



Your Generics & Biosimilars Industry

The Association for Accessible Medicines' Expanded Advocacy Strategy to Further Enhance the Security of the U.S. Pharmaceutical Supply Chain

Affordable generic and biosimilar pharmaceuticals are critical components of our nation's healthcare system and have complex global supply chains that are instrumental in ensuring access to lower-cost medicines for America's patients. While the resiliency of the U.S. supply chain stems in part from the globally diverse nature of the industry, policymakers should support greater domestic manufacturing of finished dosage formulations (FDF) and active pharmaceutical ingredients (API) for medicines listed on the U.S. Food and Drug Administration's (FDA) essential medicines list while also ensuring more extensive coordination and cooperation with U.S. allies to promote supply chain security.

Since last year, AAM's supply chain security advocacy has helped to shape the policy debate, with many recommendations reflected in Biden Administration draft policies and in bills proposed by Republican and Democratic members of Congress. As this policy debate, political landscape, and AAM members' business interests continue to evolve since publication of AAM's Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain, AAM must update its advocacy proposals to continue fulfilling the industry's mission. The AAM Board endorses the expansion of AAM's supply chain security advocacy to contain the following three workstreams:

- 1) ***Incentivize further U.S. Manufacturing of Pharmaceuticals:*** U.S. government incentives that increase the sustainability of the pharmaceutical market for U.S.-manufactured medicines on the FDA's essential medicines list are critical for the creation of a long-term market protected from lower-priced imported products. In addition to the proposals included in AAM's Blueprint, AAM's Board endorses the following:
 - a) A Tax credit for expenses related to bioequivalence studies via the R&D tax credit
 - b) A Tax credit for initial and recurring FDA user fees

- c) A 25% reduction in the tax rate for U.S.-manufactured medicines on the essential medicine list (modeled after the Section 199 tax reduction)
 - d) A 20% tax credit based on wages paid to U.S. workers directly engaged in the production of essential medicines.
- 2) ***Secure the API Supply Chain:*** Recognizing that the U.S. pharmaceutical supply chain cannot be fully secure without a diverse, redundant and resilient API supply chain, the AAM Board endorses the following:
- a) AAM's proposed International Pharmaceutical Supply Chain Agreement will be modified to emphasize the importance of ensuring the free-flow of API during times of crisis.
 - b) AAM will explore expanding membership categories to include API producers and/or the launching of an API Council within AAM to represent the API industry.
 - c) AAM will enhance its social media and messaging campaign to highlight the importance of both increasing U.S. API manufacturing and partnering with U.S. allies to ensure uninterrupted access to API during times of natural disaster, political upheaval or global pandemic.
- 3) ***Expand the Market:*** It is also important to ensure that federal health programs support the goal of a sustainable and globally diverse supply chain with greater domestic manufacturing of essential medicines. Accordingly, AAM's Board endorses the following:
- a) Wave mandatory Medicaid rebates for domestically-manufactured generic medicines on the FDA essential medicines list
 - b) Establish a Medicare Star Rating to reward Part D plan that preference domestically-manufactured generic medicines included on the FDA essential medicines list
 - c) Provide bonus payments in Medicare Part B for providers who administer domestically-manufactured generic medicines included on the FDA essential medicines list

Recognizing the imperative to ensure a secure, resilient, redundant, and sustainable U.S. pharmaceutical supply chain, the Board of Directors of the Association for Accessible Medicines (AAM) endorses the aforementioned.