Your Generics & Biosimilars Industry

May 11, 2018

Docket Number: USTR-2018-0005

The Honorable Robert Lighthizer
U.S. Trade Representative
Office of the U.S. Trade Representative
600 17th St. NW
Washington, DC 20508

Re: Proposed Determination of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation: Written Submission

Dear Ambassador Lighthizer:

The Association for Accessible Medicines (AAM) is pleased to provide comments on behalf of its members in response to your April 6, 2018, notice in the Federal Register regarding the "acts, policies, and practices of China determined to be unreasonable or discriminatory and to burden or restrict U.S. commerce." 83 Fed. Reg. 140906-14954 (the 301 Notice). AAM and its members are driven by the belief that access to safe, effective and affordable generic and biosimilar medicines can improve people's lives and provide significant savings to the U.S. healthcare system. AAM represents the manufacturers and distributors of finished generic pharmaceuticals, biosimilars, and bulk pharmaceutical chemicals and suppliers of other goods and services to the generic drug industry. In 2016, AAM members manufactured over 61 billion doses of prescription medicines in the United States in 149 facilities located in 16 states.

Imposition of tariffs on generic drugs, biosimilars, or their ingredients would have a perverse effect on health care spending in the U.S. Generic medicines generated $253 billion in savings for patients and taxpayers in 2016, and in the last decade, the U.S. healthcare system has saved $1.67 trillion due to the availability of low-cost generics. Savings for the two largest government healthcare programs, Medicare and Medicaid, totaled $77 billion and $37.9 billion, respectively in 2016.[1] Tariffs on generic or biosimilar medicines would increase prescription drug prices and increase the risk of drug shortages for affected medical products.

[1] Association for Accessible Medicines, Generic Drug Access & Savings in the U.S. 2017, p. 5, available at https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf .

As explained below, AAM believes that all finished pharmaceuticals, pharmaceutical ingredients, and active pharmaceutical ingredients (API) should be removed from the Annex of products to be subject to additional duties published in the 301 Notice, because imposing an additional 25 percent tariff on such products will increase the cost of prescription drugs for patients in the United States, taxing their health and wellbeing, which will cause disproportionate economic harm for consumers and is unlikely to result in the desired changes to China's practices.

A. All finished pharmaceutical products and active pharmaceutical ingredients (API) should be removed from the Annex.

AAM and its member companies strongly oppose USTR's proposed additional 25 percent duty on pharmaceutical products and API for medicines, because such additional duties would cause disproportionate economic harm to U.S. interests, including the interests of consumers, by significantly increasing the cost of generic prescription drugs. Due to the likely harm to patients in the United States, these products should be removed from the proposed tariff list. **Specifically, we request deletion of the medical products in the 301 Notice, including HTS subheadings 29146200 through 30067000.**

AAM is strongly aligned with President Trump's objective of lowering prescription drug prices for patients in the United States. A vibrant generic and biosimilar industry in the United States is key to achieving that objective. Use of generic drugs in the United States resulted in $253 billion dollars in savings in 2016 and $1.67 trillion in the ten-year period (2007-2016).[2] The potential savings are even more significant in the developing biosimilars industry, which has been projected to create as much as $250 billion in additional savings over the next decade.[3] AAM is concerned that the proposed additional 25 percent tariff will lead to increased costs of manufacturing generics and biosimilars in the U.S. and thus higher prescription drug prices and decreased access for patients in our country.

Many countries have recognized that tariffs on pharmaceuticals are a barrier to access to medicines. More than 90 percent of countries apply tariff rates of less than 10 percent on

[2] Id. p. 20.
[3] Steve Miller, The $250 Billion Potential of Biosimilars, Express Scripts. April 2013. http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars

medicines.[4] In fact, China is lowering its pharmaceutical tariffs now.[5] Moreover, since 1995, the United States and 21 of its trading partners have eliminated import duties on pharmaceuticals and API under the WTO Pharmaceutical Agreement, in order to lower the cost of drug prices for U.S. consumers.[6]

Given the relatively low margins for many widely-used generic medicines, any increase in their cost of production must be passed on to patients in the form of higher drug prices if companies are to continue to manufacture such drugs. Analysts have recognized that the 25 percent tariff, if imposed, is likely to have a greater impact on generic producers than their brand name counterparts because manufacturing represents a much greater proportion of generic producers' costs.[7] Under the proposed 25 percent tariff, some new products may not be cost-effective enough to bring to market at all, which could have a negative effect on new products in the development pipeline and would deprive patients of more affordable life-saving therapies. Moreover, the time necessary to secure FDA approval of potential alternative suppliers of pharmaceutical ingredients would likely prolong either higher generic drug prices or increased risk of drug shortages in the United States.

In addition to imposing economic and public harms to consumers by raising health care costs, an additional 25 percent tariff on imports of pharmaceuticals and API from China is unlikely to be effective in obtaining the elimination of China's acts, policies, and practices identified in the 301 report. Drug manufacturers are held to the same high quality and safety standards by the Food and Drug Administration (FDA) regardless of whether pharmaceutical manufacturing takes place inside or outside the United States. This is, in large part, due to FDA user fee funding provided by generic drug manufacturers, which began in 2012, and new authorities for the FDA championed by the generic drug industry at that time. These new resources and authorities gave FDA the ability to regulate the drug supply chain and hold foreign manufacturers, including those in China, to the same standards that apply to US manufacturers. In AAM's view, the 25 percent tariff is much more likely to increase the risk of

[4] Müge Olcay & Richard Laing, Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?, Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization (May 2005), http://www.who.int/intellectualproperty/studies/tariffs/en/.
[5] Reuters, China Cuts Import Tariffs on Food, Drugs and Apparel (Nov. 24, 2017) available at https://www.google.com/amp/s/mobile.reuters.com/article/amp/idUSKBN1DO0T3.
[6] Nilanjan Banik & Philip Stevens, Pharmaceutical Tariffs, Trade Flows and Emerging Economies, Geneva Network (2015), https://geneva-network.com/article/medicine-tariffs-make-sense/.
[7] Bill Meagher, Trump's Tariffs Could Hurt Generic Drug Companies and Increase Prices, TheStreet (Apr. 4, 2018), https://www.thestreet.com/story/14545510/1/china-tariffs-could-hurt-generic-drug-companies-and-patients.html.

drug shortages in the United States than it is to result in the elimination of the actions identified in the Section 301 report.

Lastly, according to the FDA[8], approximately 80 percent of APIs are manufactured outside the U.S. If the proposed pharmaceutical tariffs were applied, it is questionable that U.S.-based API manufacturing capacity could supply the U.S. market adequately. Therefore, attempting to restrict imports of API from China might only worsen the serious problem of drug shortages in the U.S. and deprive patients of essential medications.

B. Conclusion

AAM's members provide essential medicines that improve the health of patients in the United States against some of the most pressing health conditions globally. Generic drug and biosimilar competition has helped drive down drug costs and prevent extensive drug shortages in the United States, particularly for generic medicines. Imposing an additional 25 percent tariff on pharmaceutical products would tax the health and wellbeing of patients, which would cause disproportionate economic harm for consumers and is unlikely to result in the desired changes to China's practices. In line with the President's goal of lowering drug prices, pharmaceutical products and API should be eliminated from the Annex of goods of China that will be subject to the 25 percent additional tariff.

Sincerely,

/s/

Jeffrey K. Francer
Senior Vice President & General Counsel

cc: Scott Gottlieb, MD
Commissioner of the Food and Drug Administration

[8] Howard Sklamberg & Michael Taylor, In India, With Our Sleeves Rolled Up (Mar. 18, 2015), available at https://blogs.fda.gov/fdavoice/index.php/tag/globalization/