U.S. Chamber of Commerce

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Jennifer Thornton
General Counsel
Office of the United States Trade Representative
Executive Office of the President
600 17th Street NW
Washington, D.C. 20509

**RE: Request for Comments Regarding "Foreign Nations Freeloading on American-Financed Innovation," Federal Register Docket Number USTR-2025-0011**

Dear Ms. Thornton:

The U.S. Chamber of Commerce (the "Chamber") appreciates the opportunity to submit these comments in response to the Federal Register Notice (FRN) on the Most-Favored-Nation (MFN) drug pricing model. The Chamber is the world's largest business organization and network, with members ranging from small businesses and chambers of commerce across the country to startups in fast-growing industries, leading industry associations, and global corporations and is deeply invested in the health and well-being of the American economy and its citizens. We advocate for policies that sustain American leadership and investment in innovation, quality manufacturing, and sustained economic growth.

The FRN notes "Pursuant to the Executive Order titled *Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients,* USTR invites comments from interested parties regarding any act, policy, or practice that may be unreasonable or discriminatory and that has the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries."

The Chamber has long championed policies that allow U.S. pharmaceutical companies to receive fair value for their products. We strongly oppose, therefore, the imposition of price controls—domestically or abroad—through MFN pricing or other schemes. When a country imports foreign price controls, it also imports the negative consequences, including reduced month to cutting-edge treatments, reduced investments in research into new life-saving drugs, and endangering high-paying American jobs. Rather than replicate policies that limit innovation, the U.S. must focus on better protecting American innovation overseas, including through strong

intellectual property (IP) protection, such as regulatory data protection, patent linkage, and patent term restoration, as well as respect for the free market. Securing fair, equitable, and transparent market access commitments could boost U.S. exports and economic competitiveness, which could in turn provide more resources to deepen U.S. investment in R&D and expand access, choice, and competition.

As detailed below, the Chamber's submission seeks to highlight both the unintended consequences of domestic price controls and opportunities for the administration to address trade barriers that undervalue American innovation.

## I. Policy Concerns with Price Controls

### A. Reduced Access to Cutting-Edge Treatments

The implementation of the MFN model will disrupt patient access to the newest innovative medicines, which are overwhelmingly developed by American companies. For example, between 2001 and 2010, firms in the United States accounted for 57% of new medicines approved globally, while Germany and the UK accounted for only 6% and 8%, respectively. American patients deserve to benefit from American-made innovation, and it is critical the administration reject MFN pricing to achieve this objective.

Additionally, many of the countries that the United States would use to calculate drug payments based on such a model experience considerable delays in access to medicines. For example, over the past 10 years, while 87% of new medicines are available within four months of first global launch in the United States, only 55% of those medicines are available in Germany, and patients suffer an average 13-month delay in access.[1] In the UK, while 43% of innovative medicines are available through public insurance programs, with an average 26-month delay in access.[2] Similar restrictions to access are seen in France. At worst, the MFN model could lead the U.S. down the path of Korea and Canada, where only 20% and 19% of new medicines are available through public insurance programs, and patients experience average access delays between 40 and 38 months, respectively.[3]

### B. Less Investment in Life-Saving Drugs

[1] PhRMA analysis of IQVIA MIDAS®, Global Data, NAVLIN and country regulatory authority data for new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023.

[2] Id.

[3] Id.

The MFN model would implement harmful price controls that could undermine innovative companies' investment in the next generation of treatments and cures, including via inhibiting clinical trials. America's leadership in biopharmaceutical innovation is rooted in its system of market-based pricing for medicines and long-standing respect for IP protections. The U.S. free market system and strong IP framework have enabled the private sector to thrive by creating incentives for innovators to invest in the research and development (R&D) of new medicines in the United States.

Data supports the success of the U.S. model, which enables robust industry investment in clinical research. While the United States represents only 4% of the global population, it accounts for 20% of clinical trials. Clinical trials are not only a critical part of the scientific research process, but they provide patients with access to the latest medicines for diseases for which no therapies exist or for which the current standard of care can be strengthened. The expansion of price controls is estimated to reduce the number of innovative clinical trials in the United States by up to 75%.

Foreign countries that have implemented price controls serve as cautionary tales for what could happen to investments in innovation in the United States if the administration moves forward with the MFN policy. For example, in 1990, biopharmaceutical R&D investment in Europe was 45% higher than the United States. Following two decades of stringent government price controls, biopharmaceutical R&D shifted to the United States, with over 16% more invested in the U.S. than in Europe in 2017. As the United States seeks to enhance domestic production of medicines, MFN pricing will discourage investment at home, undermining the administration's broader economic and trade policy objectives.

### C. Jeopardizing American Jobs Sustained by the Biopharmaceutical Industry

The MFN model would jeopardize the biopharmaceutical industry's contributions to the U.S. economy. The U.S. biopharmaceutical industry directly employs more than 1 million hardworking Americans. An additional 3.8 million jobs are indirectly supported by biopharmaceutical industry and worker spending. Jobs in IP-intensive communities—including the biopharmaceutical industry—also pay a premium. On average, IP jobs pay $18,428 above non-IP jobs. MFN pricing would endanger an estimated 700,000 of those jobs and the local communities sustained by these positions.

In addition to supporting job creation, the industry drives economic growth by supporting more than $1.4 trillion in total economic output, accounting for 1.6% of U.S. gross domestic product (GDP). As the administration seeks to craft policies that will support the high-paying, high-skilled jobs of the future, it is critical to reject policies

that jeopardize existing American jobs and economic growth and support policies that spur appropriate workforce investments.

## II. Country-Specific Measures that Undervalue American Innovation

As USTR's National Trade Estimate and Special 301 reports emphasize, many countries have in place non-tariff barriers that limit U.S. exports of goods and services to foreign markets. These policies also prevent American companies from receiving a fair value for their innovation. The Chamber urges the administration to ensure that U.S. owners of IP have a full and fair opportunity to use their IP around the globe, which should be prioritized in negotiations with foreign governments, and utilize any other policy tools to ensure that Americans do not unfairly bear the cost of global pharmaceutical R&D.

The Department of Health and Human Services has announced plans to focus on "the lowest price in an OECD country with a GDP per capita of at least 60% of the U.S. GDP per capita." In light of these plans, Annex A prioritizes concerns in OECD economies whose GDP meets this threshold based on the CIA Factbook Data. Annex B includes country-specific concerns in OECD accession candidates.

The Chamber appreciates the opportunity to share these comments and looks forward to future discussions to ensure our trading partners' policies enable innovators to receive a fair value for their innovation.

Sincerely,

John Murphy
Senior Vice President and Head of International
U.S. Chamber of Commerce

Annex A
Country-Specific Comments

## Australia

Issue: *Delays in Australia's regulatory system for approval and reimbursement of new medicines*

Impact: Australia utilizes a health technology assessment mechanism for all new product listings, which has resulted in lengthy reimbursement times and delayed patient access. On average, it takes 32 months from regulatory approval of a product to reimbursement listing in Australia.[4] Similarly, there is a high rate of rejections with few new products appraised as being cost effective. Compared with other OECD peers, many innovative products are not launched or listed on the pharmaceutical benefits scheme (PBS) and, in effect, never made available to Australian patients. For example, of the 500 new medicines launched between 2014 and 2023, Australian patients only had access to 25% of those medicines through the PBS, while patients in the U.S. had access to 87%.[5] In addition, some existing policies don't allow appropriate value recognition of new innovative medicines, e.g. Lowest Cost Comparator policy and budget-based spending cap.

Recommendation: These issues are being addressed in an ongoing Health Technology Assessment Review (HTA), and we urge the administration to promptly implement the recommendations that meet the shared goals of the review under the Strategic Agreement to accelerate patient access and ensure that Australia is a wave 1 launch country.

Issue: *Patent notification*

Impact: Australia does not have a system to notify medicine patent holders of an application by a competitor for marketing approval of a generic version of the same product. The Therapeutic Goods Administration (TGA) registration process instead proceeds following a simple unverified declaration by the generic company that the patent is no longer valid. The declaration is not provided to the patent owner, and the first opportunity for the innovator to learn of the upcoming generic entry is when the government publishes the generic product's marketing approval on the Australian Register of Therapeutic Goods (ARTG) (i.e. at the same time as the general public

[4] PhRMA analysis of IQVIA MIDAS®, Global Data, NAVLIN and country regulatory authority data for new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023.

[5] Id.

becomes aware). This often leads to the patent holder needing to take emergency injunctive action in court to block the generic's launch and the making of its pricing and reimbursement application ahead of the next PBS listing date which, if listed, will lead to a statutory and irreversible 25% reduction in the reimbursed price. Preliminary injunctions are not automatically granted and carry risk and uncertainty for the innovator. The first instance court decision may take 12-18 months.

Recommendation: A previous legislative proposal would create a patent notification framework under which first follow-on applicants would be required to notify the rightsholder when an application for marketing approval has been submitted to the TGA but before the agency begins its review process. This would provide the patent holder with 12 months to have an orderly resolution of the patent dispute ahead of the approval. The Chamber would support the adoption of this framework, which would bring Australia in line with its obligations under Article 17.10(4) of the Australia-United States Free Trade Agreement. This process stalled through the onset of the COVID-19 pandemic and change of Government.

Issue: *Differential treatment for local vaccine manufactures*

Impact: In October 2024, the Australian government tabled the Financial Framework (Supplementary Powers) Amendment (Health and Aged Care Measures No. 4) Regulations 2024, which activated a range of new and advantageous procurement processes for one local vaccine manufacturer not available to other competitors. This included alternative methods of HTA approval and exemption from standard procurement rules, independent of merits review and transparency of decision making (such as publishing public summary documents). Accordingly, this created an uneven playing field for U.S. companies. Such a measure may also act as a disincentive to local financial investment due to the uncertainty of the application of rules for vaccine funding approval and procurement. This unfavorable treatment of imported goods appears to be in conflict with Australia's international obligations under Article III:4 of the WTO General Agreement on Trade and Tariffs, Articles 5.1.1 and 5.1.12 of the WTO Technical Barriers to Trade Agreement, Articles 4.1, 4.4, 4.6, 10.1 and 15.4 of the WTO Government Procurement Agreement, Articles 2.2, 8.7, 15.2 and 15.3 of the US-Australia Free Trade Agreement.

Recommendation: U.S.-manufactured products should be allowed to compete on an equal basis with Australian produced goods, consistent with the WTO and U.S.-Australia Free Trade Agreement articles cited above.

Issue: *Time-based price reductions on pharmaceuticals*

**Impact:** Australia's Pharmaceutical Benefits Scheme (PBS) mandates price cuts of 5% at five years, 5% at 10 years, and a steep 26.1% (rising to 30% from April 1, 2027) at 15 years if no generic or biosimilar competitor enters the market.

These “anniversary” reductions are applied solely based on the time a product has been listed, disregarding inflation, production costs, and therapeutic value. By devaluing intellectual property and undermining the ability to fund future research, the arbitrary price cut anniversary policy erodes the economic growth of the U.S. pharmaceutical sector and its financial viability to develop future innovative medicines.

While the Department of Health provides indexation to other parts of the health sector, such as hospital services and aged care funding, medicines are notably excluded from these adjustments. For example, on July 1, the annual fee indexation of the Medicare Benefits Schedule (MBS) will go into effect (as outlined on mbsonline.gov.au). This absence of inflation indexation for medicines exacerbates profitability challenges of U.S.-manufactured pharmaceuticals in Australia. Additionally, new medicines are referenced to prices that do not account for inflation adjustments, further complicating cost-effectiveness evaluations and making it difficult for entry into the Australian’s public market.

**Recommendation:** To address the challenges posed by Australia's Pharmaceutical Benefits Scheme (PBS), the Australian government should provide:

- **Inflation Indexation:** Inflation adjustments for pharmaceuticals should be implemented, similar to other sectors like hospital services and aged care funding. This adjustment ensures that price reductions account for rising production costs, maintaining the economic viability of U.S.-manufactured pharmaceuticals.
- **Therapeutic Value Consideration:** Any price adjustments should also consider the therapeutic value and innovation of medicines, rather than being solely time-based. Recognizing the therapeutic benefits and advancements of new treatments will help maintain incentives for developing new and effective medicines.

## Canada

**Issue**: *Pharmaceutical intellectual property and pricing issues*

**Impact**: Given Canada's model of healthcare and health spending, biopharmaceutical rightsholders face challenges in exercising their IP rights due to the growing focus on rigid cost control and minimizing overall biopharmaceutical spending. Over the past several years, Canadian authorities reformed how patented medicines are evaluated and priced through the Patented Medicine Prices Review Board's (PMPRB) evaluation methodology. These reform efforts have focused almost exclusively on cost and expenditure reduction. Using powers vested in the PMPRB, Canada utilizes international price comparisons. It has expanded the size of the basket to include several low-cost countries and removed the United States and Switzerland as comparator economies. The changes to the PMPRB will undermine the goals of Canada's Biomanufacturing and Life Sciences Strategy, which seeks to make Canada a "more attractive destination for leading life sciences firms to establish and grow."

In addition, Canada has not properly implemented the patent term adjustment (PTA) system required under USMCA. The adopted regulations impose limitations that prevent innovators from receiving full compensation for patent office delays, failing to meet Canada's trade obligations. PTA furthermore runs in parallel with patent term restoration (PTR) rather than consecutively meaning that they cannot both be taken into account. Canada's PTR system does not effectively compensate for marketing approval delays, adopting only the minimum term under the Canada-EU Trade Agreement, which also contained inadequate IP protections, while also including an "export" exception that further weakens protections. Restrictive eligibility criteria further limit its effectiveness, diverging from international standards.

**Recommendation**: The Chamber encourages the Canadian government to reconsider changes to the PMPRB that would compromise innovative companies' ability to receive a fair value for their innovation and undermine the goals of Canada's Biomanufacturing and Life Sciences Strategy. Canada should fully implement its IP obligations under USMCA, including the provision for the PTA system. Canada should also provide up to five years of PTR, in line with international norms, thus providing adequate additional patent life to compensate for the time lost during clinical trials and the regulatory approval process. Health Canada should put in place adequate safeguards to limit and control the release of confidential business information (CBI) to ensure the regulations are consistent with Canada's international treaty obligations.

## European Union

**Issue:** General Pharmaceutical Legislation (GPL) and Patent Package

**Impact:** The EU's proposed General Pharmaceutical Legislation (GPL) would weaken intellectual property protections, reducing incentives for U.S. pharmaceutical companies to invest in the European market. The weakening of regulatory data protection (RDP) and reduced market exclusivity would erode legal certainty and impose lower standards. The European Commission's Patent Package further threatens innovation by introducing a pan-EU compulsory licensing mechanism and pre-grant opposition to Supplementary Protection Certificates (SPCs), which, if passed, could reduce exclusivity protections for biopharmaceutical manufacturers. The U.S. exports $36 billion in pharmaceuticals to the EU, and these changes could lead to billions in lost sales and reduced R&D investment, particularly in innovative medicines.

**Recommendation:** The EU should maintain or strengthen its current framework for regulatory data protection to ensure continued investment in pharmaceutical innovation. Market exclusivity provisions should not be contingent on external factors like market access. Defining "unmet medical need" more broadly and introducing stronger incentives for innovative medicines are also important priorities. Any adoption of a pan-EU compulsory licensing mechanism should ensure compliance with the EU's WTO obligations.

**Issue:** *Clawback policies*

**Impact:** Several large EU member states—including Italy and France—impose clawback mechanisms on pharmaceutical and medical device companies, requiring firms to return revenue if healthcare spending exceeds often underfunded healthcare budget limits. These unpredictable financial penalties disproportionately impact U.S. firms, creating uncertainty, undervaluing innovation and discouraging long-term investment. If expanded, these policies could result in essentially a tax of billions of dollars on U.S. life sciences companies, potentially leading to market exits or reduced product availability in the EU.

**Recommendation**: The European Commission should assess whether national clawback mechanisms conflict with EU procurement rules, which are designed to ensure transparency, fairness, and predictability in public purchasing. When clawbacks are applied retroactively, after contracts are awarded, they can distort the actual value of those contracts and undermine the integrity of the procurement process. This is particularly relevant in the context of the MFN policy, as clawbacks reduce the net prices companies receive, making EU list prices an unreliable

benchmark for U.S. pricing policy. Member state governments should balance fiscal policies with the need for medical innovation, ensuring that clawback schemes do not create excessive burdens on industry.

## Japan

**Issue:** *Pharmaceutical and Medical Devices Pricing and Reimbursement Policies that Devalue U.S. Innovation*

**Impact**: Frequent pharmaceutical price revisions, the continued use of off-year adjustments, and other cost-containment measures have created a commercially challenging environment in Japan for U.S. pharmaceutical, medical devices, and medical technology companies. Moreover, the current pricing system in Japan has failed to keep pace with the incredible breakthroughs in science and technology associated with new pharmaceutical and medical technology products.

Most recently, Japan announced in December 2024 its decision to expand the off-year price revision impacting American-made medicines, including innovative, long-listed products (LLPs) as well as generics, effective April 1, 2025. The reduction in biopharmaceutical revenues from these price cuts is estimated to be JPY 247 billion (approximately USD 1.73 billion). Moreover, under the current budget plan, drug price cuts account for 46% of the funds raised to curb the growth of overall social security spending and to support policies outside of healthcare.

The Ministry of Health, Labour and Welfare (MHLW) also plans to consider expanding cost-effectiveness evaluations (Japanese HTA) in the FY2026 system reform and implementing market expansion re-pricing in the FY2027 off-year drug price revision. U.S. industry is deeply concerned that the value of innovative medicines will be reduced further due to the expansion. Furthermore, these latest proposals contradict Japan's efforts to address its drug lag and drug loss and could significantly discourage biopharmaceutical R&D investment and hinder the timely market presence or launch of innovative medicines in Japan, as well as the continued availability of medicines already in the market.

**Recommendations:**

1. The Japanese government should abolish the off-year price revision.
2. The U.S. and Japanese governments should establish a bilateral public-private healthcare dialogue to improve timely and continued access to U.S. innovative and high-quality medical products. This dialogue should include the participation of relevant U.S. agencies and Japanese ministries/entities (e.g., MHLW, Chuikyo, PMDA, Ministry of Finance), as well as companies representing all segments of the pharmaceutical and medical devices/technologies market so they can be consulted to provide data-driven insights into access, supply sustainability, and therapeutic value.

3. Japanese policymakers should restore market-based incentives for continued investment in life sciences and medical technology innovation and reduce the frequency of price revisions to help maintain the commercial viability of the life sciences sector in Japan.
4. The Japanese government should also consider modifying the existing Japanese HTA system, such as extending the analysis period for manufacturers or creating different evidence acceptance criteria.
5. The elimination of the price differential for long-listed products would help ensure U.S. companies' competitiveness and continued presence in the Japanese market.

Issue: *Lack of Transparency and Due Process in Japan's Pricing Decisions*

Impact: The lack of transparency and formal consultation facilitating due process in Japan's reimbursement system for health products, including pharmaceuticals and medical devices, hampers healthcare innovation and creates significant commercial uncertainty. As Japan has introduced substantial changes to pricing rules over the past decade, the decision-making bodies have failed to provide adequate and meaningful opportunities for industry input during the policy development and implementation. In addition, industry has very limited opportunities to testify before the Central Social Insurance Medical Council (Chuikyo). Although it makes key decisions on pricing, the Chuikyo is exempted from Japan's regulatory transparency regulations because it is classified as a government "advisory" committee. Further, some rules are not applied transparently, nor in a manner consistent with their stated purpose, to the detriment of U.S. companies.

Recommendation: Japanese regulators should engage in meaningful, transparent, and inclusive stakeholder consultation, including with the most heavily impacted American companies, on repricing proposals. Early, meaningful engagement would help identify unintended consequences and allow for the joint development of more effective measures to balance the interests of the public and private sectors, while ensuring continued access to medicines and medical devices. Moreover, regular consultation mechanisms between Japanese regulators and industry, such as joint working groups, formal comment periods, or appeal mechanisms would foster trust and improve the transparency of pricing, regulatory, and HTA decision-making processes.

Issue: *Pharmaceutical patent enforcement*

Impact: In 2024, Japan's Ministry of Health, Labour and Welfare (MHLW) set up a research team to consider amending the patent linkage system. They proposed

introducing the Expert Committee (EC) system where experts decide opinions on patent infringement based on opinions submitted by innovative and generic manufacturers. Under the EC system, MHLW would confirm patent infringement in reference to the experts' opinion and approves generic drugs if MHLW confirms that generic drugs do not infringe any patents.

Recommendation: MHLW should not adjudicate legal disputes between innovative and generic manufacturers, including through experts, and should instead leave legal matters to the courts. Any amended patent linkage system should include the following features at a minimum: a patent listing requirement, public disclosure of patent listings, notice of generic marketing applications, a set stay period if litigation is initiated, and market authorization at the end of the stay period or after a final court decision (whichever comes first).

## South Korea

Issue: *Delays in Korea's regulatory system for reimbursement and sub-optimal value recognition of new medicines*

Impact: Korea utilizes a health technology assessment mechanism for all new product listings, which has resulted in lengthy reimbursement times and delayed patient access. Despite efforts to foster the pharmaceutical and biotech industry, rewards for innovative new drugs in Korea remain insufficient. Prices are significantly lower compared to other advanced countries and are often reduced further through post-management systems. Only 20% of the 500 new drugs launched globally between 2014 and 2013 were covered by the National Health Insurance (NHI) in Korea. Additionally, it takes an average of 40 months for innovative new drugs to be reimbursed in Korea following their global launch.[6]

One reason for this is that the Korean ICER is low and outdated. The excessively low ICER threshold discourages the entry of innovative, investment-heavy drugs into the Korean market, potentially limiting patient access to new medicines. As a result, it is challenging for new products to be considered as cost-effective under the current ICER threshold, leading to lengthy review times or rejections. In addition, Korea allocates only 13.5% of its total drugs spending to new drugs, the lowest among the OECE countries. The OECD average spending on new drugs out of total drugs spending is 33.9%.

Recommendation: The Chamber encourages the U.S. government to work with their Korean government counterparts to increase the spending on new drugs out of total drugs spending, shorten the lead time from regulatory approval to reimbursement approval, and update the ICER threshold (~100mil.KRW/QALY) for actual price. We recommend the U.S. government share best practices with Korean officials on ways to improve the process and resolve delays in market entry. Lastly, we urge Korea to create meaningful opportunities for stakeholder input regarding the approval process.

Issue: *Post-Listing Pricing Management*

Impact: The South Korean government has a substantial post-listing price management system that drives down the prices of US pharmaceuticals, including a current consideration to revise its international reference pricing system. Such post-

[6] PhRMA analysis of IQVIA MIDAS®, Global Data, NAVLIN and country regulatory authority data for new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2014, and December 31, 2023.

listing pricing policies threaten the commercial viability of U.S. pharmaceutical in Korea.

Recommendation: The South Korean government should improve the current complex and redundant post-management mechanisms. To streamline the current complex and redundant post-management mechanisms, it is essential to eliminate multiple overlapping price reduction policies. Additionally, halting the implementation of further price cut mechanisms, including international reference pricing re-evaluation, will prevent further complications in the pricing system.

Issue: *Pharmaceutical and medical devices pricing and reimbursement and intellectual property policies*

Impact: South Korea's pharmaceutical and medical device pricing and reimbursement policies continue to undervalue U.S. intellectual property (IP) and innovation and fail to "appropriately recognize the value of the patented pharmaceutical product" in violation of Article 5.2(b) of the U.S.-Korea Free Trade Agreement (KORUS). Korea's pricing and reimbursement scheme for pharmaceuticals is extremely complex and maintains a strict focus on cost-containment measures that remain uncoordinated. More recently, the Ministry of Health and Welfare (MOHW) introduced a new "Measure to Improve Drug Pricing Systems to Reward Innovation and Strengthen Health Security." Despite the title, the criteria for "innovative company" designation effectively excludes foreign companies from the accreditation and incentives afforded with the accreditation. This new measure continues the discriminatory preferences to domestic companies over foreign companies. Altogether, these policies undermine and hinder Korea's goal to become a biotech hub and strategic partner on drug supply chain resiliency, as well as constitute a barrier to American companies' ability to supply health products in the Korean market.

Recommendation: South Korea must implement KORUS FTA commitments and both governments should restart discussions under the Medicines and Medical Devices Committee established under KORUS Article 5.7 on reforms to regulatory and reimbursement systems aimed to appropriately recognize the value of innovative technologies; improve transparency, predictability and due process; sustain a sound science regulatory approach; and overall, incentivize investment in innovation. These discussions must also involve relevant Korean government ministries, including the Ministry of Health and Welfare, to ensure a successful dialogue aimed at achieving concrete outcomes and practical solutions to barriers to innovation.

We welcome the South Korean government's efforts to improve the system and to accurately reflect the value of innovative drugs. Aside from the evaluation criteria of IPC designation, the benefits conferred after being designated as an IPC are quite

limited for multinational companies. To establish and foster a virtuous cycle in the innovation ecosystem, tangible benefits that recognize innovation for IPCs, such as preferential pricing and expedited procedures in the pricing and reimbursement processes, must be made visible.

Issue: *Patent Term Extension*

Impact: On December 27, 2024, the Korean legislature (the National Assembly) passed the Patent Act Amendment Bill. which would require no more than one patent to be eligible for patent term extension. Regarding the scope of the patent during patent term extension period, it is unclear whether the patent term extension granted to the first indication covers future approved indications or not under the Patent Act Amendment Bill whereas there has been a longstanding interpretation that the patent term extension granted to the first indication covers future approved indications in the U.S. and Europe. The uncertainty of the scope of patent term extension under the Patent Act Amendment Bill discourages research and investment for additional indication approvals in Korea. Additionally, if the Patent Office determines a certain duration of PTE that is less than the full amount originally requested by the patentee and the patentee challenges that determination and subsequently loses the challenge, no PTE is granted; even the duration previously determined by the Patent Office is lost. This all-or-nothing approach significantly undermines a patentee's right to appeal, effectively deterring appeals of erroneous calculations, and undermines the patentee's rights.

Recommendation: The Chamber encourages the U.S. government to work with their Korean government counterparts to either stop enacting the Patent Act Amendment Bill, or further amend the bill to align with the U.S. and European practice such that the patent term extension granted to the first and only patent should cover all future indications that will be approved before the expiration of the already-granted patent term extension.

## United Kingdom

**Issue:** *Drug pricing, revenue clawback and commercial environment*

**Impact:** The UK's commercial environment for branded medicines remains challenging, with potentially serious implications for investment in innovative medicines. The UK's Voluntary Scheme for Branded Medicines Pricing and Access (VPAG) imposes price caps on pharmaceutical products, limiting the overall growth of NHS spending on branded medicines. The UK spends just 9% of its healthcare budget on branded medicines, among the lowest in the OECD, compared to over 15% in peer markets. This is not a sustainable foundation for a country seeking to be a global leader in health innovation.

While companies can set prices freely, they are required to pay back a portion of their revenue if total spending exceeds a pre-agreed threshold, making VPAG a clawback mechanism rather than a direct pricing control. Clawback rates spiked to nearly 23% in 2024, three to four times higher than most comparable countries and are projected to remain high. Unlike other systems, VPAG places the entire burden of demand fluctuations, policy changes, and population growth changes on industry. These financial constraints reduce profitability, discourage investment, decrease revenue potential for U.S. drug manufacturers, and delay the introduction of innovative medicines. The UK pharmaceutical market, valued at over $30 billion, sees billions in lost revenue due to restrictive pricing measures. Reduced industry engagement risks limiting patient access to cutting-edge treatments.

The HTA process compounds these barriers. The National Institute for Health and Care Excellence (NICE) continues to apply outdated cost-effectiveness thresholds that have not changed in line with inflation and remain significantly below those used across G20 markets. As a result, the UK routinely undervalues the benefits of innovative treatments, limiting access for patients, and reducing the commercial incentive to bring new products forward. Despite recent updates to NICE methodology, the core challenge remains: the UK is paying less for innovation than other major markets, and that is directly impacting launch decisions.

**Recommendation**: The UK should refine its pricing scheme under VPAG to create a stable and predictable environment for pharmaceutical investment and ensure it reflects internationally competitive norms. This is particularly relevant in the context of the U.S. MFN policy, which proposes benchmarking U.S. drug prices to those in countries like the UK. Because VPAG reduces net revenues through clawbacks, UK list prices do not reflect the true market value of medicines, making them a poor benchmark for U.S. pricing policy. Clawback rates should be materially reduced, and a fairer, risk-sharing mechanism should be introduced. Ensuring that the NHS can

purchase high-quality, innovative medicines while maintaining incentives for drug development will benefit both patients and the broader healthcare ecosystem. In parallel, NICE's approach to valuing new medicines must be modernized. The UK's cost-effectiveness thresholds should be updated to account for inflation and the growing complexity of treatments targeting rare diseases and unmet need.

Annex B
Country-Specific Concerns for OECD-accession candidates

## Argentina

**Issue:** Restrictive patentability criteria

**Impact:** Through Resolutions 118/12, 546/12 and 107/17, the Ministries of Health, Production, and El Instituto Nacional de la Propiedad Industrial (INPI—Institute that manages National IP policy) defined a series of evaluation and patentability criteria for chemical and pharmaceutical inventions. These administrative rules and guidelines exclude most products that constitute a new entity from patent protection, limiting the patentability of inventions in the pharmaceutical industry far beyond the standards of most patent offices in the world. These regulations directly support domestic pharmaceutical companies to identically copy the drugs invented and developed by innovator companies, thereby considerably discouraging innovation by restricting patentability across various groundbreaking pharmaceutical areas.

**Recommendation:** Argentina should work to repeal its restrictive patentability criteria and extend the IPR protections it affords to all types of chemical and pharmaceutical innovations, thereby bringing these protections up to the level of international practices. This reform would improve market access for U.S. innovative pharmaceutical firms.

**Issue:** Live matter patentability

**Impact:** INPI Resolution 283/15 introduced a more restrictive interpretation of Article 6 of the Patent Act that restricts live matter or gene patentability. As a result, the patentability of nucleotides or amino acids is limited compared to other countries such as the U.S. Like the patentability guidelines for synthetic pharmaceutical products, this regulation limits the return on investment in R&D in genetic engineering. Argentina's considerable potential in genetic engineering was drastically reduced by this measure, as innovation in key areas like seeds (similar to the transgenic HB4 wheat developed domestically), animals, and functional foods lags behinds other markets due to the absence of patentability requirements. This is compounded by the fact that Argentina maintains the UPOV 1978 standard, whereby seed patents and breeders' rights cannot coexist.

**Recommendation:** Recognizing the patentability of live matter would allow Argentina to develop groundbreaking inventions in an area in which it has shown considerable comparative advantages already with the development of HB4 wheat. This could be combined with the adoption of UPOV 91 standards to ensure the protection of plant varieties to encourage innovation and level the playing field for U.S. companies.

**Issue:** Low standards for test data protection and exclusivity

**Impact:** Ongoing challenges to the innovative agricultural chemical and pharmaceutical sectors are inadequate protection against unfair commercial use, as well as the unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for products in those sectors. The Argentine IP system permits regulatory approval based on bioequivalence and bioavailability standards, which allows domestic companies to take advantage of—practically at no cost—clinical trial data published by foreign pharmaceutical companies disclosed before the regulatory authorities of other countries. This allows domestic companies to act as free riders and benefit from R&D efforts made by competitors. Compounded with strict patentability standards, the low level of protection of test data considerably discourages investment in clinical trials by foreign pharmaceutical companies in Argentina. Argentina does not protect regulatory test data as required under TRIPS. Existing laws and decrees allow officials to rely on originator-submitted data to approve competitors' products, undermining intellectual property rights.

**Recommendation:** Argentina should provide protection to test data and recognizing its exclusivity, a necessary requirement for innovation in applied chemistry and pharmaceuticals in today's world. This would bring Argentina in line with most other countries that have recognized this increased protection of intellectual property rights and open up the market for U.S. companies to conduct clinical trials.

**Issue:** Patent backlog and extensions

**Impact:** The protection afforded by an Argentine patent lasts for 20 years. However, this term is counted from the filing date as opposed to the moment the patented product receives regulatory approval or is put on the market. The period between the filing date and the moment the patent is approved or rejected usually lasts from 5 to 7 years. Additionally, even if the patent receives approval, the product must receive regulatory authorization by a regulatory authority (ANMAT in Argentina's case) to be marketed. This additional period reduces the effective protection of a patent in most countries from 20 years to 7 to 10 years. In most countries, this is resolved by granting patent holders an additional period after expiration to compensate the delay caused by the approval of the regulatory authority. This is not the case in Argentina where no patent term extensions are given despite the long periods before a patent is approved.

**Recommendation:** Extending the term of patents in a context of considerable delays for patent review would ensure that the intended level of protection granted by patents is effective in practice. Argentina should follow established international practice and consider extending patent terms by up to 5 years where applicable to foster an innovative environment that takes into consideration a delay that is not

attributable to innovators. Additionally, Argentina should allow fast-track examination of patent applications already reviewed in the U.S. and the EU through Patent Prosecution Highways. Argentina could also introduce a system of prioritized examination, which would allow applicants to pursue an expedited examination pathway for priority applications, similar to the system used by the U.S. Patent and Trademark Office.

## Indonesia

**Issue:** *Discriminatory local content rules and weak IP enforcement against U.S. firms*

**Impact:** Local content requirement (LCR) rules in Indonesia restrict market access for U.S. pharmaceutical companies and have broader implications for research and development (R&D) on a global scale. Indonesia's stringent localization criteria prioritize meeting unrealistic thresholds over fostering fair competition, effectively preventing U.S. companies from generating the revenues needed to reinvest in cutting-edge innovation and advanced technologies worldwide.

These requirements affect U.S. companies by imposing unattainable localization benchmarks, particularly for raw materials, even though many local manufacturers themselves rely on imports for up to 90% of their inputs. The LCRs are so restrictive that even when a U.S. company has made substantial investments, including establishing manufacturing facilities, it can still be excluded from public procurement unless the specific product is manufactured within Indonesia. In essence, Indonesia is forcing U.S. companies to manufacture their entire product lines within the country to gain access to the Indonesian public market. The inability to meet these criteria, in short, results in exclusion from procurement systems, leading to significant lost revenues.

Furthermore, domestic generic firms that do qualify under the LCR framework often benefit from premium pricing and exclusive access to the public market, further marginalizing U.S. originator companies.

These lost revenues directly impact the funding available for global R&D efforts, ultimately slowing the pace of innovation and limiting the development of new solutions that could benefit US patients and healthcare systems worldwide.

**Recommendations:** To address the significant market access barriers and intellectual property rights concerns posed by Indonesia's Local Content Requirements (LCRs), the Chamber requests that the Government of Indonesia take the following actions:

1. **Revise LCR Thresholds to Reflect Market Realities:** Adjust LCR benchmarks to realistic and achievable levels that account for the global nature of pharmaceutical supply chains, particularly for raw materials and active pharmaceutical ingredients (APIs).
2. **Introduce Credit Mechanisms or Waivers for Foreign Investment:** Indonesia's current credit system under the LCRs provides insufficient recognition of the substantial contributions made by foreign companies, effectively excluding them from public procurement despite significant local investment. To remedy this, Indonesia should be urged to:

a. **Substantially Increase the Value of Credits:** Ensure that credits awarded for local investment—such as manufacturing facilities, R&D centers, workforce development, and technology transfer—are **quantitatively sufficient** to enable companies to meet LCR thresholds in practice, not just in principle.
b. **Broaden the Scope of Recognized Contributions:** Expand the types of qualifying activities to include indirect contributions such as partnerships with local firms, clinical trials conducted in Indonesia, and supply chain integration efforts.
c. Companies should be eligible to receive LCR credit **even if not all products are manufactured in Indonesia,** provided their overall investment delivers substantial local economic or technological benefits.
d. The system should include **clear criteria and scoring mechanisms** to ensure predictability and fairness in how credits are awarded and applied.
e. **Allow Permanent Credits to Offset Core LCR Metrics:** Permit credits to directly offset shortfalls in raw material or component localization, especially where local sourcing is not commercially viable or technically feasible.

3. **Ensure Non-Discriminatory Access to Public Procurement:** Guarantee that U.S. pharmaceutical companies are not unfairly excluded from Indonesia's public market due to rigid localization mandates, and that procurement decisions are based on quality, efficacy, and value rather than origin alone.
4. **Strengthen Enforcement of Intellectual Property Rights:** Take immediate steps to prevent and penalize patent infringement by domestic firms, including those benefiting from LCR-related advantages. Ensure that IP protections are enforced consistently and transparently.
5. **Establish a Transparent Review and Appeal Mechanism for LCR Compliance:** Create a formal, transparent process, including for companies to appeal or seek clarification on LCR compliance decisions, including an independent review mechanism.
6. **Engage in Bilateral Dialogue on LCR Reform:** Commit to a structured bilateral dialogue with the United States to reform LCR policies in a way that supports Indonesia's development goals while enabling U.S. firms to contribute meaningfully to the local economy and global innovation.

## Thailand

**Issue:** Maximum procurement price system undervalues U.S. products and manufacturers

**Impact:** Thailand's maximum procurement price (MPP) system lacks clarity and predictability, creating challenges for the viability of U.S. pharmaceutical products within the public procurement system. The absence of transparency in the MPP process undermines fair competition and challenges U.S. pharmaceutical manufacturers from introducing or retaining medicines in Thailand's public healthcare system. This policy framework, in practice, favors local production and procurement, effectively excluding U.S. originator manufacturers from the public procurement market and raising concerns about the long-term impact on Thailand's access to U.S. pharmaceuticals.

**Recommendations:** To enhance the procurement process, the Chamber recommends the Thai government consider the following measures:

1. **Pause the implementation of the MPP:** The Thai government should temporarily halt the implementation of the MPP system to address concerns surrounding unviable pricing policies. This pause would provide an opportunity to reevaluate the framework and develop a more inclusive approach that ensures fair participation by all stakeholders, including U.S. originator manufacturers. A revised system should prioritize sustainable pricing models that reflect the value and quality of innovative treatments.
2. **Foster fair competition by advancing transparent and collaborative procurement policies in Thailand:** To promote equitable procurement policies, Thailand should introduce a formal consultation process between the government and industry stakeholders. This dialogue would enable the development of procurement guidelines that ensure fair competition, such as tiered pricing models that account for the added value of originator products in terms of quality, reliability, and long-term patient outcomes. Collaborative engagement would foster a more transparent and predictable procurement system, encouraging continued investment in the Thai market.