IMMUNOCORE

Mr. Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
United States Department of Commerce
1401 Constitution Avenue, NW
Washington, DC 20230

May 7, 2025

Dear Mr. Longnecker:

On behalf of Immunocore, a commercial-stage biotechnology company that discovered, developed, and commercialized the first-in-class T cell receptor (TCR) therapy, KIMMTRAK® (tebentafusp-tebn), we write in response to your agency's April 16, 2025, request for comments on the Section 232 investigation to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients.

We submit our comment principally to urge, should any remedies such as tariffs be adopted to restrict the import of pharmaceuticals, that they not apply to imports that:

- the Food and Drug Administration (FDA) has designated as orphan drugs;[1]
- that are patented and under exclusivity; and
- that are not manufactured or imported from a foreign entity of concern (FEOC).[2]

For the reasons outlined in this response, we believe that drugs like KIMMTRAK that meet the above criteria should be excluded from the scope of any import restrictions as the import of this class of drugs would in no way undermine the Trump Administration's efforts to protect national security through the increased production of pharmaceuticals in the United States.

Introduction

KIMMTRAK is a revolutionary, life extending therapeutic for a subgroup of patients with metastatic uveal melanoma (mUM), a rare cancer. The affected subgroup comprises around 500 patients in the US per year. KIMMTRAK (tebentafusp-tebn) received orphan drug designation from the FDA for the treatment of these patients on January 21, 2016. While we have other products in development for additional cancers, infectious diseases, and autoimmune disorders, KIMMTRAK is our only commercial product. Due to the combination of limited commercial revenue and high research and development costs, which is common for maturing biotech companies, Immunocore has experienced a net loss since inception. As of December 31, 2024, the accumulated deficit was $796 million.[3]

In addition to our UK home office, Immunocore has two U.S. headquarters in Pennsylvania and Maryland. Our CEO, CFO, Head of R&D, and Chief Commercial Officer are based in the U.S., where we employ around 150 highly skilled individuals. We support growing the American bioeconomy and developing domestic pharmaceutical supply chains. However, as a small biotech company with one product for a rare disease and limited revenue, we are concerned that import tariffs on KIMMTRAK would impact our innovation and ability to invest in U.S.

[1] The FDA defines rare diseases as those affecting less than 200,000 people in the US per year, and the drugs used to treat those rare diseases are called orphan drugs. Orphan Drug Act - Relevant Excerpts | FDA
[2] As in other contexts, a FEOC would be a foreign entity that is owned by, controlled by, or subject to the jurisdiction or direction of a government of a foreign country that is a covered nation.
[3] Immunocore 2024 Annual Report

Immunocore LLC
Six Tower Bridge, Suite 200,
181 Washington Street,
Conshohocken, PA, 19428, United States
+1 (484) 534-5261
www.immunocore.com
Registered in the United States (Delaware Division of Corporations): 5070839

employee growth. KIMMTRAK is currently manufactured in western Europe and would be subject to these tariffs if implemented.

Our comment focuses on two sections of the Bureau of Industry and Security's (BIS) request for comment on the Section 232 investigation: specifically, (viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance, and (ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security.

Analysis

(viii) the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance

In approaching this section, we interpret "feasibility" in our consideration of the practicality, the achievability, and the resources required to develop a U.S. supply chain for products like KIMMTRAK. With that understanding, it is not feasible for Immunocore to increase our domestic capacity for manufacturing KIMMTRAK, given the current regulations, resources at our disposal, and manufacturing requirements.

Because KIMMTRAK treats an orphan disease with around 1,000 patients globally, is a biologic, is the first ever commercial product of its kind, and employs microgram dosing, it requires only one specialized manufacturing site to support global supply. The supply chain was established during development with contract development and manufacturing organizations (CDMOs) in western Europe. A Danish CDMO was competitively chosen because of its specialized capabilities, particularly since in-house manufacturing would have been cost and time prohibitive.

Should Immunocore seek to transfer manufacturing to the U.S., we would need to compete for potentially limited CDMO capacity.[4,5] Given the limited manufacturing volume requirements and the technical requirements for KIMMTRAK, securing capacity for a small volume product would also be challenging as Immunocore would be competing with large volume manufacturing demands from other pharmaceutical products. This difficulty in securing manufacturing capacity would be compounded if tariffs were to be implemented, as the number of pharmaceutical companies shifting supply chains to the U.S. would exacerbate the already constrained domestic CDMO capacity for biologics.

Importantly, even if capacity were available, transfer of processes and licensure of a new CDMO in the U.S. would require 3-4 years and significant capital expenditure considering the current regulatory framework and the manufacturing, validation, comparability, and pre-approval inspection requirements. While we support the intent of the President's recent executive order promoting domestic pharmaceutical production,[6] drafting, implementation, and the realization of expanded capacity from the regulations that follow this order will take substantial time.

(ix) the impact of current trade policies on domestic production of pharmaceuticals and pharmaceutical ingredients, and whether additional measures, including tariffs or quotas, are necessary to protect national security

Immunocore understands the Trump Administration's responsibility to protect U.S. national security. We further recognize the risks associated with drug production and import from certain countries, potentially raising the

[4] CFOs on CDMO selection and capacity - BioProcess Insider
[5] Lonza | Biologics
[6] Exec. Order, "Regulatory Relief to Promote Domestic Production of Critical Medicines," May 5, 2025.

possibility of identifying Foreign Entities of Concern (FEOCs) to the extent entities are owned by, controlled by, or subject to the jurisdiction or direction of a government of those certain countries.

However, if increased domestic manufacturing of pharmaceuticals is an element of U.S. national security and import restrictions (e.g., tariffs) are recommended to disincentivize foreign manufacturing, the exclusion from the scope of any tariffs of biologic orphan drugs from non-FEOCs would in no way undermine U.S. national security. The very nature of orphan drugs is that they are used in small – sometimes extremely small – patient populations. While they are invaluable to the patients who are prescribed them, for most of the American public, they are not widely utilized critical medicines (e.g., antibiotics) nor are they of biodefense value (e.g., protecting against anthrax or smallpox). What has the potential to impact national security is the diversion of investments in innovation from small biotech companies if they are required to invest resources to onshore supply chains. Case in point, a reallocation of Immunocore resources from supporting pipeline development of novel therapeutics to establish a domestic supply chain for the manufacture of an orphan drug would result in fewer resources allotted to the type of scientific innovation the country *must have* to maintain bioeconomic competitiveness and the associated benefits to national security.[7]

In summary, any tariffs placed on our product would diminish our ability to reinvest in America, something to which we are committed. Over the past 5 years, our physical footprint in the U.S. has increased with a new site, and the number of U.S.-based employees has quadrupled over that same period.

Recommendations

#1. Exempt orphan drugs that are patented and under exclusivity from tariffs, if they are not manufactured within FEOCs.

To fall outside the scope of any tariffs or other import barriers following an affirmative determination, orphan drugs should be precluded from being manufactured or imported from a FEOC. This will ensure that a tariff scoping decision designed to maintain Americans' access to life-saving drugs for rare diseases and conditions does not otherwise undermine U.S. national security. Additionally, BIS should consider reflecting this exclusion in its Harmonized Tariff Schedule (HTS)—e.g., by adding an exempt orphan drug's International Non-proprietary Name to the HTS's Pharmaceutical Appendix.[8]

#2. If exemptions outlined above are not under consideration, delay tariffs on these drugs for a period of five years to allow for effective onshoring of operations and time for U.S. pharmaceutical manufacturing capacity to increase.

A delay in tariffs would enable CDMOs to expand capacity and for companies to transfer technology, gain necessary regulatory approvals, secure manufacturing slots, and ensure a consistent, uninterrupted drug supply to patients during the transition period. To ensure small biotech companies – from which many novel molecules originate[9] – can compete with larger pharmaceutical companies for manufacturing slots, consider using defense programs to incentivize domestic manufacturing. Via programs like BioMADE and the Defense Industrial Base Consortium, Other Transaction Agreement (OTA) funding could be provided to start-up CDMOs seeking Good Manufacturing Practice (GMP) certification. As opposed to very large CDMOs, smaller CDMOs may be better suited for small-batch production and thus a better fit for orphan drug manufacturers. Furthermore, the

[7] Understanding the U.S. Biopharmaceutical Innovation Ecosystem
[8] Harmonized Tariff Schedule
[9] Understanding the U.S. Biopharmaceutical Innovation Ecosystem

IMMUNOCORE

Department of Defense could consider preferential OTAs with start-up CDMOs that utilize biomanufacturing processes in drug development and leverage agricultural products or byproducts to do so, thereby positively impacting American farmers as well and offsetting any retaliatory tariffs on American agricultural commodities.

As part of building up its domestic pharmaceutical manufacturing capacity, the U.S. should consider incentivising decentralized pharmaceutical manufacturing. By increasing geographic representation, the U.S. Government would enable Americans from a variety of regions to benefit from job creation while derisking the effects of natural disasters on manufacturing facilities. With its mandate to protect critical infrastructure, DHS could have a role in this by evaluating the addition of biomanufacturing and biotechnology to its critical infrastructure framework.[10]

#3. Provide regulatory relief to facilitate the timely and efficient transfer of manufacturing for any products establishing alternative CDMOs in the U.S.

As mentioned previously, establishing a viable manufacturing site and transferring the manufacture of a biopharmaceutical between CDMOs can take 3-4 years. Regulatory relief/concessions may be required across industry to help facilitate and enable viability and reduce the timelines of such transfers. This could include accelerated review of licensing applications and/or streamlining of the comparability processes required to establish an alternative manufacturing site, for example.

Conclusion

Immunocore shares the Administration's interest in protecting U.S. national security. However, should the Secretary of Commerce reach an affirmative finding and recommend import restrictions like tariffs or quotas on pharmaceutical products, national security would be best served by excluding from the scope of those import restrictions any orphan drugs under patent exclusivity that do not originate in a FEOC. This is critical to ensure that efforts to reduce dangerous dependencies and increase domestic manufacturing of pharmaceuticals do not inadvertently stifle innovation of novel medicines and negatively impact American lives or the U.S. bioeconomy that rely on these lifesaving therapeutics.

Immunocore thanks the Secretary of Commerce for consideration of these comments.

Sincerely,

Signed by:
Mark Moyer
Signer Name: Mark Moyer
Signing Reason: I approve this document
Signing Time: 07-May-2025 | 21:39 BST
C2E2F665D1BF4730B5023222EF8D38E7

Mark Moyer

SVP, Regulatory Sciences

[10] Maintaining US Leadership in Advanced Biotechnology & Growing the Bioeconomy

Immunocore LLC
Six Tower Bridge, Suite 200,
181 Washington Street,
Conshohocken, PA, 19428, United States
+1 (484) 534-5261
www.immunocore.com
Registered in the United States (Delaware Division of Corporations): 5070839