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SUBMITTED ELECTRONICALLY

Mr. William Shpiece
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-2022-0002

Re: Request for Comments on the Proposed Fair and Resilient Trade Pillar of an Indo-Pacific Economic Framework, 87 Fed. Reg. 13789 (March 10, 2022)

Dear Mr. Shpiece:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates this opportunity to provide the following comments in response to the request for comments. As a general matter, PhRMA and its members welcome the proposed development of an Indo-Pacific Economic Framework (IPEF) to deepen trade relations between the United States and countries throughout this region.

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 over 4.4 million jobs across the economy, including more than 900,000 direct jobs, and contributes more than $1.4 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 and export-intensive in America, annually investing an estimated $122.2 billion in researching and developing new medicines.[2] With the right policies and incentives in place at home and abroad, our member companies can continue to bring valuable new medicines to patients around the world. In 2021, U.S. biopharmaceutical goods exports exceeded $80 billion.[3] The biopharmaceutical sector was the largest exporter of goods among the most R&D-intensive industries in 2020 – which in

[1] TEConomy Partners for PhRMA, The Economic Impact of the U.S. Biopharmaceutical Industry: 2020 National and State Estimates, Mar. 2022.

[2] Research!America, U.S. Investments in Medical and Health Research and Development, Jan. 2022.

[3] TradeStats Express™: National Trade Data for NAICS Code 3254 Pharmaceuticals and Medicines, available at http://tse.export.gov/TSE/TSEHome.aspx.

addition to biopharmaceuticals included navigational equipment, semiconductors and other electronic components, medical equipment and supplies and communications equipment.[4]

The proposed IPEF has the potential to deepen economic and diplomatic ties between the United States and countries in this important region and serve as a catalyst for increased trade and engagement with other countries. Increased trade and investment links between the United States and the Indo-Pacific region would provide critical incentives for American innovators to research and develop new products and to make those inventions available to patients around the world.

U.S. biopharmaceutical manufacturers and their employees rely on predictable and transparent regulatory, intellectual property (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 to sustaining continued economic growth and job creation in the United States.

With regard to some of the more specific negotiating objectives identified by the USTR in its Federal Register notice, please find below our initial perspectives on three topics: (1) general negotiating objectives for the proposed agreement; (2) digital economy-related matters; (3) transparency and good regulatory practices; (4) customs and trade facilitation issues; and (5) other measures or practices which undermine fair market opportunities for U.S. workers.

I. General Negotiating Objectives for the Proposed Agreements

PhRMA supports comprehensive trade agreements that open new markets, create high-paying American jobs, increase economic growth for both the United States and its trading partners, incentivize the invention and production of lifesaving medicines, and enable U.S. biopharmaceutical innovators to export those medicines to patients around the world.

PhRMA therefore encourages USTR to negotiate an IPEF agreement that is as comprehensive and ambitious as possible and that includes strong IP protections and predictable and transparent market access, regulatory and other provisions that dismantle unfair trade barriers, incentivize innovation and facilitate the manufacturing and distribution of lifesaving medicines and other IP-intensive products.

As the United States seeks to expand its trade agenda throughout the Indo-Pacific, USTR first must ensure that countries in that region are honoring existing international commitments and that longstanding trade barriers in those countries – including barriers identified by USTR in its Special 301 and National Trade Estimate Reports – are prioritized for elimination. Resolving these and similar trade issues should constitute a foundation for the IPEF. To this end, as potential partners under IPEF are announced, PhRMA would appreciate the opportunity to identify specific measures or practices that should be resolved in those countries before IPEF negotiations initiate.

[4] Analysis of National Science Foundation and Business Research and Development Survey (BRDIS) data by ndp | analytics.

II. Digital Economy

Issues concerning the digital economy play a critical role in biopharmaceutical innovation. Digital trade, data, data usage and international data flows are essential components of biopharmaceutical research, development, manufacturing and delivery. For example, digital health technology tools, such as mobile devices, wearables and sensors, enable decentralized clinical trials that can offer flexibility in how data are collected from clinical trial participants, allow sponsors to design more patient-centric drug development studies, improve research efficiency, reduce barriers to trial participation and support more diversity in clinical trials. These components also enable digital therapeutics and patient adherence technologies. In particular, a vibrant digital economy and open digital trade are essential to the following key stages of biopharmaceutical innovation:

- **Research and development (R&D)**: Digital trade enables biopharmaceutical manufacturers to access large, multi-country health data sets and genomic data to make timely, rapid and informed R&D decisions; optimize clinical trial design and enrollment and conduct multiregional clinical trials; and secure regulatory approvals in multiple countries.

- **Manufacturing**: Digital trade facilitates the manufacturing of finished biopharmaceuticals, including compliance across borders with good manufacturing practices (GMP) and other regulatory requirements.

- **Delivery**: Digital trade promotes the development and use of innovative cross-border payments systems, digital therapeutics operations and patient adherence technologies.

- **Pharmacovigilance**: Digital trade is essential to monitoring, identifying and responding across borders to any health-related impacts from biopharmaceuticals.

Sound public policies that encourage open digital trade practices related to the above stages of biopharmaceutical innovation increase digitally enabled trade in life-enhancing biopharmaceuticals and improve global public health. Conversely, government measures that discourage or restrict digital trade adversely impact biopharmaceutical innovation and, as a result, impede domestic and global advancements in patient care and economic growth.

The innovative biopharmaceutical industry therefore encourages the United States and its IPEF partners to negotiate a high-standard agreement that eliminates digital trade barriers that discourage innovative biopharmaceutical R&D, manufacturing, delivery and pharmacovigilance. **Specific policy recommendations to eliminate digital trade barriers include the following:**

- **Prohibit unnecessary data localization requirements and other restrictions on cross-border data flows**. Barriers to the cross-border movement of data and digital health services and products often take the form of provisions that (i) directly or indirectly prohibit a company from exporting any or certain types of data beyond a country's geographic border; (ii) require a company to store within a national territory data that the company stores or intends to store abroad, resulting in duplicative practices and

significant resource diversions; and/or (iii) other conditional restrictions that prohibit or impede a company's ability to transfer data beyond a geographic border (e.g., sending data to a regional data center for storage or to a third-party vendor for processing). Restrictions, if any, on data flows should be transparent, implemented clearly, developed based on input from all stakeholders, and only as restrictive as necessary.

- **Prohibit forced technology transfers**. The practice of requiring foreign companies to share sensitive technologies or proprietary data with domestic companies as a condition of doing business in a local market is a considerable barrier to trade that can have a significant negative impact on companies engaged in digital commerce. Any transfer of technology related to biopharmaceutical research, development, manufacturing or delivery should be voluntary and occur on market-based terms. Requirements to disclose source code, algorithms, trade secrets or other intellectual property assets to a government or local entity should be prohibited.

- **Prohibit and, where necessary, eliminate digital tariffs**. As the global digital economy flourishes, many governments are assessing how to impose customs duties on electronic transmissions. Given the increasing digitalization of the biopharmaceutical industry, such duties could significantly impede trade of digitally enabled products such as digital therapeutics and 3D printing. IPEF partners should reaffirm the World Trade Organization moratorium on customs duties on electronic transmissions and commit to seek to build on that moratorium in bilateral and global fora.

- **Establish appropriate legal and governance frameworks** to address access to and exchange of health data regarding health care research, delivery, policymaking and regulatory activities.

III. Transparency and Good Regulatory Practices

PhRMA strongly supports efforts to foster global best practices related to assessing the safety and efficacy of new medicines, including developing new pathways for approval of medicines, increasing capacity within regulatory agencies and eliminating unnecessary regulatory barriers. IPEF should seek to build on existing global and regional initiatives, such as those under the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use or through the Association of Southeast Asian countries (ASEAN), to harmonize regulatory standards to ensure that regulatory approval processes do not impede effective and efficient global drug development, review and evaluation. Addressing these important issues can help to optimize deployment of limited regulatory agency resources and expedite patient access to innovative and lifesaving or life-enhancing medicines.

Foreign governments, including several in the Indo-Pacific region, often impose burdensome and nontransparent regulations on the biopharmaceutical sector and employ price controls and reimbursement policies that discriminate against American products. Such practices and policies are unique to the biopharmaceutical industry, given the dominant position of such foreign governments as the sole or primary purchasers of health care. As a result, market access for innovative medicines depends not only on U.S. innovators meeting strict regulatory approval

standards and obtaining necessary IP protections, but also on obtaining positive government pricing and reimbursement determinations. Some countries in the Indo-Pacific region have resorted to using national compulsory licensing provisions improperly or threatening disclosure of confidential commercial information to coerce American manufacturers to accept pricing agreements on unreasonable commercial terms and conditions. Regulatory procedures and decisions regarding the approval and reimbursement of medicines therefore must be governed by fair, transparent and verifiable rules guided by science-based decision making. There should be meaningful opportunities for input from manufacturers and other stakeholders to health authorities and other regulatory agencies and a right to appeal government pricing and reimbursement decisions to an independent and objective court or administrative body.

PhRMA members appreciate steps that 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 to ensure that pricing and reimbursement policies abroad are fair, reasonable and non-discriminatory, and appropriately value patented biopharmaceuticals. PhRMA urges USTR and other federal agencies to continue to promote the full implementation of these commitments as part of the IPEF.

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

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

Specific regulatory determinations or pricing and reimbursement decisions should be:

- Based on fair, reasonable, consistent and non-discriminatory procedures, rules and criteria that are fully disclosed to applicants.
- Completed within a reasonable and specified timeframe. In some countries, deadlines for making decisions on whether to approve new medicines do not exist. In other countries, such deadlines exist but regularly are not met. These delays impede market access, deplete important patent terms and negatively impact patients waiting for life-saving medicines.
- Conducted in a manner that affords applicants timely and meaningful opportunities to provide comments at relevant points in decision-making processes.
- Supported by written reports which explain the rationale for the decision and include citations to any expert opinions or academic studies relied upon in making the determination.
- Subject to an independent review process.

Implementation of these bedrock principles would preserve the individual autonomy of each country to regulate the approval and reimbursement of new medicines, but establish fair and transparent procedures that provide the business certainty needed for U.S. biopharmaceutical companies to invest in innovative R&D and export American products to countries throughout the Indo-Pacific region.

IV. Customs and Trade Facilitation

To help to ensure that lifesaving and life-enhancing biopharmaceuticals efficiently reach patients across borders, USTR and its IPEF partners should take actions to ensure that trade in pharmaceuticals can occur without unnecessary obstacles, including inessential customs procedures, non-modernized entry requirements and unproductive use of time or resources.

Specific policy recommendations to facilitate trade include the following:

- **Permanently eliminate tariffs**. The imposition of tariffs on pharmaceutical products and the various inputs used to invent, manufacture and deploy those products negatively impacts the ability of patients across the globe to access lifesaving medicines. Tariffs impose a direct cost on trade in pharmaceuticals and their inputs and, in so doing, reduce patients' access to treatments and cures, including in countries throughout the Indo-Pacific region. Resources directed to tariff payments instead could be channeled into other elements of the health sector, including the research, development, clinical and manufacturing processes necessary to produce both new and existing treatments. The innovative biopharmaceutical industry therefore urges USTR and its IPEF partners to pursue tariff elimination on health products, including finished therapeutics, diagnostics and vaccines, as well as the active pharmaceutical ingredients, raw materials, chemicals, other inputs and intermediaries, and specialty equipment used to invent, manufacture and deploy these products.

- **Eliminate existing, and commit to refrain from imposing future, export restrictions**. Export restrictions impede patient access to pharmaceutical products, including immediate access to lifesaving medicines and vaccines. By imposing barriers on companies and other actors that are coordinating complex global pharmaceutical supply chains, such restrictions severely disrupt international collaborative efforts to invent, manufacture and deploy pharmaceutical products across borders. The innovative biopharmaceutical industry therefore urges USTR, as part of the IPEF negotiations, to ensure that all parties to the agreement review and promptly eliminate export restrictions on health products and commit to refrain from imposing new restrictions, in accordance with World Trade Organization (WTO) rules.

- **Improve customs practices and related trade facilitation policies**. Pharmaceutical products, when traded, are subject to both general customs procedures and additional monitoring and control requirements designed to ensure product safety and efficacy. However, overly complex and inefficient border procedures can cause unnecessary costs, delays and even loss of product. Streamlined and digitized customs procedures reduce these risks, helping to strengthen global supply chains and ensure that medicines,

vaccines and other pharmaceutical products reach patients without disruption or delay. To ensure that customs and other border procedures facilitate trade in pharmaceuticals and do not unnecessarily impede patient access to medicines, the innovative biopharmaceutical industry urges USTR to ensure that parties to the IPEF improve trade facilitation measures for pharmaceutical products through a variety of actions. These include sharing best practices, enhancing customs clearance procedures, developing and publishing national trade facilitation plans, and prioritizing full and immediate implementation of and building on the WTO Trade Facilitation Agreement.

V. Other Measures or Practices which Undermine Fair Market Opportunities for U.S. Workers

U.S. biopharmaceutical workers face a variety of trade barriers in multiple Indo-Pacific countries that significantly impede the invention, manufacturing and distribution in those countries of medicines. To address these issues, and to ensure that IPEF meets its long-term potential, PhRMA encourages the establishment of a Medicines Working Group (MWG) that commits IPEF governments to regular, frequent and sustained engagement on issues of importance to biopharmaceutical research, innovation and distribution – including implementation of IPEF commitments. The MWG should include both regular dialogues among IPEF governments, as well as regular dialogues among IPEF governments, industry and other stakeholders. Through such engagement, IPEF partners could strengthen biopharmaceutical trade initiatives and deepen biopharmaceutical regulatory cooperation, thereby advancing economic growth, spurring further biopharmaceutical innovation and improving global health outcomes.

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In summary, PhRMA and its members strongly support the promise of ambitious IPEF negotiations to address meaningful global economic challenges. We thank you for the opportunity to provide these comments and look forward to being an active stakeholder throughout the negotiations.

Sincerely,

/s/

Douglas Petersen
Deputy Vice President, International Advocacy