TARIFFS ON GENERIC DRUGS WILL INCREASE DRUG SHORTAGES - INSIDE SOURCES

Posted on January 17, 2025 by John Murphy III | INSIDE SOURCES

As President-elect Donald Trump's inauguration approaches, pundits and policymakers have debated the effect of potential new and widespread tariffs on products entering the United States. Lost in the clamor is the devastating effect that tariffs could have on low-cost generic medicines and, most important, the patients who depend on them.

While most manufacturers can pass on the cost of new tariffs to their customers, unlike brand manufacturers, the same cannot be said of generics.

Generic manufacturers sell their medicines to a highly consolidated, competitive market where three middlemen control purchases for more than 80 percent of the market. As a result, they face lopsided contract terms that can significantly limit their ability to be reimbursed beyond the already very low margin rates these purchasers offer.

Generic manufacturers cannot afford to absorb new costs. These manufacturers sell at an extremely low price, sometimes even at a loss, and are increasingly being forced to exit less profitable markets. As evidence, the overall value of all generic sales in the United States has declined by $6.4 billion in five years despite growth in volume and new generic launches.

As a result, applying tariffs to generic medicines is likely to exacerbate the growing problem of drug shortages.

All of this results from the unique value of the generic market. Unlike most other markets, generic prices in the United States generally decrease over time, not increase. Generics are the only segment of healthcare that consistently delivers lower costs. In 2023, the average out-of-pocket cost for a generic was $7.05, while the average out-of-pocket cost for a brand drug was nearly four times higher — at $27.10. In fact, the United States has some of the world's lowest prices for generic medicines.

The drug shortage problem is uniquely American — our country does not value the critical generic drug industry that supplies more than 90 percent of our daily prescription medicines at only 13 percent of the cost of providing all prescription medicines nationally. Other countries, which generally pay more for their generic drugs, do not suffer through these shortages nearly as often. A recent JAMA analysis suggests that higher prices for generic medicines may help explain why Canada has 40 percent fewer drug shortages despite having overlapping and similar regulatory processes.

Further, a study of drug shortages in Finland, Spain, Norway, Sweden and the United States showed that 41 percent of U.S. shortages affected only the United States, and only 1 percent of the 99 shortages studied affected all five countries. The authors noted that “since USA purchasing organizations have substantial purchasing power, they can likely push prices of generic injectables to lower levels. … However, without sufficient mechanisms to guarantee supply, low prices can increase injectable shortages as international drug companies see the USA market for generic injectables as a low priority.”

While every U.S. drug shortage is unique, there is a consistent thread — low unit reimbursement — a factor that increasingly cannot sustain the operations necessary to reliably produce certain medicines. The independent analysts at IQVIA found that well over half of the drugs in shortage in the United States were for medicines routinely reimbursed at $1 per unit or less. Strikingly, three-quarters of drug shortages are in markets with only generic alternatives.

At their core, shortages are a window into the broader challenges to the long-term sustainability of generic medicines. This fragility is caused by (1) market and pricing factors that undermine the sustainability of low-cost generic manufacturing and (2) government policies, including potential tariffs, that compound challenging market dynamics. That’s why Republican and Democratic FDA commissioners have pointed to unsustainably low prices as the cause of drug shortages.

New tariffs would be one more challenge to generic competition. Far from encouraging domestic production, new tariffs on generic drugs, including tariffs on active pharmaceutical ingredients and key starting materials, would erode the ability of generic manufacturers to compete in the United States — and would result in more manufacturers leaving the market and more shortages.

Policymakers must rally to protect this crown jewel — the only part of America’s healthcare system that consistently and reliably delivers lower prices.

During the last Trump administration, policymakers understood the value of generic medicines. They opted not to impose tariffs on the supply chain. The Association for Accessible Medicines and its members urge the new administration to heed this past practice and work with us on constructive policies and regulatory reforms that will bolster the resiliency and vibrance of this critical healthcare market. Such efforts could reward the American economy, lower overall healthcare costs, and, most important, keep American patients healthy.