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**XRIN 0694-XC120**

Eric Longnecker
Deputy Assistant Secretary for Technology Security
Bureau of Industry and Security
U.S. Department of Commerce
14th Street and Constitution Avenue, NW
Washington, DC 20230

**Submitted via:** *https://www.regulations.gov*

**Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients**

Dear Deputy Assistant Secretary Longnecker,

These comments are provided by the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA), an industry association of pharmaceutical manufacturers with production facilities located in Canada, in response to the the investigation initiated by the U.S. Secretary of Commerce under *Section 232* of the Trade Expansion Act to determine the effects on U.S. national security of imports of pharmaceuticals and their ingredients.

The U.S. Administration is considering how to ensure security and resiliency in pharmaceutical supply and reduce reliance on non-allied nations for important medicines and their inputs. Canada shares these concerns about national security of supply and actions that can be taken which will not cause disruptions and shortages.

As the Department of Commerce reviews pharmaceuticals and national security interests, there is a strong case for a general exemption from tariffs on pharmaceuticals imported from allied trade partners, but especially for high quality, FDA-approved medicines from Canadian pharmaceutical facilities without which the U.S. market will surely experience shortages, increased costs and supply chain disruption.

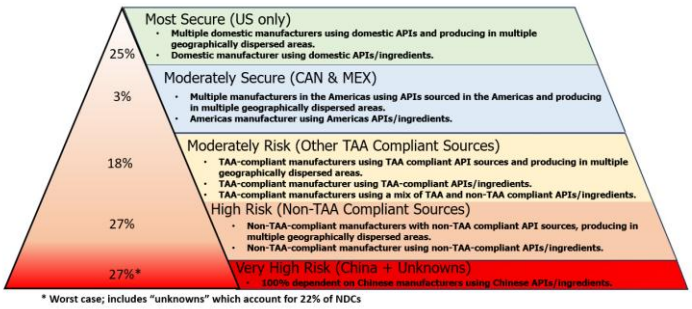
Canada and the U.S. have balanced trade in medicines and supply each others' markets with different types of products. The U.S. is the world leader in pharmaceutical innovation, investing heavily in R&D and producing the newest drug therapies. Canada has a significant home-grown generic and contract manufacturing sector, first founded in the 1970s and 1980s and clustered in Ontario and Quebec. Canadian drug makers are specialists in high quality, mass production of specialty, off-patent generic and contract manufactured medicines, and can provide a safe and reliable source of pharmaceutical production.

Together, based on the shared goals of sovereignty of supply, national security, public health, and undisrupted access to vital medications, Canada and the U.S. can build an even more secure

production and supply corridor to strengthen our mutual security. A diversified North American supply chain will safeguard against drug shortages and prioritize access to medicines.

## U.S. Department of Defense Evaluation of Pharmaceutical Supply Chain

Medicine production has been identified by the U.S. as a national defence vulnerability. The U.S. Department of Defense recently evaluated the role of foreign suppliers in the drug supply chain and potential harm to U.S. national defence from dependence on China and other countries considered as adversaries.[1]




*Report on the Department of Defense Pharmaceutical Supply Chain Risks; Office of the Under Secretary of Defense for Acquisition and Sustainment; November 2023*

From a national security point of view, **Canada was identified by the Department of Defense as the most trusted partner to the U.S. in provision of pharmaceuticals** and their inputs. The Department of Defense evaluated Canada with the lowest level of security risk, second only to the U.S. itself.

## Canada as part of the U.S. National Strategic Industrial Base

Canada is a trusted partner in the U.S. National Strategic Industrial Base - one of only three countries on whom the U.S. relies for industrial support for Defense. The U.S. National Strategic Industrial Base is a critical component of national security, enabling the U.S. to execute its strategy and project military power.

Under this arrangement, Canadian pharmaceutical suppliers have been identified as a critical source from outside the U.S. for important medicines needed by the U.S. military, and its citizens, in times of war or when under attack on home soil. Medicines made in Canada also can be procured to supply the U.S. National Stockpile program. There is no other country as trustworthy and reliable as Canada on which the U.S can depend for defense support for critical medicines outside its borders.

[1] Report on the Department of Defense Pharmaceutical Supply Chain Risks Office of the Under Secretary of Defense for Acquisition and Sustainment November 2023, Pursuant to Section 860(a) of the National Defense Authorization Act for Fiscal Year 2023 (Public Law 117-263)

## Canadian Pharmaceutical Imports Strengthen U.S. Pandemic Preparedness

Far from posing a threat, Canada enhances U.S. national security by acting as a stable and secure partner with a transparent regulatory and industrial framework. In time of crisis, Canada can rapidly respond to emergency demand from U.S. partners, helping to mitigate shortages of medications with swift cross-border collaboration, expedited logistics, and reduced dependency on overseas suppliers. It is strategically important for the U.S. to reinforce trade ties with Canadian pharmaceutical companies in preparation for future public health emergencies.

## Boosting North American Production Together

The 232 investigation will consider the feasibility of boosting domestic production to lessen import reliance. Canada, being equally concerned about reliance on imports, has also identified pharmaceutical and biopharmaceutical manufacturing as a strategic sector.

Canada published its Biopharmaceutical Strategy in 2021[2] and has committed over $1.2 B (CAD) in support for the sector through its Strategic Innovation Fund. Canada recently created a new agency, Health Emergency Readiness Canada (HERC), with a mandate to develop industrial strategy to support production of medicines.

With our shared supply chains and national security partnership, Canada and the U.S. are well positioned to work together to build a diversified North American pharmaceutical supply chain and bolster the production of medicines on both sides of the border.

## Physical Proximity Provides a Critical Logistical Advantage.

The U.S. and Canada are connected by one of the most efficient land borders in the world, enabling rapid delivery of pharmaceutical goods with minimal transit times compared to overseas suppliers. This close physical proximity reduces the risk of supply chain disruptions, ensures shorter lead times, and allows for more responsive inventory management. For temperature-sensitive or time-critical pharmaceuticals such as sterile injectables, biologics or certain vaccines, the ability to transport project products within hours instead of days is crucial to maintaining product integrity and patient safety.

The U.S. and Canada should deepen their partnership through harmonized regulatory frameworks and shared strategies for supply chain resilience, and avoid creating barriers to collaboration. Canadian imports offer a regional and politically stable alternative, improving supply diversity, which are key principles of any resilient critical infrastructure.

**For these reasons, we recommend that Canada and the U.S. form a U.S./Canada Pharmaceutical Supply Chain agreement to build an industrial base for the production of medicines in North America. With shared goals of sovereignty of supply, national security, public health, and undisrupted access to vital medications, we have the**

**opportunity to join forces in protecting the well-being and security of our citizens and our health care systems.**

## Shortages of Canadian-made Critical Medicines in the U.S.

It is well known that drug shortages have become a public health emergency. According to the American Society of Health System Pharmacists (ASHP) there are over 200 active drug shortages in the U.S. now. Tariffs on medicines imported from Canada would certainly create supply disruptions in the U.S. and will exacerbate this crisis.

Because several Canadian generic companies are significant suppliers in the U.S., one of the anticipated outcomes if tariffs are imposed on Canadian-made medicines will be drug shortages of important maintenance medications such as generic Lipitor (atorvastatin) and amoxicillin, both made by Canadian companies for the U.S. market. Canadian drug producers have significant market share in the U.S. for many generic products.

A recent report in the prestigious Journal of the American Medical Association (JAMA)[3] studied drugs made in Canada and sold in the U.S. and predicts that tariffs will result in shortages of over 300 critical medicines used by Americans every day. The JAMA study identified drugs made in Canada according to the *Structured Product Labeling Resources* from the FDA. The report identified 411[4] products manufactured in Canada representing $3B in sales, approximately 44% of the total imports from Canada. Of these, 79% were generic products and 28 were solely made in Canada.

Canadian firms manufacture drugs not readily available in the U.S. due to their limited market size or lower profitability. U.S. patients depend on these products which are vital for rare diseases, pediatric use, or hospital settings. We must avoid any situation that could jeopardize access to these essential, often irreplaceable, treatments.

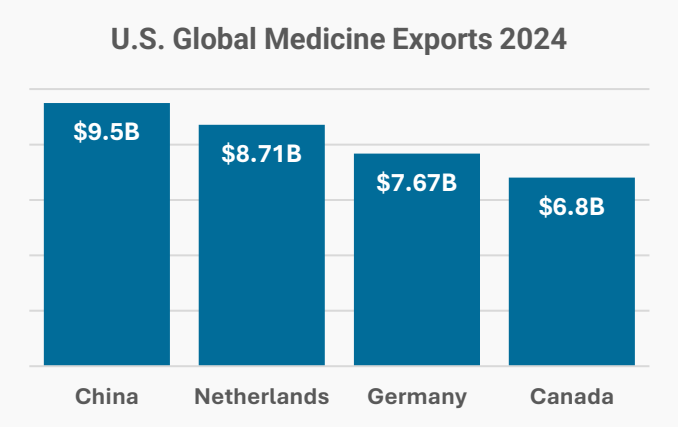
Canada has two penicillin production plants located in Ontario, one of which is dedicated to producing amoxicillin for the U.S. market. The other facility made penicillin products as well as Cephalosporins and has been recently decommissioned as a result of offshore competition and unsustainable prices. There is only one amoxicillin facility in the U.S. which speaks to the need for Canada and the U.S. to work together to build shared resilience.

[3] Tadros, Mina, et al; Trade Tariffs on Canadian Pharmaceuticals - Implications for US Drug Supply and Costs, JAMA Published online March 31. 2025 © 2025 American Medical Association
[4] IBID

Canada is a major source of generic Lipitor (atorvastatin) for American patients used to treat high cholesterol. A Canadian company supplies up to one third of all the generic Lipitor used by Americans. Tariffs on this product will certainly lead to shortages of this highly prescribed product as it will no longer be profitable to produce.

## U.S. Production and Global Trade in Pharmaceuticals

The 232 Investigation asks about the demand for pharmaceuticals and pharmaceutical ingredients in the U.S. and the extent to which it can be met by domestic production. It is important to point out that the U.S. is the global leader in pharmaceutical value, as well as the largest consumer of medicines with a market of over $800 B[5].




According to the Department of Commerce, in 2024, the U.S. exported over $94 B[6] in medicines to other markets. The main destinations for these products were China ($9.5 B), Netherlands ($8.7 B), Germany ($7.7 B) and Canada ($6.8 B).[7]

The U.S. is also a major importer of medicines bringing in $212 B[8] of pharmaceutical products in 2024. The main sources of U.S. imports were Ireland ($50 B), Switzerland ($19 B) Germany ($17 B), Singapore ($15.3 B) and India ($12.5 B).[9] The U.S. imports 47% of its generic medicines from India.

As noted above, in 2024, Canada imported $6.8B in medicines from the U.S., up from $5.8B in 2023.[10] **Imports from the U.S. represent approximately 25% of the pharmaceutical market in Canada.** In addition, Canadian pharmaceutical manufacturers are highly reliant on the U.S. for important inputs for domestic production including excipients, packaging material, capsules, syringes and manufacturing equipment, such as Servolifts made in New Jersey.

Canadian pharmaceutical exports to the U.S. were $5.33B[11] in 2024 which represents 5% of U.S. pharmaceutical imports, and most of these products are finished dose, off-patent generic and contract manufactured medicines.

[5] IQVIA, 2024
[6] Dept of Commerce; https://www.trade.gov/data-visualization/tradestats-express-us-trade-products; accessed April 24, 2025
[7] https://oec.world/en/profile/bilateral-product/pharmaceutical-products/reporter/usa; accessed April 28, 2025
[8] Dept of Commerce; https://www.trade.gov/data-visualization/tradestats-express-us-trade-products; accessed April 24, 2025
[9] https://oec.world/en/profile/bilateral-product/pharmaceutical-products/reporter/usa; accessed April 28, 2025
[10] Dept of Commerce; https://www.trade.gov/data-visualization/tradestats-express-us-trade-products; accessed April 24, 2025
[11] IBID

## Tariffs on Canadian Medicines Will Undermine U.S. Security

If the U.S. imposes tariffs on Canadian-made medicines, they will quickly be displaced by suppliers from low wage countries, and the U.S. will become even more reliant on non-allied countries for critical medicines. Such an action will benefit countries that may seek to undermine U.S. security and vulnerabilities.

Canadian generic producers, as those based in the U.S., compete against imports mostly from companies from India and China that benefit from low wages, less stringent environmental standards and significant government subsidies to promote their domestic industries. The generic market in the U.S. is extremely competitive and suppliers operate with razor thin margins. Hyper competition and consolidation in the payer market has driven prices to very low, arguably unsustainable levels. Canadian off-patent and contract manufacturing companies also operate on extremely narrow margins and the cost of export tariffs cannot be absorbed under current financial circumstances.

In addition, it is unlikely the costs of tariffs can be passed on to payers due to long standing contractual arrangements and regulatory provisions such as the CPI penalty that effectively preclude price increases to Medicare.

When costs cannot be passed on, Canadian pharmaceutical manufacturers with a proven track record of producing high-quality products in FDA approved facilities will be forced to exit the market. These same products will eventually be replaced by imports from foreign suppliers with lower cost structures, some of which have documented histories of lower quality production and regulatory issues.

## State-level Importation of Canadian Pharmaceuticals

Florida and several other states have taken action to allow the importation of medicines from Canada as a strategy to lower drug prices. The FDA has created a regulatory pathway to allow medicines licensed by Health Canada to be sold in the U.S. A recent White House Executive Order aimed at reducing drug prices in the U.S. recommends strengthening this policy action to more easily allow states to import from Canada. The same time that the U.S. Administration is encouraging Americans patients to buy Canadian medications, it is counterintuitive to impose tariffs.

## Canadian Tariff Retaliation

The Canadian government has made it clear that they intend to impose reciprocal tariffs on U.S. imports to Canada, if needed, as a retaliatory measure until the U.S. removes harmful tariffs against Canada's exports. The Department of Finance undertook a consultation process asking for input on retaliatory tariffs on many products from the U.S. including pharmaceuticals. Tariffs on U.S. pharmaceuticals will harm U.S. companies and direct business away from U.S. suppliers to those in Europe, South Korea and Japan and should be avoided.

**Foreign Trade Practices and Non-trade barriers between Canada and U.S.**

The 232 Investigations asks for information about foreign trade practices and state-sponsored overproduction and its impact on industry competitiveness. Canada does not impose any trade barriers on U.S. pharmaceuticals sold in Canada, quite the opposite. For many years, Health Canada and FDA have worked towards regulatory alignment to ease access to each other's markets.

Canada has taken great steps in recent years to ensure that access to the Canadian market for U.S.-based pharmaceutical manufacturers is fair and open. Canada has made numerous concessions in trade agreements with the U.S. to harmonize legal and regulatory systems governing pharmaceuticals. For example, in early 2025, Canada finalized the implementation of a Patent Term Adjustment (PTA) adding two additional years to pharmaceutical patents in Canada, satisfying its requirement under the USMCA agreement.

The U.S. on the other hand has many non-trade barriers in place that restrict Canadian pharmaceutical manufacturers from doing business in the U.S. For example:

- There are penalties against generic manufacturers that raise the price of a product above the CPI which prevents producers from recouping their costs. This non-tariff policy has directly harmed Canadian drug producers. The CPI penalty has also caused many drug shortages in the U.S. market.

- The U.S. does not allow generic companies to seek damages for being held off the market due to automatic stays which allow brand companies to unfairly delay competition by merely asserting patent infringement. In the U.S., damage recovery is a fundamental part of patent law in all other sectors except pharmaceuticals. This policy has prevented Canadian generic companies from recovering damages when they have successfully invested in overturning invalid patents. This discriminatory, non-tariff barrier has caused millions of dollars in lost business for Canadian generic companies. By comparison, in Canada, all companies including American drug manufacturers can sue for damages in pharmaceutical cases.

- The complexity of the Biologics Price Competition and Innovation Act (BCPIA) is a formidable non-trade barrier and has prevented Canadian biosimilar producers from accessing the U.S. market. The regulatory process for approval of biosimilars in Canada is much less restrictive, and U.S. companies have received regulatory approval for their biosimilar products many years before the same products are approved in the U.S.

**Conclusion**

The industry on both sides of the border is united in its opposition to tariffs on medicines for the benefit of our health care systems. Our patients and communities benefit from open free trade in pharmaceuticals and there is nothing to be gained by imposing tariffs on medicines; rather patients will be severely harmed due to increased prices, supply disruption and shortages that they will face if tariffs are imposed on Canadian pharmaceutical products.

One of the purposes of the America First Trade Policy is to reduce dependency on adversaries like China. We urge the Department of Commerce to work together with the Canadian government and Canadian pharmaceutical manufacturers to bolster the production of pharmaceuticals in pursuit of a shared goal.

Sincerely,

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