



Korea Pharmaceutical and Bio-Pharma Manufacturers Association

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The Honorable Alan F. Estevez

Under Secretary of Commerce for Industry and Security
U.S. Department of Commerce
Bureau of Industry and Security
1401 Constitution Avenue, N.W.
Washington, DC 02230

May 7, 2025

RE : Notice of request for public comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [XRIN 0694-XC120]

Dear Under Secretary Estevez,

On behalf of the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA), I would like to express our sincere appreciation for the opportunity to submit comments regarding the Section 232 National Security Investigation concerning imports of pharmaceuticals and pharmaceutical ingredients.

KPBMA, established in 1945, is the leading organization representing Korea's pharmaceutical and biopharmaceutical industry. Our association represents approximately 300 diverse member companies and plays a vital role in fostering public-private collaboration both domestically and internationally to ensure the development and stable supply of innovative and high-quality medicines.

We greatly value the strong and cooperative relationship between Korea and the United States, built on mutual trust and our shared commitment to ensuring reliable access to essential medical products. It is in this context that we respectfully submit our comments for your consideration.

Importance of Health Security and Stable Pharmaceutical Supply

The global drug shortages during the COVID-19 pandemic highlighted the critical role of pharmaceuticals in national health security. Recognizing this, many countries, including the United States, have introduced various policies aimed at enhancing self-sufficiency and strengthening supply chains, and we fully support these efforts.

However, the pharmaceutical industry is highly globalized and specialized, encompassing cross-border procurement, R&D, manufacturing, regulatory review, and distribution. It is therefore impractical for any single country or region to fully achieve self-sufficiency without international



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cooperation.

Particularly for essential medicines such as antibiotics, vaccines, and blood products, which directly impact public health and national security, stable supply and shortage management are critical. Given the low profitability and frequent supply risks associated with such products, strengthening supply chain partnerships with trusted allies like Korea, rather than reducing import reliance indiscriminately, is a more sustainable approach.

Potential Impact of Tariffs on Patient Access to Medicines

The United States is the world's largest pharmaceutical market, representing approximately USD 714.3 billion in global sales in 2023 (Source: IQVIA).

Imposing uniform and immediate tariffs on pharmaceuticals may have unintended consequences, potentially disrupting the global pharmaceutical value chain and creating unforeseen supply discontinuities in essential sectors.

In addition, building new domestic biomanufacturing facilities typically requires 5 to 10 years and up to USD 2 billion in investment per site. Even with such facilities, the procurement of starting materials and raw ingredients would still heavily rely on global partners.

In this context, tariff measures could increase the cost structure of the U.S. pharmaceutical industry and may ultimately affect timely and affordable access to medicines for American patients.

Korea as a Trusted and Complementary Partner for U.S. Supply Chain Resilience

Korea is a trusted U.S. ally and a partner committed to free trade and fair competition. The Korean pharmaceutical industry operates under market principles and does not engage in unfair trade practices such as export subsidies.

Throughout global health crises, Korea has proven to be a responsible and trusted partner to the United States, actively working together to safeguard public health by providing essential products — notably vaccines through development, production, and global contract manufacturing and supply, along with diagnostic kits and personal protective equipment.

Korean pharmaceutical and biopharmaceutical manufacturers are globally recognized for their high-quality production capabilities, holding certifications from the FDA, EMA, WHO PQ, and more. Our manufacturers play an essential role in stabilizing global supply chains and are capable of supplying key products, including essential medicines and affordable biosimilars.



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In addition, Korea's share of U.S. pharmaceutical imports is only 1.6% as of 2024, demonstrating that Korean exports do not negatively impact U.S. health security. Instead, Korea offers complementary strengths and can contribute significantly to ensuring supply chain resilience and diversity.

Conclusion

Korea remains fully committed to supporting U.S. health security and supply chain diversification efforts as a responsible and trusted partner.

While we understand and respect the objectives of the U.S. government, we respectfully recommend careful consideration of the following points:

- Where tariffs are unavoidable, sufficient grace periods should be provided to accommodate the time and challenges involved in establishing domestic manufacturing capacity.
- Essential medicines, particularly those prone to shortages and critical to public health, needs to be excluded from tariff measures to ensure uninterrupted patient access.

KPBMA sincerely looks forward to constructive discussions based on mutual trust and shared values. We remain committed to continued close collaboration with the U.S. government to strengthen global health security and ensure sustainable and stable pharmaceutical supply chains.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Yunhong Noh', is written over a horizontal line.

Yunhong Noh

President

Korea Pharmaceutical and Bio-Pharma Manufacturers Association