한국무역협회 Korea International Trade Association
KITA
서울 강남구 무역센터 트레이드타워, Trade Tower, World Trade Center, Gangnam-gu, Seoul 06164, Korea, TEL:+82-2-6000-5114, http://www.kita.net

May 7, 2025

The Honorable Howard W. Lutnick
Secretary of Commerce
1401 Constitution Avenue, N.W.
Washington, DC 20230

Re: Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [BIS-2025-0022]

Dear Secretary Lutnick:

On behalf of the members of the Korea International Trade Association ("KITA"), I appreciate this opportunity to provide comments and views on the Section 232 National Security Investigation on imports of pharmaceuticals and pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items.

KITA, established in 1946, represents more than 77,000 Korean companies engaged in global trade, many of which have long-standing commercial ties with the United States.

Importance of Pharmaceutical Security and a Reliable Pharmaceutical Supply Chain

The pharmaceutical industry is not only essential to public health but also serves as a critical foundation of national security. In particular, the global shortage of pharmaceuticals during the COVID-19 pandemic underscored significant vulnerabilities in the supply chain and heightened concerns regarding pharmaceutical security. In this context, we fully recognize the concerns that the United States has due to potential pharmaceutical shortages and support its efforts to ensure a reliable, secure, and resilient pharmaceutical supply chain.

However, due to the complex nature of the pharmaceutical industry, it is challenging for any single company or country to independently participate in all stages of the value chain. Therefore, strengthening collaboration with key partners in ally countries is just as essential as advancing domestic capabilities. A global partnership built on mutual trust will further enhance the United States' ability to respond to and recover effectively from future healthcare crises.

Korea is a Reliable Partner of the United States that Makes Contribution to the U.S. Pharmaceutical Industry

Korea is a reliable partner of the U.S. pharmaceutical industry and it is expected to make even greater contributions to the stability and security of the U.S. pharmaceutical supply chain. While it is essential for the United States to develop a robust domestic pharmaceutical supply chain, constructing production facilities and establishing a supply chain in the Unites States require significant time and investment. According to the Pharmaceutical Research and Manufacturers of America (PhRMA), it takes approximately five to ten years and $2 billion to build a new pharmaceutical production facility in the United States.

Given the steady increase of pharmaceutical demands, which is driven by multiple factors such as an aging population, the United States may face difficulties in meeting this demand domestically in the short term. Therefore, it is essential to maintain imports of pharmaceutical products from trusted international suppliers such as Korea.

According to the US Census data (NAICS 3254), Korea accounted for less than 2% of total U.S. pharmaceutical import—1.6% in 2022, 1.3% in 2023, and 1.6% in 2024. This limited share indicates that Korea's pharmaceutical exports pose minimal risk to U.S. national security. Furthermore, Korea's exports are primarily concentrated in biomedical products, highlighting that Korea is not directly associated with the active pharmaceutical ingredients (API) supply challenges that the United States faces.

In recent years, Korean pharmaceutical companies have contributed to the stable supply of pharmaceutical products in the United States and are increasingly recognized as reliable partners in the biopharmaceutical supply chain through active collaboration with U.S. pharmaceutical companies.

Korean biopharmaceutical companies doing businesses in the United States enable American patients to have a better access to medications by supplying affordable products. These efforts align with the current policy direction under the Trump administration, which emphasizes reducing pharmaceutical costs. Korean companies serve an important role in the U.S. market by ensuring a stable supply of biosimilars and biopharmaceutical products at relatively low prices.

Moreover, pharmaceutical industries of Korea and the United States are deepening their relationship with their supply chain. For example, Korean companies are manufacturing

finished drug products using APIs sourced from the United States. In other cases, Korean companies are producing pharmaceutical products at the request of U.S. biopharmaceutical companies with the purpose to supply them to Americans. These active collaborations underscore Korea's ongoing commitment and contribution to strengthening the U.S. pharmaceutical supply chain and supporting the healthcare system.

Conclusion

We recognize that the United States aims to reduce its dependence on imported pharmaceuticals and to establish a reliable, secure, and resilient domestic supply chain. However, given the current domestic pharmaceutical production falls short of meeting demand, imposing import restrictive measures on pharmaceutical products could weaken the competitiveness of the U.S. pharmaceutical industry. Such measures may reduce consumer access to medications and ultimately run counter to U.S. national security and public health objectives.

If the United States decides to impose Section 232 tariffs on pharmaceutical products, we respectfully urge that exemptions be granted for goods originating from countries that do not pose a threat to U.S. national security. Korean pharmaceutical companies are committed to expanding cooperation with U.S. partners in ways that can contribute to the stability and security of the U.S. pharmaceutical supply chain. Korea's pharmaceutical industry accounts for only a small share of total U.S. pharmaceutical imports and does not present a security risk. In this regard, KITA respectfully requests that pharmaceutical products from Korea be exempted from any measure adopted as the result of the ongoing Section 232 investigation.

In particular, we urge your priority consideration for tariff exclusions on the following categories:

- Finished drug products manufactured by processing active pharmaceutical ingredients sourced from the United States and then re-exported to the U.S. market;
- Biosimilars or generics that improve access to medications for U.S. patients by offering more affordable pricing;
- APIs for biological or synthetic medicines that help ensure a resilient U.S. pharmaceutical supply chain
- Biopharmaceutical products produced under contract manufacturing agreements with U.S. biopharmaceutical products.

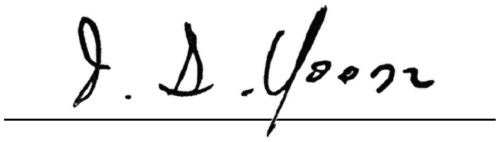
Lastly, if the pharmaceutical products falling under the categories outlined above cannot be fully excluded, we respectfully request that a sufficient grace period be granted before implementation of any tariffs, given that reshoring pharmaceutical production and constructing

manufacturing facilities require significant time and investment. In the long term, a phased approach would help support the construction of additional production facilities in the United States while minimizing disruptions to the pharmaceutical supply chain.

As an important and critical trading partner, Korea remains committed to further enhancing and strengthening its partnership with the United States. KITA respectfully asks the Department of Commerce to take into account the important role that Korean companies play in maintaining, strengthening, and expanding the U.S. pharmaceutical supply chain, as well as their ongoing commitment to supporting the growth and resilience of the U.S. economy.

I thank you again for the opportunity to express KITA's views on this very important matter.

Respectfully submitted,



Jin Sik Yoon

Chairman

Korea International Trade Association