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November 26, 2018

SUBMITTED ELECTRONICALLY

Mr. Edward Gresser
Chair of the Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, N.W.
Washington, DC 20508

PUBLIC DOCUMENT
USTR-2018-0034

Re: Request for Comments on Negotiating Objectives for a U.S.-Japan Trade Agreement, 83 Fed. Reg. 54,164 (October 26, 2018)

Dear Mr. Gresser:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the notice of public hearing and request for comments on negotiating objectives for a U.S.-Japan Trade Agreement, 83 Fed. Reg. 54,164 (October 26, 2018). We also provide notice of our intent to testify at the hearing scheduled for December 10, 2018, and attach hereto a summary of the planned testimony.

PhRMA member companies are devoted to inventing, manufacturing, and distributing valuable medicines that enable people to live longer, healthier, and more productive lives. The U.S. biopharmaceutical industry is the world leader in medical research – producing more than half the world's new molecules in the last decade. As a key component of America's high-tech economy, the research-based biopharmaceutical sector supports nearly 4.7 million jobs across the economy, including more than 800,000 direct jobs, and contributes nearly $1.3 trillion in economic output on an annual basis when direct, indirect, and induced effects are considered.[1] Our sector also continues to be one of the most research-intensive in America, annually investing an estimated $90 billion in researching and developing new medicines.[2] Innovators in this critical sector depend on strong regulatory systems, robust intellectual property (IP) protections and enforcement, and fair and transparent access to overseas markets through the operation of competitive markets or by adopting or maintaining procedures that appropriately recognize the value of innovative medicines. With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new medicines to patients and contribute powerfully to the American economy.

In 2017, the biopharmaceutical industry exported more than $55.8 billion in biopharmaceuticals, making the sector one of the top U.S. exporters among IP-intensive industries. Japan is a critical destination for

[1] TEConomy Partners; for PhRMA. The Economic Impact of the U.S. Biopharmaceutical Industry. Columbus, OH: TEConomy Partners; July 2017.

[2] Research!America, U.S. Investments in Medical and Health Research and Development, 2013-2016, Arlington, VA, Fall 2017, available at https://www.researchamerica.org/sites/default/files/RA-2017_InvestmentReport.pdf (last visited Nov. 26, 2018).

U.S. biopharmaceutical exports, representing the fourth largest export market for pharmaceuticals in 2017 (with exports to Japan valued at just under $4 billion).[3] Moreover, the U.S. biopharmaceutical industry enjoys a surplus with Japan (more than $1.4 billion in 2017),[4] and a strong trade agreement with Japan that eliminates Japanese barriers to trade would foster even greater exports to this important market.

U.S. biopharmaceutical manufacturers rely on predictable and transparent IP and pricing and reimbursement policies that support innovation ecosystems to produce valuable new medicines for patients. These policies are fundamental to innovation, providing necessary incentives for the discovery of new treatments and cures, and also fundamental to sustaining continued economic growth and job creation in America. The recently concluded U.S.-Mexico-Canada Agreement (USMCA) provides a very strong base from which to negotiate a trade agreement with Japan. Addressing Japan's trade impediments (discussed further below and in PhRMA's recent comments on the National Trade Estimate Report) – including through the establishment of rules to ensure that Japan appropriately values and protects innovation, provides greater transparency in pricing and reimbursement (P&R) decisions and seeks to optimize its regulatory processes – would facilitate greater access for U.S. biopharmaceutical exports in this important market.

Consistent with the Joint Statement by the United States and Japan issued on September 26, 2018, we strongly encourage the U.S. Government to consider the impediments faced by the U.S. innovative pharmaceutical industry as it identifies areas in which it could secure "early achievements" as part of these trade negotiations. Further, we believe that the Japanese government should "refrain from taking measures", including in relation to major revisions to Japan's P&R system that would have a serious impact on U.S. companies' ability to access the market (including the proposals to move to annual repricing and to implement a Health Technology Assessment (HTA) system), that would be against the mutual trust and the spirit within which these trade negotiations have been entered.

I. Implement and Enforce Existing International Obligations

The initiation of trade negotiations with Japan provides a critical opportunity for the United States to resolve a number of outstanding issues that stem from the failure by Japan to implement or enforce existing commitments. Effectively addressing these Japanese practices would spur U.S. innovation and move us closer to a level-playing field for U.S. companies. At a minimum, the U.S. Government should work with Japan to:

- **Enforce Commitment to List Drugs within 60 days, and Not Later Than 90 days, After Regulatory Approval**: As part of the bilateral U.S.-Japan "Market-Oriented Sector Specific" (MOSS) talks in 1986, Japan made the following commitment: "New drugs will be regularly listed four times a year in accordance with the timing of manufacturing or import approval for the purpose of their faster introduction into the drug tariff after their approvals. They will be listed as soon as possible after their approvals, within 60 days in principle, and not later than 90 days." This commitment has proved very important in terms of ensuring prompt market access for U.S. biopharmaceutical innovators, and yet is under threat to be unilaterally abrogated by some of the proposed pricing reforms.

[3] See PhRMA analysis of data from U.S. Department of Commerce, International Trade Administration (ITA), http://tse.export.gov/tse/tsehome.aspx (accessed Nov. 14, 2018).

[4] Id.

- **Eliminate Discriminatory Revisions to the Price Maintenance Premium (PMP) System**: Japan's new drug pricing package announced last December contains several new pricing policies that define innovation in a unique and non-science-based way and run counter to the government's pledge to fuel innovation in Japan and efforts to appropriately value innovation. In particular, PhRMA member companies are concerned that the number of innovative products to qualify for the PMP has been reduced dramatically and fewer companies qualify for the full benefit of the PMP under the new company requirements for the PMP. According to the Ministry of Health, Labor and Welfare, the number of products eligible for the PMP was reduced by approximately 40 percent.[5] This move severely undervalues U.S. IP. Specifically, the new PMP product criteria equate "innovativeness" with the speed and order in which pharmaceutical products are launched. This is a non-science-based evaluation of innovation that is unique in the world. Under the new criteria, several U.S. global best-selling products have been deemed "non-innovative" and stripped of their PMP eligibility. Further, the PMP company criteria appear to be inherently biased towards domestic companies and seriously call into question Japan's commitment to fair and non-discriminatory policies consistent with its WTO obligations.

II. Promote Adequate and Effective Protection of American Medical Innovation

As the Administration considers objectives for negotiations, ensuring that Japan continues to encourage and value innovation will significantly contribute to greater opportunities for trade and investment and improve U.S. biopharmaceutical competitiveness. Such commitments should appropriately recognize and reward the value of innovative medicines, provide due process, embrace science-based decision-making, reflect international best practices and norms, and uphold 21st century-level IP standards. These commitments are critical features of U.S. law. To this end, the innovative biopharmaceutical industry encourages the U.S. Government to pursue a trade agreement with Japan that meets the following robust negotiating objectives:

- **Build on the Strong IP Standards in the USMCA**: These trade negotiations between the United States and Japan – two of the most innovative countries in the world – offer a unique opportunity to establish ambitious IP provisions to protect and provide effective enforcement mechanisms for inventions from each country. The recently concluded negotiations with Canada and Mexico resulted in an agreement that includes high-standard IP protections that, if included and enhanced in a U.S.-Japan trade agreement, would address several of the deficiencies in Japan's IP regime, including the lack of formal early and effective resolution mechanisms for patent disputes, the need to provide patent term adjustments in the event of patent office delays and the extension of the grace period in Japan from 6 to 12 months.

  In addition, the negotiations with Japan offer an opportunity to ensure Japan protects regulatory test data against reliance and disclosure for a sufficient period of time. Regarding biologics, for example, Japan's system of post-marketing surveillance currently has the effect of providing protection that is similar to 8 years of regulatory data protection (RDP). RDP complements patents on innovative medicines and provides critical incentives for investment in new treatments and cures. RDP is particularly critical for biologic medicines, which may not be adequately protected by patents alone. Because they are often made through the use of living organisms, biologics are so complex that it is possible for follow-on manufacturers to produce a

[5] Ministry of Health, Labor and Welfare, Official Notification, Mar. 5, 2018.

version, “biosimilar,” of the original biologic that may not be covered within the scope of the innovator’s patent. For this reason and others, U.S. law provides 12 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. Consistent with U.S. law and the negotiating objectives prescribed by the Bipartisan Congressional Trade Priorities Act of 2015 (TPA), the proposed trade agreement should require Japan to implement a RDP system that provides at least 12 years of RDP for biologics.

- **Ensure That P&R Decisions Appropriately Recognize and Reward the Value of Medicines**: Policies imposed by trading partners that artificially lower the prices of medicines hamper investment in research and development and delay or reduce the availability of new medicines for patients. In order to address these concerns, government pricing and reimbursement policies should appropriately recognize the value of innovative pharmaceuticals, for example, by making determinations through competitive market-based mechanisms. As such, the negotiations with Japan provide an opportunity, consistent with TPA, “to ensure that government regulatory reimbursement regimes [in Japan] are transparent, provide procedural fairness, are non- discriminatory, and provide full market access for United States products.”

  In addition to addressing the discriminatory elements of the revised PMP program (noted above), it will be important to ensure that should the Japanese government move to adopt a new HTA system, that it incentivize continued innovation and timely patient access to new treatments. To achieve this, the system should be applied in a supplemental manner to validate the price premium granted at launch through a balanced assessment of factors that recognize the full value of innovative medicines. The current HTA pilot program runs counter to these principles and uses methods and processes that are out-of-step with international best practices.

- **Ensure That the Development and Application of Procedures and Rules That Apply to Pharmaceutical P&R Decisions are Predictable and Transparent**: The intensive investment in the development of innovative medicines requires a favorable business environment and a predictable and transparent public policy environment that fosters medical advancements. This includes creating efficient and transparent processes for bringing new medicines to market, such as publishing rules related to P&R decisions in advance of adoption and allowing ample time for stakeholders to provide comments, making decisions in a timely fashion, and allowing stakeholders meaningful opportunity to participate in the development of rules and regulations in the pharmaceutical sector. A favorable business environment also requires that rules and procedures once developed are applied fairly and transparently.

  The need for greater transparency and due process in Japan related to the development of government P&R rules and procedures is exemplified by the recent drug pricing reform initiatives in 2017. During the development of these reforms, there were few formal attempts by the decision-making bodies to seek input from stakeholders, including the innovative pharmaceutical industry and several aspects of the reforms have never been captured in writing. For example, details on the topics for discussion at meetings of the Chuikyo were not shared in advance and industry representatives generally were able to attend Chuikyo meetings only as observers. Discussions this year on a possible move to annual price revisions, starting

with an ad hoc price cut to be implemented in 2019 in conjunction with the planned consumption tax increase and implementation of a new HTA system, continue to be conducted largely behind closed doors. To date, there have been very limited opportunities for industry to publicly comment on any aspect of the reform program. Any agreement with Japan should ensure that PhRMA's member companies have regular and meaningful opportunities to provide input regarding the development of further reforms to Japan's government P&R system.

Further, when P&R decisions are made, the results can lack predictability and transparency. For example, under the new PMP system's "company criteria," companies with products eligible to receive the PMP were ranked and sorted into three tiers. The number of companies eligible for Tier 1 status was limited to "25% but not exceeding 30%, even if there are many companies with the same score." However, the way this new system is being enacted remains non-transparent. For example, while MHLW announced the criteria being used to sort companies into the three tiers, it did not provide any explanation as to the weighting of these criteria or how companies would be sorted in the case where companies' scores were tied. Further, MHLW has not published a list of which companies were placed in which tiers.

- **Ensure Transparency and Application of International Standards in the Drug Approval Process**: A strong regulatory framework not only ensures patients have fast access to safe, high-quality, and effective medicines, but also encourages scientific research and innovative drug development. Technical regulations, standards, and conformity assessment procedures, including marketing authorization and notification procedures, should seek to adopt harmonized regulatory best practices and international, science-based regulatory standards. Thus, as the Japanese Government continues to seek to accelerate and expand drug development in Japan and ensure that patients have prompt access to the newest drugs, further flexible approaches are needed in the approval and regulatory process to promote simultaneous global development. This includes reviewing the required sample size for multi-regional clinical trials and long-term clinical studies, increasing the number of drugs designated and approved under the Sakigake designation, and developing conditional early approval systems that are equivalent to those in the United States.

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

As trade negotiations with Japan progress, PhRMA and its members stand ready to provide additional information related to the trade barriers that the industry faces in this important trading partner.

Sincerely,

/s/

Jay T. Taylor