May 7, 2025

Eric Longnecker
Deputy Assistant Secretary for Technology
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
U.S. Department of Commerce
1401 Constitution Ave NW
Washington, DC 20230

RE: "Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients," Federal Register docket number BIS-2025-0022 (XRIN 0694-XC120)

Dear Mr. Longnecker,

The Canadian Generic Pharmaceutical Association (CGPA) is the national trade association representing the generic and biosimilar medicines industries in Canada. The CGPA appreciates the U.S. Department of Commerce's request for comments cited above and welcomes the Administration's initiative to enhance the U.S. pharmaceutical supply chain. The Administration has stated its intent to use these comments "to determine the effects on national security of imports of pharmaceuticals and pharmaceutical ingredients, and their derivative products."

The competition provided by generic and biosimilar medicines manufacturers provides affordable and accessible medicines that save lives and support the health and well-being of American and Canadian patients. According to IQVIA data, 90% of all drug prescriptions in the United States are filled with cost-saving generic medicines.[1]

Canada's generic pharmaceutical manufacturers are trusted partners for a secure pharmaceutical supply chain for Americans, and have supplied high-quality, safe and efficacious medicines to American patients for more than 50 years. These products are approved by the U.S. Food and Drug Administration (FDA), in facilities that are inspected and approved by the FDA on a regular basis.

The Canadian drug supply is supported by imports of U.S. manufactured generic pharmaceuticals, including essential medicines that are used in hospitals. It is also supported by the imports of key inputs from the U.S. that are used in the Canadian generic pharmaceutical production process, including drug components, excipients and packaging, which supports other important sectors of the U.S. economy.

[1] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024

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Generic pharmaceutical supply chains in the U.S., Canada and around the world are strained and in need of strengthening. Generic pharmaceutical companies operate on low margins and are unable to absorb increased costs and economic shocks to their supply chains. Current pricing levels for generic medicines in both the United States and Canada are not sustainable. Manufacturers are simply unable to supply medicines when the reimbursement level falls under the cost of production.

Both the United States and Canada are experiencing significant market shortages of generic medicines. According to the American Society of Health System Pharmacists (ASHP), there are currently 270 active drug shortages in the United States.[2]

There have been several studies examining the root causes of drug shortages in both the United States and Canada. Economic pressures, regulatory barriers, and lean supply chain limitations have been identified as major contributors to shortages in both countries. Medicines also cannot be manufactured immediately to address drug shortages, as generic pharmaceutical supply chains typically require long lead times.

The products supplied by Canadian generic pharmaceutical manufacturers support a healthy and productive workforce in the United States and are essential to the supply of critical medicines for American patients. A recent analysis published in the *Journal of the American Medical Association (JAMA)* found that among the 3,099 unique drugs sold in the U.S. market, 52 (1.7%) depended on Canada for at least 50% of the supply, including 28 with no alternative suppliers.[3] Of these 52 drugs, 23 (44.2%) are rated as clinically important and 27 (51.9%) have a history of shortages.[4]

The United States and Canada have had reciprocal 0% tariffs on pharmaceuticals and most-favored nation treatment for pharmaceuticals for the past 30 years.[5] This includes pharmaceutical products classified (or classifiable) in HS chapter 30.

A resilient and reliable generic and biosimilar medicines supply chain is critical to patient health, healthcare and national security interests in both the United States and Canada. The imposition of trade barriers such as tariffs on generic and biosimilar medicines would disrupt fragile supply chains and increase the risk of new drug shortages for American and Canadian patients. It could also reduce Canadian generic manufacturing capacity and increase U.S. reliance on imports from countries outside of North America that have lower domestic cost structures.

Measures focused on addressing the root causes of drug shortages in the U.S. and ensuring more timely access to generic and biosimilar medicines competition at sustainable pricing levels would be the most effective approach to addressing U.S. national security interests in the context of generic and biosimilar medicines.

[2] https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics?loginreturnUrl=SSOCheckOnly
[3] March 31, 2025. doi:10.1001/jama.2025.4583
[4] *Ibid.*
[5] Agreement on Trade in Pharmaceutical Products (1994), North American Free Trade Agreement (1994), United States-Canada-Mexico Agreement (2018).

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Recommended Policies to Strengthen Pharmaceutical Supply Chain Security

The Canadian Generic Pharmaceutical Association encourages the Administration to implement holistic and pragmatic policies and regulatory reforms to strengthen the supply chain for generic and biosimilar medicines, bolster the resiliency of the market to the benefit of the U.S. economy, lower healthcare costs for Americans, and keep the patients healthy.

1. Maintain zero-rated tariff status for generic and biosimilar medicines, especially for USMCA-compliant generic pharmaceutical imports from Canada, to contribute to the security of the U.S. drug supply for patients and avoid the potential for increased drug shortages for Americans.

2. Address patent abuses by U.S. brand-name drug companies and provide a statutory safe harbor for skinny label generic drug submissions as recommended by the FDA and AAM to promote timely competition from cost-saving medicines.

3. Ensure sustainable reimbursement levels for generic and biosimilar medicines.

4. Streamline FDA processes to ensure faster generic and biosimilar medicines approvals, while maintaining FDA's high standard of safety, efficacy, and quality.

5. Pursue a transatlantic pharmaceutical supply chain security agreement as recommended by AAM, CGPA and Medicines for Europe.[6]

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The Canadian Generic Pharmaceutical Association appreciates the opportunity to share these comments and looks forward to further discussion of the importance of the Canadian and U.S. generic pharmaceutical manufacturers in supporting U.S. and North American economic security and supporting the sustainability of access to affordable medicines for patients.

Sincerely,

Jim Keon
President

[6] https://www.medicinesforeurope.com/wp-content/uploads/2024/07/AAM-CGPA-Medicines-for-Europe-A-new-transatlantic-partnership-for-the-secure-supply-of-medicines.pdf

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