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May 7, 2025

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: Amended and Restated Comment in Response: 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* (DOC-2025-0022 / XRIN 0694-XC120).

Dear Deputy Assistant Secretary Longnecker:

Aurobindo Pharma USA, Inc., on behalf of itself, its U.S. subsidiaries, and its U.S. affiliates (collectively, "Aurobindo USA") is pleased to provide its comments in response to the U.S. Department of Commerce's "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients." 90 Fed. Reg. 15,951 (April 16, 2025).

Headquartered in East Windsor, New Jersey, Aurobindo USA is a direct subsidiary of Aurobindo Pharma Limited (APL) in India (together with Aurobindo USA and its other worldwide affiliates, "Aurobindo"). Aurobindo is an innovation led, integrated global pharmaceutical company producing a wide range of quality, finished dose formulations and Active Pharmaceutical Ingredients (APIs) for the developed and developing markets of the world. With over 700 ANDAs, Aurobindo USA is the largest U.S. generic pharmaceutical company in terms of prescriptions dispensed, supplying over 24 billion tablets in the U.S. annually.

From its finished dose manufacturing plants, packaging plant, logistics center, and research and development and similar intangible assets, spanning New Jersey and North Carolina, Aurobindo has invested over $680 million in its U.S. operations. In recent years, Aurobindo USA renovated its manufacturing facility in New Jersey, and acquired a large manufacturing facility and almost 33 acres of land in Puerto Rico. By December 2025, Aurobindo USA will be capable of manufacturing [redacted] units in its New Jersey facility. With certain capital improvements subject to financing, the New Jersey facility could increase production by another [redacted] units, and the Puerto Rico facility could be capable of producing [redacted] units. Considering our position in the U.S. industry and commitment to U.S. growth, we appreciate the opportunity to provide the following detailed responses to the topics outlined in the Notice:

(i) The current and projected demand for pharmaceuticals and pharmaceutical ingredients in the U.S.

Based on IQVIA's Information Management System (IMS) database, we estimate the total current market demand to be [redacted] units of pharmaceutical product per year. With the genericization of certain brands over the next five years, the generic pharmaceuticals market is expected to grow by over 5% year over year.

(ii) The extent to which domestic production of pharmaceuticals and pharmaceutical ingredients can meet domestic demand.

As noted above, Aurobindo USA will have the capacity to manufacture [redacted] tablets domestically this year. If Aurobindo USA receives an investment or concessional funding for additional capital improvements, that capacity could increase to over [redacted] tablets domestically per year.

(iii) The role of foreign supply chains, particularly of major exporters, in meeting U.S. demand for pharmaceuticals and pharmaceutical ingredients.

Between cost differentials in manufacturing, regulatory hurdles for establishing production facilities (including environmental considerations for API production facilities specifically), and predatory pricing, many generic manufacturers depend on procurement from and manufacturing in foreign countries, namely India, the EU, and China. This is particularly the case with respect to APIs, 88% of which are imported for U.S. drug products; as described in section (viii) below, APIs are extremely costly to produce, and current U.S. regulations impose restrictions on manufacturing these chemicals. Notwithstanding the foregoing, not all foreign supply chain risks are created equal: the national security concerns related to India, for example, vary greatly from others given that India is the largest democracy in the world and has a long-term partnership with the U.S. Although foreign supply chains play a critical role in product availability and supply continuity, each supply chain bears its own national security analysis. During the peak of the Covid-19 pandemic, Aurobindo responded to the U.S. FDA's direct request for supply of critical antibiotics (e.g., Amoxicillin, Amoxicillin-Clavulanate, Azithromycin, etc.) and other life-saving drugs by air-lifting quantities, at a significantly higher expense, to meet the need in this national emergency; without our foreign supply chain, the country could not have accessed such drugs in such a short period.

(iv) The concentration of U.S. imports of pharmaceuticals and pharmaceutical ingredients from a small number of suppliers and the associated risks.

We presume at least some of the Administration's national security concerns with pharmaceutical imports stems from the high volume of API sourced from single sources who are not reliable. However, there are a number of suppliers for pharmaceutical ingredients. Although we appreciate the Administration's priority to lessen foreign supply generally, as noted in section (iii), not all foreign countries pose the same national security risks. Again, considering India's long-term partnership with the U.S., Aurobindo USA believes that sourcing pharmaceuticals and pharmaceutical ingredients from India should not be considered a national security risk. [redacted]

(v) The impact of foreign government subsidies and predatory trade practices on U.S. pharmaceuticals industry competitiveness.

As the Administration has recognized, pricing pressure (among other things) pushes manufacturing outside the U.S. to locations with lower labor and other manufacturing overhead costs, less environmental and health regulations, and, in certain countries other than India, high government subsidies. These predatory trade practices are more prevalent in some countries than others. But for the significant subsidies offered to

foreign businesses, such companies could not sell their products for substantially lower costs, and but for the pricing pressure in the U.S. demanding extremely low-priced generic products, manufacturers could source ingredients from other countries that may present less of a national security risk. Domestic manufacturing of APIs—to the extent it exists or will exist—cannot compete with dumping and unfair subsidization. For this reason, Aurobindo appreciates that tariffs may be appropriate in some cases for countries other than India while encouraging domestic industry under the right circumstances.

(vi) The economic impact of artificially suppressed prices of pharmaceuticals and pharmaceutical ingredients due to foreign unfair trade practices and state-sponsored overproduction.

Please see our response to section (v) above regarding the impact of foreign unfair trade practices and state-sponsored overproduction. Regarding trade practices in the U.S., customers are limited and consolidated, which results in pricing pressure.

(vii) The potential for export restrictions by foreign nations, including the ability of foreign nations to weaponize their control over pharmaceuticals supplies.

The potential for export restrictions exists with some—not all—of our foreign trade partners. Aurobindo, which is headquartered in India, does not anticipate any export restrictions affecting its supply chain. As the Wall Street Journal recently reported, "India and the U.S. have grown closer in recent years as trade partners and defense allies . . ."[1] To date, Indian pharmaceutical manufacturers have invested approximately [redacted] in the U.S. [redacted]

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

As described above, companies can increase their capacity by either expanding their existing facilities or breaking ground on new facilities—but this comes at a cost. To evaluate the feasibility of constructing an API facility, for example, Aurobindo USA must consider the multitude of factors that accompany API manufacturing: complex manufacturing process requiring specialized personnel; volume; environmental regulations; high power and utility costs (which are critical to API production and stability); appropriate locality; etc. [redacted]

[1] Shan Li, *JD Vance Sees an India That America Can Work With*, WALL STREET J. (Apr. 22, 2025).

(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.

Put simply, tariffs are not the answer where a trade partnership agreement is possible. Unlike subsidies and other incentives, tariffs will create erratic supply, increase pricing, and hamper U.S. investment. The generic and biosimilar industries are already operating at razor-thin margins. Many manufacturers may decide it is more cost effective to discontinue a product than to compete with the reduced margins that come with the new tariff duties imposed. Between some manufacturers arbitrarily withdrawing from the market and others unable to afford the tariff duties at port, shortages are a near certainty. Furthermore, pharmaceutical manufacturers contracted with the Centers for Medicare & Medicaid Services (CMS) are subject to the Medicaid Drug Rebate Drug Program, a health benefits coverage program for low-income residents who would otherwise be eligible to purchase coverage through the Health Insurance Marketplace. The Program imposes an inflation penalty on manufacturers when the price of Medicaid-covered drugs increases faster than the rate of inflation; ultimately, manufacturers must pay a penalty (rebate) to CMS for the difference between the inflated drug price and the inflation-adjusted price. At a certain point, the higher duties and other absorbed costs will result in an operational loss, and when profitability drops into the negative, the business imperative is similarly reduced.

If the Administration is keen in maintaining tariffs against certain countries, the tariffs should be (i) triaged and phased, (ii) only on the riskiest partners and only for products that will be manufactured in the U.S., and (iii) in balance with other regulatory mandates. In terms of timing, the Administration could decline to impose any tariffs on certain API and other components for a period of 5 years while companies work on tech transferring and constructing facilities to bring such manufacturing to the U.S. In the vein of limiting by party/product, the Administration could also remove tariffs on India—which otherwise would undoubtedly result in a shortage—and prioritize countries that pose the greatest national security risk for the most vulnerable products. Those tariffs should also be limited to products that can or will be manufactured in the U.S. Lastly, the Administration could suspend application of the Medicaid Drug Rebate Program inflation penalty for selective life-saving products (e.g., Amoxicillin, Azithromycin, oncology products, etc.) that could be "weaponized" by a hostile foreign country.

(x) Any other relevant factors.

The generic drug market has consistently delivered affordable medicine for U.S. patients, supporting our U.S. healthcare system and broader U.S. national security. The relative concentration of pharmaceutical drug production in certain foreign markets may cause certain U.S. government concern, but the outcome of this investigation should mitigate, rather than aggravate, the existing unfair trade practices. Tariffs on finished pharmaceutical products, APIs, and other ingredients will only increase costs, leading to more shortages and less reshoring. Unless the Administration is willing to offer incentives and tackle the root cause of unfair trade practices, the tariffs will ultimately result in harm to U.S. patients and reduced availability of much-needed medicine in the U.S., and a sick nation poses a greater national security risk than a phased reshoring of pharmaceutical finished product and ingredient manufacturing.

For pharmaceutical companies to consider reshoring production, relaxing regulatory hurdles (like permitting) will only help with timing, but not costs. Generic pharmaceutical companies operate on much smaller margins than our branded counterparts; not all companies are willing to spend tens of millions in capital to build a facility without envisioning a return on that investment. If the Administration is focused on bringing pharmaceutical manufacturing to the U.S., then it should consider the motivator other foreign governments are using: subsidies. If a U.S. company is offered, among other things, (i) grant money for construction, (ii) a government contract for product at a fixed price and with volume commitments for a defined period, and (iii) a safe harbor for any policy changes later on, then such company may be incentivized to embark on such an endeavor. The Administration should also consider triaging the approach, identifying the most critical APIs and other products for which it wishes to have manufacturing done domestically.

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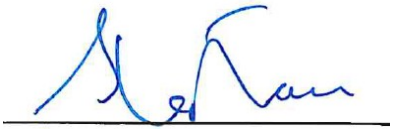
Should you have any questions or require any additional information, please do not hesitate to contact me at ssmurty@aurobindousa.com.

Respectfully submitted,



Swami S. Iyer
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