

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 [XRIN 0694-XC120]

Dear Secretary Lutnick:

On behalf of the members of the Korea Biotechnology Industry Organization ("KoreaBIO"), I appreciate the opportunity to provide comments in response to the Bureau of Industry and Security, United States Department of Commerce's request for public comments regarding the Section 232 National Security Investigation on imports of pharmaceuticals and pharmaceutical ingredients.

KoreaBIO, representing the interests of 650 member companies in Korea's biotechnology industry, is an organization dedicated to promoting biotechnology development and fostering international cooperation, including with the United States.

Korea as a "Reliable Partner" in the U.S. Pharmaceutical Supply Chain

Pharmaceuticals are essential for patients in the United States, and the stable supply of pharmaceuticals within the U.S. is crucial to national security, the economy, and public health.

On April 8, 2025, the National Security Commission on Emerging Biotechnology, an advisory body to the U.S. Congress, issued a set of recommendations to strengthen the development of innovative biotechnologies and enhance supply chain resilience to safeguard U.S. national security. These recommendations include the need for increased collaboration with allied nations.

To develop pharmaceuticals and supply them to patients in the United States, a variety of partners are needed. Korea has long played a vital role both in the development of innovative pharmaceuticals and as a trusted contract manufacturing partner for products needed by the

Korea Biotechnology Industry Organization

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United States. In particular, Korea has been expanding cooperation with U.S. companies in the field of biopharmaceutical contract manufacturing.

Meanwhile, it will take several years at a minimum to develop a stable pharmaceutical supply chain in the United States. However, if tariffs are imposed before a strong pharmaceutical and pharmaceutical ingredient supply chain is established within the United States, it could result in limited access to essential pharmaceuticals for American patients, ultimately having a negative impact on U.S. national security and public health.

Korea as an “Affordable Partner” in the U.S. Prescription Drugs Supply

The Biotechnology Innovation Organization (BIO), a long-time U.S. partner of the KoreaBIO, conducted a survey in March this year among its members regarding the impact of tariffs on pharmaceuticals. The results raised concerns that imposing tariffs would lead to a significant increase in pharmaceutical manufacturing costs and a decrease in access to affordable medicines.

On April 15, 2025, President Donald Trump signed an executive order aimed at lowering prescription drug prices. The order includes measures to increase the availability of generics and biosimilars, which are more affordable than brand-name drugs, with the goal of providing American patients with more affordable medications.

As of April 24, 2025, among the 70 biosimilars approved by the U.S. Food and Drug Administration (FDA), Korean companies have received the second-highest number of approvals, after U.S. companies. Korea is making significant contributions to the Trump administration's efforts to lower drug prices and expand access to affordable medicines through the active development and supply of biosimilars in the U.S. market.

Pharmaceuticals are essential for national security and patient protection, and many countries, including the United States, depend on each other for the pharmaceutical supply chain. Korea has played a key role as a partner of the United States in providing a stable and affordable supply of essential pharmaceuticals and pharmaceutical ingredients to American patients.

In light of the above, KoreaBIO requests that the U.S. government refrain from imposing tariffs or other trade-restrictive measures on pharmaceuticals and pharmaceutical ingredients. If action is necessary based on the results of the ongoing Section 232 investigation into pharmaceuticals and pharmaceutical ingredients, we respectfully request that pharmaceuticals and pharmaceutical ingredients produced in allied countries, such as Korea, that do not pose a threat to U.S. national security to be granted an exemption.

I thank you again for the opportunity to provide our views on this important matter.

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Respectfully submitted,



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