Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

RE: "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients," Federal Register docket number BIS-2025-0022 (XRIN 0694-XC120).

Dear Director Astle,

Viatris appreciates the opportunity to provide comments on the Department of Commerce's 232 investigation of imports of pharmaceuticals and pharmaceutical ingredients. As a U.S.-based company and a leading provider of medicines to patients in the U.S. and across the world, **Viatris supports the Administration's goals of creating a stable and secure supply of medicines for U.S. patients** and we look forward to collaborating on advancing policies to mitigate supply chain disruptions, enhance pharmaceutical supply chain resiliency, and address barriers to patients' access to affordable medicines.

Viatris is a global healthcare company uniquely positioned to bridge the traditional divide between brand and generics, combining the best of both, to more holistically address healthcare needs. Access to medicines is fundamental to our mission of empowering people worldwide to live healthier at every stage of life.

Viatris is headquartered in Canonsburg, Pennsylvania and offers a large, diversified portfolio of both generics and brands that reaches approximately 1 billion patients [1]around the world annually. We manufacture more than 45 medicines on the list of essential medicines established under President Trump's Executive Order on *Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs are Made in the United States (2020)* and we produce more than 80 billion doses of medicine each year, with more than 8.5 billion of those doses manufactured in the United States. We operate 6 facilities in the United States across manufacturing, R&D, and distribution. Approximately 55% of our total U.S. revenue is sourced from a U.S. manufacturing site.

As a U.S. company and a significant domestic producer of medicines, we are aligned with the objective of enhancing the resiliency of the U.S. supply chain and addressing potential national security risks. However, we also encourage the Department of Commerce to carefully weigh the significant potential negative consequences of imposing pharmaceutical tariffs, **in particular on generic medicines**. Imposing tariffs on generic drugs, which provide the greatest value proposition to the U.S. healthcare system in terms of savings and access to medicines, may run counter to the Administration's goal of making medicines more affordable and accessible, as articulated recently in President Trump's *Executive Order on Lowering Drug Prices by Once Again Putting Americans First*. In fact, the consequences of such tariffs

[1] Building Sustainable Access at Scale, Viatris 2023 Sustainability Report

could include exacerbating drug shortages and threatening access to essential medicines that millions of American patients rely on daily for life-sustaining treatment.

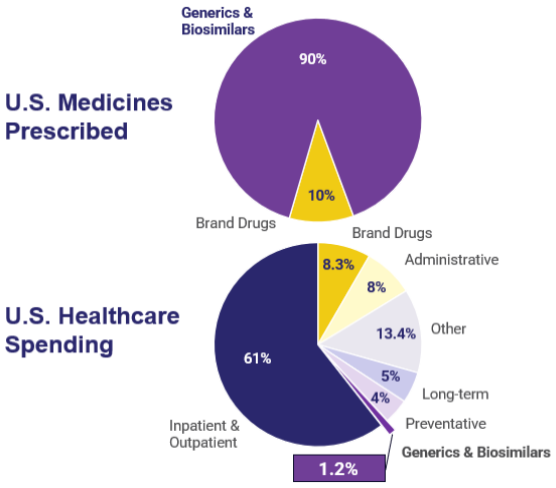
Generic Medicines are Critical for Patient Access and Savings

While Viatris manufactures both brand and generic medicines, given our long-standing leadership in the generic industry, we would like to take this opportunity to provide background on the unique dynamics associated with the U.S. generic market, as we believe it merits special attention as the Administration considers how to meet its goals of a stable and secure supply of medicines for U.S. patients.

Spending on medicines in the United States represents approximately 9.5 percent of the country's overall healthcare investment of $4.9 trillion. Breaking that percentage down even further, brand medicines make up 8.3 percent of spending (approximately $398 billion) while **generic medicines account for only 1.2 percent of spending (approximately $58 billion), despite generics comprising 90 percent of the prescriptions dispensed in the U.S.**[2] Generic medicines are a critical component of containing costs both for patients and the entire healthcare system in the United States.

Total U.S. Savings from Generics and Biosimilars

- Total generic and biosimilar savings in 2023: **$445 billion**
- Total generic and biosimilar savings for the past ten years: **$3.1 trillion**
- Total generic and biosimilar savings in Medicare in 2023: **$137 billion ($2,672 per beneficiary)**
- Total generic and biosimilar savings in the commercial market in 2023: **$206 billion**
- Share of total U.S. prescriptions filled: **90 percent**
- Share of total U.S. prescription drug spending: **13.1 percent**
- Share of total U.S. healthcare spending: **1.2 percent**



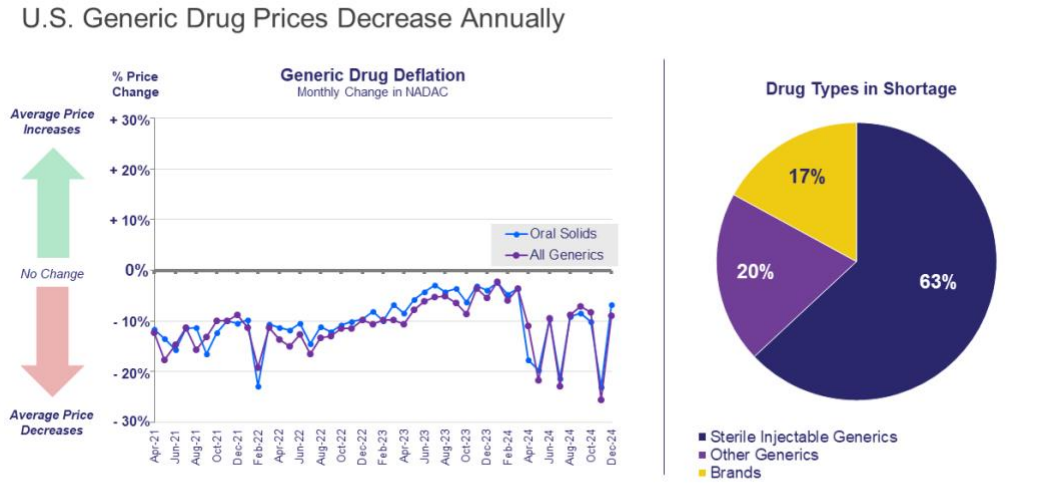
Patient Access to Generic Medicines Already at Risk

Generally, prices within the generic market are deflationary by nature, with NADAC[3] prices in 2024 decreasing between 6 percent and 25 percent at different points throughout the year. Additionally, the industry is subject to numerous other financial pressures, including steep price concessions required to gain access to distribution channels, multi-year duration fixed-term contracts, and government mandates including the Medicaid Generics Penalty, not to mention various state laws related to price controls and transparency. The combination of this pattern of generic drug price deflation coupled with significant discounting and other pressures has severely compressed industry margins, leading to several manufacturer bankruptcies and broad product discontinuations that negatively affect U.S. patients. In turn, these bankruptcies and discontinuations have led to an increase in shortages across the market,

[2] IQVIA National Prescription Audit, December 2023

[3] The National Average Drug Acquisition Cost is intended to be a national average of the prices at which pharmacies purchase a prescription drug from manufacturers or wholesalers.

with generic medicines making up 83 percent of all drug shortages. Most recently, patients have experienced significant shortages of generic oncology[4] medicines, leading to delays and changes in care and creating a significant public outcry about the impact to patients.



<u>Tariffs on Generic Medicines Would Increase the Risk of Additional Shortages</u>

Given that we know President Trump is committed to providing U.S. patients access to a stable and secure supply of medicines, should the administration move forward with tariffs on pharmaceuticals, **we encourage the Department of Commerce to consider providing relief from tariffs on generic medicines. Imposing such tariffs on these essential medicines may likely have the opposite effect than the administration's original intention and result in significantly reduced patient access to affordable medicines**. It is a reality that generic manufacturers regularly have to face difficult decisions about whether to continue producing products that have flat or negative profitability. The factors that play a part in these decisions include patient access needs, contracting commitments, overhead absorption/cost considerations at manufacturing sites, and market dynamics, among others. Levying tariffs on these products will result in medicines that are already operating on negative or razor thin margins becoming more unprofitable, making them potentially unsustainable from a manufacturing and/or financial perspective. The imposition of tariffs may also eliminate the small positive margin that exists on many essential medicines, leading manufacturers to have to make difficult decisions about whether to continue to manufacture those medicines. Generic drug discontinuations due to unfavorable economics are on the rise, increasing 40% in 2023[5], with almost 50% of the products discontinued costing less than $4. Further financial strain on these essential medicines as a result of tariffs may further erode the sustainability of this market, accelerate the trend of product discontinuations, and exacerbate drug shortages. Patient groups are also raising concerns about the same dynamics as they consider the impact that tariffs may have on patient care and access to medicines.[6] When a manufacturer

[4] https://acsjournals.onlinelibrary.wiley.com/doi/full/10.1002/cncy.22788
[5] USP Annual Drug Shortage Report
[6] https://nationalhealthcouncil.org/blog/what-could-changes-in-tariff-policies-mean-for-patients/

discontinues a product, there is often a significant lag time until alternatively sourced supply becomes available to patients due to the time-intensive process of obtaining regulatory approvals, batch testing products, shifting manufacturing and operations schedules, and considerations around the financial viability of even launching that product. In short, if one manufacturer discontinues a product, there is no guarantee that others have the ability, capacity, or economic incentive to step in and fill that market void.

Additionally, the resulting financial impact from tariffs could have a chilling effect on the ability of manufacturers to invest in new generic products, especially complex products that are difficult to manufacture and require significant upfront investment. Complex generics and first-to-market generic medicines are critical to enhancing competition in pharmaceutical markets, expanding patient access to therapeutics used to treat chronic conditions, and lowering prescription drug costs for patients. With a long history of developing generic "firsts", Viatris has extensive knowledge of the significant investments necessary to bring these products from the laboratory to the pharmacy counter, with hundreds of millions of dollars of investments made in research and development, regulatory, intellectual property, and manufacturing capacity to develop and launch complex generics in particular. For instance, the investment associated with developing and launching Wixela (the first FDA approved bioequivalent alternative to Advair Diskus; indicated for patients with chronic obstructive pulmonary disease (COPD)) was $700 million. Additional examples of our first-to-market complex generics that required significant capital investment include medicines used to treat asthma and COPD (Breyna – a generic to Symbicort), multiple-sclerosis (Glatiramer Acetate Injection), and dry-eye disease (Cyclosporine Ophthalmic Emulsion). Future investment in the next generation of complex generic medicines may be at risk due to the potential negative financial impacts from tariffs, which could stifle competition and delay patient access to affordable medicine alternatives.

Manufacturing Decisions Include Many Factors

Viatris has a global and diverse supply chain that is optimized to support patients where they live. As a U.S. company, Viatris has a substantial operations presence in the U.S. and we make more than 8.5 billion doses of medicine in the U.S. annually. We are continually exploring ways to better support U.S. patients, including the potential to increase our U.S. capacity.

With respect to question VIII posed in the Federal Register notice related to the feasibility of increasing domestic capacity for pharmaceutical manufacturing, a variety of factors impact decisions about where to manufacture our products, ultimately leading to the cost at which a patient accesses our products. These factors are especially relevant to our generic portfolio and include the ability to utilize capacity in our current network, the timeline and capital expenditures needed to bring manufacturing online, and the contribution of a particular site to the cost of goods sold (COGS). All of these impact the way a product is priced when it goes to market.

It generally takes multiple years and significant (hundreds of millions of dollars) of up-front and long-term financial commitments to build a new manufacturing site. This means that we often try first to identify capacity to manufacture new products at existing sites in order to contain costs, which allows us to continue to provide savings to patients. However, it can also be costly and time consuming to move products from one site to another – it often takes 12 to 18 months to obtain the required regulatory

approvals necessary to move a product from one site to another and upwards of $1 million per product transfer, and at times significantly more.

While Viatris frequently considers our existing U.S. manufacturing footprint when striving to maximize patient access and affordability, these factors, along with no price premium assigned by purchasers to pharmaceuticals manufactured in the U.S., requires us to also rely extensively on our geographically diverse network to meet the needs of patients, including those requiring high volumes of essential low-cost/low-margin medicines. The ability to compete and obtain market share, and therefore remain viable within the industry, is directly related to a manufacturer's capacity to reliably supply significant volumes of medicines at low prices.

Policy Levers to Encourage Domestic Manufacturing and Improve Supply Chain Resiliency

We appreciate the Administration's commitment to enhancing the resiliency of the U.S. pharmaceutical supply chain and we encourage the consideration of additional policy solutions that can help enable stable and secure access to medicines for U.S. patients without the risk of increased barriers to access and drug shortages. These policies include:

- Adjustments to tax and regulatory policies that level the playing field with other developed economies.
- Stockpiling of essential medicines at U.S. sites with support from the U.S. government.
- Fast-tracking FDA review of product manufacturing transfers or new manufacturing facilities.
- Pursuing trade agreements with ally countries that enable exports of U.S. produced pharmaceuticals while maintaining the significant benefits of U.S. patient access to the global pharmaceutical manufacturing network.

Viatris appreciates the opportunity to provide comments on this important matter and looks forward to future collaboration on policies that enhance the U.S. pharmaceutical supply chain.