



# New “Buy American” requirements on medicines would limit patient access to affordable medicines and increase the risk of drug shortages during the COVID-19 pandemic

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- Developers of generic and biosimilar medicines support diversification of the pharmaceutical supply chain – and incentives to increase manufacturing in the United States – but we must not hinder our response to the COVID-19 emergency.
  - Changes to the “Buy American” provisions should not limit the ability of the U.S. government to provide medicines to veterans, soldiers and other patients during or after this time of national emergency.

## **Generics and Biosimilars Are Integral to Patient Health and COVID-19 Care**

Generic and biosimilar medicines play an integral role in the health and well-being of America’s patients. As families and the health care system prepare and respond to COVID-19, one of the [recommendations](#) from the Centers for Disease Control and independent [sources](#) such as Consumer Reports is to stock up on needed prescriptions and over-the-counter medications. This is especially critical for patients with chronic conditions and older Americans. In addition, generic manufacturers are directly involved in the treatment and care of patients with COVID-19. Generic medicines help treat the symptoms of the illness (for example, acetaminophen to reduce fever and cough suppressants such as dextromethorphan) and AAM’s members are partnering with health organizations and governments around the world to evaluate the use of currently available generic medicines for the treatment of patients with COVID-19.

## **The Global Pharmaceutical Supply Chain Delivers Medicines Safely and Efficiently**

America’s patients benefit from access to low-cost generics and now rely on generic manufacturers to fill [90 percent of all prescriptions](#). The FDA ensures all pharmaceuticals meet the same high-quality standards regardless of where medicines are manufactured. Globalization of the supply chain – a market reality for the entire pharmaceutical sector of brand-name drug companies and generic and biosimilar manufacturers – has a clear record of success. The United States has one of the safest drug supply chains in the world.

In order to meet the health care needs of America’s patients, 60 percent of all generic finished dosage form (FDF) facilities and 87 percent of all generic active pharmaceutical ingredients (API) facilities are [currently](#) located outside of the United States. Shifting the manufacturing and production of generic medicines and API to the United States as part of the diversification of the supply chain is a desirable long-term goal, but it is simply not feasible in the short-term and would negatively impact patient access to low-cost generics.

Current regulations and costs – setting aside the additional economic limitations posed by COVID-19 – require 5-10 years and up to \$2 billion to establish a new FDA-approved facility in the United States. Even shifting production from one facility to another requires FDA approval, a minimum of 18 months and an investment of several million dollars.

## **Unintended Consequences**

New requirements to apply “Buy America” provisions to the manufacturing and production of generic medicines and API would thus limit patient access to essential medicines, increase the risk of shortages and increase the cost of prescription drugs.

- **Limits Patient Access** – COVID-19 is currently disrupting daily routines and the lives of Americans across the country. The transportation of goods may be limited and manufacturing facilities are dealing with the same workplace challenges faced by all employers. Patients should be confident they can order their prescriptions online and, where permitted, pick up their prescriptions at the pharmacy.
- **Increases the Risk of Shortages** – With the CDC recommendations, generic manufacturers are experiencing increased demand for essential prescriptions and over-the-counter medicines. AAM’s members are working around the clock to meet this demand and ensure continued patient access to their medications. Limiting the supply of medicines based on a manufacturer’s location disrupts the current supply chain and would increase the risk of shortages.
- **Increases the Cost of Medicine** – Imposing “Buy America” provisions on pharmaceuticals, even if it were feasible, would contribute to higher prescription drug costs. One of the reasons pharmaceutical manufacturing, for both brand-name and generic drugs, has shifted overseas over the last few decades is the ability to manufacture in other countries at a lower cost. Without support from the federal government, the cost to build new facilities, expand capacity and comply with state and federal regulations is significant.

## **Getting to Supply Chain Diversification**

Promoting a globally diverse supply chain, which includes an increased manufacturing presence in the United States, is a critical goal for the generic and biosimilar industry. However, any immediate requirement for increased U.S. manufacturing of API or finished pharmaceuticals would be impossible to meet and thus could have a detrimental impact on the supply of medicines for America’s patients. This is especially important now when the supply chain for many manufacturers is stressed due to the COVID-19 crisis.

A medium-term solution to this challenge would be to encourage a more diverse supply chain that benefits from API, excipient and key starting materials (KSM) sourcing and manufacturing with allies such as Europe, India, Israel, Jordan and other countries that have free trade agreements with the United States. This would allow manufacturers to more quickly diversify their supply chains while they are investing in domestic manufacturing plant construction and refurbishment. As part of this effort, the FDA should also reduce the time necessary to approve switching between API suppliers.

To accomplish the goal of attracting the manufacturing of generic medicines to the United States, it will be critical for the federal government to provide both financial incentives and implement regulatory reforms. Examples of this support includes:

- Providing grants and low-cost loans for plant construction or refurbishment;
- Policies to ensure that significant new investments in the U.S. production of medicines are not undermined by imported products that make the medicines produced in those plants non-competitive; and
- Streamlining regulatory and environmental requirements to allow new or refurbished facilities to come online quickly.

AAM and its members stand ready to work with policymakers on how best to achieve these goals and enhance patient access to safe, effective and affordable generic and biosimilar medicines.