



June 17, 2019

Docket Number: USTR-2019-0004

The Honorable Robert Lighthizer  
U.S. Trade Representative  
Office of the U.S. Trade Representative  
600 17<sup>th</sup> Street, NW  
Washington, DC 20508

Re: Request for Comments Concerning Proposed Modification of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation

Dear Ambassador Lighthizer:

The Association for Accessible Medicines ("AAM") is pleased to provide comments on behalf of its members in response to the request for comments concerning a proposed modification of action pursuant to Section 301.<sup>1</sup> AAM and its members believe that access to safe, effective, and affordable generic and biosimilar medicines can improve lives and provide significant savings to the U.S. healthcare system. AAM represents 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.

AAM strongly supports the Office of the U.S. Trade Representative's decision to continue excluding pharmaceuticals and certain pharmaceutical inputs from the expanded list of Chinese exports that will face tariffs when imported into the United States. Our explanation for why this continues to be the correct policy position follows.

Last year, the initial list of goods from China proposed for a 25 percent tariff ("List 1") included finished generic pharmaceuticals and active pharmaceutical ingredients ("API") for medicines. AAM opposed subjecting these products to an additional duty 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. Fortunately, finished drugs and API were removed from List 1 and they have not been proposed as part of the current list of goods ("List 4"). AAM appreciates that the Administration continues to recognize the potential harmful impact that an increased tariff would have on efforts to reduce drug prices in the United States. In particular, AAM would like to underscore a few key points:

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<sup>1</sup> *Request for Comments Concerning Proposed Modification of Action Pursuant to Section 301: China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation*, 84 Fed. Reg. 22564 (May 17, 2019) (the "301 List 4 Notice").

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- The imposition of tariffs on generic drugs, biosimilars, or their ingredients would have a perverse effect on healthcare spending in the United States. Tariffs on generic or biosimilar medicines would increase prescription drug prices and increase the risk of drug shortages for affected medical products.
- Analysts have recognized that if a 25 percent tariff is imposed, it would likely have a greater impact on generic producers than their brand name counterparts because manufacturing represents a much greater proportion of generic producers' costs.<sup>2</sup> Considering that generics are 90% of the US drug supply but only 23% of the overall pharmaceutical spend, such a negative impact on this industry could significantly undermine the Administration's goal of lowering drug prices
- 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.
- The imposition of tariffs on pharmaceuticals is much more likely to increase the risk of drug shortages in the United States than it is to result in the elimination of the actions identified in the Section 301 report.

AAM recognizes that the Administration is balancing a number of important interests as it continues to press China to address the concerning acts and practices identified in the Section 301 Report. AAM appreciates the continued recognition an additional duty on finished drugs and API would harm access to safe, effective, and affordable generic and biosimilar medicines are an important and essential to improving the lives and providing savings to the U.S. healthcare systems.

Sincerely,



Jonathan Kimball  
Vice President, Trade and International Affairs

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<sup>2</sup> Bill Meagher, *Trump's China 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>.