agreement.

## **Intellectual Property Protection**

### Regulatory Data Protection (RDP)

In January 2005, Taiwan passed RDP legislation to implement Article 39.3 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 39.3 of the TRIPS Agreement requires governments to prevent unfair commercial use of valuable test data gathered by innovative companies to secure marketing approval. Although the revised Pharmaceutical Affairs Law provides for five years of RDP, this protection should clearly and consistently be provided to biologics and extended to new indications.

### Effective Patent Enforcement

Taiwan has not yet established systems to effectively prevent marketing of patent-infringing generic pharmaceutical products. According to a recent industry survey conducted by International Research-Based Pharmaceutical Manufacturers Association (IRPMA) in Taiwan, at least 65 patent-infringing drugs were approved in Taiwan, and most of them were subsequently included on the reimbursement lists. This significantly disadvantages innovator companies, particularly in view of pending proposals to alter regulatory approval procedures. Under a 2005 revision to the Pharmaceutical Affairs Law, the Taiwanese Government asks patent-owners to declare their patents upon receiving product licenses; thus, data similar to the Orange Book system in the United States is available. That change provides limited benefit, however, given that Taiwan does not have effective patent enforcement mechanisms in place. PhRMA is encouraged by proposals introduced in the Legislative Yuan that would provide meaningful patent protection and provide sufficient time to resolve patent disputes before follow-on products are approved to enter the market. PhRMA urges the Government of Taiwan to pass and implement this legislation as soon as possible.

## THAILAND

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

### Key Issues of Concern:

- **Discriminatory government procurement:** The current regulations governing government procurement for medicines in Thailand are discriminatory and lack transparency. Requirements that hospitals purchase medicines exclusively from the state-owned Government Pharmaceutical Organization (GPO) discriminate against foreign manufacturers and the selection criteria and process for setting the ceiling purchasing price for public procurement lack transparency and do not sufficiently value innovative medicines.
- **Generally weak IP environment:** PhRMA's member companies recognize and commend the Department of Intellectual Property's (DIP's) inclusion of industry in the discussion and construction of the Patent Examination Guidelines. However, additional improvement in the intellectual property environment in Thailand remains necessary to avert negative impact on market access. Concerns include delays in obtaining pharmaceutical patents, inadequate regulatory data protection (RDP), and weak patent protection and enforcement regimes.
- **Counterfeit medicines:** PhRMA's member companies recognize the advancements made by the Royal Thai Customs in enforcing IP, but encourage the Royal Thai Government to place a higher priority on curbing the distribution and use of counterfeit medicines through increased resources and penalties for criminals caught manufacturing, supplying, or selling them.

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**

#### Discriminatory and Non-Transparent Government Procurement Regulations

As a result of special procurement privileges granted to Thailand's state-owned Government Pharmaceutical Organization (GPO), competition remains increasingly difficult for PhRMA's member companies. Procurement Regulation B.E. 2535 (Sections 60-62) issued by the office of the Prime Minister, mandates that hospitals affiliated with the Ministry of Public Health spend 80 percent of their allocated pharmaceutical budget on medicines listed on the National List of Essential Medicines (NLEM). Furthermore, products produced or supplied by the GPO must be selected for hospital procurement when using public funds, even when sold at higher prices. The GPO is also exempt under the Drug Act (Articles 12 and 13) from the requirement to obtain a license from the TFDA to produce, sell, or import pharmaceutical products.

A proposed Public Procurement Bill is intended by the Royal Thai Government to promote transparency, fair competition and efficient and effective public procurement. While the Bill should ensure that the GPO is subject to the same regulatory requirements as the private sector, without a clear statement on the GPO's existing privilege under the current procurement system, there is the risk that the GPO's privilege will be retained even after passage of the Bill through the ministerial regulation.

The innovative pharmaceutical industry would like to better understand the overall selection criteria and process for setting the ceiling purchasing price, known as the "Median Price or Maximum Procurement Price (MPP)" for public procurement in Thailand. The current methodology and implementation of the MPP setting process lacks clarity and transparency. The government has selectively referenced generic prices to price innovative, life-saving medicines. The process has been implemented in a manner that is often arbitrary in nature. The government of Thailand should revise the current process to ensure that the pharmaceutical industry has an opportunity to provide timely input about innovative products for Thai patients. Greater stakeholder engagement between the pharmaceutical industry and the government regarding pricing decisions that affect the availability of innovative medicines for Thai patients would be mutually beneficial.

#### New Drug Act Amendment

Thailand's new amendment to the Drug Act is presently at the Ministry of Public Health after being remanded for redrafting. Key concerns expressed by the innovative biopharmaceutical industry include articles that would enable the regulatory authority to deny marketing authorization for patented medicines based on price and mandate disclosure of price structures.

This proposed legislation disproportionately impacts innovative medicines, threatens patient access to innovative therapies, and undermines the government's goals of making Thailand a regional trading center and a leader in the area of medical innovation. The innovative biopharmaceutical industry recommends that the draft legislation be opened to stakeholder comment through a transparent consultation process before it is passed on to the National Legislative Assembly.

#### Regulatory Reform

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

## **Intellectual Property Protection**

### Patent Backlogs

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

However, unresolved issues remain, including how to clear the patent backlog and ensure that there are sufficient resources to maintain the patent registration process. The waiting-period for a patent review and grant in Thailand is unpredictable and averages ten years after application submission. Further, these long patent grant delays create uncertainty regarding investment protection and increase the risk that a third party will use a patentable invention that is the subject of a pending patent application during the pending/review periods. Patent term adjustments are not available in Thailand to compensate for unreasonable patent office delays, thereby reducing the effective patent term and further exacerbating the uncertainty caused by its patent grant delays.

### Restrictive Patentability Criteria

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

### Weak Patent Enforcement

PhRMA's member companies strongly encourage the Thai Food and Drug Administration (TFDA) to implement effective mechanisms to allow for sufficient time to resolve patent disputes before follow-on products are approved. Effective patent enforcement could greatly enhance the business environment in Thailand by: (1) providing transparency and predictability to the process for both innovative and generic

firms; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

### Regulatory Data Protection Failures

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

PhRMA's member companies strongly encourage the Royal Thai Government to institute meaningful RDP. Specifically, Thailand should: (1) implement new regulations that do not permit generics producers to rely directly or indirectly on the originators' data, unless consent has been provided by the originator, for the approval of generic 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 pharmaceutical product.

### Compulsory Licensing

Despite assurances that Thailand would be judicious in its use of compulsory licenses (CLs) and consult with affected parties as required by the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (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.

### **Counterfeit Medicines**

PhRMA's member companies are encouraged by the Royal Thai Government's efforts to develop the National IPR Center of Enforcement; however, most of the focus has been on products such as clothing and media, rather than on pharmaceuticals. Enforcement has also been limited to those illicit products sold online. Moving forward, there is also an urgent need to address counterfeits in the pharmaceutical sector and enhance penalties for criminals caught manufacturing, supplying, or selling counterfeit or unsafe medicines. While the Royal Thai Government has acknowledged the need to suppress counterfeits in a Memorandum of Understanding (MoU) for "Cooperation on Prevention and Suppression of Trademark Infringing Pharmaceuticals" signed on September 2010, no action has yet been taken to implement the MoU. There is also an urgent need to take action against non-trademark counterfeit pharmaceuticals.

## TURKEY

PhRMA and its member companies face significant market access barriers in Turkey due to the deficiencies in Turkey's intellectual property (IP) framework and slow and unpredictable product registration, reimbursement, and government pricing systems. During the last decade, Turkey has undertaken reforms to modernize its economy and expand its health care system in many positive ways for Turkish patients. However, a general lack of transparency and inconsistency in decision-making has contributed to unclear policies that undermine Turkey's investment climate and damage market access for PhRMA member companies.

While PhRMA and its member companies appreciate the increased dialogue that exists between the Turkish Government and the innovative pharmaceutical industry in Turkey, still more attention needs to be paid to the link between the short-term impact of Turkish government policies and the innovative pharmaceutical industries' research and development process, including the potential of PhRMA member companies to invest in Turkey.

### **Key Issues of Concern:**

- **Localization policies:** Provisions in Article 46 of the 64<sup>th</sup> Government Action Plan (released on December 10, 2015), provide preferential reimbursement arrangements for healthcare products produced domestically and the delisting of imported products from the reimbursement list. PhRMA and our members believe that these measures, if implemented, would be inconsistent with Turkey's national treatment obligations under the World Trade Organization (WTO) Agreements. These measures would also contradict Turkey's goal of attracting investment from the world's leading pharmaceutical companies. The Turkish Government's delay in implementing the delisting provision provides an opportunity to reform this component of the plan. The Turkish Government has also suggested it will provide more efficient regulatory approvals and long term bulk procurement agreements for high technology manufacturing investments especially for vaccines and biotech products.
- **Local inspection requirements:** PhRMA and its member companies appreciate the Turkish Drug and Medical Device Agency's (TITCK) efforts to improve the regulatory approval procedures of highly innovative and/or life-saving products with no or limited therapeutic alternatives in Turkey. Specifically, prioritizing the Good Manufacturing Practices (GMP) audit procedures and allowing a parallel marketing application process for those products has decreased the delays in approving those products. However, while products deemed highly innovative are receiving preferential reviews, products without this designation face increased delays due to the lack of resources and the absence of efficient procedures for conducting GMP inspections. In addition, TITCK now requires on-site GMP audits for imported products registered before 2010, adding additional pressure to an inspectorate lacking resources and potentially violating Turkey's GATT

national treatment obligations. These GMP inspection delays are adding to registration delays, delaying patient access to innovative medicines; thus negating the benefits of the patent and data protection periods for many products.

- **Other market access barriers:** The Turkish Government continues to impose unrealistic pharmaceutical budgets that disregard parameters such as economic growth, inflation and exchange rate fluctuations, and result in forced government price discounts that hinder access to innovative medicines. Turkey's Research based Pharmaceutical Manufacturers' Association (AIFD) estimates that the financial damage to the industry from the fixed Turkish Lira (TL) to Euro conversion issue alone was 15 billion TL (\$5 billion) between July 2011 and April 2015.
- **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. Turkey does not provide an effective mechanism for resolving patent disputes before the marketing of follow-on products. Further, Turkey inappropriately ties the regulatory data protection period (RDP) to the patent term and the lack of RDP for combination products is still an unresolved issue. Finally, the RDP term begins with first marketing authorization in the European Union and thus, as a result of significant regulatory approval delays in Turkey, the effective RDP term is reduced significantly. Consistent with Turkey's international obligations, the RDP term should begin when a product receives marketing authorization in Turkey. In addition, Turkey does not provide RDP for biologic-based medicines.
- **Regulatory approval delays:** While PhRMA and its member companies appreciate the Turkish Drug and Medical Device Agency's efforts to improve the period required to complete the regulatory approval procedures for medicinal products, this period exceeds on average 446 days,<sup>172</sup> significantly more than the 210 days targeted in Turkish regulations. Regulatory approval delays have a negative impact on access to medicines 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

Provisions in Article 46 of the 64<sup>th</sup> Government Immediate Action Plan (released on December 10, 2015), provide preferential reimbursement arrangements for healthcare products produced domestically and the delisting of imported products from

---

<sup>172</sup> Based on AIFD Survey 2015.

the reimbursement list. PhRMA and our members believe that these measures, if implemented, would be inconsistent with the WTO's national treatment requirements. These measures would also contradict Turkey's goal of attracting investment from the world's leading pharmaceutical companies. The Turkish Government has also suggested it will provide more efficient regulatory approvals for products manufactured locally and, on January 26, 2016, the Minister of Health announced a program to provide a seven-year contract for a foreign firm that agrees to establish a Hepatitis A vaccine manufacturing facility in Turkey.

### Pharmaceutical Product Registration

Marketing of new drugs in Turkey is governed by the regulatory procedures prescribed by the Medicines and Medical Devices Agency of Turkey (TITCK) and the Ministry of Health (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.<sup>173</sup> Although the legislation requires the Turkish MOH to assess and authorize the registration of medicinal products within 210 days of the dossier being submitted and efforts have been taken to improve the regulatory process, surveys by the AIFD indicate that the average regulatory approval period is 446 days.<sup>174</sup>

PhRMA and our member companies are concerned with new registration prioritization criteria published in the TITCK's May 2016 "Guideline for the Operating Procedures and Principles of the Priority Evaluation Committee of Medicinal Products for Human Use." These new criteria, which are used to determine which products receive prioritized attention by the health regulator, introduce a range of factors outside of the safety and efficacy of the product. Based on the new guidelines, TITCK will prioritize the registration of products, based on:

- Mode of action, rapid effect, tiered treatment, additional benefit, patient compliance, specific effect on certain diseases, safety advantage, synergistic-additive effect, interaction with other medicines, duration of effect, efficacy on the society, unmet therapeutic need;
- Positive contribution to public finance;
- Technology transfer to Turkey; and
- At least 10% of the total number of patients involved in global Phase III clinical trials must be from Turkey or the bioequivalence study must be conducted in Turkey.

And, while not included in the May 2016 TITCK document, the agency is now requiring companies to commit to a specific retail and public sale price and to project an estimate number of SKUs that will be sold, while the company is submitting their prioritization application. Finally, companies must commit to introducing TITCK

---

<sup>173</sup> Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).

<sup>174</sup> Based on AIFD Survey 2015.

approved products into Turkey within six months of being granted marketing authorization, a timeframe that is unrealistic given the delays in government decisions related to products being included on the reimbursement list.

### Local Inspection Requirements

The MOH's revisions to the Registration Regulation have compounded the country's registration delays.<sup>175</sup> Effective March 1, 2010, a Good Manufacturing Practices (GMP) certificate that is issued by the Turkish MOH must be submitted with each application to register a medicinal product for each of the facilities at which the product is manufactured. The GMP certificate can only be issued by MOH following an on-site inspection by Ministry staff, or by the competent authority of a country that recognizes the GMP certificates issued by the Turkish MOH. However, for the reasons explained further below, neither option can be completed in a timely manner.

Despite increasing the number of inspectors at the end of 2013, the MOH still does not have adequate resources to complete these GMP inspections in a timely manner. However, the period required to complete the regulatory approval procedures of highly innovative and/or life-saving products with no or limited therapeutic alternatives in the country is improved by prioritizing their GMP audit procedures and allowing a marketing application process that runs parallel to the GMP determination (rather than occurring only after the GMP process is complete). Nevertheless, PhRMA and our members remain concerned that the process for determining the innovativeness of the products lacks transparency and is often inconsistent. In addition, the focus of regulatory resources on those products which have been determined, through non-transparent means, to be highly innovative, has reduced the speed at which other products are approved.

In addition, the Ministry of Health published the "Important Announcement on GMP Inspections" on June 16, 2016, which included, among other provisions, the requirement that all "imported" products on the market prior to March 1, 2010 and all "imported" products registered after 2010 whose facilities were either partially or not fully inspected, must receive GMP inspections. PhRMA and our members are concerned that this new GMP inspection requirement not only appears to violate GATT's national treatment obligations, but further burdens an inspectorate already unable to improve the backlog of GMP applications.

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. There are two significant hurdles to this mutual recognition arrangement. First, Turkey is not yet a member of the PIC/S (Pharmaceutical Inspection Convention and

---

<sup>175</sup> 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).

Co-operation Scheme) that provides guidance on international GMP standards. Second, Turkey will need to negotiate mutual recognition agreements with each participating country. In the meantime, registration of new medicinal products is substantially delayed, which, in turn, hinders patients' access to innovative medicines. To avoid imposing this unnecessary non-tariff barrier to trade, as a temporary measure, Turkey should revert to recognizing GMP certificates accepted by institutions like the FDA, EMA, or other PIC/S members for medicinal products. Such measures should remain in force until MOH either has the staff and resources necessary to conduct GMP inspections in a timely manner, or Turkey has entered into mutual recognition agreements with the United States and other key trading partners, a prospect that PhRMA recognizes may not occur in the short-term.

### Non-Transparent and Delayed Reimbursement

In Turkey, pharmaceutical pricing is regulated by the MOH and TITCK. The reimbursement system is based on a positive list and reimbursement decisions are the responsibility of the inter-ministerial Reimbursement Commission, led by the Social Security Institution (SSI). Reimbursement decision criteria are not clearly defined and while SSI is encouraging managed entry agreements, the institution's approach to these agreements is not yet fully formed. The process is non-transparent and excessively lengthy as a result of frequent delays in decision-making and erratic meeting schedules. On average, according to the AIFD survey, it takes 255<sup>176</sup> days to receive a listing decision for pharmaceutical products that hold marketing authorization.

Moreover, PhRMA member companies are still burdened by a draconian government price regime that saddles products with a substantial price reduction and fixed exchange rate:

- *Original products without generics*: In December 2009, Turkey imposed an additional 12 percent discount on the prices of original products without generics, over the existing 11 percent discount. In December 2010 and November 2011, further discounts of 9.5 and 8.5 percent, respectively, increased the total social security discount for innovative products to 41 percent. Although the latter discounts were imposed ostensibly to meet short-term budget overruns in 2010-2011, those cuts were retained in Turkey's pharmaceutical budget for 2013-2016. Further discounts have been imposed by the SSI.
- *Original products with generics*: Turkey reduced prices for originals and generic products from 66 percent to 60 percent of the reference price (previously original products were at 100 percent and their generics were at 80 percent of the reference price). However, if the reference price decreases at some point in the future, no further price reductions are imposed until the reference price is equal to or below 60 percent of the original reference price. No similar relief is provided to original products without generics; if the reference price decreases at some

---

<sup>176</sup> Based on AIFD Survey in 2015.

point in the future, the SSI applies discounts (41 percent), as noted above, on top of the reference price decrease. The pricing and reimbursement system should, at a minimum, be revised to address this inequity. For original and generic products in this category, additional discounts of 9.5 and 7.5 percent were also imposed as of December 2010 and November 2011 with a total SSI discount of up to 28 percent for this category of products.

- *Fixed Exchange Rate for Pharmaceuticals:* In April 2009, the GOT fixed the Euro to TL exchange rate for pharmaceutical pricing purposes only, 1 Euro to 1.9595 Turkish Liras. Following two successful lawsuits by AIFD, the Price Assessment Commission (PAC) convened on May 18, 2015, to revise the rate, but made only a nominal adjustment (changing the rate from 1.9595 TL to the Euro to 2.0 TL to the Euro). This minimal adjustment flouted the Court's finding that Turkish law requires the PAC to adjust the fixed exchange rate to match the actual exchange rate. AIFD and the IEIS officially objected to the 2.0 TL rate on June 11, 2015. On July 9, 2015, the Government of Turkey published a new Pharmaceutical Pricing Decree and annulled the former decree, which had included the fixed exchange rate. Under the new decree, the Euro-to-TL exchange rate for pharmaceuticals will be 70% of the average exchange rate during the previous year. Exceptions to the new pricing regime, at the discretion of the PAC, can be granted for locally manufactured products that were not previously available in Turkey, products subject to alternative reimbursement models and certain special product groups (such as orphan drugs and biosimilars). Pursuant to the new Pricing Decree, on January 11, 2016 (with effect 45 days later), the Turkish Drug Agency set the exchange rate at 2.1166 TRY/EUR. Based on data from IMS, AIFD estimates the financial damage to the industry from the low Euro to TL conversion rate to be 15 billion TL, for the period between July 2011 and April 2015.

PhRMA and our members are also concerned with a recent regulation stipulating that fixed dose combination products will be priced at 80% of the mono products; previously prices for these combination products were set by the government at 95% of the mono product price.

### Orphan Drug Guidelines

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

practices, including EU prevalence standards, and thereby better ensure that Turkish citizens have access to the medicines they need and to further the Turkish Government's ambitions of being a globally-competitive hub for medical innovation.

## **Intellectual Property Protection**

### Weak Patent Enforcement

Turkey does not provide an effective mechanism for resolving patent disputes. Although the Decree Law concerning Protection of Patent Rights ("Patent Decree") includes protections for patent rights holders, in practice the IP Courts' interpretation is quite narrow, with most court decisions being determined against the patent holder. Neither the IP Court Judges, nor the technical expert panels that they often appoint and defer to, have the substantive expertise to hear pharmaceutical patent disputes. In addition, the expert examination system lacks appropriate procedural safeguards. Consequently, few patent related actions receive appropriate judicial review in Turkey.

In April 2016, the Turkish Parliament began considering Draft Patent Law 1/699. While Draft law 1/699 would improve IP protection in Turkey, it lacks some important guarantees. Specifically, the draft law does not clearly provide strong patent protection for biopharmaceuticals, does not guarantee protections for second medical use claims, and does not fully align Turkey's IP regime with the European Patent Convention (Turkey joined the EPC in November 2000).

PhRMA and our member companies are also concerned that the draft law introduces arbitrary criteria into Turkey's compulsory license regime. According to language in the draft, "at the end of three years after publication of a patent grant ... any interested party can request the issue of a compulsory license if at the date of application [of the compulsory license] the following applies (i) The patented invention is not being used or (ii) The level of current use does not satisfy domestic demand." These provisions are vague, subjective, and create tremendous uncertainty for patent holders, and may be abused by competitor third parties.

Draft Law 1/699 also proposes moving from national exhaustion of IP rights to international exhaustion of IP rights. The innovative pharmaceutical industry is deeply concerned by this development and believes the current Customs Union principle of national exhaustion should be retained. It is important that the draft law aligns closely with Turkey's commitments under WTO Agreements and the European Patent Convention. PhRMA and its member companies will continue to monitor the draft Bill as it moves through Parliament.

### Regulatory Data Protection Failures

In 2005, the Turkish Government took positive steps toward establishing protection for the commercially valuable regulatory data generated by innovative pharmaceutical companies, and now provides RDP for a period of six years for products

starting from first MA registration in the European Customs Union (ECU), limited by the patent protection period of the product. RDP is an independent and separate form of IP protection that should not be limited to the period of patent protection.

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

Another concern of the innovative pharmaceutical industry is that the legislation governing RDP has been changed by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.<sup>177</sup> The change that has been introduced is incompatible with EU standards in that it eliminates RDP for combination products, unless the combination product introduces a new indication. Innovative companies invest considerable amounts of time and effort to develop products that provide increased efficacy and safety, as well as new indications, from new combinations of separate molecules.

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

---

<sup>177</sup> Official Gazette No. 27208 (Apr. 22, 2009).

## VENEZUELA

PhRMA member companies face several market access and intellectual property (IP) barriers in Venezuela, including restrictions on access to foreign currency and virtually non-existent IP protections.

### Key Issues of Concern:

- **Foreign currency access:** In 2003, Venezuela established restrictive foreign currency controls. Since 2010, the total amount of foreign currency authorized for pharmaceutical imports has decreased by 46.5%, resulting in unpaid debt to multinational laboratories, between 2010 and October 2013, of US\$3.84 billion dollars. In turn, the supply of medicines has fallen dramatically in the country with the consequent impact on health and on manufacturing and importing companies.
- **Prohibitive market access barriers:** A wide array of barriers is sharply limiting market access for medicines and other staples in Venezuela. Price controls on Essential Medicines (as defined by the World Health Organization) have been in place in Venezuela since 2003, with no price increases to account for devaluation or inflation. Likewise, beginning in 2011, maximum retail price mechanisms were put in place to limit profit margins for companies operating in areas such as food and non-essential medicines. The combination of the price controls and restrictions on free market pricing of medicines and other products has had a devastating impact on patients and consumers in Venezuela.
- **Weak patent enforcement and regulatory data protection failures:** Venezuela essentially has not granted patent protection or regulatory data protection (RDP) to pharmaceuticals since 2002.
- **Excessive patent filing and maintenance fees:** There has been a significant increase in filing and maintenance fees in Venezuela. Effective May 2015, the official cost for the filing and maintenance of patent and trademark applications and granted patents in Venezuela has increased by between 940-2,000%, with particular impact on foreign applicants/patentees. For example, annuities now stand at approximately US\$2,381 due at filing, with significant annual increases until year 20 (year 20 is now approximately US\$48,000).

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**

### Foreign Currency Access Policy

In 2003, Venezuela established restrictive controls on access to foreign currency for all economic sectors. Although the preferential (official) exchange rate may be used to fund finished medicines and pharmaceutical raw materials, requests by pharmaceutical companies to use foreign currency for transfer of capital and earnings, and to pay for technical assistance, business expenses or to import other goods and services indirectly related to the manufacture of medicines or the normal operation of companies, have generally been denied.

In February 2013, after devaluing the official exchange rate of the Venezuelan Bolivar from VEB 4.3 to 6.3 per USD, the Venezuelan government set up the Complementary System of Administration of Foreign Currency (Sistema Complementario de Administración de Divisas or SICAD) to address the purchase of foreign currency by importers operating in Venezuela who do not have access to the Commission for the Administration of Foreign Currency (Comision de Administración de Divisas or CADIVI).

In October 2013, the Government created CENCOEX (Centro Nacional de Comercio Exterior) to replace CADIVI, arguing irregularities in the previous system and lack of controls. As a result, for those importations made or services provided before October 2013 (deemed to be “old debt”), payments were suspended to “revise” the debt based on individual negotiations with each company based on goods imported, prices, *etc.* Since October 2013, the total amount of foreign currency authorized for pharmaceutical imports has decreased by 46.5%, resulting in payment delays exceeding two or more years.

In addition, Venezuela has implemented several foreign currency systems (CENCOEX, SICAD, DIPRO, and DICOM). Depending on the nature of the goods or services, importing companies are subject to greatly varying exchange rates:

### Government Procurement

The Venezuelan Bidding Law applies to government procurement of all goods and services, including pharmaceutical products, and mandates, other than in certain limited circumstances, a competitive bidding process. However, in practice the Bidding Law is not consistently enforced by Venezuelan authorities, and it is very common for public contracts to be: (1) awarded without regard to the Bidding Law, or (2) based upon broad interpretations of the exceptions set forth in the Bidding Law in order to avoid a competitive bidding process. The government’s failure to enforce the Bidding Law results in a lack of transparency with respect to government procurement.

### Non Production Certificate

Venezuelan manufactured medicines have been exempted from Venezuela's value added tax (VAT) since 2002. In order to obtain a VAT exemption for imported medicines, companies must request a certificate from the government, stating either that the product is not manufactured domestically, or that it is manufactured in insufficient quantities that will not satisfy patient demands. This certificate, initially intended for the sole purpose of demonstrating eligibility for the VAT exemption, is now also required by foreign exchange authorities to provide currencies at the official rate. As restrictions in currency availability increase, the authorities have restricted the number of exemption certificates and the amount of foreign currency requested, thus creating shortages at any given time of approximately 40% of medicines, to the obvious detriment of Venezuelan patients.

### Prohibitive Market Access Barriers

Beginning in 2003, the Venezuelan government imposed price controls for Essential Medicines (as defined by the World Health Organization) comprising close to one-third of the medicines marketed in-country. On October 6, 2005, the Government issued a Resolution to establish a system of notification that provided for price increases for all medicines not deemed to be covered under the Essential Medicines price controls. Since then, statistics released by the Central Bank of Venezuela and the National Institute of Statistics indicate that prices of medicines have not been sufficiently increased to take into account accumulated inflation (more than 799 percent), and 46.5% devaluation.

On July 18, 2011, the Venezuelan Government issued a Decree on Fair Costs and Prices (hereinafter "LCYPJ" as per its Spanish Acronym),<sup>178</sup> which established the National Superintendence of Costs and Prices (hereinafter the "SUNDECOP" as per its Spanish Acronym). In turn, SUNDECOP establishes the standards for the National Registry of Prices of Goods and Services, and has overall responsibility to regulate, supervise, control, and monitor prices, and set Maximum Retail Prices (PMVP) or the price range for goods and services, thereupon ending Venezuela's long-standing practice of allowing free-market pricing for non-essential medicines (accounting for approximately 90 percent of the market by value). This Decree was further revised on January 23, 2014, to establish a cost-based pricing system for locally produced medicines.

In late 2014 the government passed the "Ley Orgánica de Precios Justos" (LOPJ) which amends and restates the previous pricing regime. The LOPJ creates a "Superintendencia Nacional para la Defensa de los Derechos Socio Economicos" (SUNDDE) and sets the criteria to calculate cost, expenses and profits margins.

---

<sup>178</sup> Official Gazette N° 39.715 (July 2011).

Price controls and other restrictions described above have sharply limited market access for medicines and many other products in Venezuela, jeopardizing the ability of pharmaceutical firms to supply medicines and harming local patients and consumers.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

As a practical matter, Venezuela has not granted patent protection to pharmaceuticals since 2002. As a legal matter, Venezuela was obliged to grant patent protection to pharmaceuticals as a Member of the Andean Community (AC). However, in April 2006, Venezuela formally withdrew from the AC, and all rights and obligations for Venezuela, including application of Intellectual Property Decision 486, ceased upon withdrawal in accordance with Article 135 of the Cartagena Agreement. Although there was legal uncertainty as to whether Decision 486 still applied in Venezuela, a decision by the Supreme Court of Justice issued on March 17, 2011, confirmed that following Venezuela's withdrawal from the AC, Venezuela IP law reverted to the Industrial Property Law of 1956 (IPL). The IPL is replete with provisions that violate the international obligations of Venezuela under TRIPS. For example, the law prohibits the granting of patents for pharmaceutical products, and thus directly contravenes Article 27 of the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Paris Convention.

### Excessive Patent Filing and Maintenance Fees

There has been a significant increase in filing and maintenance fees in Venezuela. Effective May 2015, the official cost for the filing and maintenance of patent and trademark applications and granted patents in Venezuela has increased by between 940 and 2,000 percent, with particular impact on foreign applicants/patentees. For example, annuities now stand at approximately US\$2,381 due at filing, with significant annual increases until year 20 (year 20 is now approximately US\$48,000).

### Regulatory Data Protection Failures

Although Venezuela provided RDP between 1998 and 2001, it has not done so since 2002. It has instead granted second regulatory authorizations and relied on the original data during the period when data protection should be applied, raising serious concerns under TRIPS Article 39.3.

According to the local innovative pharmaceutical association, Cámara Venezolana del Medicamento (CAVEME), it has become common practice in the last decade for the health authority (the Venezuelan National Institute of Health (INH)) to grant sanitary registration to "copy" products before the expiration of the five-year data protection period. Individual research based pharmaceutical companies have filed challenges against the government in the courts to enforce data protection, with no results to date. Many companies have also acted directly against marketers of the copy

products at the Venezuelan Antitrust Agency, which has dismissed all unfair competition claims. Claims were also brought by pharmaceutical companies to the Administrative Courts and then to the Supreme Court of Justice, but both courts denied preliminary remedies and continue to process claims with no decision in sight. On June 6, 2005, CAVEME sued the INH for not granting the data protection stipulated by TRIPS Article 39.3. The claim was accepted by the Court in 2006, but a decision has not been issued.

### **Counterfeit Medicines**

As noted by the Direction of Drugs, Medicines and Cosmetics of the Health Ministry in 2010, and recent findings by the local Investigation Police department (CICPC, May 2014), Venezuela has witnessed an increase in counterfeit medicines (more than 10 percent of the market) as well as other illicit activities, such as smuggling, robbery and adulteration. This increase can be attributed to a combination of factors: (1) the Government's lack of attention and political will to address the problem; (2) administrative inefficiency; (3) lack of enforcement of existing laws, most of which are inadequate; (4) insufficient penalties; and (5) an ineffective judicial system that does not consider counterfeit medicines a priority. Notwithstanding many other challenges, Venezuela is taking moderate steps to place a higher priority on curbing the distribution and use of counterfeit medicines through increased resources and penalties for criminals caught manufacturing, supplying, or selling them, encouraged by the efforts of the Pharmaceutical Industry, Chambers and Associations (such as CAVEME or Federación Farmacéutica Venezolana).<sup>179</sup>

---

<sup>179</sup> See <http://www.noticias24.com/venezuela/noticia/187872/aseguran-que-incidentes-causados-por-medicamentos-falsos-se-han-elevado-7/> (in Spanish) (last visited Oct. 27, 2016).

## VIETNAM

PhRMA's member companies face significant market access and intellectual property (IP) concerns in Vietnam. Furthermore, many of the reforms proposed by the Government of Vietnam are out of step with international or regional best practices.

### Key Issues of Concern:

- **Burdensome clinical trial and quality testing requirements:** Domestic clinical trial requirements in Vietnam are mandated for marketing approval of pharmaceuticals that have not been made available in their country of origin for more than five years. These studies are unnecessary and burdensome, lead to an escalation in costs, and reduce the number of innovative medicines available to Vietnam's patients. While the New Pharma Law (approved on April 6, 2016 and scheduled to be go into effect on January 1, 2017) removes the five-year post launch data requirement, it does not provide detail or clear conditions surrounding the local clinical trial waiver. The law is very general and stipulates that "clinical trial is waived in case the new drug has been licensed for marketing in at least one country in the world and of which data on safety, effectiveness are fully available, except vaccines". PhRMA is concerned that the existing vague language could lead to burdensome local clinical trial requirements for new drug licensing.
- **Discriminatory government procurement policies:** Current Ministry of Health (MOH) initiatives aim to increase the share of locally procured pharmaceuticals to 80% of market volume and value by 2030, which could significantly impact U.S. exports to Vietnam. In addition, proposed revisions to the tendering system are still not fully clear and may limit participation of foreign companies.
- **Trading rights and distribution restrictions:** Vietnam's MOH should provide clear guidelines for effective implementation of full import rights of all pharmaceutical products. While the Draft Decree to implement the Pharma Law currently provides for greater freedom to import and export, it does not ease Vietnam's distribution restrictions. The MOH should also permit PhRMA's member companies to contract with foreign-owned storage and logistical service companies who have obtained suitable certifications according to international standards for their facilities and practices.
- **Discriminatory market access policies:** Vietnam's decision to use cost, insurance, and freight (CIF) prices as a benchmark to set pricing for pharmaceuticals relative to neighboring countries creates unequal opportunities and restrictions for imported and locally produced pharmaceuticals, which are exempt from associated costs and restrictions.
- **Generally weak IP environment:** 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, could greatly assist Vietnam in creating a more predictable environment for investment in innovation and enhance transparency and predictability.

In addition, the MOH is drafting a circular on compulsory licensing for pharmaceutical patents (CL Circular) that in its current form would grant overly broad and arbitrary powers to grant compulsory licenses (CLs). Specific concerns include the lack of clarity as to the conditions for granting compulsory licenses, the procedures for examining applications, and the calculation of “adequate remuneration” in the event of a CL. Further the draft CL Circular fails to require negotiations with the patentee prior to granting the CL, contrary to Vietnam’s obligations under the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

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**

### **Burdensome Clinical Trial and Quality Testing Requirements**

PhRMA’s member companies continue to express concern with domestic clinical trial requirements in Vietnam for the marketing approval of all pharmaceuticals (including chemical drugs, vaccines and biologics) that have not been made available in their country of origin for more than five years. Not only is this practice unnecessary, given the stringent standards of regulatory authorities such as the United States Food and Drug Administration and European Medicines Agency, but Vietnam does not possess the resources or infrastructure to acquire reliable clinical trial results from domestic sources. These requirements also apply to new variations of pharmaceutical products already registered in Vietnam. PhRMA’s member companies urge Vietnam to permit regulatory officials to accept reliable clinical trial data collected from appropriate clinical trial sites located outside of Vietnam when domestic capabilities are not in place. Such an amendment could quickly improve patient access to new, life-saving medicines. While PhRMA’s members applaud efforts by the MOH in the new Pharma Law to eliminate the requirement to conduct clinical trials in Vietnam in order to attain regulatory approval, they remain concerned that the legislative reforms to eliminate this requirement have stalled and encourage the Vietnamese Government to remove this barrier to patient access immediately.

Furthermore, Vietnam’s requirement that all new batches of vaccines undergo quality testing is scientifically unnecessary and time consuming. These tests must be conducted by the National Institute for Control of Vaccine and Biologicals, which does not have the capacity to effectively conduct such tests.

### Burdensome and Unnecessary Product Registration Renewals

Vietnam currently requires pharmaceutical firms to reapply for product renewal or “visas” every five years. This requirement has become a significant administrative burden since the process to obtain or renew a product visa can take from 18-24 months, and it is not possible to submit a dossier for renewal until twelve months before the expiry of the existing registration. These delays and restrictions can lead to “off-visa” periods, during which importation and promotion of the product is not typically permitted<sup>180</sup> – resulting in shortages for hospitals and patients - and medical education activities are significantly restricted. We are encouraged that the Drug Administration Vietnam (DAV) has outlined a process for reducing the visa review/renewal process to 12 months and hope to work collaboratively with the DAV in meeting this target.

### Onerous Government Procurement Tenders

The procedure for the selection of innovative medicines for tender includes onerous and impractical requirements for submitting documents, which have caused delays for companies applying for tender. For example, in August 2012, the Ministry of Health issued Decision 2962 “Decision on Promulgating Temporary Regulation on Documents Needed In Order To Announce Lists of Original Proprietary Medicines, Medicines Used for Treatment Similar with Original Proprietary Medicines, Medicines with Documents Proving Bioequivalence.” This Temporary Decision 2962 specified the documents, including patents, and additional parameters for qualifying as an innovator pharmaceutical product for the bidding process (see Article I, paragraph 2).

Temporary Decision 2962 details two ways in which patents will be accepted. First, it only recognizes patents from selected countries. Under the Temporary Decision 2962, patents will only be accepted from 14 National Patent Offices (since expanded to 16 offices under decision 1545/QD-BYT). Second, Temporary Decision 2962 limits the innovative products eligible for tenders to those with “molecular patents” (it has since been expanded to also include “dosage form patents” in Decision 1545). This serves to exclude from the tendering process those pharmaceuticals with process patents or patents for second uses and combinations, thereby disregarding the benefits these medicines could bring to Vietnamese patients.

Since 2015, the MOH removed innovative drugs from the innovative pharmaceutical product list (IPP) if their manufacturers are not ICH members despite the lack of any written guidance or previous inclusion on the list. Moreover, the MOH’s activity limits foreign companies from applying for or winning tenders.

In addition, a new tendering regime is being implemented that will include a price negotiation and a centralized tendering system, the parameters and application of which are unclear and may limit participation of foreign companies. Greater clarity and

---

<sup>180</sup> In special circumstances, import licenses may be granted during “off-visa” periods for individual shipments based on historical volume.

transparency is needed for the technical requirements and price negotiation criteria as well as communication with industry before implementation. Furthermore, the ban of foreign products where it is determined that there are domestically-manufactured drugs meeting the therapeutic, price and supply capacity requirements is an area that will be important to monitor as it is implemented.

### Certificate of Pharmaceutical Product (CPP) Requirements

Currently manufacturers seeking to register new products in Vietnam are required to submit a CPP from the country of origin or certain reference countries with the technical dossier. In turn, this delays Vietnamese patient access to innovative medicines by approximately 26-36 months. To avoid these unnecessary delays, Vietnam should allow manufacturers to submit their technical dossiers without the CPP, and then supplement their applications once the CPP is issued.<sup>181</sup>

### Trading Rights and Distribution Restrictions

As part of Vietnam's WTO accession commitments, the country agreed to extend full import rights to pharmaceutical products in January 2009. Despite this commitment, international pharmaceutical companies must still establish foreign representative offices and rely on a complex set of arrangements for their foreign parent companies to export pharmaceuticals to Vietnam. Further, foreign representative offices are prohibited from "conducting sales/trading activities" and, as such, are not allowed to issue invoices to business partners, collect receivables, or provide educational information on their medicines. PhRMA's member companies urge the MOH as part of planned legislation in 2017 to issue clear guidelines that embrace full trading rights for the export, import and distribution of finished pharmaceutical products in Vietnam.

Research-based pharmaceutical firms also face limited control over the distribution of their products. Therefore, foreign investors and their parent companies turn to local distributors to import and sell their products on the Vietnamese market and are forced to rely on those partners to ensure the quality and safety of product delivery to patients. This is particularly challenging as foreign pharmaceutical companies (as the product registration license holder) remain liable for adverse events caused by their pharmaceutical drugs and vaccines, yet are unable to control the quality and safety of product delivery to patients. In addition, the lack of control over distribution poses a barrier to trade due to the complexity it adds to operations and the potential compliance risk in terms of not being able to own, train and discipline field-force personnel in a timely manner.

The pharmaceutical supply chain requires careful monitoring to ensure product safety, reliable maintenance (*i.e.*, an unbroken cold chain for vaccines), and timely

---

<sup>181</sup> To the extent that Vietnam also uses the CPP as a proxy to demonstrate that the product is safe, the industry stands ready to work with Vietnam to determine other methods to demonstrate safety and efficacy.

delivery, as well as the protection of sensitive proprietary technology. The MOH should permit PhRMA's member companies to contract with foreign-owned storage and logistical services companies who certify that their methods meet international standards.

### Discriminatory Market Access Policies

Vietnam uses cost, insurance, and freight (CIF) prices as a benchmark to compare pricing for pharmaceuticals with neighboring countries. This creates unequal opportunities and restrictions for imported versus locally produced pharmaceuticals. First, Vietnam's unique import regime (described above) results in inflated CIF prices within Vietnam relative to other regional markets that do not impose similar import and distribution restrictions. Second, the adopted pricing circular only applies to imported products as no similar restrictions or requirements are imposed on locally manufactured goods. The price monitoring system should be based on Price to Trade (PTT), which covers both locally manufactured and imported products.

### Market access challenge for innovative biological products

Biological medicines are large molecules that are more scientifically complex to manufacture than small-molecule medicines. Quality is of particular concern for biologics to ensure patient safety. The new Pharma law that goes into effect on January 1, 2017 includes requirements for evidence on quality testing for bio-similar products to ensure patient safety. However, these provisions have not yet been implemented in hospital procurement. This raises enormous concerns for patient safety as well as access to quality biologics.

### Ban on Imports of Products with "Old" Packaging

Currently, all approval letters related to any variations in imported drugs, including variation related to artwork (e.g. packaging insert update, changing information on carton, blister, label etc.) stipulate that: "*After 3 months since the signed date of this letter, your company is not allowed to import drugs with old artwork/packaging insert*". In practice, however, due to global supply chains, it can take PhRMA members six to nine months to ship products using the new approved artwork to Vietnam, resulting in product shortages or stock-outs. To ensure that patients have continued access to their medicines and that manufacturers are able to meet their active tender contracts with hospitals and the Services of Health, Vietnam should provide greater flexibility to use the former packaging.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

The Vietnamese National Office for Intellectual Protection (NOIP) has misconstrued Article 4.12 of the Law on Intellectual Property (2005) to omit "second

use” inventions from the definition of “invention.” Article 4.12 provides that an “invention means a technical solution in [the] form of a product or a process which is intended to solve a problem by application of laws of nature.” The Ministry of Science and Technology expounded that definition in 2007 in Circular No. 01/2007/TT-BKHCHN, providing that patent protection will only be offered to an invention if it is a “technical solution,” including a product or “a process (technological process; diagnosing, forecasting, checking or treating method).”

Notwithstanding the clear scope of a patentable invention as set forth in Vietnam’s Law on Intellectual Property and Circular No. 01/2007/TT-BKHCHN, NOIP began to systematically reject any claims for “second uses” of existing pharmaceutical products in 2005. The rationale for many of these rejections purports to be grounded in the definition of “invention” found in Article 4.12 of the Law on Intellectual Property and in Article 25 of Circular No. 01/2007/TT-BKHCHN even though the result contravenes these cited sources. In all, NOIP has made “second use” inventions *de facto* ineligible patent subject matter. Yet, NOIP is obligated to examine these inventions because “second use” inventions fall within the meaning of invention in TRIPS Article 27.1 and Vietnam’s own definition of “invention” in Article 4.12 of the Law on Intellectual Property.

#### Draft Compulsory License Circular

Earlier this year, the MOH issued a draft circular on compulsory licensing for pharmaceutical patents (CL Circular) that in its current form would grant overly broad and arbitrary powers to grant compulsory licenses (CLs). Specific concerns include the lack of clarity as to the conditions for granting compulsory licenses, the procedures for examining applications, and the calculation of “adequate remuneration” in the event of a CL. Further the CL Circular fails to require negotiations with the patentee prior to granting the CL, contrary to Vietnam’s obligations under TRIPS. Industry is highly concerned that if the CL Decree were implemented, it could create significant uncertainty for innovators and would run counter to Vietnam’s ongoing efforts to attract and sustain pharmaceutical innovation and investment.

#### Patent Backlogs

PhRMA’s member companies continue to face burdensome delays in the granting of patents. Vietnam lacks a means for adjusting the patent term to compensate for these delays, thus eroding the effective term of patent protection available for innovative medicines. There are various reasons for these delays, including insufficient personnel capacity.

#### Weak Patent Enforcement

Vietnam fails to provide an effective patent enforcement mechanism that allows for resolution of patent disputes prior to the grant of marketing approval for follow-on products. PhRMA’s member companies strongly encourage Vietnam to adopt such mechanisms. Such a patent enforcement mechanism could greatly enhance the

business environment by: (1) providing process transparency and predictability for both the innovative and the generic sectors; (2) creating a more predictable environment for investment decisions; and (3) ensuring timely redress of genuine disputes.

### Regulatory Data Protection Failures

The DAV continues to engage with PhRMA's member companies on the adoption of meaningful RDP measures. However, the implementation guidelines of the current Data Protection Circular fall short of making the necessary improvements.

As part of the implementation of Vietnam's obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the Data Protection Circular provides, on paper, for five years of RDP. In practice, however, this protection has proved illusory. First, 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) data be classified as a "trade secret" under Vietnamese law, which as defined may not cover undisclosed confidential business information; and (3) 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 DAV; to our knowledge, no PhRMA member company has received RDP in Vietnam to date.

### **Counterfeit Medicines**

PhRMA's member companies applaud efforts by the National Institute for Drug Quality Control (NIDQC) to partner with the U.S. Government to raise awareness of the dangers posed by unsafe medicines and strongly support enhanced coordination on anti-counterfeit initiatives, including training for regulatory and security officials. NIDQC has also consulted with PhRMA's member companies on best practices to promote the use of safe medicines. Increasing the penalties for criminals manufacturing, supplying, or selling counterfeit medicines will help improve enforcement efforts.