



대한민국정부

The Government of the Republic of Korea

**Comments on the Section 232**  
**National Security Investigation on**  
**Imports of Pharmaceuticals and**  
**Pharmaceutical Ingredients**

May 4, 2025

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The Government of the Republic of Korea submits its comments on the U.S. Department of Commerce’s Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [BIS-2025-0022, XRIN 0694-XC120]. The Government of the Republic of Korea wishes to emphasize that imports of Korean pharmaceuticals and pharmaceutical ingredients do not pose a threat to U.S. national security, but on the contrary positively contribute to the U.S. economy, supply chain stability and health security of American people.

## **Introduction**

The Republic of Korea and the United States—hereinafter referred to as the ROK and the U.S., respectively—are long-standing security allies and reliable trading partners, supported by a close economic partnership, particularly including the Korea-U.S. Free Trade Agreement (KORUS FTA). The alliance was formally established with the signing of the ROK-U.S. Mutual Defense Treaty in 1953, and has since evolved into a comprehensive strategic partnership that extends beyond military cooperation to encompass economic, technological, and health domains—positioning both nations as key pillars of peace and stability in the Indo-Pacific region.

As the concept of security increasingly expands beyond traditional military dimensions to include economic stability, technological leadership, and the health and well-being of populations, health cooperation between the ROK and the U.S. has emerged as a vital component of national security for both countries. National health security refers to a nation's capacity to safeguard the health and welfare of its citizens from both internal and external threats, such as infectious disease outbreaks, bioterrorism, and disruptions to essential medical services and supplies. Strengthening such health security requires international collaboration, and its significance is particularly pronounced among close allies who share strategic interests and democratic values.

Building on this, pharmaceutical supply chains that span multiple countries exemplify the kind of strategic collaboration that is only possible among trustworthy partners—and such supply chains are most resilient when grounded in reciprocal and fair benefits. This form of collaboration is particularly well demonstrated in the U.S.-ROK relationship, where shared interests and mutual reliability have fostered a “good business relationship” that consistently delivers tangible, two-way gains in the pharmaceutical sector.

## **Pharmaceutical Trade and Shared Security Benefits**

Far beyond economic significance, pharmaceutical imports from the United States represent a strategic foundation for the national health security of both nations. The ROK imports approximately USD 1.1 billion worth of pharmaceutical products and pharmaceutical ingredients from the U.S. in 2024, while exporting around USD 1 billion in return for the same year—resulting in an annual trade deficit of roughly USD 0.1 billion on the part of the ROK. Notably, the U.S. is the ROK’s largest source of pharmaceutical imports, accounting for 13.8% of the ROK’s total pharmaceutical imports in 2024. For the comparison, the ROK accounts for 1.6% of the U.S. total pharmaceutical imports in 2024.

The strategic value of this trade becomes even more apparent when viewed in light of the vast difference in market size: the U.S. pharmaceutical industry is nearly 20 times larger than that of the ROK (e.g., USD 457 billion vs. USD 23 billion in 2023), and its overall

healthcare market exceeds the ROK's by over 25 times. Despite this disparity, the ROK's import levels underscore its commitment to a mutually beneficial partnership between the two countries.

The ROK's expenditures on pharmaceutical imports from the U.S. have yielded tangible benefits in terms of national health security. Of particular note, during the pandemic, American COVID-19 vaccines and therapeutics constituted the largest category of pharmaceutical import into the ROK. Comirnaty, Pfizer's mRNA-based vaccine which was a single largest imported pharmaceutical item in 2022, accounted for approximately USD 1.11 billion in import value, reflecting the critical role of ROK-U.S. cooperation in responding to global public health emergencies.

Moreover, many of the high-cost, life-saving medicines essential for treating cancer and immune-related diseases in the ROK—such as immune checkpoint inhibitors and immunosuppressants—are sourced primarily from the U.S., playing a direct role in saving Korean lives.

These health security benefits are mutually reinforcing. For instance, during the early and urgent stages of the pandemic, the two countries shared critical resources for the initial COVID-19 responses, demonstrating a deep, trust-based partnership that played a direct role in saving lives in both nations.

As a key example of bilateral cooperation, the ROK government provided comprehensive support for U.S. Forces Korea (USFK) and their families during the early phase of the COVID-19 pandemic. This support included essential services such as COVID-19 testing, specialized point-of-entry procedures, and measures to prevent cross-infection within the base, all of which played a critical role in safeguarding the health of both USFK personnel and the nearby Korean communities. Such timely and effective collaboration was made possible by a long-standing alliance between the ROK and the U.S.

In addition, the ROK has served as a key production hub for U.S.-developed COVID-19 vaccines, including Spikevax by Moderna, manufacturing tens of millions of doses that supported not only the ROK and the U.S., but also advanced global health security under U.S. leadership. Korean CDMO firms also provide manufacturing support to the major U.S. pharmaceutical companies, playing a critical role in dual sourcing strategies and optimizing supply chain efficiency. Reliable access to raw materials and advanced manufacturing capabilities in the ROK not only supports surge production during global health emergencies but also contributes to maximizing mutual interests.

Despite the strength of the ROK-U.S. partnership across trade, health security, and biomanufacturing, opportunities remain to further align institutional frameworks and regulatory practices. However, there have been significant efforts by the government of the ROK to address these, which are essential to unlocking the full potential of bilateral pharmaceutical cooperation—ensuring that shared strategic and commercial interests are supported by a transparent, predictable, and mutually trusted policy environment.

Meanwhile, through sustained policy efforts, the Government of the ROK has consistently advanced shared policy priorities—particularly by enhancing transparency and ensuring stakeholder participation in the drug pricing process, and by improving transparency in the evaluation of eligibility for incentive-based pricing policies. These commitments by the Government of the ROK will continue going forward.

## **Building a Robust and Sustainable U.S.-ROK Partnership**

The ROK and the U.S. share a long-standing alliance rooted in mutual trust and shared democratic values. Over time, this partnership has evolved beyond traditional defense and security cooperation into a broader strategic framework encompassing public health, pharmaceuticals, and global supply chain resilience. In the face of growing global health challenges, demographic shifts, and emerging biotechnologies, the ROK and the U.S. are uniquely positioned to deepen cooperation in the bio-health sector—not only for the benefit of both nations, but for regional and global stability.

### **1. Strategic Alignment to Achieve the Shared Interests**

The convergence of ROK-U.S. interests in healthcare innovation, public health security, and pharmaceutical accessibility underscores the growing importance of bilateral cooperation in this sector. Both countries face increasing demand for advanced, but accessible therapeutics due to aging populations, rising chronic disease burdens, and the need for preparedness against future pandemics. As leading players in biomedical research and manufacturing, the ROK and the U.S. share a common vision of fostering innovation while securing access to essential medicines.

### **2. Expanding Collaborative Mechanisms Further to Reinforce Bilateral Relationship**

The government of the ROK seeks to further institutionalize policy coordination in the pharmaceutical sector based on the pragmatic partnerships with the U.S. government and expert groups in the U.S., as well as existing trade and industry platforms.

To further strengthen our partnership, particularly in alignment with shared national security objectives, future areas of policy linkage may include, but are not limited to, collaborative research initiatives in regulatory science to promote reciprocal health security benefits; shared incentives for cross-border R&D and investment in the context of national security; and enhanced cooperation in strategic technologies, including deeper bilateral joint development and expanded collaboration in digital health and health AI.

Such mechanisms will enhance predictability for businesses, accelerate innovation pipelines, and reduce redundancies in regulatory burdens—supporting both public health outcomes and industrial competitiveness.

### **3. Building a Resilient and Trusted Supply Chain**

In a world increasingly defined by geopolitical uncertainty and supply chain vulnerabilities, ensuring access to reliable and secure sources of pharmaceuticals has become a top priority. The ROK offers a high-performing, transparent, and technologically advanced manufacturing base, with proven capacity to deliver under pressure—including during the global-scale pandemic.

Securing the reliable supply chains for the entire pharmaceutical ecosystem requires efforts beyond what any single country can pursue. Given the critical role of pharmaceutical products in public health, trustworthiness must serve as a core value to consider throughout this process. The ROK will continue its role as a trusted partner. This strategic alignment enhances stability in an increasingly complex international environment, while reinforcing shared values of reliability and preparedness.

With advanced bioproduction facilities, a mature and internationally aligned regulatory framework, and a proven record of collaboration with U.S. firms, the ROK serves as an optimal hub for dual sourcing, surge capacity, and innovation-driven manufacturing. Strengthening this partnership will contribute significantly to U.S. national security—particularly in the domain of biosecurity—by reinforcing the responsiveness and integrity of critical medical supply networks during times of global crisis.

#### **4. Enhancing Mutual Benefits and Future Directions**

The deepening of ROK-U.S. cooperation in the pharmaceutical sector presents opportunities not only for bilateral economic gains, but also for advancing shared values of access, resilience, and public good. The openness of the Korean healthcare market, combined with the innovation strength of U.S. companies, creates a synergistic environment for growth and impact.

Looking ahead, the ROK will continue to strengthen this strategic partnership by aligning health policies, expanding private sector collaboration, and advancing equitable, sustainable innovation across borders. In this context, the ROK welcomes the Executive Order 14273 issued on April 15, 2025, titled “Lowering Drug Prices by Once Again Putting Americans First,” which outlines a comprehensive strategy to reduce prescription drug costs through expanded importation, greater access to generics and biosimilars, Medicare reform, and improved market transparency. These priorities align closely with the ROK’s capabilities as a leading global manufacturing hub.

A significant portion of the ROK’s pharmaceutical exports to the United States consists of biosimilar medicines. In fact, the ROK ranks second only to the U.S. in terms of the number of biosimilars per country approved by the U.S. Food and Drug Administration (FDA), and continues to advance efforts to accelerate this momentum. This national capacity has consistently supported—and is well positioned to continue supporting—U.S. efforts to reduce drug prices in a sustainable and reliable manner.

With advanced bioproduction infrastructure, proven CDMO capacity, and strong ties with U.S. firms, the ROK is particularly capable of supporting dual sourcing, efficient contract manufacturing, and reliable access to affordable medicines. The ROK stands ready to contribute to the implementation of these initiatives in ways that lower costs for American patients while safeguarding innovation and health outcomes across both nations. Together, the ROK and the U.S. can help shape a more resilient, inclusive, and prosperous global health landscape.

#### **Conclusion: A Commitment to Shared Security and Prosperity**

Given the mutual interdependence between the two countries in the pharmaceutical sector, Imports of Korean pharmaceutical products—widely recognized for their world-class quality—do not pose any threat to U.S. health security. Putting tariffs on Korean pharmaceutical products does not offer any practical benefit to the U.S. pharmaceutical industry, rendered ultimately unnecessary. As such, their imposition stands contrary to the shared interests and long-standing partnership between the ROK and the U.S.

In light of the shared strategic interests and mutual benefits detailed above, the Government of the ROK suggests the U.S. to consider waiving tariffs and, even if not, introducing tailored measures that incorporate shared national security values and reflect

competences of trusted partners while conducting the investigation, which ensures continued cooperation that advances both nations' access to affordable medicines, public health, and ultimately, safeguarding national security.