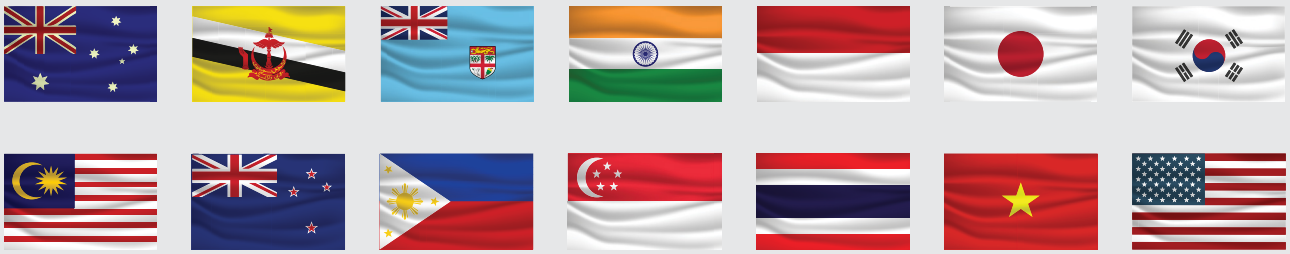
DRIVING MEDICAL INNOVATION AND PATIENT ACCESS THROUGH THE INDO-PACIFIC ECONOMIC FRAMEWORK

In December 2022, the United States launched negotiations for the Indo-Pacific Economic Framework for Prosperity (IPEF) with Australia, Brunei, Fiji, India, Indonesia, Japan, Korea, Malaysia, New Zealand, the Philippines, Singapore, Thailand and Vietnam. The IPEF aims to deepen economic relations in the region and foster collaboration on global economic challenges.

Indo-Pacific Economic Framework Countries



As IPEF countries pursue an agreement, PhRMA encourages them to be comprehensive and ambitious. IPEF should include strong intellectual property protections and predictable and transparent market access, regulatory and other provisions that advance scientific research, incentivize invention and production of medicines, dismantle unfair trade barriers, strengthen supply chains and improve the ability of U.S. biopharmaceutical manufacturers to export medicines.

U.S. companies and their employees rely on such policies to produce important new medicines for patients throughout the United States, the Indo-Pacific region and the rest of the world. By promoting a more innovative global environment and encouraging Indo-Pacific trading partners to adopt stronger standards, the United States can expand exports and access to new medicines, create high-paying American jobs and increase economic growth in the United States and the Indo-Pacific. Due to trade barriers that IPEF can address, patients in major Indo-Pacific markets can access only a small portion of the new medicines launched globally since 2012 (compared to 85% in the United States) and often wait years for medicines that become available (compared to 4 months in the United States).

Biopharmaceutical Trade and Access in IPEF's Largest Economies

Country	U.S. Biopharmaceutical Exports (2021), USD	New Medicines Availability	Months from First Global Launch to Country Launch	Months from First Global Launch to Public Reimbursement
Australia	$1,669,462,520	34%	21.9	29.8
India	$750,460,303	17%	22.1	22.1
Indonesia	$410,877,407	9%	22.0	32.6
Japan	$5,261,934,001	51%	15.3	16.3
Korea	$1,885,636,550	33%	28.1	36.1

Sources: U.S. Census Bureau International Trade Dataset; PhRMA analysis of IQVIA MIDAS and country regulatory data. October 2022.

As detailed in comments to the U.S. Trade Representative and the U.S. Department of Commerce, PhRMA encourages the U.S. administration to pursue a comprehensive and ambitious IPEF agreement that prioritizes intellectual property and other pro-innovation policies. Unfortunately, and despite regional partners' strong appetite for robust U.S. trade engagement, the U.S. administration intends to pursue a narrow IPEF agreement that excludes many of these critical components. At a minimum, the IPEF should include the following:

- **Transparency in policymaking and good regulatory practices** | Several governments in the Indo-Pacific region impose burdensome and nontransparent regulations on the biopharmaceutical sector and employ pricing and reimbursement policies that disadvantage innovative American medicines. IPEF should ensure that stakeholders are afforded meaningful opportunities to provide input to regulators and that regulatory procedures and decisions, including with respect to the approval and reimbursement of medicines, are governed by fair, transparent and verifiable rules guided by science-based decision making. IPEF should address these issues by building on similar commitments in U.S. trade agreements with Canada, Korea and Mexico.
- **Creation of medicines working groups** | Given the complexity of issues and the variety of trade barriers that can significantly impede the development, manufacturing and distribution of innovative medicines, PhRMA encourages the establishment of Medicines Working Groups that commit IPEF participants to regular, frequent and sustained engagement on issues of importance to biopharmaceutical innovation and access, including implementation of IPEF commitments.
- **Open digital trade practices** | Digital trade, data, data usage and international data flows are essential components of biopharmaceutical research and development (R&D), manufacturing, delivery and pharmacovigilance. PhRMA encourages the U.S. and its IPEF partners to prohibit forced technology transfers, customs duties on electronic transmissions, restrictions on cross-border data flows and unnecessary data localization requirements.
- **Improved customs and trade facilitation policies** | The U.S. and its IPEF partners should take actions to ensure that trade in biopharmaceuticals can occur without unnecessary obstacles, including by eliminating tariffs, prohibiting export restrictions and improving customs practices and related trade facilitation policies.
- **Supply chain resilience** | Diverse global supply chains are key to ensuring continuity, safety and resilience in the supply of medicines to patients in the U.S. and worldwide. The U.S. and its IPEF partners should bolster biopharmaceutical supply chain policies to prepare for future global health challenges and strengthen trade and investment by leveraging regional manufacturing infrastructure to expand R&D and production capacity, facilitating free movement of pharmaceuticals, inputs and personnel, and strengthening cybersecurity capabilities and infrastructure to address threats.

IPEF has the potential to deepen the United States' economic relationships with countries throughout the region and address meaningful global economic challenges. By adopting stronger pro-innovation policies and eliminating trade barriers, policymakers can drive more global collaboration on biopharmaceutical R&D to deliver new and existing medicines to patients throughout the world.