

**PHARMACEUTICAL RESEARCH AND  
MANUFACTURERS OF AMERICA  
(PhRMA)  
SPECIAL 301 SUBMISSION 2017**

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# **PhRMA 2017 SPECIAL 301 OVERVIEW**

## **PhRMA 2017 SPECIAL 301 OVERVIEW**

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide this submission for the *2017 Special 301 Report*.

The following overview highlights the critical role adequate and effective intellectual property rights protections and fair and equitable market access play in enabling biopharmaceutical innovators in the United States to research, develop and deliver valuable new medicines for patients who need them around the world. It describes serious and pressing intellectual property and market access barriers abroad and recommends steps the Office of the U.S. Trade Representative (USTR) and other federal agencies can take to address and resolve these barriers. The attached country profiles provide additional details and examples.

This submission focuses on the most urgent barriers and threats in 18 countries that are significant and increasingly important markets for medicines invented, developed and manufactured in the United States. For the reasons explained in the following pages, PhRMA urges USTR and other federal agencies to prioritize action to address and resolve challenges in **Canada, China, Colombia, India** and other countries recommended for inclusion on the Priority Watch List.

### **I. The Innovative Biopharmaceutical Sector**

The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world’s new molecules in the last decade.<sup>1</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>2</sup> 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

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<sup>1</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 February 9, 2017).

<sup>2</sup> TEconomy Partners, *The Economic Impact of the US Biopharmaceutical Industry*, April 2016, available at <http://pharmacdn.connectionsmedia.com/sites/default/files/pdf/biopharmaceuticaul-industry-economic-impact.pdf> (last visited February 9, 2017).

since 2000<sup>3</sup> and investing in many of the over 7,000 new drugs currently in development worldwide.<sup>4</sup>

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 more than \$1.2 trillion to the U.S. economy and supported 4.4 million American jobs, including indirect and induced jobs.<sup>5</sup> For all occupations involved in the biopharmaceutical industry, the average total compensation per direct employee is twice the average compensation in any other U.S. private sector industry.<sup>6</sup> In 2015, the industry exported \$55 billion in biopharmaceuticals,<sup>7</sup> making the sector one of the top U.S. exporters among intellectual property-intensive industries.<sup>8</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 2014, life expectancy for women and men in the United States increased by more than a decade<sup>9</sup> – adding trillions of dollars to the U.S. economy.<sup>10</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

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<sup>3</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 February 9, 2017); U.S. Food and Drug Administration, “New Drugs at FDA: CDER’s new molecular entities and new therapeutic biological products, available at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm20025676.htm> (last visited February 9, 2017); and U.S. Food and Drug Administration, Biological approvals by year, available at <http://www.fda.gov/BiologicsBloodVaccines/DevelopmentApprovalProcess/BiologicalApprovalsbyYear/default.htm> (last visited February 9, 2017).

<sup>4</sup> *Adis R&D Insight database*, accessed March 2016.

<sup>5</sup> TEconomy Partners, *The Economic Impact of the US Biopharmaceutical Industry*, April 2016, available at <http://pharmacdn.connectionsmedia.com/sites/default/files/pdf/biopharmaceuticaul-industry-economic-impact.pdf> (last visited February 9, 2017).

<sup>6</sup> *Id.*

<sup>7</sup> PhRMA analysis of data from US Department of Commerce, International Trade Administration, Web site. <http://tse.export.gov/TSE/TSEhome.aspx>.

<sup>8</sup> Industry R&D data from National Science Board of the National Science Foundation, *Science and Engineering Indicators 2012*, 2012; Industry export data from PhRMA analysis of data from U.S. ITA, *TradeStats Express: National Export Data*; Software publishers data from the International Intellectual Property Alliance.

<sup>9</sup> U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, *Health, United States, 2015*, Table 15, May 2016, available at <https://www.cdc.gov/nchs/data/abus/abus15.pdf> (last visited February 9, 2017).

<sup>10</sup> Between 1970 and 2000, increased longevity added about \$3.2 trillion per year to national wealth in the United States. See Murphy, K.M. and R.H. Topel, “The Value of Health and Longevity”, National Bureau of Economic Research, June 2005, available at <http://www.nber.org/papers/w11405> (last visited February 9, 2017).

expectancy gains in the United States and other high-income countries between 2000 and 2009.<sup>11</sup>

For example, the AIDS death rate has dropped nearly 87 percent since the approval of antiretroviral treatments in 1995.<sup>12</sup> Today, a 20-year old diagnosed with HIV can expect to live another 50 years.<sup>13</sup> New medicines have cut heart disease deaths by 38 percent, according to the Centers for Disease Control and Prevention.<sup>14</sup> More than 80 percent of the increase in life expectancy of cancer patients since 1980 is attributable to new treatments.<sup>15</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>16</sup>

PhRMA member companies are building on these achievements and pioneering new treatments and cures for some of the world's most devastating diseases. Researchers are developing more than 1,200 new medicines for infectious diseases, including viral, bacterial, fungal, and parasitic infections such as the most common and difficult-to-treat form of hepatitis C, a form of drug-resistant malaria, a form of drug-resistant MRSA, and a novel treatment for smallpox.<sup>17</sup> Advances in biotechnology and genomics are propelling the discovery of new medicines to treat a range of chronic and infectious diseases. Made using living organisms, biologic medicines are revolutionizing the treatment of cancer and autoimmune disorders. Biologics are critical to the future of

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<sup>11</sup> Lichtenberg, F.R., "Pharmaceutical Innovation and Longevity Growth in 30 Developing and High-income Countries, 2000-2009," *National Bureau of Economic Research*, July 2012, available at <http://www.nber.org/papers/w18235> (last visited February 9, 2017).

<sup>12</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 February 9, 2017).

<sup>13</sup> *Id.*

<sup>14</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", December 2013, available at <http://www.cdc.gov/media/dpk/2013/dpk-vs-heart-disease.html> (last visited February 9, 2017); and U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, "Vital Signs: Avoidable Deaths from Heart Disease, Stroke, and Hypertensive Disease—United States, 2001-2010", September 2013, available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6235a4.htm> (last visited February 9, 2017).

<sup>15</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, available at [http://hwmain.meeting.ascopubs.org/cgi/content/abstract/26/15\\_suppl/6616](http://hwmain.meeting.ascopubs.org/cgi/content/abstract/26/15_suppl/6616) (last visited February 9, 2017); A more recent article by the American Cancer Society (dated February 9, 2017) 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 February 9, 2017).

<sup>16</sup> See, for example, U.S. Food and Drug Administration News Release, "FDA approves Viekira Pak to treat hepatitis C", December, 2014, available at <http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm427530.htm> (last visited February 9, 2017).

<sup>17</sup> *Adis R&D Insight database.*

the industry and promise progress in the fight against conditions like Alzheimer's, which today lack effective treatments.<sup>18</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>19</sup> Every \$24 spent on new medicines for cardiovascular diseases in OECD countries saves \$89 in hospitalization costs.<sup>20</sup> Treating high blood pressure according to clinical guidelines would result in annual health system savings of about \$15.6 billion.<sup>21</sup>

PhRMA members are working to overcome significant systemic challenges that can prevent the poorest patients from accessing medicines. Together with governments, academia and others, they are leading more than 340 initiatives with more than 600 partners to help shape sustainable solutions that improve the health of all people.<sup>22</sup> Last month, more than 20 biopharmaceutical companies joined the World Bank and the Union for International Cancer Control to launch Access Accelerated – a first-of-its-kind global initiative to address cancer and other non-communicable diseases that cause more than 28 million deaths per year in low and lower-middle income countries.<sup>23</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>24</sup> Between 2000 and 2011, they contributed an estimated \$98.4 billion dollars

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<sup>18</sup> *Id.*

<sup>19</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*, October 2012, available at <http://content.healthaffairs.org/content/31/10/2276.full.pdf> (last visited February 9, 2017).

<sup>20</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 February 9, 2017).

<sup>21</sup> Cutler, D.M., G. Long et al., "The Value of Antihypertensive Drugs: A Perspective on Medical Innovation", *Health Affairs*, January 2007, available at <http://content.healthaffairs.org/content/26/1/97.full> (last visited February 9, 2017).

<sup>22</sup> See Global Health Progress, available at <http://www.globalhealthprogress.org>.

<sup>23</sup> Access Accelerated, "Biopharma Companies Partner and Launch First-of-its-Kind Global Initiative to Address Rise of Non-Communicable Diseases", January 2017, available at <http://www.accessaccelerated.org/biopharma-companies-partner-and-launch-first-of-its-kind-global-initiative-to-address-rise-of-non-communicable-diseases/> (last visited February 9, 2017).

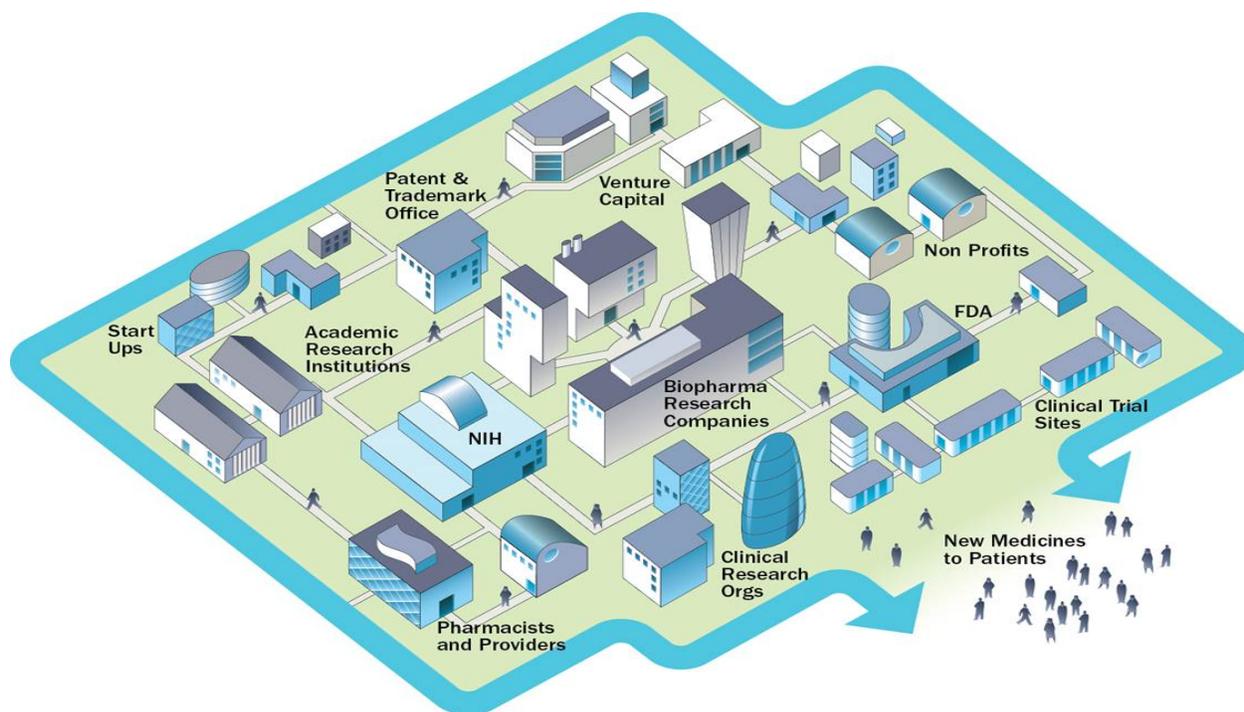
<sup>24</sup> International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), "The IFPMA Health Partnerships Survey", *validated by LSE Health and Social Care at the London School of Economics and Political Science*, March 2006, available at: [http://www.policy-centre.com/downloads/IFPMA\\_LSE\\_Report\\_08Mar06.pdf](http://www.policy-centre.com/downloads/IFPMA_LSE_Report_08Mar06.pdf) (last visited February 9, 2017).

toward achieving health-related Millennium Development Goals.<sup>25</sup> Despite a three percent drop in public funding for neglected disease (excluding Ebola) research and development in 2014, biopharmaceutical industry funding increased by 28 percent during the same period.<sup>26</sup>

### ***B. Intellectual property powers prevention, treatments and cures***

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

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



As highlighted in Figure 1 above, research, development and distribution of innovative medicines increasingly involves collaboration and the exchange of

<sup>25</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 February 9, 2017).

<sup>26</sup> Global Funding of Innovation for Neglected Diseases: G-Finder.

commercially sensitive information between multiple partners across borders and around the world. Strong intellectual property protection and enforcement enable innovators to license their patented inventions to others with the certainty that valuable information disclosed is secure. Thanks to the technology transfer framework established by the Bayh-Dole Act, licensing of intellectual property is also enabling collaboration among industry, university and public sector researchers in the development of new medicines and other products – adding \$518 million to the U.S. economy and supporting more than 3.8 million American jobs between 1996 and 2013, according to one study.<sup>27</sup> Such collaboration is delivering similar benefits in other countries. Recent research in the United Kingdom found that public expenditure on biomedical and health research leveraged even greater private sector investment, delivering a total rate of return to public biomedical and health research of up to 28 percent.<sup>28</sup>

Patents promote competition and greater treatment options. In exchange for the limited period of protection patents provide, innovators must fully disclose their inventions to the world. That disclosure accelerates innovation and empowers potential competitors to build on those inventions. Competition means more medicines in the same therapeutic class, more options for patients and even lower prices.<sup>29</sup> For example, less than a year after market entry of the first in a new class of hepatitis C treatments, there were multiple suppliers that competed both on price and clinical effects. Indeed, competition was so fierce that the largest U.S. pharmacy benefit manager claims hepatitis C treatment is less expensive in America than in other western countries.<sup>30</sup>

Today, biopharmaceutical innovators face competition faster – both from other innovators and from generic drug companies. In the 1970s, a new medicine might remain the only innovative treatment available in its therapeutic class for ten years or more. By the 2000s, that period had declined to about two years.<sup>31</sup> Generic competitors now challenge patents earlier and more frequently – even as early as four years after

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<sup>27</sup> Pressman, L., D. Roessner et al., “The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2013”, March 2015, available at [https://www.bio.org/sites/default/files/files/BIO\\_2015\\_Update\\_of\\_I-O\\_Eco\\_Imp.pdf](https://www.bio.org/sites/default/files/files/BIO_2015_Update_of_I-O_Eco_Imp.pdf) (last visited February 9, 2017).

<sup>28</sup> Sussex, J., Y. Feng et al., “Quantifying the economic impact of government and charity funding of medical research on private research and development funding in the United Kingdom”, *BMC Medicine*, February 2016, available at <http://bmcmmedicine.biomedcentral.com/articles/10.1186/s12916-016-0564-z> (last visited February 9, 2017).

<sup>29</sup> International Federation of Pharmaceutical Manufacturers and Associations, *The New Frontiers of Biopharmaceutical Innovation, 2012*, available at [http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA\\_New\\_Frontiers\\_Biopharma\\_Innovation\\_2012\\_Web.pdf](http://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_New_Frontiers_Biopharma_Innovation_2012_Web.pdf) (last visited February 9, 2017).

<sup>30</sup> LaMattina, J., “For Hepatitis C Drugs, U.S. Prices are Cheaper Than in Europe”, *Forbes*, December 2015, available at <http://www.forbes.com/sites/johnlamattina/2015/12/04/for-hepatitis-c-drugs-u-s-prices-are-cheaper-than-in-europe/#1483772d64bb> (last visited February 9, 2017).

<sup>31</sup> Tufts Center for the Study of Drug Development, “First-in-class drugs in competitive development races with later entrants”, *Impact Report*, December 2015, available at <http://csdd.tufts.edu/files/uploads/Summary-NovDeclR2015.pdf> (last visited February 9, 2017).

the launch of an innovative medicine.<sup>32</sup> Today, over 94 percent of innovative medicines experience at least one patent challenge prior to generic entry – compared to 25 percent in 1995.<sup>33</sup>

Patents promote faster access to new medicines. A major 2014 study found firms launch innovative medicines sooner in countries where there is effective patent protection and enforcement. The study looked at data from the launch of more than 600 drugs in almost 80 countries between 1983 and 2002. It showed strong patent protection accelerates new product launches in higher and lower income countries alike.<sup>34</sup> Launching a medicine in a particular country also has important effects on the whole healthcare system. For instance, when a new medicine is introduced, biopharmaceutical companies invest in educating healthcare providers on the science and appropriate use of that medicine.<sup>35</sup> This investment later enables accelerated acceptance of generic versions once relevant patents expire.

Strong intellectual property protection and enforcement has long been a critical goal of America's trade policy agenda. Strong intellectual property protection and enforcement at home and abroad provides essential incentives for investment in the biopharmaceutical sector and in all of the innovative industries that today account for nearly 40 percent of U.S. gross domestic product.<sup>36</sup> For each of these industries, developing and bringing new products and processes to market is a risky endeavor; it requires time and substantial resources. In most cases, new products will fail to deliver returns that meet or exceed investment. Some three-quarters of all venture capital-backed internet startups fail.<sup>37</sup> And even those that succeed often fail to make a profit. Biopharmaceutical firms face similar challenges. Just two of every ten marketed medicines achieve returns that match or exceed average research and development costs.<sup>38</sup> Of the approximately 1,200 biopharmaceutical companies in the United States, more than 90 percent do not earn a profit.<sup>39</sup>

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<sup>32</sup> Grabowski, H., G. Long et al., "Updated trends in US brand-name and generic drug competition", *Journal of Medical Economics*, September 2016, available at <https://www.ncbi.nlm.nih.gov/pubmed/27064194> (last visited February 9, 2017).

<sup>33</sup> *Id.*

<sup>34</sup> Cockburn, I.M. et al., "Patents and the Global Diffusion of New Drugs", *National Bureau of Economic Research*, September 2014, available at <http://nber.org/papers/w20492> (last visited February 9, 2017).

<sup>35</sup> Wilsdon, Tim and Glyn Chambers, "The wider value delivered to patients, healthcare systems and competitors when innovators launch new products," *Charles River Associates*, April 2013.

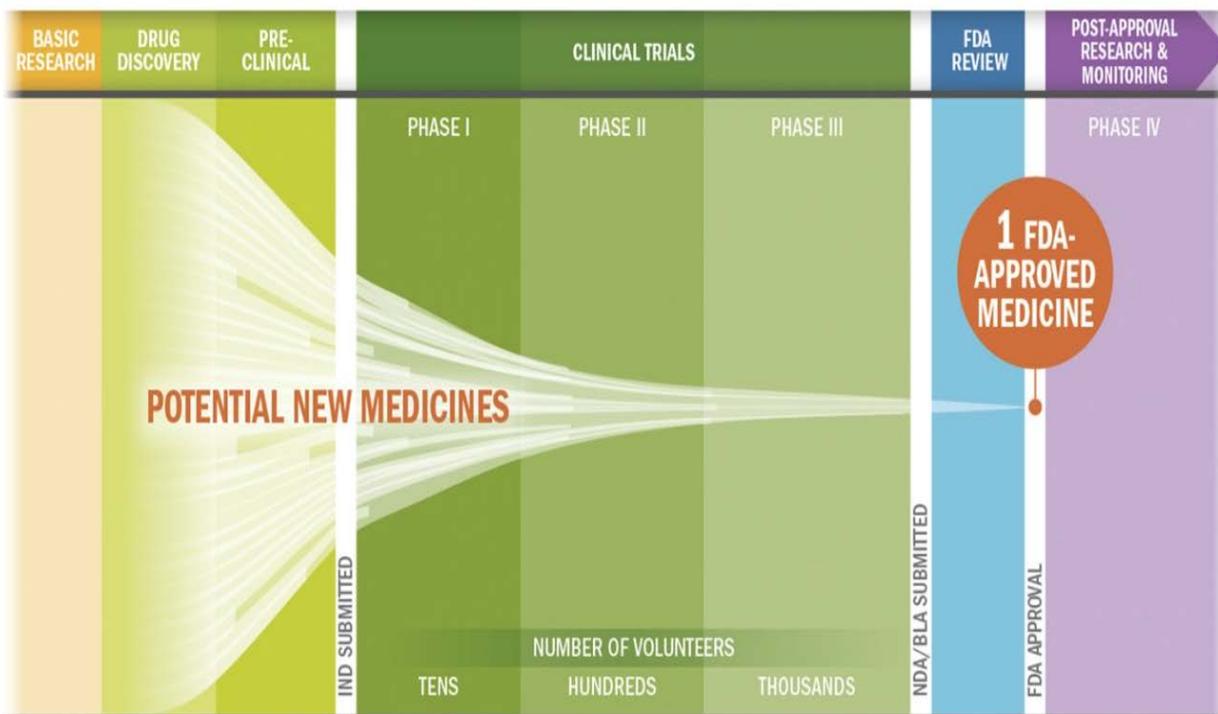
<sup>36</sup> U.S. Department of Commerce, *Intellectual Property and the U.S. Economy: 2016 Update*, September 2016, available at <https://www.uspto.gov/sites/default/files/documents/IPandtheUSEconomySept2016.pdf> (last visited February 9, 2017).

<sup>37</sup> Gage, D., "The Venture Capital Secret: 3 Out of 4 Start-Ups Fail", *The Wall Street Journal*, September 2012, available at <http://www.wsj.com/articles/SB10000872396390443720204578004980476429190> (last visited February 9, 2017).

<sup>38</sup> Vernon, J.A., J.H. Golec and J.A. DiMasi, "Drug development costs when financial risk is measured using the fama-french three-factor model", *Health Economics*, August 2010, available at <http://onlinelibrary.wiley.com/doi/10.1002/hec.1538/abstract> (last visited February 9, 2017).

<sup>39</sup> Biotechnology Industry Organization, *Unleashing the Next Generation of Biotechnology Innovation*, available at <http://www.bio.org/sites/default/files/Whitepaper-Final.pdf> (last visited February 9, 2017).

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



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

The long times to market make the research-based biopharmaceutical sector particularly reliant on the temporary protection intellectual property rights provide.<sup>40</sup> Unlike products made by other innovative industries, new medicines are not market-ready at the time they are developed. As highlighted in Figure 2 above, biopharmaceutical firms rigorously test and evaluate potential therapies through a series of clinical trials to demonstrate they are safe and effective for treatment of a particular disease or condition.<sup>41</sup> In 2013, the innovative biopharmaceutical industry sponsored nearly 6,200 clinical trials across all 50 states.<sup>42</sup> Test data generated through those trials is then submitted to national regulatory agencies for marketing approval.

<sup>40</sup> Without patent protection, an estimated 65 percent of pharmaceutical products would not have been brought to market, compared with an average of 8 percent across all other industries. See Mansfield, E., "Patents and Innovation: An Empirical Study", *Management Science*, February 1986, available at [https://www.jstor.org/stable/2631551?seq=1#page\\_scan\\_tab\\_contents](https://www.jstor.org/stable/2631551?seq=1#page_scan_tab_contents) (last visited February 9, 2017).

<sup>41</sup> PhRMA adaptation based on Dimasi J.A., "Cost of Developing a New Drug", Tufts Center for the Study of Drug Development, *R&D Cost Study Briefing* available at [http://csdd.tufts.edu/files/uploads/Tufts\\_CSDD\\_briefing\\_on\\_RD\\_cost\\_study\\_-\\_Nov\\_18,\\_2014..pdf](http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf) (last visited February 9, 2017); and U.S. Food and Drug Administration, *Drug Approval Process*, available at <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/UCM284393.pdf> (last visited February 9, 2017).

<sup>42</sup> Battelle Technology Partnership Practice, *Biopharmaceutical industry-sponsored clinical trials: impact on state economies*, Battelle Memorial Institute, February 2015, available at <http://www.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-sponsored-clinical-trials-impact-on-state-economies.pdf> (last visited February 9, 2017).

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>43</sup> Between 2013 and 2015, the U.S. biopharmaceutical sector invested more than \$50 billion annually in research and development.<sup>44</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>45</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>46</sup>

Advances in the treatment of diseases typically are not driven by large, dramatic developments, but more commonly build on a series of 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>47</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>48</sup> This step-by-step transformation in knowledge has led to increased survival, improved patient outcomes and enhanced quality of life for many patients.<sup>49</sup>

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<sup>43</sup> Pham, N., *IP-Intensive Manufacturing Industries: Driving U.S. Economic Growth*, *NDP Analytics*, March 2015, available at <http://www.ndpanalytics.com/ip-intensive-manufacturing-industries-driving-us-economic-growth-2015/> (last visited February 9, 2017).

<sup>44</sup> PhRMA, *Annual Membership Survey*, 2016.

<sup>45</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 February 9, 2017).

<sup>46</sup> PhRMA, *2016 Profile Biopharmaceutical Research Industry*, available at <http://phrmacdn.connectionsmedia.com/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf> (last visited February 9, 2017).

<sup>47</sup> Jin, G. and S. Wong, “Toward better drug repositioning: prioritizing and integrating existing methods into efficient pipelines,” *Drug Discovery Today*, January 2014, available at <http://www.sciencedirect.com/science/article/pii/S1359644613003991> (last visited February 9, 2017).

<sup>48</sup> See Cohen, J. and K. Kaitin, “Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice”, *American Journal of Therapeutics*, January-February 2008, available at [http://journals.lww.com/americantherapeutics/Citation/2008/01000/Follow\\_On\\_Drugs\\_and\\_Indications\\_\\_The\\_Importance\\_of.15.aspx](http://journals.lww.com/americantherapeutics/Citation/2008/01000/Follow_On_Drugs_and_Indications__The_Importance_of.15.aspx) (last visited February 9, 2017).

<sup>49</sup> Sweeney, N. and Goss, T.F., *The Value of Innovation in Oncology Innovation*, Boston Healthcare, May 2015, available at [http://phrma-docs.phrma.org/sites/default/files/pdf/bha\\_value\\_of\\_cancer\\_innovation-whitepaper.pdf](http://phrma-docs.phrma.org/sites/default/files/pdf/bha_value_of_cancer_innovation-whitepaper.pdf) (last visited February 9, 2017).

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

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

For well over a century, governments have recognized the need for global minimum standards that enable inventors to effectively and efficiently protect and share their inventions in a territorial system of intellectual property rights. Signed in 1883, the Paris Convention for the Protection of Industrial Property allowed inventors, regardless of nationality, to claim priority for their inventions and to take advantage of the intellectual property laws in each member country. To facilitate the process of filing patent applications around the world, many members of the Paris Convention established the Patent Cooperation Treaty (PCT) in 1970. Today, more than 90 percent of all countries are members of the Paris Convention and the PCT.

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which entered into force in 1995, 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>50</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.

Critically, the United States and other countries have promoted, given effect to and built on the global minimum standards of protection international rules provide through eligibility criteria for trade preference programs, WTO accessions and regional and bilateral trade agreements. However, certain U.S. trading partners maintain or are considering acts, policies or practices that are harming or would harm the ability of biopharmaceutical innovators to research, develop and deliver new treatments and cures for patients around the world. These acts, policies or practices deny or would deny adequate and effective intellectual property protection and/or fair and equitable market access for innovative medicines. In many cases, they appear to be inconsistent with global, regional and bilateral rules.

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<sup>50</sup> 164 members as of July 29, 2016.

Multilateral organizations that once served as custodians of the international rules-based system increasingly are seeking to undermine and even eliminate intellectual property protections that drive and sustain biopharmaceutical innovation in the United States and around the world. By reinterpreting international agreements and through meetings, reports, guidelines and training programs, the WHO, the United Nations Development Program (UNDP), the United Nations Conference on Trade and Development (UNCTAD) and other organizations are promoting acts, policies and practices globally and in specific countries that prevent biopharmaceutical innovators from securing and maintaining patents and from protecting regulatory test data.<sup>51</sup>

The following sections highlight the most serious challenges facing PhRMA members around the world. The acts, policies and practices of specific countries are described further below. PhRMA members urge USTR and other federal agencies to highlight these challenges, acts, policies and practices in the 2017 Special 301 Report and to use all available tools to address and resolve them.

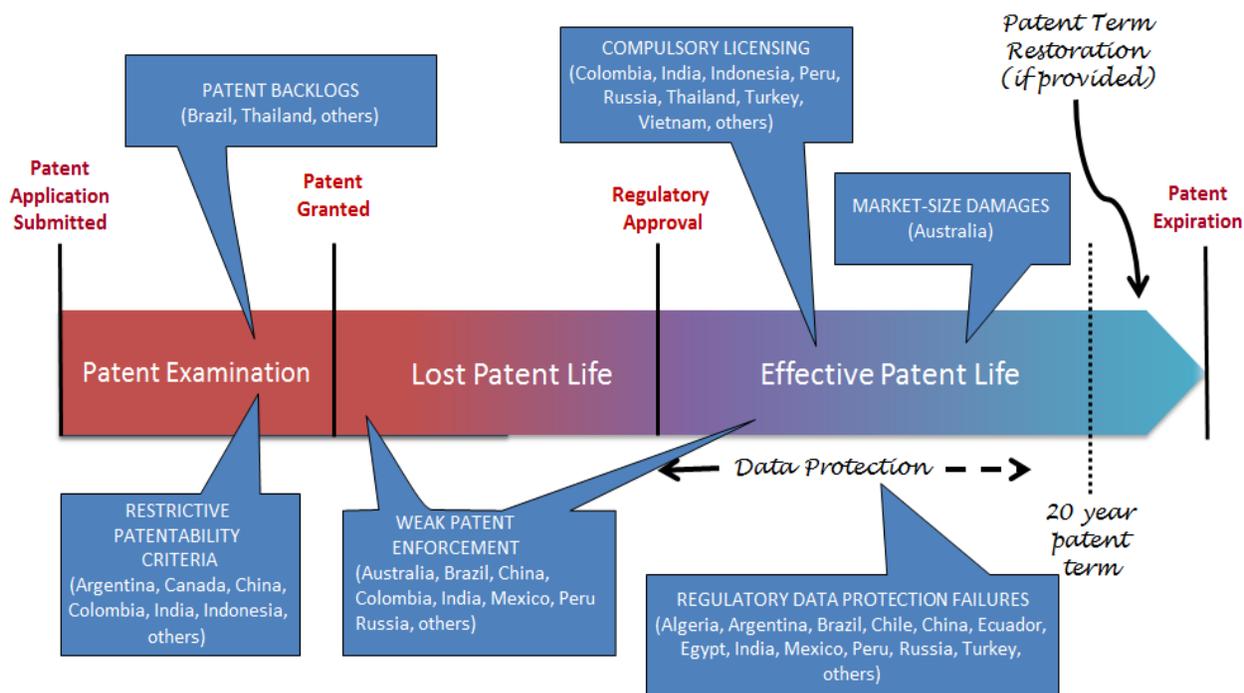
#### ***A. Practices that undermine biopharmaceutical innovation***

The six intellectual property challenges described below and highlighted in Figure 4 are having the most serious and immediate impact on the ability of PhRMA members to invest in discovering and transforming promising molecules and proteins into useful new medicines for patients around the world. These challenges hinder or prevent biopharmaceutical innovators from securing patents (restrictive patentability criteria and patent backlogs), maintaining and effectively enforcing patents (market-size damages, weak patent enforcement and compulsory licensing,) and protecting regulatory test data (regulatory data protection failures).

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<sup>51</sup> Hudson Institute, “The Patent Truth about Health, Innovation and Access”, 2016, available at <https://s3.amazonaws.com/media.hudson.org/files/publications/20160706ThePatentTruthAboutHealthInnovationandAccess.pdf> (last visited February 9, 2017).

**Figure 3: Biopharmaceutical intellectual property challenges**



### *Restrictive Patentability Criteria*

To bring valuable new medicines to patients, biopharmaceutical innovators must be able to secure patents on all inventions that are new, involve an inventive step and are capable of industrial application.<sup>52</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>53</sup> and reduce costs<sup>54</sup> by making

<sup>52</sup> See, generally, TRIPS Article 27.1.

<sup>53</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 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*, February 2009, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2737824/> (last visited February 9, 2017).

it easier for patients to take medicines and by improving patient adherence to prescribed therapies. Some of the most serious examples of restrictive patentability criteria challenges facing PhRMA members in countries around the world include:

- *Heightened patent utility requirements.* Based on a novel 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.<sup>55</sup>

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<sup>54</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*, August 2005, available at <http://www.nejm.org/doi/full/10.1056/NEJMra050100> (last visited February 9, 2017); and DiMatteo, M. Robin, “Variations in Patients’ Adherence to Medical Recommendations: A Quantitative Review of 50 Years of Research,” *Medical Care*, March 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 February 9, 2017); 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, August 2000, available at <https://aspe.hhs.gov/basic-report/price-trends-prescription-pharmaceuticals-1995-1999> (last visited February 9, 2017).

<sup>55</sup> Forrest, P. and L. Dempsey, “Canada’s Tighter Controls on Patents Create Problems Beyond Its Borders”, *The National Law Journal*, March 2016, available at <http://patentsprotect.org/wp-content/uploads/2016/03/Canadas-Tighter-Controls-on-Patents-Create-Problems-Beyond-Its-Borders.pdf> (last visited February 9, 2017); and Stevens, P. and M. Schultz, “How Canada’s Catch-22 drug-patent laws are stifling innovation”, *Financial Post*, April 2016, available at <http://business.financialpost.com/fp-comment/how-canadas-catch-22-drug-patent-laws-are-stifling-innovation> (last visited February 9, 2017). For additional information, see [www.patentsprotect.org](http://www.patentsprotect.org).

- *Patentability restrictions and additional patentability criteria.* A number of countries maintain laws and regulations that, *per se*, prevent the patenting of a wide range of specific improvements to existing medicines – improvements that are valuable to patients and payers and that require significant investment and research to develop. For example, **Argentina** issued regulations in 2012 that prevent biopharmaceutical innovators from securing patents on certain types of inventions, including new dosage forms and combinations. In the **Philippines**, national law limits the patentability of new forms and new uses of existing medicines. **Indonesia** adopted a new patent law in 2016 that similarly prohibits patents for new forms and new uses of existing medicines. **India's** Patent Law prohibits patents on known substances, unless applicants can demonstrate they meet an additional “enhanced therapeutic efficacy” test. While UNDP does not appear to have specialized expertise on intellectual property matters, it issued patent examination guidelines in 2016 that, if followed, would prevent innovators from securing patents on many kinds of biopharmaceutical inventions.<sup>56</sup>
- *Restrictions on post-filing submissions.* Unlike patent offices in the United States, Europe, Japan, Korea and other major markets, **China's** State Intellectual Property Office 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. Last year, China's State Intellectual Property Office issued draft Patent Examination Guidelines that would require examiners to consider post-filing experimental data and that appear intended to implement its December 2013 U.S.-China Joint Commission on Commerce and Trade (JCCT) commitment to allow patent applicants to submit additional data after filing patent applications. PhRMA and other associations representing the innovative biopharmaceutical sector provided comments on the draft Guidelines. We look forward to final Guidelines that reflect those comments.

Restrictive patentability criteria in many of these countries and others appear contrary to WTO rules and U.S. trade agreements, which require parties to make patents available for inventions that are new, involve an inventive step and are capable of industrial application. These laws also appear to apply solely to pharmaceutical products, either expressly by law or in a *de facto* manner as applied. This is not consistent with the obligations of WTO Members and U.S. trade agreement partners to make patents available without discrimination as to the field of technology.

PhRMA members appreciate steps USTR and other federal agencies have taken to address restrictive patentability criteria and look forward to continuing to work closely with these agencies to secure concrete progress and real results. Effective enforcement

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<sup>56</sup> United Nations Development Program, “Guidelines for the Examination of Patent Applications relating to Pharmaceuticals”, 2016, available at <http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/guidelines-for-the-examination-of-patent-applications-relating-t.html> (last visited February 9, 2017).

of U.S. trade agreements is needed to resolve these challenges in particular countries and to prevent others from adopting similar practices.

### *Patent Backlogs*

Long patent examination and approval backlogs harm domestic and overseas inventors in every economic sector. Backlogs undermine incentives to innovate, prevent timely patient access to valuable new treatments and cures, and impose huge societal costs.<sup>57</sup> 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.<sup>58</sup> 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.<sup>59</sup> 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.<sup>60</sup> In 2015, India granted one patent based on an application filed 19 years earlier.<sup>61</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.<sup>62</sup> Excessive patent filing and maintenance fees add to problems in **Venezuela**.

Long patent examination delays cause significant damage. A London Economics study estimated the value of lost innovation due to increased patent pendency at £7.6

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<sup>57</sup> Schultz, M. and K. Madigan, "The Long Wait for Innovation: The Global Patent Pendency Problem," George Mason University, Center for the Protection of Intellectual Property, 2016, available at <http://cpip.gmu.edu/wp-content/uploads/sites/31/2016/10/Schultz-Madigan-The-Long-Wait-for-Innovation-The-Global-Patent-Pendency-Problem.pdf> (last visited February 9, 2017).

<sup>58</sup> Business Standard, Delay in Patents Can Slow Down Improvements in Medicines: Experts, October 2016, available at [http://www.business-standard.com/article/news-ians/delay-in-patents-can-slow-down-improvement-in-medicine-experts-116101600452\\_1.html](http://www.business-standard.com/article/news-ians/delay-in-patents-can-slow-down-improvement-in-medicine-experts-116101600452_1.html) (last visited February 9, 2017).

<sup>59</sup> Schultz, M. and K. Madigan, "The Long Wait for Innovation: The Global Patent Pendency Problem," George Mason University, Center for the Protection of Intellectual Property, 2016, available at <http://cpip.gmu.edu/wp-content/uploads/sites/31/2016/10/Schultz-Madigan-The-Long-Wait-for-Innovation-The-Global-Patent-Pendency-Problem.pdf> (last visited February 9, 2017).

<sup>60</sup> *Id.*

<sup>61</sup> IndiaSpend, *Patent Delays Threaten 'Make In India'*, January 2016, available at <http://www.indiaspend.com/cover-story/patent-delays-threaten-make-in-india-67033> (last visited February 9, 2017).

<sup>62</sup> Cipriano, M., "Biodiversity Law Reform Spurs Innovation, But Patent Backlog Remains", October 2016, available at <https://pink.pharmamedtechbi.com/PS119423/Biodiversity-Law-Reform-Spurs-Innovation-But-Patent-Backlog-Remains> (last visited February 9, 2017).

billion per year.<sup>63</sup> Patent backlogs are a particular challenge for small start-up firms that are playing an increasingly important role in biopharmaceutical innovation. According to a U.S. Patent and Trademark Office (PTO) Economic Working Paper, for every year an ultimately-approved patent application is delayed, a start-up firm's employment growth decreases by 21 percent and its sales growth decreases by 28 percent on average over the following five years.<sup>64</sup> Each year a patent application is delayed, the average number of subsequent patents granted decreases by 14 percent, and the probability that a startup will go public is cut in half.<sup>65</sup>

PhRMA members support patent term restoration provisions in trade agreements and national laws to address unreasonable patent examination delays. They support initiatives to increase the efficiency of patent prosecution and reduce patent backlogs, including the PCT and work sharing arrangements through the IP5 and Patent Prosecution Highway (PPH) programs. Through these and other initiatives, national and regional patent offices in the European Union, Japan, Korea, Mexico and elsewhere are succeeding in reducing patent examination delays. Further work is needed to consolidate these gains and to extend effective models to other countries.

### *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** Therapeutic Goods Act passed as part of legislation implementing the U.S.-Australia Free Trade Agreement,<sup>66</sup> provided for market-size damages in certain instances. Since 2012, the Australian government has stated its intent to seek – and has sought – market-size damages from biopharmaceutical innovators that have pursued unsuccessful patent claims. Those damages are designed to compensate Australia's pharmaceutical reimbursement scheme (PBS) for any higher price paid for a patented medicine during the period of a provisional enforcement measure. The PBS imposes automatic price cuts on medicines as soon as competing versions enter the

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<sup>63</sup> London Economics, *Patent Backlogs and Mutual Recognition report to the UK Intellectual Property Office*, January 2010, available at [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/328678/p-backlog-report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/328678/p-backlog-report.pdf) (last visited February 9, 2017).

<sup>64</sup> Farre-Mensa, J., D. Hegde, and A. Ljungqvist, "The Bright Side of Patents," USPTO Economic Working paper No. 2015-5, December 15, 2015, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2704028](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2704028) (last visited February 9, 2017).

<sup>65</sup> *Id.*

<sup>66</sup> See Schedule 7 of the US Free Trade Agreement Implementation Act 2004, available at [http://www.austlii.edu.au/au/legis/cth/consol\\_act/uftaia2004363/sch7.html](http://www.austlii.edu.au/au/legis/cth/consol_act/uftaia2004363/sch7.html) (last visited February 9, 2017).

market, but the policy entails no corresponding mechanism to compensate innovators for losses if an infringing product is launched prematurely.

By pursuing market-size damages, Australia is unfairly tipping the scales in commercial patent disputes – encouraging competitors to launch at risk and discouraging innovators from enforcing their patents. It is creating 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 is exposing 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. Allowing governments or other non-parties to a patent dispute to collect market-size damages undermines legal certainty, predictability and the incentives patents provide for investment in new treatments and cures. Australia's practice appears to be inconsistent with the U.S.-Australia Free Trade Agreement and with WTO intellectual property rules, including with respect to provisional measures.

In a 2004 letter<sup>67</sup> to Australia's trade minister, USTR raised concerns about the significant and negative impact that the Therapeutic Goods Act amendments permitting market-size damages could have on patent rights and the consistency of those amendments with Australia's international obligations. The letter stated that the "United States reserves its right to challenge the consistency of these amendments with such obligations". PhRMA members urge USTR and other federal agencies to prioritize actions to address Australia's pursuit of market-size damages.

### *Weak Patent Enforcement*

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

At a minimum, effective early resolution mechanisms (1) require governments to notify the holder of a patent on a biopharmaceutical product if another party applies for marketing approval for a generic or biosimilar versions of that product, (2) enable the holder of a patent on a biopharmaceutical product to seek provisional enforcement measures, such as a stay, preliminary injunction or interlocutory injunction, to prevent the marketing of a potentially infringing generic or biosimilar version of that product, and

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<sup>67</sup> Letter from U.S. Trade Representative Robert B. Zoellick to Australian Minister of Trade Mark Vaile, November 17, 2004, available at [https://ustr.gov/archive/assets/Trade\\_Agreements/Bilateral/Australia\\_FTA/Implementation/asset\\_upload\\_file393\\_6951.pdf](https://ustr.gov/archive/assets/Trade_Agreements/Bilateral/Australia_FTA/Implementation/asset_upload_file393_6951.pdf) (last visited February 9, 2017).

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

U.S. trade agreements generally require parties to notify patent holders, to act expeditiously on requests for provisional enforcement measures and to prevent the marketing of generic or biosimilar products during the patent term without the consent of the patent holder. However, some U.S. trade agreement partners do not comply with these obligations. For example, biopharmaceutical innovators in the United States do not receive any notice of a third party's intention to enter the market in **Australia** and are unable to quickly secure effective preliminary injunctions in **Mexico**. Resolving a patent dispute in **Peru** involves a two-step sequential administrative and judicial process that can take as long as four years, on average. Effective early resolution mechanisms are also needed in **China, India, Russia** and other countries, where innovators are not notified of marketing approval applications filed for potentially infringing products and generally are unable to secure provisional enforcement measures.

PhRMA members appreciate steps the United States and other economies around the world have taken to promote effective patent enforcement and to encourage 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. The National Strategy on Industrial Property released late last year by **Chile's** National Institute of Industrial Property points to potential progress toward implementing that country's early resolution commitments in the U.S.-Chile Free Trade Agreement.<sup>68</sup>

PhRMA urges USTR and other federal agencies to enforce intellectual property commitments in existing U.S. trade agreements and to continue to promote effective patent enforcement abroad, including through the JCCT, the U.S.-India Trade Policy Forum and other bilateral dialogues.

### *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 research and development that delivers new treatments and cures. These limited and temporary intellectual property rights are not a barrier to access to medicines – particularly when governments and the private sector partner to improve health outcomes.

Some governments, including **India** and **Indonesia**, have issued compulsory licenses that allow local companies to make, use, sell or import particular patented medicines without the consent of the patent holder. Other governments, including **Chile, Colombia, Peru, Russia, Turkey** and **Vietnam**, have adopted or are currently considering resolutions, laws and regulations that promote or provide broad discretion

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<sup>68</sup> National Institute of Industrial Property (INAPI), "Chile Estrategia Nacional de Propiedad Industrial", August 2016, available at [http://www.inapi.cl/portal/publicaciones/608/articles-9870\\_recurso\\_1.pdf](http://www.inapi.cl/portal/publicaciones/608/articles-9870_recurso_1.pdf) (last visited February 9, 2017).

to issue such licenses. PhRMA believes governments should grant compulsory licenses 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>69</sup> or speed access<sup>70</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>71</sup> In sub-Saharan Africa, for example, the majority of antiretrovirals are manufactured under voluntary licenses to local generic drug companies.<sup>72</sup>

Unfortunately, some countries appear to be using compulsory licenses 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 compulsory license for a patented oncology medicine, based in part on a finding that the patented medicine was not being manufactured in India.<sup>73</sup> Indonesia's new patent law enables the government to grant compulsory licenses on the grounds that an inventor is not manufacturing a patented product in Indonesia within three years after the patent was granted.

PhRMA members urge USTR and other federal agencies to closely monitor the consideration and use of compulsory licenses and to encourage decisions on public

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<sup>69</sup> Beall, R.F. et al., "Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement," *Health Affairs*, March 2015, available at <http://content.healthaffairs.org/content/34/3/493.abstract?etoc> (last visited February 9, 2017).

<sup>70</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, E. and K. Saggi, "Compulsory licensing, price controls, and access to patented foreign products", Vanderbilt University, April 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 February 9, 2017).

<sup>71</sup> IFPMA Policy Position, *Voluntary Licenses and Non-Assert Declarations*, available at <http://www.ifpma.org/wp-content/uploads/2016/03/IFPMA-Position-on-VL-and-Non-Assert-Declarations-18FEB2015.pdf> (last visited February 9, 2017).

<sup>72</sup> Chien, C., "HIV/AIDS Drugs for Sub-Saharan Africa: How Do Brand and Generic Supply Compare?" *PLoS One*, March 2007, available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1805689/> (last visited February 9, 2017).

<sup>73</sup> Chatterjee, P., "India's First Compulsory License Upheld, But Legal Fights Likely to Continue", Intellectual Property Watch, April, 2013, available at <http://www.ip-watch.org/2013/03/04/indias-first-compulsory-licence-upheld-but-legal-fights-likely-to-continue/> (last visited February 9, 2017).

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 of all kinds. Prior to 1984, generic drug companies in the United States were required to generate their own test data for marketing approval. The Hatch-Waxman Act introduced abbreviated pathways that enabled generic drug companies to rely on test data developed by innovators.<sup>74</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>75</sup>

RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Made using living organisms, biologics are so complex that it is possible for others to produce a version – or “biosimilar” – of a medicine that may not be covered within the scope of the innovator’s patent. For this reason and others, U.S. law provides twelve years of RDP for biologics. This was not an arbitrary number, but rather the result of careful consideration and considerable research on the incentives necessary to ensure biopharmaceutical innovators and the associated global scientific ecosystem are able to sustainably pursue groundbreaking biomedical research.<sup>76</sup>

Unfortunately, many U.S. trading partners do not provide RDP. This is contrary to WTO rules, which require parties to protect regulatory test data submitted as a condition of obtaining marketing approval against both disclosure and unfair commercial use. Examples, some of which are described further in the country profiles below, include **Algeria, Argentina, Brazil, China, Ecuador, Egypt, India, Turkey and Venezuela**. U.S. trade agreements generally require parties to provide RDP for a specified period of time, but some partner countries have not fully honored their commitments. For example, **Mexico** and **Peru** provide RDP for small-molecule treatments, but not for biologics. In **Chile**, RDP is not made available for new uses, formulations, compositions

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<sup>74</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>75</sup> PhRMA analysis based on IMS Health, IMS national prescription audit™, 2016.

<sup>76</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 February 9, 2017).

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.

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

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

The Special 301 provisions of the Trade Act of 1974 also require USTR to identify countries that deny fair and equitable market access to U.S. persons who rely on intellectual property protection. PhRMA members increasingly encounter acts, policies and practices abroad that deny fair and equitable market access. These barriers undermine the ability of biopharmaceutical innovators in the United States to bring new medicines to patients around the world and to invest in future treatments and cures. By contributing to an unpredictable business environment, they threaten U.S. exports and jobs and delay access to or reduce the availability of new medicines in key countries. Some examples of the most serious barriers that prevent access to innovative medicines include:

- *Import barriers.* High tariffs and taxes can limit U.S. biopharmaceutical exports and prevent access to new treatments in overseas markets. Under the WTO Pharmaceutical Agreement, the United States and the 33 other countries do not impose any import duties on a wide range of medicines and other health products.<sup>77</sup> However, biopharmaceutical innovators in the United States do not benefit from the same access to China, India and other emerging economies that are leading producers and net exporters of drugs<sup>78</sup> and active pharmaceutical ingredients<sup>79</sup> but are not parties to the WTO Pharmaceutical Agreement. Between 2006 and 2013, the value of worldwide biopharmaceutical trade in countries that are not parties to that Agreement increased at a compound annual growth rate of more than 20 percent. This means that a larger proportion of

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<sup>77</sup> General Agreement on Tariffs and Trade, "Trade in Pharmaceutical Products" (L/7430), March 1994, available at <https://ustr.gov/sites/default/files/WTO%20Pharmaceutical%20Agreement%20March%201994.pdf> (last visited February 9, 2017).

<sup>78</sup> World Health Organization, World Intellectual Property Organization and World Trade Organization, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, 2012, available at [https://www.wto.org/english/res\\_e/booksp\\_e/pantiwhowipowtoweb13\\_e.pdf](https://www.wto.org/english/res_e/booksp_e/pantiwhowipowtoweb13_e.pdf) (last visited February 9, 2017).

<sup>79</sup> China is the world's leader in active pharmaceutical ingredient manufacturing and exports. See Huang, Y., "Chinese Pharma: A Global Health Game Changer?", Council on Foreign Relations, March 2015, available at <http://www.cfr.org/china/chinese-pharma-global-health-game-changer/p36365> (last visited February 9, 2017).

medicines distributed around the world are potentially subject to tariffs.<sup>80</sup> For example, the United States is by far the largest market for Indian generic drug exports,<sup>81</sup> but **India's** basic import duties on biopharmaceutical products and active ingredients average about ten percent.<sup>82</sup> Additional duties and assessments can raise the effective import duty to as high as 20 percent or more.<sup>83</sup> Federal and state taxes on medicines in **Brazil** can add nearly 34 percent to the retail price of medicines – among the highest tax burdens on medicines in the world.<sup>84</sup> 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,<sup>85</sup> and a policy regarding the acceptance of multi-regional clinical trial data is further extending this timeline. PhRMA was encouraged by commitments in the 2014 JCCT<sup>86</sup> 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, but significant further work is needed. Other markets with complex and lengthy regulatory approval processes include **Korea, Russia and Turkey**. Accelerating regulatory approval in these countries and others will improve the efficiency of global drug development, facilitate U.S. exports and reduce the time it takes for new medicines to reach patients.
- *Government pricing and reimbursement delays.* Restrictive government pricing and reimbursement policies delay market access for biopharmaceutical innovators in the United States and prevent timely patient access to new

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<sup>80</sup> Banik, N. and P. Stevens, "Pharmaceutical tariffs, trade flows and emerging economies", Geneva Network, September 2015, available at <http://geneva-network.com/wp-content/uploads/2015/09/GN-Tariffs-on-medicines.pdf> (last visited February 9, 2017).

<sup>81</sup> Pharmaceuticals Export Promotion Council of India, *12<sup>th</sup> Annual Report 2015-16*, 2016, available at <http://www.pharmexcil.com/annual-report> (last visited February 9, 2017).

<sup>82</sup> Banik, N. and P. Stevens, "Pharmaceutical tariffs, trade flows and emerging economies", Geneva Network, September 2015, available at <http://geneva-network.com/wp-content/uploads/2015/09/GN-Tariffs-on-medicines.pdf> (last visited February 9, 2017).

<sup>83</sup> Olcay, M. and R. Laing, "Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation", World Health Organization, May 2005, available at <http://apps.who.int/intellectualproperty/studies/TariffsOnEssentialMedicines.pdf> (last visited February 9, 2017).

<sup>84</sup> Globally, on average, taxes account for 6.3 percent of the retail price of medicines. See EMIS, "Pharmaceutical Sector in Brazil", December 2013, available at <https://www.emis.com/sites/default/files/EMIS%20Insight%20-%20Brazil%20Pharmaceutical%20Sector.pdf> (last visited February 9, 2017).

<sup>85</sup> Centre for Innovation in Regulatory Science, "Characterizing the Influencers of Submission Lag Time for Medicines in Emerging Markets", August 2012, available at [http://cirsci.org/publications/CIRS\\_R&D\\_Briefing\\_51\\_Lag\\_Time\\_in\\_EM.pdf](http://cirsci.org/publications/CIRS_R&D_Briefing_51_Lag_Time_in_EM.pdf) (last visited February 9, 2017).

<sup>86</sup> U.S. Department of Commerce, "U.S.-China Joint Fact Sheet on 25<sup>th</sup> Joint Commission on Commerce and Trade", December 2014, available at <https://www.commerce.gov/news/fact-sheets/2014/12/us-china-joint-fact-sheet-25th-joint-commission-commerce-and-trade> (last visited February 9, 2017).

treatments and cures. In **China**, for example, the National Reimbursement Drug List (NRDL) has not been updated since 2009. In **Mexico**, delays can stretch as long as 1,500 days or more, on average, compared to 230 days in other countries.<sup>87</sup> PhRMA is encouraged by efforts China and Mexico have made to accelerate updates to their reimbursement lists. However, patients would be better served by a model that allows new drugs to be reviewed for reimbursement on a regular, or rolling, basis.

- *Lack of transparency and due process.* Lack of transparency, due process, and delayed reimbursement decisions are widespread across the world. 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**, excessive regulatory approval delays are compounded by consolidated procurement processes that lack transparency and are applied inconsistently. In **Turkey**, reimbursement decision criteria are not clearly defined, the process is non-transparent, and unpredictable delays in decision-making significantly postpone patient access to innovative medicines.

PhRMA members continue to face price controls in many overseas markets that threaten innovation, delay and deny market access and diminish the value of U.S. intellectual property. A 2004 Commerce Department study<sup>88</sup> found that many countries employ systems, such as reference pricing, that “rely heavily on government fiat to set prices rather than competition in the marketplace”. The report showed that moving to market-based systems would add billions to research and development for new medicines and lower overall healthcare costs around the world by promoting greater utilization of generic drugs.

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 to ensure patients have faster access to new treatments and cures, including through effective enforcement of U.S. trade agreements.

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<sup>87</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 February 9, 2017). See also Salieri, G. and F. Fuentes, “Biopharmaceutical Innovation in Mexico: At the Crossroads”, Fundación IDEA, 2016, available at <http://geneva-network.com/article/biopharmaceutical-innovation-mexico-crossroads/> (last visited February 9, 2017).

<sup>88</sup> U.S. Department of Commerce, International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, December 2004, available at <http://www.trade.gov/td/health/drugpricingstudy.pdf> (last visited February 9, 2017).

### ***C. Localization barriers – A cross-cutting challenge***

Like businesses in many other sectors of the U.S. economy, PhRMA members are witnessing a proliferation of acts, policies and practices abroad that are designed to benefit local producers at the expense of manufacturers and their employees in the United States and elsewhere around the world. In countries like **Algeria, 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.

These discriminatory measures put American jobs at risk and appear to violate the most basic principles of the global trading system found in the General Agreement on Tariffs and Trade, TRIPS and the WTO Agreements on Technical Barriers to Trade and Trade-Related Investment Measures. They deny adequate and effective intellectual property protection for biopharmaceutical innovators in the United States and fair and equitable market access for new medicines, vaccines and other health technologies. Some examples of the most serious localization barriers that are undermining the ability of PhRMA members to develop and deliver new treatments and cures include:

- *Market participation or other benefits conditioned on local manufacturing.* While a number of economies provide positive incentives for businesses to conduct research and development and to manufacture in their markets,<sup>89</sup> an alarming number are seeking to grow their economies by discriminating against innovators in the United States and other countries. For example, **Algeria** prohibits imports of virtually all biopharmaceutical products that compete with similar products produced 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. **China** has never implemented its WTO accession obligation to provide six years of regulatory data protection for innovative biopharmaceuticals, but provides similar benefits (a five-year “monitoring period”) for medicines that are manufactured and first marketed in China. **Indonesia's** new Patent Law permits the government to compulsory license patented medicines if the patent holder does not begin manufacturing that medicine in Indonesia within three years after the patent is granted.<sup>90</sup>

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<sup>89</sup> Pugatch Consilium, “Separating Fact From Fiction – How Localization Barriers Fail Where Positive Non-Discriminatory Incentives Succeed: A Global Assessment of Localization Policies and Incentivizing Life Science Investment and Innovation”, 2016, available at [http://www.pugatch-consilium.com/reports/Localization%20Paper\\_US\\_FINAL.pdf](http://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf) (last visited February 9, 2017).

<sup>90</sup> Cory, N., “The Worst Innovation Mercantilist Policies of 2016”, Information Technology and Innovation Foundation, January 2017, available at [http://www2.itif.org/2017-worst-innovation-mercantilist-policies.pdf?\\_ga=1.176855585.581989633.1484510758](http://www2.itif.org/2017-worst-innovation-mercantilist-policies.pdf?_ga=1.176855585.581989633.1484510758) (last visited February 9, 2017).

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

Recent research<sup>91</sup> is demonstrating the significant and widespread damage localization barriers can inflict on the global economy and on markets that put such barriers in place. They cost businesses and their employees in the United States and other leading nations by cutting tens of billions of dollars in global trade and by reducing global income and innovation. They do not increase biopharmaceutical investment or knowledge-intensive employment in countries that adopt localization barriers. In fact, they can even reduce employment – particularly for the less skilled – by raising input costs and severing connections to global value chains.<sup>92</sup>

PhRMA members appreciate the attention USTR and other federal agencies have given to localization barriers in recent reports and publications. However, urgent

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<sup>91</sup> See, for example, Stone, S., J. Messent and D. Flaig, “Emerging Policy Issues: Localisation Barriers to Trade”, OECD Trade Policy Papers, No. 180, 2015, available at <http://www.oecd-ilibrary.org/docserver/download/5js1m6v5qd5j-en.pdf?expires=1484515369&id=id&accname=guest&checksum=850B3014CCE8D43338D0840413F7637B> (last visited February 9, 2017); Ezell, S.J., R.D. Atkinson and M.A. Wein, “Localization Barriers to Trade: Threat to the Global Innovation Economy”, Information Technology and Innovation Foundation, September 2013, available at [http://www2.itif.org/2013-localization-barriers-to-trade.pdf?\\_ga=1.136058805.581989633.1484510758](http://www2.itif.org/2013-localization-barriers-to-trade.pdf?_ga=1.136058805.581989633.1484510758) (last visited February 9, 2017). Hufbauer, G.C., J.J. Schott et al., *Local Content Requirements: A Global Problem*, Peterson Institute for International Economics, September 2013, available at <http://bookstore.piie.com/book-store/6802.html> (last visited February 9, 2017).

<sup>92</sup> Pugatch Consilium, “Separating Fact From Fiction – How Localization Barriers Fail Where Positive Non-Discriminatory Incentives Succeed: A Global Assessment of Localization Policies and Incentivizing Life Science Investment and Innovation”, 2016, available at [http://www.pugatch-consilium.com/reports/Localization%20Paper\\_US\\_FINAL.pdf](http://www.pugatch-consilium.com/reports/Localization%20Paper_US_FINAL.pdf) (last visited February 9, 2017).

action is needed to remove these barriers and to discourage other countries from adopting similar acts, policies and practices. Biopharmaceutical innovators in the United States look forward to concrete progress and real results in 2017.

### **III. Addressing Challenges and Securing the Benefits of Biopharmaceutical Innovation**

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

#### ***A. Enforce and defend global, regional and bilateral rules***

USTR and other federal agencies should use all available tools and leverage to ensure America's trading partners live up to their obligations in global, regional and bilateral trade and investment agreements. Stepping up enforcement activity in the months ahead will be critical to address longstanding intellectual property challenges around the world – and particularly in countries that are U.S. trade and investment agreement partners, that have made important unfulfilled WTO accession commitments and that benefit from U.S. trade preference programs.

U.S. regional and bilateral trade agreements affirm globally accepted standards for the patentability of biopharmaceutical and other inventions and require countries to protect regulatory test data, provide mechanisms that enable innovators to resolve patent disputes prior to the marketing of potentially infringing products, and establish a stronger intellectual property framework. However, **Australia, Canada, Colombia, Peru** and other U.S. trading partners fail to adequately comply with some or all of these obligations. USTR and other federal agencies should consider a process to systematically review compliance with trade and investment agreements and take steps necessary to ensure agreed rules are followed.

On joining the WTO in 2001, **China** committed to provide six years of protection for clinical test and other data submitted for regulatory approval of biopharmaceutical products containing a new chemical ingredient.<sup>93</sup> China has never implemented this obligation, despite agreement to do so during the 2012 U.S.-China Joint Commission on

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<sup>93</sup> World Trade Organization, "Report of the Working Party on the Accession of China" (WT/ACC/CHN/49), October 2001, available at [https://www.wto.org/english/thewto\\_e/acc\\_e/completeacc\\_e.htm](https://www.wto.org/english/thewto_e/acc_e/completeacc_e.htm) (last visited February 9, 2017).

Commerce and Trade meeting.<sup>94</sup> In fact, China is seeking to discriminate against biopharmaceutical innovators in the United States and other countries by defining a “new drug” as a chemical ingredient that is “new to the world”. Drugs manufactured and first marketed in China would benefit from a type of protection (“monitoring period”) for clinical test and other data submitted for regulatory approval, but no protection would be granted for data submitted for imported medicines first marketed in another country.

The Generalized System of Preferences (GSP) program provides unilateral duty-free access to the U.S. market for more than 3,500 products.<sup>95</sup> Before granting GSP benefits to an eligible country, the President must take into account a number of factors, including the extent to which the country is willing to “provide equitable and reasonable access to its markets” and is “providing adequate and effective protection of intellectual property rights”.<sup>96</sup> However, leading GSP beneficiaries like **Brazil, Ecuador, India, Indonesia** and **Turkey** do not provide adequate and effective protection of intellectual property rights or equitable and reasonable market access.

The Special 301 Report is an important tool to identify and prioritize acts, policies and practices in these and other overseas markets that are harming America’s creative and innovative industries by denying adequate and effective intellectual property protection and fair and equitable market access. PhRMA members urge USTR and other federal agencies to ensure this tool is used effectively. Action plans required by the Trade Facilitation and Trade Enforcement Act of 2015 should be developed for countries listed on the Priority Watch List with input from relevant stakeholders.<sup>97</sup> Out-of-cycle reviews announced in the Special 301 Report should actually be conducted and should involve the participation of relevant stakeholders.

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

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

Global, regional and bilateral trade and investment negotiations provide critical opportunities to build on the existing foundation of international rules and to secure commitments necessary to drive and sustain 21<sup>st</sup> Century biopharmaceutical innovation. Eliminating restrictive patentability criteria, addressing unreasonable patent examination

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<sup>94</sup> Office of the U.S. Trade Representative, “Fact Sheet: 23<sup>rd</sup> U.S.-China Joint Commission on Commerce and Trade”, December 2012, available at <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2012/december/23rd-JCCT> (last visited February 9, 2017).

<sup>95</sup> Office of the United States Trade Representative, *U.S. Generalized System of Preferences Guidebook*, September 2016, available at <https://ustr.gov/sites/default/files/GSP-Guidebook-September-16-2016.pdf> (last visited February 9, 2017).

<sup>96</sup> See Title V of the Trade Act of 1974 (19 U.S.C. 2461 et seq.), as amended.

<sup>97</sup> See Section 182 of the Trade Act of 1974 (19 U.S.C. 2242), as amended.

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.

The extent to which America's existing trade agreements approach these goals varies, but agreements that come closest have resulted in significant increases in U.S. biopharmaceutical exports. For example, the value of U.S. biopharmaceutical exports to Korea grew by more than 48 percent between 2011 (the year before the U.S.-Korea Free Trade Agreement entered into force) and 2015 to nearly \$935 million.<sup>98</sup> High-standard agreements that are faithfully implemented and effectively enforced should deliver even better results.

PhRMA supports trade agreements that include strong protections for intellectual property, enhance market access and enable biopharmaceutical innovators in the United States to export lifesaving medicines to patients around the world. Free and fair trade agreements open new markets. They help grow our economy and create better, higher-paying jobs. PhRMA members look forward to working with USTR and other federal agencies to review and update existing trade agreements and to consider opportunities to further improve public health and grow American manufacturing exports and jobs through additional trade agreements, including with leading U.S. biopharmaceutical export markets.<sup>99</sup>

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

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

The U.S. government can play a critical role in ensuring transparency and due process of pricing and reimbursement policies, as well as in highlighting the global benefits to patients that result from a reduction in trade barriers. PhRMA members appreciate steps USTR and other federal agencies have taken to ensure fair and equitable market access for innovative medicines in overseas markets, including seeking and securing commitments in trade agreements that ensure pricing and

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<sup>98</sup> Office of the United States Trade Representative, "Fact Sheet: Four Year Snapshot: The U.S.-Korea Free Trade Agreement", March 2016, available at <https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/2016/March/Four-Year-Snapshot-KORUS> (last visited February 9, 2017).

<sup>99</sup> U.S. Department of Commerce, International Trade Administration, "2016 Top Markets Report: Pharmaceuticals", 2016, available at [http://trade.gov/topmarkets/pdf/Pharmaceuticals\\_Executive\\_Summary.pdf](http://trade.gov/topmarkets/pdf/Pharmaceuticals_Executive_Summary.pdf) (last visited February 9, 2017).

reimbursement policies abroad appropriately recognize the value of innovative medicines and are fair, reasonable and non-discriminatory.

PhRMA urges USTR and other federal agencies to continue to promote the full implementation of these commitments and to build on them in future trade negotiations by ensuring future trade agreements meet the Trade Promotion Authority objective to “eliminate[e] ... government measures such as price controls and reference pricing which deny full market access for United States products”.<sup>100</sup>

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

PhRMA members view counterfeit medicines as a critical public health and safety concern threatening patients around the world. At best, counterfeit medicines have no effect on patients. At worst, they may contribute to drug-resistant forms of tuberculosis and other serious diseases and contain impurities or toxins that can cause harm or even death.<sup>101</sup> This challenge is exacerbated by the ease with which counterfeiters can offer fake medicines over the Internet<sup>102</sup> and ship them by mail<sup>103</sup> to patients and consumers worldwide.<sup>104</sup>

Counterfeit medicines are a potential danger to patients everywhere, including in the United States. During fiscal year 2015, U.S. Customs and Border Protection seized

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<sup>100</sup> Section 102(b)(7)(F) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2016 (P.L. 114-26).

<sup>101</sup> Testing reported in *The Lancet* found one-third of anti-malarial medicines in sub-Saharan Africa and South East Asia lacked active ingredients. See Guarvika, M.L.N. et al., “Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa,” *The Lancet*, June 2012, available at <http://www.thelancet.com/journals/laninf/article/PIIS1473-3099%2812%2970064-6/fulltext> (last visited February 9, 2017). See also testimony of Howard Sklamberg, U.S. Food and Drug Administration Deputy Commissioner for Global Regulatory Operations and Policy, before the House Energy and Commerce Subcommittee on Oversight and Investigations, “Counterfeit Drugs: Fighting Illegal Supply Chains”, February 2014, available at <http://www.fda.gov/NewsEvents/Testimony/ucm387449.htm> (last visited February 9, 2017).

<sup>102</sup> Of more than 11,000 web sites selling prescription medicines to patients in the United States, the National Association of Boards of Pharmacy® has found approximately 96 percent of them are operating illegally. See National Association of Boards of Pharmacy, “Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators”, October 2016, available at [https://awarerx.pharmacy/system/ckeditor\\_assets/attachments/63/nabp\\_internet\\_drug\\_outlet\\_report\\_october\\_2016.pdf](https://awarerx.pharmacy/system/ckeditor_assets/attachments/63/nabp_internet_drug_outlet_report_october_2016.pdf) (last visited February 9, 2017).

<sup>103</sup> An OECD study published last year found that more than 60 percent of counterfeit goods seized around the world between 2011 and 2013 were shipped by mail or express carrier. See OECD, “Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact”, 2016, available at [http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods\\_9789264252653-en#.WHv5mpcraBc#page1](http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#.WHv5mpcraBc#page1) (last visited February 9, 2017).

<sup>104</sup> Institute of Medicine (IOM), *Countering the Problem of Falsified and Substandard Drugs*, February 2013, (noting that “because the internet facilitates easy international sales, online drug stores have spread the problem of falsified and substandard drugs...”), 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 February 9, 2017).

more than 1,000 shipments of counterfeit pharmaceuticals at America's borders.<sup>105</sup> Using a broader measure that includes counterfeiting, illegal diversion and theft, the Pharmaceutical Security Institute documented more than 3,000 incidents of pharmaceutical crime in the United States in calendar year 2015 – the highest number ever recorded since the Institute began compiling such data 14 years ago.<sup>106</sup> Across all sectors, the Organization for Economic Cooperation and Development (OECD) found that global counterfeiting and piracy accounts for 2.5 percent of world trade and disproportionately harms innovators in the United States.<sup>107</sup>

**China and India** are leading sources of fake medicines seized at ports of entry in the United States<sup>108</sup> and elsewhere,<sup>109</sup> though many other jurisdictions are involved – particularly in online sales.<sup>110</sup> According to the WHO, regions where protection and enforcement systems are weakest also see the highest incidence of counterfeit medicines. In these jurisdictions and others, customs and other law enforcement officials often are not able to seize counterfeit medicines, particularly goods in transit, goods in free trade zones and goods offered for sale on the Internet. Violations of limited laws on the books often are not effectively enforced or do not come with sufficient, deterrent penalties.<sup>111</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

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<sup>105</sup> U.S. Customs and Border Protection, Office of Trade, “Intellectual Property Rights: Fiscal Year 2015 Seizure Statistics”, January 2017, available at <https://www.cbp.gov/sites/default/files/assets/documents/2017-Jan/2015%20IPR%20Annual%20Statistics.pdf> (last visited February 9, 2017).

<sup>106</sup> Pharmaceutical Security Institute, “Incident Trends”, available at <http://www.psi-inc.org/incidentTrends.cfm> (last visited February 9, 2017).

<sup>107</sup> OECD, “Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact”, 2016, available at [http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods\\_9789264252653-en#.WHv5mpcraBc#page1](http://www.keepeek.com/Digital-Asset-Management/oecd/governance/trade-in-counterfeit-and-pirated-goods_9789264252653-en#.WHv5mpcraBc#page1) (last visited February 9, 2017).

<sup>108</sup> Office of the United States Trade Representative, 2016 Special 301 Report, April 2016, available at <https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf> (last visited February 9, 2017).

<sup>109</sup> See, for example, European Commission, “Report on EU customs enforcement of intellectual property rights: Results at the EU border”, 2015, available at [http://ec.europa.eu/taxation\\_customs/sites/taxation/files/2016\\_ipr\\_statistics.pdf](http://ec.europa.eu/taxation_customs/sites/taxation/files/2016_ipr_statistics.pdf) (last visited February 9, 2017).

<sup>110</sup> United States Government Accountability Office, “Internet Pharmacies: Federal Agencies and States Face Challenges Combatting Rogue Sites, Particularly Those Abroad” (GAO-13-560), July 2013, available at <http://www.gao.gov/assets/660/655751.pdf> (last visited February 9, 2017).

<sup>111</sup> Office of the U.S. Intellectual Property Enforcement Coordinator, “Supporting Innovation, Creativity & Enterprise: Charting a Path Ahead”, U.S. Joint Strategic Plan on Intellectual Property Enforcement, FY2017-2019, available at [https://obamawhitehouse.archives.gov/sites/default/files/omb/IPEC/spotlight/eop\\_ipec\\_jointstrategicplan\\_hi-res.pdf](https://obamawhitehouse.archives.gov/sites/default/files/omb/IPEC/spotlight/eop_ipec_jointstrategicplan_hi-res.pdf) (last visited February 9, 2017).

facilitate the early detection of criminal counterfeiting activity. They partner with law enforcement officials around the world.

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

### ***E. Build and strengthen global cooperation***

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

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

All this provides a valuable foundation on which to build in the coming year and beyond. Fostering and strengthening coalitions that support innovation will be particularly critical in multilateral organizations, such as the WHO, the World Intellectual Property Organization (WIPO), the WTO, UNDP and UNCTAD. At best, work in these forums and others is focused on limitations and exceptions to intellectual property rights. At worst, international organizations are actively seeking to undermine and even eliminate the intellectual property protections that drive America's innovation economy. This is even the case at WIPO – an organization that was created to “encourage creative activity” and to “promote the protection of intellectual property throughout the world.”<sup>112</sup>

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<sup>112</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 February 9, 2017).

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

#### **IV. Country Designation Index**

##### ***A. Priority Watch List***

PhRMA recommends that 13 countries be included on the Priority Watch List. We further recommend that China continue under Section 306 Monitoring. The detailed information presented in the country-specific sections below demonstrates that the acts, policies and practices of these countries are denying adequate and effective intellectual property protection and fair and equitable market access. They are harming biopharmaceutical innovators and their employees in the United States and limiting their ability to bring new treatments to patients around the world. In many cases, they appear to be inconsistent with relevant global, regional and bilateral trade and investment agreement rules.

PhRMA urges USTR and other federal agencies to use all available tools to remedy serious intellectual property and market access concerns in these countries. To evaluate progress on these important issues and dedicate the bilateral attention necessary to secure action and results, PhRMA recommends that USTR conduct meaningful Out-of-Cycle Reviews for **Canada, Colombia** and **India**.

##### ***B. Watch List***

PhRMA recommends that five countries be included on Watch List. We urge USTR and other federal agencies to include all of these countries in the *2017 Special 301 Report* – particularly **Australia, Korea** and other countries that are U.S. bilateral trade agreement partners. USTR and other federal agencies should monitor developments in these countries and address specific intellectual property and market access concerns through bilateral and multilateral engagement.

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**SECTION 306**  
**MONITORING**

## **THE PEOPLE'S REPUBLIC OF CHINA**

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

PhRMA is pleased to see in the November 2016 U.S.-China Joint Commission on Commerce and Trade (JCCT) China's affirmation that drug registration review and approval shall not be linked to pricing commitments and shall not require specific pricing information. This follows a particularly concerning 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. However, PhRMA is very concerned that China is not yet fully implementing the 2016 JCCT outcome, and is committed to working collaboratively and expeditiously with the appropriate government authorities to support practical implementation, as well as to address patient access and affordability challenges.

PhRMA is encouraged by China's ongoing work to amend the Drug Administration Law (DAL), Drug Registration Regulation (DRR), and Patent Examination Guidelines, 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.

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

**Key Issues of Concern:**

- **Restrictive patentability criteria:** PhRMA is encouraged by the November 2016 State Intellectual Property Office (SIPO) draft amendment to its Patent Examination Guidelines that would require examiners to examine the post-filing experimental data submitted by the applicant. This amendment appears to be intended to implement China's commitment, made during the 2013 JCCT to permit patent applicants to file additional data after the application filing date. PhRMA recognizes and welcomes this positive step, but concerns remain regarding SIPO implementation and interpretation of the proposed amendment.
- **Weak patent enforcement:** Transparent mechanisms are needed in China to ensure parties are afforded the opportunity to resolve patent disputes before potentially infringing pharmaceutical products are launched on the market. Neither China's DAL nor the DRR provide an effective mechanism for enforcing an innovator's patent rights vis-à-vis regulatory approval of follow-on products and the proposed DRR revisions would eliminate the existing weak mechanism.
- **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 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. It is imperative that China implement its RDP commitments and that this protection be made available to all innovative pharmaceutical regardless of whether they are small molecule drugs or biologics.
- **Government pricing and reimbursement:** The draft CFDA Price Commitment policy 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. Furthermore, the NRDL has not been updated since 2009, delaying market access to innovative pharmaceuticals and preventing their timely availability to patients. PhRMA is encouraged by ongoing efforts to update the NRDL. 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.

- **Regulatory approval process:** The process for approving a medicine in China still 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. A new mechanism has been put in place to particularly accelerate marketing authorization applications for specific drugs, which, if implemented in a transparent and non-discriminatory manner, could be an encouraging step to make needed medicines faster available to patients. However, some concerns have arisen about its operation. Broader benefits can be gained by streamlining and speeding-up the overall regulatory approval process, which will improve the efficiency of global drug development and reduce the time it takes for all 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 that some proposed measures are inconsistent with international standards.
- **Counterfeit medicines:** China has been implementing national plans to improve drug safety and severely crack down on the production and sale of counterfeit medicines, resulting in several positive and tangible actions on the enforcement front. However, the production, distribution and sale of counterfeit medicines and unregulated APIs remain rampant in China and continue to pose a threat to China and its trading partners. PhRMA looks forward to meaningful implementation of China's commitment made during the sixth meeting of the U.S.-China Strategic and Economic Dialogue (S&ED) in July 2014 related to effective regulatory control of APIs and anti-counterfeiting.

For these reasons, PhRMA requests that China remain on the **Priority Watch List** and be subject to **Section 306 Monitoring** for the 2017 Special 301 Report and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

Pursuant to the 2006 patent examination guidelines,<sup>113</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

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<sup>113</sup> See Guidelines for Patent Examination, State Intellectual Property Office (2010), Rule 17.

out.”<sup>114</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>115</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 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.

PhRMA is encouraged by the November 2016 State Intellectual Property Office (SIPO) draft amendment to its Patent Examination Guidelines that would require examiners to examine the post-filing experimental data submitted by the applicant. This amendment appears to be intended to implement China’s commitment, made during the 2013 JCCT, to permit patent applicants to file additional data after the application filing date. PhRMA views the amendment to Section 3.5 as an important step toward implementing a clear and consistent standard that permits pharmaceutical manufacturers to submit additional data to confirm that the invention is novel, useful and contains an inventive step. The submission of supplemental data will also support and confirm statements that have already been disclosed in the patent application. We assume that by requiring the examiner to examine supplemental experimental data, this

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<sup>114</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 Feb. 8, 2017).

<sup>115</sup> Patent Cooperation Treaty, 28 U.S.T. 7645 (1970), Art. 28.

new provision will be implemented in such a way that the supplemental data can be relied upon to successfully respond to an examiner's rejection or to expand on the disclosure provided in the patent application.

While PhRMA recognizes and welcomes this positive step, we have two concerns with the data supplementation amendment as currently proposed. First, the amendment to Section 3.5 would make the data supplementation approach applicable only to "Sufficiency of Disclosure of Chemical Inventions." We believe the same approach should be taken to the examination of other patentability issues, such as inventive step, and therefore should be incorporated into Section 6, Chapter 10 of Part II as well. Second, we are concerned that certain language in the proposed amendment may be interpreted too narrowly by SIPO examiners, resulting in less patent incentives for new medicines in China and thereby harming Chinese patients. Specifically, the amendment permits data supplementation only where "the technical effect to be proved by the supplemented experimental data shall be one which can be derived by a person skilled in the art from the disclosure of the patent application." If this is interpreted so as to require the application to already disclose or demonstrate the precise technical effect to be proven by the offered supplemental data, the result would be that supplemental data is rarely accepted. This result can be avoided by incorporating more detailed guidance in the Guidelines to make it explicit that the requirements are in line with those commonly used in other countries. For example, the European Patentability Examination Guidelines (Section 11) provide that supplemental data will be accepted if it proves effects that "are implied by or at least related to the technical problem initially suggested in the originally filed application."<sup>116</sup> In implementing this provision, we urge SIPO to keep these considerations, goals and benefits in mind and provide additional guidance consistent with them.

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. The JCCT commitment speaks broadly to the acceptance of post-filing, or supplemental, data, and therefore includes all kinds of supplemental data, including data that would address the inventive step issue. 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

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<sup>116</sup> Available at

[http://documents.epo.org/projects/babylon/eponet.nsf/0/0791474853510FFFC125805A004C9571/\\$File/guidelines\\_for\\_examination\\_part\\_g\\_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/0791474853510FFFC125805A004C9571/$File/guidelines_for_examination_part_g_en.pdf) (last visited Feb. 8, 2017).

innovator later wins its patent litigation. This could undermine the goal of encouraging innovation in China. In fact, CFDA has approved infringing follow-on products, and research-based pharmaceutical companies have not been able to consistently resolve patent disputes prior to the marketing of those infringing drugs. Further, although China's laws and regulations provide for injunctive relief, in practice 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 current DRR govern the current patent enforcement mechanism, recognizing patents associated with drug registration.<sup>117</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>118</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 pharmaceutical 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.

### 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

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<sup>117</sup> Provisions for Drug Registration (SFDA Order No. 28), Arts. 18 and 19.

<sup>118</sup> Id., Art. 18.

Trade-Related Aspects of Intellectual Property Rights (TRIPS).<sup>119</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>120</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" (sometimes referred to as "new chemical entity") and "unfair commercial use" are undefined or are not in line with international standards. This leads to the inconsistent and arbitrary application of the law by CFDA, in addition to confusion and uncertainty for sponsors of marketing approval applications. The term "new chemical ingredient" should be clearly defined in the DAL, DRR, and other relevant laws and regulations in line with international standards and include biologic and chemically synthesized drugs, recognizing the considerable investment by innovative pharmaceutical companies in developing and proving safety and efficacy of a new product. 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>121</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 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.

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<sup>119</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>120</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>121</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 Feb. 8, 2017)).

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.

### **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>122</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 periods of time between each NRDL update delay market access to innovative pharmaceuticals and prevent their timely availability to patients. PhRMA recommends an accelerated update to the NRDL and provincial reimbursement drug lists followed by the establishment of a transparent, predictable, and regular reimbursement review – for example, on an annual or rolling 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 ongoing efforts to update the NRDL and the Work Plan’s aim to establish a regular adjustment mechanism for the NRDL in 2017. We appreciated 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>123</sup> Notwithstanding that commitment, PhRMA is concerned that reforms to China’s government pricing mechanisms have created an uncertain business

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<sup>122</sup> IMS Consulting Group, *China Drug Lag and the Impact of Reimbursement Delays* (July 2014).

<sup>123</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.

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.

PhRMA is pleased to see in the 2016 U.S.-China Joint Commission on Commerce and Trade (JCCT) China's affirmation that drug registration review and approval shall not be linked to pricing commitments and shall not require specific pricing information; however PhRMA is concerned that China is not fully implementing the outcome. This JCCT outcome follows a particularly concerning 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. No measure implementing the JCCT outcome has yet been released in draft form for public notice-and-comment at time of writing, much less finalized.

This draft CFDA Price Commitment (now changed by the JCCT outcome) would have made price concessions a pre-condition for marketing approval of new drugs, required that the price in China be no higher than the price in the drug's country of origin or in select neighboring markets and mandated that the price be published 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 pharmaceutical research and development (R&D) system. PhRMA is committed to working collaboratively and expeditiously with the appropriate government authorities in conjunction with the full implementation of the 2016 JCCT outcome and to address patient access and affordability challenges.

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>124</sup>

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<sup>124</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).

### *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 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.

## Counterfeit Medicines

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

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

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

While CFDA plays a critical role in developing future solutions, any significant reform plan will require coordination and consultation among all relevant ministries within the central government. These efforts to crack down on unregulated API must go

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

China has continued to coordinate joint special enforcement campaigns targeting counterfeit drug crimes.<sup>125</sup> It also appears that China is beginning to spend more efforts tackling the sale of counterfeits on the Internet. In 2013, CFDA and the State Information Office jointly led a 5-month crackdown campaign with collaboration of several ministries and offices against illegal online sales of drugs. Reportedly, the government also demands major search engines to filter out fake drug posts, which is a significant partnership with the private sector aimed at protecting Chinese patients.<sup>126</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, given the importance of protecting patients. China's actions in this area could serve as a model for other countries facing similar challenges online.

PhRMA encourages China and the U.S. Government to continue and increase further their cooperation related to counterfeit medicines sold on the Internet, given the role of the Internet in the global counterfeit drug trade. This 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 pharmaceutical exports. PhRMA believes that more and better trained resources and support should be targeted to monitoring pharmaceutical and chemical exports to ramp up efforts against counterfeiting and unregulated API producers. This could include, for example, encouraging greater cooperation between Chinese Customs and the Public Security Bureau to ensure the identification and prosecution of those manufacturing and exporting counterfeit medicines. In addition, Chinese Customs could consider working with the World Customs Organization to exchange information and potentially align activities.

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<sup>125</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 Feb. 8, 2017); "China Detains 1,300 People Suspected of Making and Selling Counterfeit Drugs," Dec. 15, 2013, available at [http://www.huffingtonpost.com/2013/12/16/counterfeit-drugs-china-medicine\\_n\\_4447483.html](http://www.huffingtonpost.com/2013/12/16/counterfeit-drugs-china-medicine_n_4447483.html) (last visited Feb. 8, 2017).

<sup>126</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.

# **PRIORITY WATCH LIST**

# **ASIA-PACIFIC**

## INDIA

We support the Indian Government's efforts to create a stronger business, innovation, and healthcare environment through the "Make in India" initiative, the 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 by enhancing India's global competitiveness and improving ease of doing business. However, despite some positive signs, PhRMA's members remain concerned about the challenging policy environment in India.

Pharmaceutical innovators again saw positive signs from the Indian Government in 2016; however, these signals have not yet been translated into real policy and practical change. To research, develop, and deliver new treatments and cures to patients, biopharmaceutical innovators must be able to secure and effectively enforce intellectual property (IP) rights. With the right policies put in place, India could one day become a globally-competitive leader in life sciences and biomedical development. The new National IPR Policy puts forward an important framework for strengthening India's innovation ecosystem; still, greater predictability and reliability is needed and implementation of the policy offers an opportunity to advance concrete policy improvements and could serve as a basis for revisiting India's designation in the future.

Market access challenges persist and despite important announcements to expand healthcare programs, the Indian Government has not increased investment in this critical area, leaving public healthcare spending at a very low level of approximately 1% of GDP. There are delays and cumbersome procedures which prevent India from becoming a part of a global clinical trial programs and thereby limit patient access to innovative medicines in India. Data from the Indian drug regulator shows that since 2011, when a total of 41 new medicines were approved, the number has dropped significantly to only 11 new medicines in 2015.<sup>127</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 both Governments to improve access to medicines for patients and advancing a "Healthy India" by removing market access barriers and fostering legal and regulatory certainty for the protection of IP in India.

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

- **Unpredictable 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

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<sup>127</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 Feb. 8, 2017).

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. In 2016 alone, at least 12 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.
- **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 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 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.
- **Unpredictable environment for clinical research:** While the Government is keen to reinvigorate clinical research in India, ambiguities in the Indian regulatory space prevail. In particular, the definition of "trial related injury" is not well defined, and the determination of local clinical trials requirements is highly subjective and perpetuates a burdensome environment for clinical research that undermines the availability of new treatments and vaccines for Indian patients.

As noted above, the issues outlined in USTR's 2016 Special 301 Report remain significant areas of concern. In its 2016 report, USTR noted that "India has maintained strong channels of engagement with the United States on IPR issues, improved communication with industry stakeholders, increasingly publicly recognized the

importance of IPR and linked it to India's future development, and taken positive steps to address or avoid further erosions of the IPR regime....However, at the same time, India has not taken the opportunity to address long-standing and systemic deficiencies in its IPR regime." Continued attention to IP and market access barriers in India has sent a strong signal of the importance of these issues to the bilateral relationship, has fueled constructive industry-government dialogue, and has been critical in preventing further deterioration of the innovation environment in that country. Nevertheless, many of the same issues remain and no meaningful action has been taken to address the unpredictability in IP protection and enforcement that remains.

For these reasons, PhRMA requests that India remain on the **Priority Watch List** in the 2017 Special 301 Report. Further, we urge USTR to provide an opportunity for a meaningful assessment of India's IP regime through an **Out-of-Cycle Review**, so that the U.S. Government can evaluate progress on these important issues and dedicate the required bilateral attention necessary to translate India's commitments into substantive and real policy change that addresses the IP and market access barriers confronted by U.S. businesses in India.

## Intellectual Property Protection

India announced the new National Intellectual Property Rights (IPR) Policy in May 2016.<sup>128</sup> India's National IPR Policy recognizes the tremendous economic and socio-cultural benefits that a strong IP regime could bring to India through economic growth, employment, and a vibrant R&D environment. The policy also puts forward important administrative and procedural improvements. However, it should be strengthened to accelerate the reforms needed to foster medical innovation and enhance India's global competitiveness. For example, while the policy focuses on government, open source R&D, Corporate Social Responsibility credits, tax breaks, loan guarantees for start-ups, support systems for Micro-, Small- and Medium-sized Enterprises and other mechanisms to encourage innovation in India, it is also important to incentivize the private sector and scientific institutions by providing effective and meaningful IP protection and enforcement mechanisms. We welcome India's explanation of plans to implement the National IPR Policy – specifically efforts to reduce the patent examination backlog and to clarify patent application procedures. At this year's India-U.S. Trade Policy Forum, "both sides affirmed the importance of transparency, predictability, speed, clarity and streamlining of procedures."<sup>129</sup> Implementation of the National IPR Policy should include a consultative process with relevant stakeholders and meaningful reforms to India's IP policies that lead to improvements in IP protection and enforcement for medicines.

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<sup>128</sup> Department of Industrial Policy and Promotion, "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 Feb. 8, 2017).

<sup>129</sup> "India and United States Joint Statement on the Trade Policy Forum," October 20, 2016, available at: <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2016/october/%E2%80%8BIndia-US-Joint-Statement-TPF#> (last visited Feb. 8, 2017).

## 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 those enumerated in the TRIPS Agreement (requiring inventions to be new, involve an inventive step and capable of industrial application) are inconsistent with India’s international obligations. For example, Article 27 of the TRIPS Agreement provides an exclusive list of the types of subject matter that can be precluded from patent coverage, and this list does not include “new forms of known substances lacking enhanced efficacy,” as excluded by Section 3(d) of the Indian law. Therefore, Section 3(d) is inconsistent with the framework provided by the TRIPS Agreement. Moreover, Section 3(d) represents an additional hurdle for patents on inventions specifically relating to chemical compounds and, therefore, the Indian law is in conflict with the non-discrimination principles provided by TRIPS Article 27 and WTO rules.<sup>130</sup> In 2016, two anti-cancer products and a schizophrenia product were denied patents as India claimed they showed no enhanced efficacy and thus not patentable under Section 3(d). All three products successfully obtained U.S. patent protection. 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.

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>131</sup> State regulatory authorities are not required to verify or consider the

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<sup>130</sup> The additional patentability hurdle imposed by section 3(d) was recently reinforced by the Pharmaceutical Patent Examination Guidelines issued in October 2014.

<sup>131</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

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's National IPR Policy calls for identification of important areas of potential policy development related to ambiguities between IP laws and other laws or authorities whose jurisdictions impact administration or enforcement of patents.<sup>132</sup> India should amend the definition of a new drug, as well as ensure innovators have timely notice of marketing approval applications and are able to seek injunctive relief before potentially infringing products enter the market.

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

In one example, the patent holder waited two and a half years before a court provided injunctive relief.<sup>133</sup> In another example, the patent holder waited seven years before receiving a court decision upholding its patent. In that case, the court ultimately did not grant an injunction because by the time the decision was issued the patent was close to expiration.<sup>134</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 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>135</sup>

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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.cdsc0.nic.in/writereaddata/Drugs&CosmeticAct.pdf> (last visited Feb. 8, 2017).

<sup>132</sup> See Secs. 3.8 and 3.8.3 of the National IPR Policy.

<sup>133</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 Feb. 8, 2017).

<sup>134</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 Feb. 8, 2017).

<sup>135</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 Feb. 8, 2017); "National Intellectual Property Rights Policy," May 12, 2016, available at

## Compulsory Licensing

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. While the Indian Government continues to take a more measured and cautious approach in responding to recent CL cases, the Ministry of Health (MOH) continues to entertain potential recommendations to impose CLs on certain anti-cancer medicines under the special provisions of Section 92 of India's Patents Act, which would make it even more difficult for patent owners to defend their patents. Moreover, Indian pharmaceutical companies continue to make requests for voluntary licenses under Section 84(6)(iv) of the Patent Act as a strategy and subsequently seek a CL by using it as a commercial tool under the guise of better access to medicines, rather than a measure of last resort. Internationally, in various multilateral forums, India has advocated for the broad adoption and implementation of legislation that facilitates the use of CLs, contrary to the spirit of the TRIP Agreement. 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>136</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 by other governments, both developed and developing.<sup>137</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.

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[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 Feb. 8, 2017).

<sup>136</sup> *Bayer v. Union of India*, Writ Petition No. 1323 of 2013.

<sup>137</sup> See, e.g., <http://thehill.com/blogs/congress-blog/campaign/316883-india-honors--not-dishonors--patent-laws> (last visited Feb. 8, 2017). 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.

## Administrative Burdens

PhRMA welcomes the Indian Government's ongoing work to address India's patent examination backlog including the commitment to reduce examination periods from up to 6 years to 18 months. Backlogs undermine incentives to innovate and hinder timely patient access to valuable new treatments and cures. Because the term of a patent begins on the date an application is filed, unreasonable delays can directly reduce the value of granted patents and undermine investment in future research activity. For biopharmaceutical companies, patent examination backlogs can postpone clinical trial activity and ultimately the introduction of new medicines. Generic manufacturers are also affected by patent examination backlogs. So long as a patent application is unreasonably delayed, generic manufacturers cannot assess whether they will have freedom to operate. That lack of certainty could disincentive the launch of generic medicines and expose generic companies to damages once the patent is granted. In addition to increasing the number of patent examiners, it is equally important to assess administrative procedures that unduly extend patent examination timelines.

Section 8 of the Patents Act sets forth requirements that have been interpreted in a manner that creates heightened and unduly burdensome procedures that mainly impact foreign patent applicants – those most likely to have patent applications pending in other jurisdictions. Section 8(1) requires patent applicants to notify the Controller and “keep the Controller informed in writing” of the “detailed particulars” of patent applications for the “same or substantially the same invention” filed outside of India. Section 8(2) requires a patent applicant in India to furnish details to the Indian Controller about the processing of those 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. Recent court decisions provide greater clarity on the applicability and scope of Section 8. In particular, current jurisprudence limits Section 8 to information that is material to patentability and to deliberate failures to disclose this information.<sup>138</sup>

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<sup>138</sup> See, *Telefonaktiebolaget Lm Ericsson v. Intex Technologies (India) Ltd.*, Delhi High Court Judgment dated Mar. 13, 2015 in CS (OS) No. 1045 of 2014, available at <http://lobis.nic.in/ddir/dhc/MAN/judgement/16-03-2015/MAN13032015S10452014.pdf> (last visited Feb. 8, 2017); *Sukesh Behl & Anr. v. Koninklijke Philips Electronics*, Delhi High Court, 2015(61) PTC183(Del); *Merck Sharp & Dohme Corp. v. Glenmark Pharms*, Delhi High Court, 2015 (64) PTC417(Del).

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 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>139</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>140</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

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<sup>139</sup> See, e.g., *Ajantha Pharma Ltd. v. Allergan*, Intellectual Property Appellate Board (2013).

<sup>140</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 Feb. 8, 2017).

countries as its agents. Approval by the Indian regulatory authorities based on third-country approvals amounts to indirect reliance on the clinical trial and other test data that underlie the third-country approvals. This indirect reliance results in unfair commercial use prohibited by TRIPS Article 39.3.

## **Market Access Barriers**

### High Tariffs and Taxes on Medicines

PhRMA member companies operating in India face high effective import duties for active ingredients and finished products. Though the basic import duties for pharmaceutical products average about 10 percent, additional duties and assessments are imposed that bring the effective import duty total to approximately 20 percent. Moreover, excessive duties on the reagents and equipment imported for use in research and development and manufacture of biotech products make biotech operations difficult to sustain. Compared to 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>141</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>142</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>143</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 increase health coverage for low-income families<sup>144</sup> and the Employees' State Insurance Corporation (ESIC) has announced a raise to the threshold limit for

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<sup>141</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 Feb. 8, 2017).

<sup>142</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 Feb. 8, 2017).

<sup>143</sup> "National Health Policy 2015 Draft." Ministry of Health & Family Welfare. Dec. 2014.

<sup>144</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 Feb. 8, 2017).

mandatory coverage for organized-sector workers.<sup>145</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>146</sup> Still, government spending on healthcare remains at about 1% of GDP, one of the lowest levels of expenditure in the world.<sup>147</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>148</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>149</sup> Focusing on the key barriers to access in India – insufficient financing, infrastructure, and quality – would significantly improve access to medicines for patients.

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>150</sup> For example, medicines and vaccines which are offered free of charge often do not reach the patients who need these medicines.<sup>151</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 been high-income patients, rather than the intended low-income population.<sup>152</sup> A

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<sup>145</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 Feb. 8, 2017).

<sup>146</sup> “Health Systems Financing: The Path to Universal Coverage,” *The World Health Report*, World Health Organization, 2010.

<sup>147</sup> “National Health Policy 2015 Draft.” Ministry of Health & Family Welfare. Dec. 2014.

<sup>148</sup> “Health workforce, infrastructure, essential medicines”, World Health Statistics 2013, The World Health Organization.

<sup>149</sup> Analysis based on IMS MIDAS Data.

<sup>150</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 Feb. 8, 2017).

<sup>151</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 Feb. 8, 2017).

<sup>152</sup> IMS, “Assessing the Impact of Price Control Measures on Access to Medicines in India.” June 2015.

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>153</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>154</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.

PhRMA members believe that competitive market conditions are the most efficient way of allocating resources and rewarding innovation; however, the research-

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<sup>153</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>154</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.

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.

### Unpredictable Environment for Clinical Research & Drug Approval

India has many of the components of an effective regulatory system, such as institutional capacity across central and state regulators and a robust technical framework. India also has several components to support a broader ecosystem for clinical research and drug development, such as the presence of a highly skilled workforce of qualified scientists, hundreds of medical colleges, and a large and diverse patient pool. Still, India faces the consequences of an unpredictable regulatory environment as clinical trials falter<sup>155</sup> and new medicines face significant launch delays.<sup>156</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>157</sup> In the meantime, inconsistencies and ambiguities continue to prevail in the Indian regulatory space resulting in lack of clarity and a cumbersome approval process for trial sponsors. In particular, the Indian regulatory system exhibits slow approval times, ambiguities in the interpretation of compensation rules, and a lack of an appeals mechanism in decisions about causation. The piecemeal approach to reform continues to reinforce the unpredictability of the clinical trials regime and the slow resurgence of trials, especially in the presence of global multiregional trials. As a result, clinical trial investment in India has decreased significantly since 2010.<sup>158</sup> Such uncertainty in the regulatory process for clinical trials

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<sup>155</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 Feb. 8, 2017); Asia Sentinel “Southeast Asia Steals Indian Pharma,” July 14, 2014, available at <http://www.asiasentinel.com/econ-business/southeast-asia-steals-indian-pharma/> (last visited Feb. 8, 2017).

<sup>156</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>157</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-idINKCN0Z819O> (last visited Feb. 8, 2017).

<sup>158</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 Feb. 8, 2017).

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>159</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. Definitions for “trial related injury”, “standard of care,” and “medical management” remain uncertain. Further, clinical trial waiver decisions related to cases of national emergency, extreme urgency, epidemics and for orphan drugs for rare diseases can be considered, but are often highly subjective. The 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>160</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.

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<sup>159</sup> CDSCO Notice, Aug. 4, 2016, available at <http://www.cdscsco.nic.in/writereaddata/NOTICE%20DATED%204th%20August%202016.pdf> (last visited Feb. 8, 2017).

<sup>160</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 Feb. 8, 2017).

## INDONESIA

PhRMA and its member companies operating in Indonesia remain concerned with the country's discriminatory intellectual property (IP) and market access 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:

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

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

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

For these reasons, PhRMA requests that Indonesia remain on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

The recently revised Patent Law would preclude patents on new uses (indications) and establish an additional patentability 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 appears to add an impermissible hurdle to patentability by adding a fourth substantive criterion of “increased meaningful benefit” to the TRIPS requirements. Moreover, this additional hurdle appears to be applied only to chemicals.

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

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

### Burdensome and Vague Disclosure Obligations

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

## Compulsory Licensing

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

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

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

## **Market Access Barriers**

### Registration Delays

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

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

### 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>161</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

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<sup>161</sup> However, there are no restrictions on foreign ownership of raw material production.

and lack of required technology within their local facilities to produce innovative products.

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

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

### 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.

### Mandatory Halal Certification

Indonesia's Mandatory Halal Certification Bill, enacted in September 2014, mandates Halal certification and Halal labeling for food and beverages, medicines,

cosmetics, chemical products, biological products, and genetically-engineered products. The legislation establishes a new Halal certification authority, and requires pharmaceutical firms to hire a Halal specialist and disclose sensitive product formulas to the new Halal authority.

Despite public opposition to the Law, including the objection of the Ministry of Health, the most recent draft of the government regulation on the implementation of the Halal Law unfortunately still includes drugs and cosmetics in the regulation. PhRMA's member companies recognize and support the religious and cultural sensitivities of all Indonesians, but are concerned that this Act may have negative implications for patient health. In particular, significant questions remain regarding the process for securing halal certification and how the government will ensure that the new requirements do not impact patient access to the medicines they need.

### **Counterfeit Medicines**

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

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

## THAILAND

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

### Key Issues of Concern:

- **Generally weak IP environment:** PhRMA's member companies recognize and commend the Department of Intellectual Property's (DIP's) inclusion of industry in the discussion and construction of the Patent Examination Guidelines. However, additional improvement in the IP environment in Thailand remains necessary to avert negative impact on market access. Concerns include delays in obtaining pharmaceutical patents, inadequate regulatory data protection (RDP), and weak patent protection and enforcement regimes.
- **Discriminatory government procurement:** The 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.
- **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 Thailand remain on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

### **Intellectual Property Protection**

#### Patent Backlogs

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

However, unresolved issues remain, including how to clear the patent backlog and ensure that there are sufficient resources to maintain the patent registration

process. The waiting-period for a patent review and grant in Thailand is unpredictable and averages ten years after application submission. Further, these long patent grant delays create uncertainty regarding investment protection and increase the risk that a third party will use a patentable invention that is the subject of a pending patent application during the pending/review periods. Patent term adjustments are not available in Thailand to compensate for unreasonable patent office delays, thereby reducing the effective patent term and further exacerbating the uncertainty caused by its patent grant delays.

### Restrictive Patentability Criteria

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

### Weak Patent Enforcement

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

### Regulatory Data Protection Failures

Ministerial regulations issued by the TFDA regarding the Trade Secrets Act of 2002 do not provide RDP that would prevent generic 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, Thailand continues to threaten the use of CLs. Further, royalty payments have not been made on products for which CLs have been issued. Thailand's compulsory licensing regime lacks sufficient due process and dialogue with affected companies, and suffers from a lack of transparency in the reasoning behind CL decisions.

### **Market Access Barriers**

#### Discriminatory and Non-Transparent Government Procurement 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 Public Procurement Bill intended by the Royal Thai Government to promote transparency, fair competition and efficient and effective public procurement passed the National Legislative Assembly on December 15, 2016. 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.

### **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.

# CANADA

## 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:

- **Restrictive patentability criteria:** Contrary to the Canadian Patent 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 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 (CBI):** In November 2014, Canada enacted legislation to update its Food and Drugs Act (Bill C-17). Provisions in that law granted the Health Minister discretion to disclose a company's CBI without notice to the owner of the CBI and in accordance with a standard that is both inconsistent with other similar Canadian legislation and Canada's treaty obligations under NAFTA and TRIPS.
- **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. In addition, recent comments by the federal Minister of Health suggest that the Canadian government intends to remove the United States from the PMPRB’s current set of comparator countries, a decision with significant and negative financial consequences for innovative companies operating in Canada. Any changes to the PMPRB’s basket of comparator countries, likewise, must be based on evidence, only made after a sound consultative process, and must include reasonable transitional measures to avoid or minimize disruptions to existing business arrangements.

For these reasons, PhRMA requests that Canada be placed on the **Priority Watch List** for the 2017 Special 301 Report. Further, we urge the USTR to provide an opportunity for a meaningful assessment of Canada’s IP regime through an **Out-of-Cycle Review**, so that the U.S. Government can identify opportunities to resolve the problems described herein quickly and effectively and to evaluate progress.

## 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>162</sup> While it was

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<sup>162</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.

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 do.”<sup>163</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 research and development (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

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<sup>163</sup> *Eli Lilly Canada Inc. v. Novopharm*, 2010 FCA 197 at ¶ 76.

patent' . . . has to be demonstrated or soundly predicted on the basis of information disclosed in the patent application at the filing date."<sup>164</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.

Given that this issue has been created by case law, the conventional remedy is for a higher court to fix the problem. On November 8, 2016, the Supreme Court of Canada heard oral arguments in *AstraZeneca Canada Inc., et al. v. Apotex Inc., et al.*, AstraZeneca's appeal concerning the invalidation of the NEXIUM patent on the basis of the promise doctrine. A decision is not expected until the end of Q1/early Q2 2017. The NEXIUM case presents an opportunity for Canada's Supreme Court to fix these distortions in its patent system by adopting a utility requirement in-line with the rest of the world.

Failing this, and 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 "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

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<sup>164</sup> See [https://www.wto.org/english/tratop\\_e/tptr\\_e/s314\\_e.pdf](https://www.wto.org/english/tratop_e/tptr_e/s314_e.pdf) at p.104 (last visited Feb. 8, 2017).

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>165</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, 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.

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<sup>165</sup> *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2007 FCA 359.

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>166</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.

The final text of the Comprehensive Economic Trade Agreement (CETA)<sup>167</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.

### 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.

### 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

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<sup>166</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>167</sup> See CETA, Final Text, as published by the Government of Canada, available at <http://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng> (last visited Feb. 8, 2017).

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 reasons of the majority in the Federal Court of Appeal.<sup>168</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) seeks to compensate for a portion of the crucial effective patent life lost due to clinical trials and the regulatory approval process. Most of Canada's major trading partners, including the United States, the European Union and Japan, offer forms of PTR which generally allow patent holders to recoup a valuable portion of a patent term where time spent in clinical development and the regulatory approval process has kept the patentee off the market. In these countries up to five years of lost time can be recouped. 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

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<sup>168</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 Feb. 8, 2017).

minimum level of 2 years required by CETA).<sup>169</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.

### 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>170</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

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<sup>169</sup> See <http://international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/understanding-comprendre/technical-technique.aspx?lang=eng#p5> (last visited Feb. 8, 2017).

<sup>170</sup> See <http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=6676418&File=4> (last visited Feb. 8, 2017).

requirement for the disclosure to occur, only that it be related to protecting or promoting health. NAFTA and TRIPS do not refer to disclosure for the promotion of health, but rather to disclosure needed to protect the health of the public.

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

In July 2015, a final guidance document was issued by Health Canada with respect to the administration of its powers to require and disclose CBI.<sup>171</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>172</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.

## **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

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<sup>171</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-droguessedangeuses-amendments-modifications-eng.php> (last visited Feb. 8, 2017).

<sup>172</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 Feb. 8, 2017); Anne Kingston, "Health Canada OKs research into popular morning-sickness drug" *Macleans* (Nov. 23, 2015), available at <http://www.macleans.ca/society/health/health-canada-oks-research-into-popular-morning-sickness-drug/> (last visited Feb. 8, 2017).

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>173</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>174</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.

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>175</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, the availability of new medicines to Canadian patients, and the competitiveness of Canada as a site for research-based pharmaceutical investment.

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

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<sup>173</sup> Canadians Facing Delayed Access to New, Innovative Medicines: Report (May 24, 2016, available at <http://innovativemedicines.ca/canadians-facing-delayed-access-to-new-innovative-medicines-report/> (last visited Feb. 8, 2017).

<sup>174</sup> *Patent Act*, R.S.C. 1985, c.P-4, ss.79-103.

<sup>175</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 Feb. 8, 2017).

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.

In addition, it has recently come to light that Canada plans to make changes to the basket of seven comparator countries traditionally used for pricing comparison purposes. Currently, and in accordance with the *Patent Act* and *Patented Medicines Regulations*, patentees must report publicly available prices of patented drug products for a "basket" of seven foreign comparator countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. The federal Minister of Health recently indicated that the U.S. will be removed from this "basket", to be replaced by one or more jurisdictions with lower pricing.<sup>176</sup> This will have the effect of reducing the potential price ceiling for all patented medicines in Canada. PhRMA members are deeply concerned that such a change may be highly disruptive to their operations in Canada, and that they will experience reduced revenues as a result of lower ceiling prices being established in accordance with this new group of comparator countries.

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. Any changes to the PMPRB's basket of comparator countries, likewise, must be based on evidence, only made after a sound consultative process, and must include reasonable transitional measures to avoid or minimize disruptions to existing business arrangements.

The PMPRB is also required to report to the Federal Minister of Health on pharmaceutical trends and on R&D spending by pharmaceutical patentees. Due to the antiquated 1987 tax law formula used to measure R&D spending included in its governing regulations, PMPRB has consistently and systematically 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 urgently update the regulatory R&D definition in order that the PMPRB can more accurately calculate the significant R&D contributions made by pharmaceutical patentees to the Canadian knowledge-based economy.

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<sup>176</sup> See Full interview with Minister of Health Jane Philpott, available at <http://www.cbc.ca/fifth/blog/full-interview-with-minister-of-health-jane-philpott> (last visited Feb. 8, 2017).

# EUROPE

## RUSSIA

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

### Key Issues of Concern:

- **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>177</sup> Russia's Federal Anti-monopoly Service (FAS) continues to express strong support for expanded use of compulsory licenses (CLs) and expressed its intent to adopt restrictive patentability criteria for pharmaceuticals.
- **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>178</sup> that entered into force in 2016. PhRMA and its member companies are concerned that provisions added to the Law since 2012, as well as proposed amendments substantially weaken RDP protection for innovative medicines in Russia. Russian court rulings in 2016, not upholding RDP protections, also demonstrate a worrying trend.
- **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>179</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. The Government has proposed disqualifying products from tenders if any product within the same INN is on the Russian market and includes locally produced active pharmaceutical ingredients.
- **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

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<sup>177</sup> Strategy for Developing the Russian Pharmaceutical Industry until 2020, approved by the Order of the Ministry of Industry and Trade, dated October 23, 2009, No. 956.

<sup>178</sup> Federal Law No. 61-FZ dated April 12, 2010 "On the Circulation of Medicines". Relevant amendments were introduced by Federal Law No. 429-FZ dated December 22, 2014.

<sup>179</sup> Includes, Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia.

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 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. The Intergovernmental Council of the EAEU has approved the regulations underpinning the single EEU market for pharmaceuticals and allowing parallel trade in the region; however the market will not operate as planned until the regulations are approved and implemented at the national level.

For these reasons, PhRMA requests that Russia remain on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Compulsory Licensing

PhRMA and its member companies are concerned about ongoing FAS proposals<sup>180</sup> to expand the use of CLs in Russia. Under these proposals, FAS suggests that Russia could address access and pricing concerns with an expanded use of CLs. These broad proposals are not aligned with the intent of the TRIPS Agreement and would weaken Russia's intellectual property framework and thereby undermine the incentive system that underpins the ability of our members to undertake essential R&D. They would also discourage investment in Russia and 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 greater 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.

Meanwhile, on December 5, 2016, the Ministry of Health also put forward draft regulations to restrict identifying criteria for medicines in the state procurement process;

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<sup>180</sup> See, e.g., "On Amendments to Federal Law 'On Protection of Competition' and to the Civil Code of the Russian Federation" released on November 25, 2016.

dosage form, treatment method or other characteristics would no longer determine eligibility, only INN. This would further undermine incentives to innovate and the quality, safety and efficacy of treatments available to patients.

### Regulatory Data Protection Failures

PhRMA member companies are concerned that recent court decisions and proposed amendments to the Law on the Circulation of Medicines will further erode RDP in Russia. According to a May 26, 2016 Supreme Court ruling, 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.*, relying on the data reported in scientific journals following approval of the innovative product to seek marketing approval for its own follow-on product during the RDP term. As a result of this ruling, in late October 2016, the Ministry of Health proposed amendments to Article 18 of the Law on the Circulation of Medicines that would enshrine the court ruling. 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.

In addition, 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>181</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>182</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, the recent Supreme Court decision and proposed amendments to the relevant legislation as discussed above, 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

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<sup>181</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>182</sup> Federal Law No. 61-FZ, "Law on the Circulation of Medicines" (Apr. 12, 2010).

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 via damages.

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

Regulations are under development to allow for the parallel import of pharmaceuticals within the EAEU. The Intergovernmental Council of the EAEU has approved the regulations underpinning the single EEU market for pharmaceuticals and allowing parallel trade in the region; however the market will not operate as planned until the regulations are approved and implemented at the national level. Parallel imports currently 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 if the Treaty were amended to allow for parallel imports of pharmaceuticals, it could create unreasonable risks for patients.

## **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.

In early November 2016, the Russian Government proposed additional discriminatory measures aimed at further restricting the ability of foreign manufacturers to win tenders for products included on the EDL.<sup>183</sup> According to the proposed amendments, the order of prioritization for evaluating tenders will be: 1) products with full cycle production in Russia, 2) products manufactured in Russia or other Member States of the EAEU using foreign sourced active pharmaceutical ingredients, and 3) foreign produced products. PhRMA and its members are concerned that not only will these provisions, if enacted, discriminate against foreign products, they may also impact patient access to quality innovative medicines. The Russian Government has also taken a number of steps to isolate certain segments of the pharmaceutical market for sole-supply contracts given to Russian companies. For example, in 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.

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<sup>183</sup> The Ministry of Industry and Trade, “On Amending the Regulation of the Government of the Russian Federation No. 1289 dated November 30, 2015.”

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 November 16, 2016, the EAEU Intergovernmental Council approved the necessary regulations to establish a common pharmaceutical market in the EAEU. These regulations must now be approved and implemented at the national level. 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.

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

### Key Issues of Concern:

- **Weak patent enforcement and regulatory data protection failures:** While patents and regulatory test data have received IP protection in Turkey since 1995 and 2005, respectively, significant improvements are still needed. For instance, while Turkey's new Industrial Property Law, which was passed by the Turkish Parliament on December 22, 2016, better aligns Turkey with the European Patent Convention, certain provisions in the new law expand the possibility of granting compulsory licenses (CLs) in Turkey. In addition, Turkey does not provide an effective mechanism for resolving patent disputes before the marketing of follow-on products. Further, Turkey inappropriately ties the regulatory data protection period (RDP) to the patent term and the lack of RDP for combination products is still an unresolved issue. Finally, the RDP term begins with first marketing authorization in the European Union and thus, as a result of significant regulatory approval delays in Turkey, the effective RDP term is reduced significantly. Consistent with Turkey's international obligations, the RDP term should begin when a product receives marketing authorization in Turkey. In addition, Turkey does not provide RDP for biologics.
- **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.
- **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>184</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 Turkey be placed on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

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<sup>184</sup> Based on AIFD Survey 2015.

## **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.

On December 22, 2016, the Turkish Parliament ratified the Industrial Property Law (no. 6769) which, among other topics, updates Turkey’s regime for pharmaceutical patenting. While much of the agreement better aligns the Turkish patent regime with its European Patent Convention obligations, PhRMA and our member companies are strongly concerned that the new provisions governing compulsory licensing are too liberal and could too easily lead to the granting of CLs for pharmaceuticals. Of particular concern, the law allows for CLs to be granted if a third party can make the argument that current market demands are not being met.

### Regulatory Data Protection Failures

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

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

Another concern of the innovative pharmaceutical industry is that the legislation governing RDP has been changed by the Regulation to Amend the Registration Regulation of Medicinal Products for Human Use.<sup>185</sup> The change that has been

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<sup>185</sup> Official Gazette No. 27208 (Apr. 22, 2009).

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.

## **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 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>186</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>187</sup>

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<sup>186</sup> Official Gazette No. 25705 (Jan. 19, 2005) (Registration Regulation).

<sup>187</sup> Based on AIFD Survey 2015.

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 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>188</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

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<sup>188</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).

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 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>189</sup> days to receive a listing decision for pharmaceutical products that hold marketing authorization.

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<sup>189</sup> Based on AIFD Survey in 2015.

Moreover, PhRMA member companies are still burdened by a draconian government price regime that saddles products with a substantial 41 percent price discount from the lowest price in a basket of six European countries (including Greece). In addition, since 2010 the industry has endured a fixed exchange rate system that resulted in a minimum 50 percent financial burden for the pharmaceutical industry. Following significant and repeated advocacy by the U.S. Government, PhRMA, and our local sister association, a new Pharmaceutical Pricing Decree was published on July 9, 2015 that annulled the former decree and established that the Euro-to-TL exchange rate for pharmaceuticals would 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 Pricing Decree, on January 3, 2017, the Turkish Drug Agency set the exchange rate for the year (effective February 20) at 2.3421 TL/EUR (the current rate is 3.97). 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.

Finally, on November 25, 2016, the Turkish Government proposed highly troubling revisions to the government pricing system in Turkey. First, they suggested that if a price for the product in question is not available in the six European reference countries, the Turkish Government would reference the lowest price in the 45 countries participating members of the Pharmaceutical Inspection Cooperation Scheme (PIC/S), a non-binding, informal co-operative arrangement between Regulatory Authorities in the field of GMP of medicinal products for human or veterinary use. PhRMA questions the relevance of a global organization designed to promote regulatory best-practice sharing as the basis for setting prices in Turkey. Second, the government proposed an automatic 20 percent price reduction for original biologics when the first biosimilar is approved of that product.

### Orphan Drug Guidelines

In August 2015, the Ministry of Science, Industry and Technology (MoSIT) published an in-depth analysis of the impact of rare diseases on Turkey's population within its "Pharmaceutical Sector Strategy and Action Plan of 2015". This study called for the creation of a national orphan drug policy, which is due to be fully implemented by January 1, 2019. The innovative pharmaceutical industry looks forward to working with key stakeholders, including the MOH, SSI, MoSIT, Ministry of Economy, Ministry of Development, Ministry of Finance, Treasury and other civil society organizations, to establish a market access pathway and appropriate incentives to facilitate the development and commercialization of medicines to treat rare diseases. As part of this

process, it will be critical for Turkey to define orphan drugs based on international best practices, including EU prevalence standards, and thereby better ensure that Turkish citizens have access to the medicines they need and to further the Turkish Government's ambitions of being a globally-competitive hub for medical innovation.

# **LATIN AMERICA**

## ARGENTINA

PhRMA and its member companies operating in Argentina recognize the important economic reforms the Government of Argentina has implemented over the last year. We welcomed the resumption of bilateral dialogue through the Trade and Investment Framework Agreement concluded in March 2016. Recent reforms have the potential to drive future economic growth in Argentina, and constructive dialogue that delivers real results could transform an important bilateral trade and investment relationship.

However, biopharmaceutical innovators in the United States continue to face serious and longstanding intellectual property (IP) issues and market access barriers put in place by the previous Argentine Government. IP issues include patentability restrictions, a lengthy patent application backlog, and the lack of regulatory data protection (RDP). Argentina continues to maintain a reimbursement system that does not provide a level playing field for overseas manufacturers.

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

- **Restrictive patentability criteria:** The Argentine Government amended its criteria for granting pharmaceutical patents in 2012. A joint regulation issued by the Ministries of Health and Industry and the Argentina Patent Office (Instituto Nacional de la Propiedad Industrial or INPI) established guidelines that significantly limit the type of pharmaceutical inventions that can be patented. These guidelines appear contrary to Argentina's obligations under the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and have led to the rejection of many pharmaceutical patent applications. In addition, there have been reported instances of courts invalidating patents granted under the previous rules by applying the new guidelines retroactively.<sup>190</sup>
- **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.
- **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.

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<sup>190</sup> See, e.g., Argentina: Polymorph patents under fire, available at <http://aippi.org/no-show/argentina-polymorph-patents-under-fire/> (last visited Feb. 8, 2017).

For these reasons, PhRMA requests that Argentina remain on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

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

## Regulatory Data Protection Failures

Biopharmaceutical innovators work with hospitals, universities and other partners to rigorously test potential new medicines and demonstrate they are safe and effective for patients who need them. Less than 12 percent of medicines that enter clinical trials ever result in approved treatments.<sup>191</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.

## 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.

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<sup>191</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 Feb. 8, 2017).

## 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 hire additional qualified examiners and consider participating in work sharing arrangements, such as Patent Prosecution Highway programs, with other major patent offices. Argentina should also accede to the Patent Cooperation Treaty (PCT), a step that would facilitate the filing and examination of patent applications in Argentina as it does now in more than 140 Contracting Parties. Accession to the PCT could allow Argentina to reduce its current patent application backlog and use the PCT system to reduce the review period for future patent applications.

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

## **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.

## BRAZIL

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

### Key Issues of Concern:

- **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.*, patents related to biopharmaceutical products or agrochemical compounds that were filed after Brazil acceded to the World Trade Organization (WTO) on January 1, 1995, but before the Patent Law went into effect on May 14, 1997. These lawsuits, primarily affecting pharmaceutical patents, are currently proceeding through the legal system including the Court of Appeals, but most decisions have upheld INPI's retrospective decision to no longer provide a minimum ten years of post-grant patent protection.
- **Regulatory data protection failures:** Although Brazil applies RDP for veterinary, fertilizer, and agrochemical products, the same protection is not given to biopharmaceutical products.
- **Regressive taxes on medicines:** Combined federal and state taxes add up to 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>192</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.

For these reasons, PhRMA requests that Brazil be placed on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria and Procedures

One of the most serious problems facing the pharmaceutical industry today in Brazil was created by Article 229-C, the 1999 amendment to the Brazilian Patent Law that authorizes the health regulatory agency (ANVISA) to review patent applications claiming pharmaceutical products and/or processes that may present a “health risk.” This review 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 WTO 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 and March 2010, the Federal Attorney General (AGU Office) issued opinions stating that ANVISA’s role in the examination process is limited to health and safety risks. As a result of these opinions, 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 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

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<sup>192</sup> The Brazilian PDPs follow the same principles of regular PPP agreements with adaptations designed to respond the specificities of the local pharmaceutical market.

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 INPI has stated that ANVISA's review is supplementary and subsidiary to its own patent examination, INPI currently refrains from continuing patent prosecution where ANVISA's prior consent grant decisions contain any reference to "technical examination on the merits" or "that a search for prior art references was performed." 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 term for patents relating to biopharmaceutical or agrochemical compounds that were filed between January 1, 1995 and May 14, 1997 (known as "mailbox patents"). Brazilian Patent Law 9,279/96 Article 40 provides that "Patents will be given a 20-year protection from the date of filing" (caput) and "A minimum of ten-year protection will be given from the date of grant" (paragraph one).<sup>193</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 a result, INPI has filed multiple lawsuits in Federal District Courts against the impacted mailbox patent holders seeking to invalidate their patents. Many of those cases are now before the Court of Appeals, which has upheld INPI's retrospective decision to no longer provide a minimum ten years of post-grant patent protection.

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

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<sup>193</sup> It should be noted that there are two constitutional challenges pending before the Brazilian Supreme Court requesting that article 40, sole paragraph, of the Brazilian IP Law be declared unconstitutional. The first constitutional challenge was filed by ABIFINA, a Brazilian association representing national companies with chemical interests including many generics companies. The second one was filed by the Brazilian Federal Public Prosecutor Office. Interfarma, among others, has successfully petitioned to participate in these cases as *amicus curiae*.

## Regulatory Data Protection Failures

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

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

## **Market Access Barriers**

### Regressive Taxes on Medicines

Combined federal and state taxes add up to 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. A new regulation aimed to replace Portaria 2531/14 and further clarity on newly approved PDPs is expected in 2017.

### 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.

## COLOMBIA

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

### Key Issues of Concern:

- **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.
- **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), citing new compulsory licensing provisions of the National Development Plan, issued a DPI for the patented medicine Glivec®. In Colombia, a DPI must be made by the MSPS before a CL 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). On November 22, 2016, the National Pricing Commission issued Circular 03 of 2016, which sets out a *general* pricing methodology that will apply to all medicines subjected to a DPI. This methodology is the same as the price reduction imposed on Glivec and likewise, unduly targets patented products by effectively expropriating relevant patents.
- **Increased regulatory barriers under the National Development Plan (NDP):** Colombia’s NDP, which passed into law on May 7, 2015, undermines recent gains Colombia has made to encourage innovation, delays access for Colombians to cutting edge technologies, and is inconsistent with Colombia’s international commitments on IP and trade. Particular concerns include Article 72, which makes price and health technology assessment (HTA) criteria in the regulatory approval process, and Article 70, which establishes a role for the MSPS in reviewing pharmaceutical patent applications and elevates the risk of unjustified compulsory licenses (CLs). 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.

- **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.
- **Substandard biologics regulation:** On September 18, 2014, Colombia issued Decree 1782, which establishes marketing approval evaluation requirements for all biologic medicines. As part of the Decree, Colombia has established an unprecedented “abbreviated” pathway for the registration of non-comparable products, which is inconsistent with sanitary and WHO standards and practices in the United States and other countries and which could result in the approval of medicines that are not safe and/or effective.
- **Arbitrary and non-transparent market access policies:** Colombia’s international reference pricing methodology and other cost containment measures, are being used to set the same price for both the public and private segments of the market, 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.

For these reasons, PhRMA requests that Colombia be placed on the **Priority Watch List** for the 2017 Special 301 Report. Further, we urge the USTR to provide an opportunity for a meaningful assessment of whether there has been progress on these important issues through an **Out-of-Cycle Review**, so that the U.S. Government can identify opportunities to resolve the problems described herein quickly and effectively.

## **Intellectual Property Protection**

### 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.

### 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>194</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

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<sup>194</sup> An innovative leukemia medicine that contains the active ingredient imatinib.

“alternative” to issuing a compulsory license (while still leaving open the possibility of issuing a CL).

The DPI was issued following the recommendation of a technical committee. In its recommendation, the committee stated that the objective of the price reduction would be to return Glivec prices to “the point of ... simulated competition,” with “a price comparable to that of the competitors before the patent was granted”. 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.

On November 22, 2016, the National Pricing Commission issued Circular 03 of 2016, which sets out a *general* pricing methodology that will apply to all medicines subjected to a DPI. This methodology is the same as the price reduction imposed on Glivec and likewise, unduly targets patented products rendering their patents worthless.

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

Limiting the price of patented medicines to levels equivalent to those of generics 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 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>195</sup>

### 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 MSPS 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 MSPS by mandating that on an ongoing basis it review patents relating to health technologies that are susceptible to CLs. As provisions that appear to apply exclusively to healthcare technologies, they discriminate against pharmaceuticals contrary to TRIPS and the U.S.-Colombia FTA.

### 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.

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<sup>195</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.

## 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.

## **Market Access Barriers**

### 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.

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.

## 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:**

- **New intellectual property (IP) law:** The National Assembly, under the Code of Knowledge (INGENIOS Code), developed a new IP regime that includes, among other things, limited data protection for 5 years. Additionally, a number of the prior IP deficiencies in Ecuador are not addressed in this Code. The implementation of the Code is ongoing and needs to be monitored to ensure strong IP principles are upheld.
- **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. The INGENIOS Code also excludes polymorphs from patentable subject matter – even if the relevant polymorphs meet all patentability criteria.
- **Regulatory data protection (RDP):** PhRMA and its members welcome the provision of five years of RDP in the new INGENIOS Code, and will be closely monitoring implementation of the Code to ensure that the regulation sufficiently supports and values 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.
- **Government price controls:** 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 Resolution No. 10-2015 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.

For these reasons, PhRMA requests that Ecuador be placed on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

The National Assembly developed a new IP regime under the INGENIOS Code. Although the Code provides for five years of RDP (discussed further below), it does not address a number of the other previously existing IP deficiencies in Ecuador. Industry will be closely monitoring implementation of the Code to ensure strong IP principles are upheld.

### 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, salts, and polymorphs of compounds are improperly considered inherent properties of the compound and not an invention.

### Regulatory Data Protection

PhRMA and its members welcome the provision of five years of RDP in the new INGENIOS Code, and will be closely monitoring implementation of the Code to ensure that the regulation sufficiently supports and values 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.

### 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 reformatory Decree issued on August 22, 2016 only amended the second subparagraph of the original Decree 522, leaving greater ambiguity in the regulation. The new Decree (1159) introduces the concept of a reference product in Ecuador. To date, the specific issuance of the regulation for implementation by the Agency for Health Regulation and Monitoring (ARCSA) is still pending.

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.

## **Market Access Barriers**

### Government price controls

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 Resolution 10-2015 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.

## PERU

PhRMA and its member companies operating in Peru are concerned about weakness of certain intellectual property (IP) protections and market access barriers 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:

- **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. Although the petition was not granted, some in Congress have sought to renew the petition through legislation (Bill 275/2016). As in the original petition, the Bill fails to provide any compelling reasons to issue a CL.
- **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.
- **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.

For these reasons, PhRMA requests that Peru be placed on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Weak Patent Enforcement

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 (INDECOP) 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. Although the petition was not granted, the technical analysis being undertaken was done without consulting the manufacturer, raising significant due process concerns. In August 2016, some in Congress sought to renew the CL petition through legislation (Bill 275/2016), once again failing to demonstrate a legitimate public interest in issuing a CL

### 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>196</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. 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.

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<sup>196</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 Feb. 8, 2017).

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 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.

### **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.

### 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.

# **MIDDLE EAST/ AFRICA**

## ALGERIA

Last year represented a particularly challenging year for U.S. innovative biopharmaceutical companies operating in Algeria, a country where leading U.S. headquartered companies have been active for decades.

PhRMA and its member companies 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 stating publicly its support for a new strategy that better integrates the innovative pharmaceutical sector into Algeria's economy and healthcare system. Subsequent Ministers have reaffirmed their commitment to boosting Algeria's competitiveness in the innovative biopharmaceutical sector, but dozens of proposed reforms have not been implemented. Despite deterioration in the overall business and investment environment, PhRMA's member companies are hopeful for a similarly cooperative dialogue with the government in 2017.

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

- **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).
- **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.
- **Pricing procedures:** Algeria's pricing and reimbursement mechanisms are cumbersome and delayed. Historically, some patented medicines with no generic equivalent on the market have been referenced against generic products deemed to be in the same therapeutic class. In addition, the new drug pricing procedure issued in August 2015 has key weaknesses related to its reference pricing system and the frequency of updates. As a result, prices in Algeria do not recognize the value of innovative products, nor do they reward the significant investment involved in developing new medicines, or encourage the development of tomorrow's new cures.
- **Cumbersome and Slow Regulatory System:** Despite significant improvements in the MOH's registration process in 2013, the registration process remains slow and burdensome. As a result, patient access to innovative medicines in Algeria lags significantly behind neighboring peer countries.

For these reasons, PhRMA requests that Algeria remain on the **Priority Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Weak Patent Enforcement

Marketing approval authorities in Algeria improperly interpret current laws and regulations by granting marketing approval to copies of patent protected products while the original patent is still in effect. In some cases, this is happening many years in advance of the original product patent expiration despite the owners repeated attempts to alert the authorities and present documentation confirming that the product is under patent in Algeria.

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.

## **Market Access Barriers**

### Import Restrictions

On October 21, 2008, the Algerian Government issued a decision<sup>197</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 was essentially a reinstatement of a previous ministerial decree<sup>198</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

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<sup>197</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.

<sup>198</sup> Instruction #5 for the Generalization of Generics (Sept. 2003).

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

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

### Investments and Commercial Laws

In December 2008, the Algerian Government declared that any company engaged in foreign trade should have a minimum of 51 percent of local Algerian shareholders. This decision applies prospectively, not to companies engaged in foreign trade prior to December 2008. Despite the lack of success in attracting significant new investment, the new government has recently confirmed that this law will continue to be enforced for the foreseeable future.

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

In May 2010, the MOH issued a circular that prohibits local manufacturers from selling products to wholesalers, and requires them to sell such products directly to pharmacies. Therefore, PhRMA members who invested in local manufacturing will now 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.

### 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. The narrow focus on cost means that it cannot capture the underlying value of promising new medicines for patients or reduce other costs in the healthcare system, such as avoiding expensive hospitalizations, surgery, rehabilitative or long-term care.

## Cumbersome and Slow Regulatory System

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

Additional burdensome requirements for obtaining registration to market pharmaceutical products, especially innovative products, have been implemented. As a result, patient access to innovative medicines in Algeria lags significantly behind 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 biopharmaceutical association. PhRMA member companies look forward to working with the Government on securing the legal approval for such an association. Establishing an association is a critical step for industry to be able to work with the Algerian Government on realizing the goals set forth in the Vision 2020 report and the various undertakings that the industry and government have agreed to in recent years.

## Pricing Procedures

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 because it doesn't take into consideration the local health and economic interests. 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, industrial goals or market structures.

In short, IRP as a policy is not consistent with Algeria's goal of promoting a local innovative biopharmaceutical 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 references 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. This measure ignores the damage that such policies have had on the innovative biopharmaceutical industry in those countries, where investment has stagnated and the industry is in a state of contraction. As such, Turkey and Greece should be removed from Algeria's basket of reference countries.
- To ensure 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.

# **WATCH LIST**

# **ASIA-PACIFIC**

## AUSTRALIA

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

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

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

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

- **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 patent expiry.
  - The Australian Government recently commissioned another Productivity Commission (Commission) inquiry into Australia's "Intellectual Property

Arrangements.”<sup>199</sup> The Commission’s report was publicly released on December 20, 2016 and contains a number of findings that the industry does not consider appropriate or reasonable. 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.
- **Difficulties in listing new medicines on the PBS:** Companies continue to face uncertainty in the listing of new medicines on the PBS. Navigating the regulatory framework of market authorization and reimbursement remains complex and, particularly for reimbursement, 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.

For these reasons, PhRMA requests that Australia be placed on the **Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

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<sup>199</sup> See <http://www.pc.gov.au/inquiries/current/intellectual-property#issues> (last visited Feb. 8, 2017).

## 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 if the patent is ultimately not upheld or found not to be infringed. The precedent set by this policy jeopardizes well-accepted principles of due process and severely discourages innovators from exercising their IP rights. Moreover, this policy contravenes Australia's obligations under TRIPS Article 50.

The 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 another Productivity Commission (Commission) inquiry into Australia's "Intellectual Property Arrangements."<sup>200</sup> The Commission issued its final report on December 20, 2016, and the report contains a number of findings that the industry does not consider appropriate or reasonable, such as calls to restrict patent term restoration in Australia, to allow manufacture for export during the restored patent term, and to raise the threshold for inventive step.<sup>201</sup> Industry is now awaiting the Australian Government's response to the report and there is heightened concern that the current fiscal environment in Australia and increased budget deficit will encourage the Australian Government to act on the recommendations as a cost management/savings measure.

### 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>202</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

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<sup>200</sup> Id.

<sup>201</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 [http://www.pc.gov.au/\\_\\_data/assets/pdf\\_file/0010/194770/sub087-intellectual-property.pdf](http://www.pc.gov.au/__data/assets/pdf_file/0010/194770/sub087-intellectual-property.pdf) (last visited Feb. 8, 2017).

<sup>202</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 Feb. 8, 2017).

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.

## **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>203</sup> Accordingly, the reimbursement process to obtain PBS-listing, as well as Pharmaceutical Benefits Advisory Committee (PBAC) guidelines and decision making, effectively dictate access for the Australian innovator pharmaceutical market. The outcomes and processes in PBS listings are therefore critical to securing market access to ensure Australian patients have access to innovative medicines.

The 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>204</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 in April 2016 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

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<sup>203</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 Feb. 8, 2017).

<sup>204</sup> See <http://www.pbs.gov.au/info/general/pbs-access-sustainability-package> (last visited Feb. 8, 2017).

by the PBAC through the rigorous Pharmaceutical Benefits Scheme (PBS) 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 PBS processes so that Australian patients can access innovative treatments as soon as possible. While the rate of PBAC's positive recommendations for PBS-listing has improved somewhat over recent years, many of these "positive" recommendations are now accompanied by onerous conditions such that in some instances, sponsors are unable to comply or are having to lodge resubmissions for PBAC reconsideration. These cause further delay in patient access to medicines.

Additionally, the PBAC are increasingly seeking to compare new products to the 'lowest cost' comparator. As the price-disclosure measure has expanded and matured, creating downward pressure on prices in the multi-brand, competitive market for off-patent medicines, this means that comparators are increasingly being drawn from very low cost drugs. This will act as an additional disincentive to bring innovative medicines to Australia.

Furthermore, the Australian Government retains the ability to create Therapeutic Groups to manage costs and pricing of medicines within a therapeutic category where drugs are deemed by the PBAC to be 'interchangeable at a patient level' regardless of patent status or formulary placing. Under the MOU 2010-2014 there was a moratorium on new Therapeutic groups. Although no new Therapeutic groups have been formed since 2010, there is speculation that this measure will be reintroduced in the lead up to the next budget. The industry is examining this option and determining the likely consequences.

### 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>205</sup>

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<sup>205</sup> See <http://www.pbs.gov.au/info/browse/reviews> (last visited Feb. 8, 2017).

PhRMA has previously expressed strong concerns about the cost-focus of post-market reviews of medicines listed on the PBS. While the stated objective of the reviews has been to improve Quality Use of Medicine, 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.

## KOREA

PhRMA and its member companies remain concerned with several intellectual property (IP) and market access 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:**

- **Patent enforcement concerns:** While Korea has implemented a patent enforcement mechanism pursuant to its South Korea-U.S. Free Trade Agreement (KORUS) commitment, certain key issues of concern remain. These issues include the discretion afforded to the Ministry of Food and Drug Safety (MFDS) as to whether to list a patent in the Green List or to permit a change to the patent listing and the limited period of only nine months for a sales stay. Furthermore, the patent enforcement mechanism should be based on the patents as granted by the Korean Intellectual Property Office (KIPO) and apply to all generic products when a sales stay is sought.
- **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 innovative medicines. Consistent with 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.

For these reasons, PhRMA requests that Korea be placed on the **Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

### **Intellectual Property Protection**

#### **Patent Enforcement**

Consistent with its IP obligations under KORUS,<sup>206</sup> effective March 15, 2015, Korea implemented the framework of an effective patent enforcement system. Key issues that PhRMA continues to monitor include:

- The discretion afforded to MFDS to determine whether to list a patent in the Green List or to permit a change to the patent listing.

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<sup>206</sup> See U.S.-Korea Free Trade Agreement, Art. 18.9, para. 5.

- 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.

## **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>207</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>208</sup> of oncology drugs were listed for reimbursement. It is difficult for a new drug to be listed under Korea's pharmacoeconomic (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>209</sup> listed since 2007.

Effective May 29, 2015, MOHW implemented new listing processes that exempt certain new drugs from completing a pharmacoeconomic (PE) evaluation and provide 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

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<sup>207</sup> EK Lee, "Price comparison among OECD countries" (2014).

<sup>208</sup> IMS Health analysis (2016).

<sup>209</sup> KRPIA analysis based on a report from the Drug Reimbursement Evaluation Committee.

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.

## VIETNAM

PhRMA's member companies face significant intellectual property (IP) and market access 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:

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

- **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 and for all vaccines regardless of how long they have been available in their country of origin. 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 a "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.

For these reasons, PhRMA requests that Vietnam remain on the **Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Restrictive Patentability Criteria

The 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

In 2016, the MOH issued the CL Circular, which in its current form grants overly broad and arbitrary powers to grant 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 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.

## **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 adequate 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 for registration purposes. Such an amendment could quickly improve patient access to new essential and life-saving medicines and reduce public health issues. 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>210</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.

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<sup>210</sup> In special circumstances, import licenses may be granted during "off-visa" periods for individual shipments based on historical volume.

### 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 1, 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 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>211</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 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

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<sup>211</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.

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 biosimilar 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.

### **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.

# **LATIN AMERICA**

## MEXICO

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

### Key Issues of Concern:

- **Weak patent enforcement and regulatory data protection failures:** Mexico's health regulatory agency (COFEPRIS) and the Mexican Patent Office (IMPI) have committed to improve the application of Mexico's 2003 Linkage Decree and to provide protection for data generated to obtain marketing approval for pharmaceutical products. Despite these commitments, 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.
- **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.

For these reasons, PhRMA requests that Mexico remain on the **Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

### **Intellectual Property Protection**

#### Weak Patent Enforcement

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 medicine-related patents is a positive step toward the goal of eliminating unnecessary, costly and time consuming court actions to obtain appropriate legal protection for biopharmaceutical patents. However, it is unclear whether and how COFEPRIS consults the Official Gazette and

with the Patent Office to verify that there is no patent infringement, before issuing marketing authorizations.

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

A critical tool to protect against irreparable harm from the loss of IP rights is the availability of preliminary 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.

In Mexico, PhRMA member companies are unable to obtain accurate and timely information from COFEPRIS prior to marketing authorization being granted on a generic or biosimilar drug where the innovator product is used as a reference. As a result, PhRMA members have little to no notice that a potentially patent infringing product is entering the market. Further, obtaining effective preliminary injunctions or final decisions on cases regarding IP infringement within a reasonable time (as well as collecting adequate damages when appropriate) remains the rare exception rather than the norm. Although injunctions may be initially granted subject to the payment of a bond, counter-bonds, or in some proceedings mere applications, may be submitted by the alleged infringer to lift the injunction. 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>212</sup>

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<sup>212</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 Feb. 8, 2017).

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

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

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

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

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

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

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

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

## **Market Access Barriers**

### Market Access Delays

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

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

After COFEPRIS grants marketing authorization to a new medicine, the national Committee of Health decides which drugs should be included on the national formulary. Recommended prices for patented and unique drugs (or those with exclusive distributors) for all public institutions are negotiated with the Coordinating Commission for the Negotiation of Prices of Medicines and Other Medical Supplies. Following this recommendation, the public health institutions at federal and local levels, such as the Mexican Institute for Social Security (IMSS), 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 products with regulatory approval and wide reimbursement throughout the world are often denied listing in Mexico based on alleged inadequate efficacy or safety defined through non-transparent criteria. As a result, there has been a dramatic reduction in public formulary listings for innovative medicines that have been approved by COFEPRIS for inclusion in the national formulary. Decisions denying institutional approval are not subject to any effective method of appeal.

# **MIDDLE EAST / AFRICA**

## EGYPT

Despite progress at the end of 2016, PhRMA and its member companies remain 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. Conditions prevailing in the regulatory and IP areas today make it increasingly difficult for PhRMA member companies to operate, though there are encouraging signs that the government may be willing to implement key reforms.

During the past several very challenging years, PhRMA and its member companies have tried to work in good faith with Egyptian officials to address health and industrial issues. 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 announcement at the end of 2016 that the country would implement a new medicines licensing system that is expected to significantly reduce review times by 90%. If implemented fully, this new system could accelerate patient access to promising new medicines.

PhRMA also notes the Health Ministry's pledge to adjust prices of medicines following many years of rigid control and a precipitous decline in the value of the Egyptian Pound following the conversion to a freely floating currency. Those policies had induced widely-reported shortages of medicines that were no longer economic to produce. PhRMA's member companies welcome the recent announcement that prices for a portion of their portfolios will be adjusted to reflect the current exchange rate, and looks forward to working with the government on revising Egypt's pricing system to more systematically address such currency fluctuations.

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

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

For these reasons, PhRMA requests that Egypt remain on the **Watch List** for the 2017 Special 301 Report, and that the U.S. Government continue to seek assurances that the problems described herein are quickly and effectively resolved.

## **Intellectual Property Protection**

### Weak Patent Enforcement

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

Some officials have opposed putting in place an effective patent enforcement system similar to the process used by the United States or, 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.

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.

## **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 to 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.

In addition, the Minister of Health recently announced that as of January, 2017, Egypt will provide an expedited 30-day registration process for products approved by the U.S. Food and Drug Administration and the European Medicines Agency, or a 60-day registration process if approved by one of the two entities. The announcement follows the publication of a similar process in Saudi Arabia.

PhRMA believes that this new policy could constitute a major step forward for Egypt. Guidelines for implementation, however, have not been communicated at this time.