May 6, 2025

Docket Number: BIS-2025-0022

Mr. Eric Longnecker, Deputy Assistant Secretary for Technology Security
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, D.C. 20230

RE: Department of Commerce Docket No. 250414-0065, Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, XRIN 0694-XC120

Dear Deputy Assistant Secretary Longnecker:

Zydus Pharmaceuticals (USA) Inc. is providing comments in response to the April 16, 2025 Federal Register notice regarding an investigation to determine the effects on the national security of imports of pharmaceuticals and pharmaceutical ingredients. Zydus Pharmaceuticals (USA) Inc. is a wholly owned subsidiary of Zydus Lifesciences Limited based in Ahmedabad, India. Zydus has several US-based companies that are heavily focused on improving access to medications and healthcare to patients across the US. Zydus currently has four divisions that are commercialized in the US market: Zydus Pharmaceuticals (USA) Inc. is one of the top 5 suppliers of generic pharmaceuticals in the US; Viona Pharmaceuticals Inc. is another generic division primarily focused on topical and liquid products; Sentynl Therapeutics, Inc. is a rare disease organization that brings important life-saving medications to our patients in the US; and ZyVet Animal Health Inc. is actively growing within the companion animal health space. Zydus is also the first generic pharmaceutical company from India looking to bring a new molecular entity in the liver space that would be in a rare disease therapeutic category for PBC (Primary Biliary Cholangitis). Zydus employs over 130 employees across its U.S. businesses. Our purpose is to ensure US citizens have access to medications for rare/orphan diseases and to further help patients live a better life.

In addition to the crucial role our companies play in supplying pharmaceutical products for the US market, we also have a venture capital firm, Zynext Ventures, that is focused on investing in seed and early-stage disruptive healthcare technologies that have the potential to bring innovative medicine and treatment options to US patients.

Zydus supports the Administration's goals of (1) lowering prescription drug prices in the US and (2) ensuring that the pharmaceutical supply chain is safe, secure and diversified, however, Zydus does not agree that tariffs are the solution.

Zydus Pharmaceuticals (USA) Inc.
(A wholly owned subsidiary of Zydus Lifesciences Limited)
73 Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900 | Fax: 609-730-1998

Spending and Demand for Medicine Will Increase

Spending on medicine in the US is expected to increase by 4-7 percent through 2028[i]. The number of days of therapy per capita has grown 12 percent over the past five years, with growth of the total days of therapy outpacing population growth[ii]. While it is important to continue to incentivize brand pharmaceutical companies to innovate and introduce newer therapies to the market, we feel it is imperative that the generic pharmaceutical industry is protected to ensure a stable, quality, and affordable supply of medications for the American people.

Generic pharmaceuticals are an integral part of the US healthcare system and provide affordability and accessibility to patients. In 2023, generics made up 90 percent of total US generics filled while only 13.1 percent of US prescription drug spending and 1.2 percent of total US healthcare spending[iii]. Total generic and biosimilar savings in 2023 were $445 billion[iv]. Because of the economic pressures facing manufacturers in the US generics pharmaceutical market, tariffs have the potential to increase prescription drug prices for patients.

While demand for generic pharmaceuticals has continued to increase, consolidation of buyers has created an environment that limits manufacturer negotiating power. In the retail generic pharmaceutical market, three buying groups account for almost 80 percent of drug purchases.[v] Similarly in the institutional market, three organizations account for at least 80 percent of hospital drug purchases.[vi] This consolidation, along with the vertical integration that has taken place between wholesalers, buying groups, and Pharmacy Benefit Managers (PBMs), has enabled buyers of generic pharmaceuticals to demand one-sided contract terms. Contract terms such as most-favored nations clauses and failure to supply have led generic manufacturers to make the difficult decision to exit products or risk paying significant penalties on supply issues that may be outside their control.

Outside of one-sided contracts, generic manufacturers struggle with limited conversion to generic products as a result of rebates and other strategies brand manufacturers put in place to keep patients on the branded product. Today, brand manufacturers pay rebates to many commercial and government formularies to prevent access to generic products and prioritize use of the branded products.[vii] In addition to implementing rebate strategies to prevent generic manufacturers from gaining share in the market, brand manufacturers have been using patent thickets and on-going litigation to keep generics off the market. While we believe brand manufacturers should be able to recoup their investments and earn a profit for innovating new and improved pharmaceutical products, it is not uncommon to see 50 or more patents listed in the Orange Book which can make it difficult for a generic manufacturer to litigate financially and delay patient access to a more affordable generic. Humira®, for example, obtained over 160 patents on the product, with most being listed several years after the original FDA approval.[viii] The constant price erosion faced by generic manufacturers combined with delayed coverage of new generics to market disincentives generic manufacturers to invest in bringing more generic pharmaceuticals to market.

Imposing tariffs on pharmaceuticals could potentially put 20% of the Zydus portfolio in jeopardy potentially risking drug shortages, or an overall increase in drug pricing, both negatively impacting patients in need of these critical medications. 56 percent of drug shortages today are on products that are priced at $1 per unit or less[ix]. While Zydus, along with many of its peers, ultimately want to ensure a stable supply of life saving medications for

Zydus Pharmaceuticals (USA) Inc.
(A wholly owned subsidiary of Zydus Lifesciences Limited)
73 Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900 | Fax: 609-730-1998

Americans, sustainability becomes a concern when there is a lack of economic incentives to produce products yielding little to no margins.

There is a history in the US where state and federal policies have had unintended consequences on generic pharmaceutical availability in the US. In 2015, a new price inflation penalty for generics was implemented in the Medicaid program. This program was intended to penalize pharmaceutical companies for taking price increases but failed to consider the volatility of the generics market. While brand manufacturers operate in a monopoly market and can control their price, the average price of generic manufacturers fluctuates due to market forces that are outside their control (for example, a purchaser deciding to move to another generic supplier which in turn causes average price to go up as a result of customer mix). Since the Medicaid generic drug penalty was implemented, generic manufacturers have faced millions of dollars in penalties on generic products that have not actually taken a price increase. These penalties have driven some generic manufacturers to exit the market on certain products, increasing the likelihood of shortages.[x]

Domestic Production of Pharmaceuticals Cannot Meet Demand

The pharmaceutical supply chain is complex. Key starting materials (KSMs) are used to manufacture Active Pharmaceutical Ingredients (APIs) and inactive ingredients that are ultimately combined to create finished drug products[xi]. Getting from KSMs to finished API can involve several steps through a variety of processing technologies[xii]. Once API is produced, it is formulated into a finished pharmaceutical product, which is then packaged and ultimately shipped to wholesalers and pharmacies across the US.

Zydus is aligned with the Administration that manufacturing in the US is an opportunity that would help improve access to key molecules within the US and ensure access to critical medications for all Americans; however, there are numerous challenges with US manufacturing. Up until 2024, we had four manufacturing plants in the US employing over 300 people in facilities containing over 300,000 square feet. Because of a variety of factors, we ultimately made the difficult decision to close the plants. There were a multitude of reasons including: (1) as we exited the market for the majority of products manufactured at these sites as there was no business environment to transfer new products to these facilities. (2) It is difficult to compete with foreign-manufactured products as the manufacturing cost per 1,000 pills is significantly higher in the US. (3) We faced the challenge of retaining talent and hiring employees at the facilities. (4) There are environmental concerns that arise when manufacturing key starting materials and active pharmaceutical ingredients. While we do not have any manufacturing facilities in the US today, Zydus is committed to evaluating opportunities that would allow us to bring some of our manufacturing to the US and are willing to further invest in US infrastructure if there is an opportunity to do so. Diversifying the supply chain and assuring supply for US patients is critical, but we believe bringing manufacturing to the US is not the only solution.

The Role of Foreign Supply Chains in US Medicine

In addition to supporting efforts to bring pharmaceutical manufacturing back to the US, Zydus sees an opportunity for the US Administration to create alliances with key stakeholders that can help minimize the cost of critical medications for Americans while ensuring stable access. In 2022, four out of ten prescriptions filled in the US were supplied by Indian manufacturers, with 47% of all generic prescriptions coming from India[xiii]. Pharmaceutical

products supplied by Indian manufacturers provided $1.3 trillion in savings to the US healthcare system between 2013 and 2022[xiv]. These savings, along with consistent supply, help ensure the accessibility of life-saving medications for patients across the US.

India is aligned with the US Administration that diversification of the pharmaceutical supply chain is critical for national security. In recent years, India has incentivized the production of APIs and KSMs through production-linked incentive (PLI) programs[xv]. While India is a significant supplier of generic drugs to the US, India depends on China for almost 70% of its API[xvi]. PLI 1.0, which offered an incentive to promote domestic manufacturing of KSMs and APIs over 6 years and promoted creation of bulk drug park, was followed by PLI 2.0 in March 2021, which included incentives to enhance India's manufacturing capabilities by diversifying into complex generics, biologics, and biosimilars[xvii]. Reducing the dependence on imports helps support the overall goal of de-risking supply of safe and affordable medications for Americans.

Zydus believes India can provide the US Administration a strong ally in achieving its goal of a secure and affordable healthcare system. India has a cost advantage in skilled human resources and has become an essential part of the US drug supply chain[xviii]. Historically, Indian companies have made significant investments in creating infrastructure and jobs in the US[xix]. Generic manufacturers that belong to the Association of Accessible Medicines (AAM) manufacture over 60 billion doses of prescription medicines in the US and employ over 36,000 US-based workers[xx]. We believe that creating an alliance that leverages the skilled labor and established infrastructure in India along with the shared desire of creating a secure pharmaceutical supply chain for Americans can provide a sustainable partnership for years to come. Product-specific long-term contracts with Indian manufacturers that are willing to negotiate with the US government can be a win-win relationship; the US Administration will gain assured, quality supply of critical molecules at an affordable cost while Indian manufacturers benefit from predictable demand. Moreover, it is critical for the US to rely on trusted partnerships with allied countries to ensure that access to life-saving medications continues while US manufacturing capabilities are built.

While we are aligned with the US Administration that it is critical that the US has a safe and secure supply of pharmaceutical products, the investment to bring manufacturing to the US would be considered in conjunction with other government action including (1) streamlining the FDA regulatory process and removing regulatory barriers for pharmaceutical companies to bring products to market; (2) cracking down on anticompetitive practices of buyers and others in the pharmaceutical supply chain; (3) accelerating investment in the pharmaceutical industry to provide financial stability for companies; (4) reforming environmental permitting to allow faster approval of manufacturing capabilities.

Should you have any questions or need additional information, please feel free to contact us.

Sincerely,

Punit Patel
President & CEO – Zydus Americas

Zydus Pharmaceuticals (USA) Inc.
(A wholly owned subsidiary of Zydus Lifesciences Limited)
73 Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900 | Fax: 609-730-1998

[i] IQVIA Institute for Human Data Science. The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028. April 2024. Available from www.iqviainstitute.org.
[ii] IQVIA Institute for Human Data Science. The Use of Medicines in the U.S. 2024: Usage and Spending Trends and Outlook to 2028. April 2024. Available from www.iqviainstitute.org.
[iii] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. September 2024. Available from www.accessiblemeds.org.
[iv] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. September 2024. Available from www.accessiblemeds.org.
[v] AAM Response to FTC's Request for Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages. May 2024. Available at https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Response-to-FTC-HHS-RFI-on-Drug-Shortages-5-30-2024.pdf
[vi] AAM Response to FTC's Request for Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages. May 2024. Available at https://accessiblemeds.org/wp-content/uploads/2024/11/AAM-Response-to-FTC-HHS-RFI-on-Drug-Shortages-5-30-2024.pdf
[vii] Medicare Plans Continue Trend of Restricting Generic Drugs. Available from https://accessiblemeds.org/resources/ press-releases/medicare-plans-continue-trend-restricting-generic-drugs/
[viii] Hatch-Waxman turns 40. Is it over the hill?(Or is the Hill over Hatch-Waxman…). February 2024. Available from https://accessiblemeds.org/resources/press-releases/aam-white-paper-hatch-waxman-turns-40/
[ix] Association for Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. September 2024. Available from www.accessiblemeds.org.
[x] Association for Accessible Medicines. Drug Shortages: Causes & Solutions. Available from www.accessiblemeds.org.
[xi] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xii] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[2] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xiv] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xv] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xvi] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xvii] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xviii] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xix] IQVIA Institute for Human Data Science. U.S.-India Medicine Partnership: India's Contribution to the U.S. Healthcare System. April 2024. Available from www.iqviainstitute.org.
[xx] Association for Accessible Medicines. Tariff Actions Should Ensure Access to Lower-Cost Generic and Biosimilar Medicines. February 2025. Available from www.accessiblemeds.org.

Zydus Pharmaceuticals (USA) Inc.
(A wholly owned subsidiary of Zydus Lifesciences Limited)
73 Route 31 North • Pennington, NJ 08534 | Phone: 609-730-1900 | Fax: 609-730-1998