

**CANADA'S SUBMISSION TO XRIN 0694-XC120 PHARMACEUTICALS 232 NOTICE  
DOCKET # BIS-2025-0022**

**A. INTRODUCTION**

The Government of Canada provides these comments concerning the Department of Commerce's section 232 investigation of imports of pharmaceuticals and pharmaceutical ingredients under the Trade Expansion Act of 1962,<sup>1</sup> to demonstrate that the imports of Canadian pharmaceuticals and pharmaceutical ingredients do not in any way threaten to impair U.S. national security.

In fact, the opposite is true – imports of pharmaceuticals and pharmaceutical ingredients from Canada contribute to U.S. national security and complement efforts by U.S. domestic industries to reinforce strong and resilient pharmaceutical supply chains. Canada-U.S. collaborations on pharmaceutical manufacturing help maintain and improve trusted North American supply chains to advance regional industrial capabilities, build complementary capacity to mitigate global dependencies, and decrease risks associated with the production of critical and innovative medicines outside of North America.

These combined efforts will not only enhance resiliency against emerging national security threats in North America such as chronic diseases and emerging pathogens, but they will also ensure the availability, affordability, and accessibility of life-saving medicines for Americans.

Canada and the U.S. have a long history of cross-border collaboration and partnership on pharmaceuticals and pharmaceutical ingredients. We have one of the most closely interconnected pharmaceutical production networks, with Canadian and U.S. facilities supplying essential medicines, vaccines, and active pharmaceutical ingredients (APIs) to one another. This collaboration has enabled our two countries to leverage our respective strengths and areas of expertise to produce essential medicines, develop novel treatments to diseases, including chronic illnesses, and to build strong and resilient pharmaceutical supply chains. It has also enabled the U.S. to respond swiftly and effectively to a range of health threats and national emergencies, protecting the health and safety of millions of Americans. In short, the integrated Canada-U.S. pharmaceutical supply chain is a critical factor in protecting the health of U.S. citizens and strengthening economic and national security.

In the face of biosecurity threats, continued Canada-U.S. collaboration has proven essential to protect national security. The continued partnership and integration between our countries is vital to prevent and manage the spread of diseases, detect early threats, and respond effectively to unknown biological agents that may pervade our common border. Continued strategic alignment in our scientific, technological and industrial capabilities will help ensure national and economic security.

Canada understands the need to assess, anticipate, and build-up capabilities at the local, national and regional levels to ensure greater resilience and support national security goals. However, trade actions against pharmaceuticals in Canada would significantly disrupt existing supply chains, negatively impacting the ability of U.S. producers and suppliers to continue supplying life-saving medication to its citizens. Tariffs, or other trade actions, could also increase the risk of drug

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<sup>1</sup> 19 U.S.C. § 1862.

shortages, jeopardize the safety of patients, and put at risk the delivery of health services. The impact of these disruptive actions would be felt directly by the most vulnerable and could compromise the national security of our countries.

Moving forward, the best **national security outcome** we can attain is to assure that our collective efforts lead to better access to medications during times of health emergencies. The best health and **social outcome** we can aim for is to align our collective actions to improve the accessibility and affordability of medicines for those who need them most. The best **economic outcome** we can reach is to ensure that our populations lead the world in terms of quality of life and life expectancy. These are common goals that both of our nations can appreciate.

Canada is ready to work with the United States to fortify supply chains in North America to make our citizens safer and healthier, and help our governments manage chronic diseases.

## **B. Section 232 of the Trade Expansion Act of 1962**

Section 232, codified as 19 U.S.C. § 1862, indicates that the Secretary, in conducting an investigation to determine the effects of imports on the national security, is to determine whether the article is being imported in quantities or unfair circumstances “as to threaten to impair the national security”. The statute and implementing regulations do not appear to define “national security” or the phrase “threaten to impair the national security”. However, the plain meaning of the text provides that the Secretary must find a direct causal link between the imports and the threat of impairment of the national security. Canada understands the Department of Commerce’s findings in prior investigations has confirmed this approach.

Section 232(d) sets out non-exhaustive factors that should be considered in determining the effect of imports on national security, such as whether the domestic industry’s production and capacity can meet U.S. defence requirements as well as the relationship between national security and national economic welfare, including the impact of foreign competition on the economic welfare of individual domestic industries. Importantly however, these factors do not create a separate ground to determine that imports threaten national security, and the key question remains whether the imports at issue are being imported in such quantities or circumstances as to impair, or threaten to impair, national security.

To interpret section 232(d) otherwise would duplicate and render superfluous other mechanisms that Congress has legislated to provide recourse for injury to domestic industries, namely the imposition of antidumping or countervailing duties under Title VII of the Tariff Act of 1930, or the imposition of safeguards through Section 201 of the Trade Act of 1974. That the focus of the Secretary’s investigation is on the effect on national security, and not on any injury to domestic industry, is also reinforced by other statutory context. For instance, the title of section 232 is: “Safeguarding national security”. In addition, section 232(b) requires the involvement of the Department of Defense throughout. This is a factual determination and, clearly, not every economic effect meets the high threshold imposed under the section.

### **C. PHARMCEUTICAL TRADE WITH CANADA DOES NOT THREATEN TO IMPAIR U.S. NATIONAL SECURITY – IT SUPPORTS IT**

Maintaining open Canada-U.S. trade in pharmaceuticals, in all its forms, directly supports U.S. national security given that health-related emergencies – naturally-occurring (e.g., emerging/re-emerging pathogens), intentional (e.g., bioterrorism, and chemical, biological, radiological, and nuclear (CBRN) events) or accidental – can threaten the health of a nation and region, create serious economic and social disruptions, strain government resources, destabilize governments and threaten a country's overall ability to function. To defend against this, Canada and the U.S. have maintained strong government-to-government collaboration and highly integrated pharmaceutical industry supply chains for the production and delivery of medicines that protect public health and address national security in both countries. This partnership leverages complementary capabilities to tackle emerging health threats and ensures access to treatments for chronic diseases as well as life-threatening conditions or pathogens.

During times of need, Canadian companies and facilities have worked closely with U.S. counterparts to mitigate adverse impacts on U.S. pharmaceutical supply and make sure patients have access to the products they need. Safeguarding trade relations and ongoing collaboration in North America is essential to the ability of our countries to work together to address arising threats and emergencies.

For instance, in the face of an unprecedented health threat, the first treatment authorized for COVID-19 was the result of strong cross border collaboration during President Trump's first term as President. A Canadian company discovered and developed the first monoclonal antibody treatment against COVID-19 in partnership with the Vaccine Research Center (VRC) at the National Institutes for Allergy and Infectious Diseases (NIAID). At the onset of the pandemic, the U.S. Defense Advanced Research Projects Agency (DARPA) provided a coronavirus sample to this company in view of its technologically proven capabilities to identify a rapid treatment that was commercialized and brought to market by a U.S.-based company, supplying up to 600,000 doses to the U.S. government, saving American lives and protecting U.S. national security. Only through close collaboration and integrated supply chains could this treatment have been brought to market in record time.

Similarly, in the event of natural disasters, contaminations, and disruptions, Canada-U.S. collaboration ensures a robust and resilient response, safeguarding public health and protecting our common national security interests. When a critical facility in Marion, North Carolina, sustained significant water damage caused by Hurricane Helene in September 2024, the U.S. Food and Drug Administration (FDA) granted a major U.S. company – a producer of intravenous medicines and dialysis solutions – temporary permission to import products from its facility in Canada. According to the American Hospital Association (AHA), the U.S. facility produces 60 percent of the U.S. supply of intravenous (IV) solutions; any disruptions have significant implications to the delivery of health services, unless threats are mitigated by regional partners, such as Canada. By activating its regional manufacturing network, this U.S. company was able to swiftly supply IV solutions to U.S. patients, demonstrating the effectiveness of cross-border cooperation.

The availability of Canadian pharmaceuticals in the United States serves as a strategic and accessible line of defence for the U.S. to mitigate the impacts of natural disasters, related supply chain disruptions and any other unforeseen threats. In addition, Canadian companies are trusted partners that support critical efforts to prevent or alleviate drug shortages of medically necessary generic drugs. For example, the U.S. FDA has recognized a Canadian company with a Drug Shortage Assistance Award, one of only nine companies to receive this honour. The award highlights the efforts of companies which have worked in cooperation with the U.S. FDA to implement strategies to help provide a steady supply of medically necessary drugs for patients, while maintaining a commitment to quality manufacturing. This is at a time when critical drug shortages pose national security challenges.

In addition to addressing drug shortages, safeguarding niche pharmaceutical products against low probability but high impact CBRN threats is crucial, due to limited market and alternative options. Any measures that would affect pharmaceutical supply chains, could have a very significant impact on our collective ability to launch an effective response to CBRN threats in particular at a time where geopolitical tensions are rising and the risk of bad actors is of heightened concern. For example, a CBRN event along the shared U.S.-Canada border would require a coordinated and collaborative response to mitigate adverse health impacts to the U.S. population. Trade actions by the United States may create shortages or constraints on access to, and supply of, essential pharmaceutical products. It may also affect Canadian and U.S. capabilities to adopt CBRN medical countermeasures, which puts the lives of Canadians and Americans at risk.

The existing integrated pharmaceutical supply chains in Canada and the United States are critical to achieving national and economic security objectives.

#### **D. MITIGATE GLOBAL DEPENDENCIES THROUGH REGIONAL INTEGRATION CAN ENHANCE U.S. NATIONAL SECURITY**

Pharmaceutical supply chains are complex and multinational, often involving components sourced from multiple countries and various manufacturing stages spread across different locations. Consequently, the U.S. relies on international partners, including Canada, for essential medicines and critical inputs.<sup>2</sup> Regardless of where medicines are manufactured, the process typically consists of various components, such as Active Pharmaceutical Ingredients (APIs), excipients, and other parts sourced globally.

Our countries share an interest in bolstering strong and resilient pharmaceutical supply chains. Currently, global supply chains enable the production of over 23,000 prescription drug products,<sup>3</sup> each with distinct manufacturing requirements and inputs, including APIs. We recognize the U.S.'s concerns regarding concentrated supply base, given that of the over 3,000 API companies worldwide, two countries account for a combined 57%.<sup>4</sup> This highlights potential gaps and vulnerabilities to distribution networks and domestic production of essential medicines.

However, this is an opportunity for Canada and the U.S. to strengthen the stability of the pharmaceutical supply chain in North America and mitigate external supply chain vulnerabilities. Over the years, Canada has proven to be a favourable and reliable partner to our allies, most

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<sup>2</sup> [Building Resilience into the Nation's Medical Product Supply Chains](#)

<sup>3</sup> [FDA at a Glance October 2024](#)

<sup>4</sup> [Global API Market: Crunching the Numbers - DCAT Value Chain Insights](#)

notably the U.S. The current functioning of the North America pharmaceutical supply chain system is a result of stable collaboration between our two countries, ensuring safe, secure, and timely access to high quality medicines. According to a recent research letter published in the Journal of the American Medical Association (JAMA), approximately USD\$6.75 billion in selected pharmaceuticals were exported from Canada to the United States in 2023. It is estimated that USD\$3 billion in U.S. pharmaceutical sales depended on Canadian manufacturing, of which 79 percent were generic products and 21 percent were brand-name products.<sup>5</sup> Any trade action targeting pharmaceuticals would increase costs to American patients and have negative consequences to the resilience of our supply chain linkages.

Our countries have also established strong regulatory cooperation. Due to the critical importance and sensitivity of medications for health protection, the manufacturing of pharmaceuticals is a highly regulated process. Canada and the U.S. play a crucial role in ensuring the quality of APIs sourced from abroad that are used in the production of medicines. Canada's regulatory agency, Health Canada, upholds pharmaceutical approval criteria<sup>6</sup> that align with those of the United States, ensuring excellence in safety, quality and efficacy. Health Canada is also a longstanding trusted partner of the United States Food and Drug Administration (FDA). In light of good manufacturing practice violations and data integrity concerns that have occurred in other countries, Health Canada and the FDA actively align their approaches to health product regulation through initiatives like the Generic Drug Cluster,<sup>7</sup> the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH),<sup>8</sup> the Pharmaceutical Inspection Co-operation Scheme (PIC/S),<sup>9</sup> and the Canada-U.S. Regulatory Cooperation Council<sup>10</sup>, in order to ensure stringent regulatory frameworks that minimize risks and mitigate harms to patient care in both countries.

Trade action that targets imports of pharmaceuticals and critical inputs could result in the U.S. relying on suppliers from countries with less stringent regulatory requirements. This would expose the United States to higher risks of non-compliance with safety and quality protocols, as well as increased reliance on non-allied countries for critical medicines which compromise national security interests. Furthermore, diminished global cooperation carries the possibility of reduced transparency and data sharing across the international pharmaceutical supply chain with regards to manufacturing practices, ingredient qualities, and shortages,<sup>11</sup> which ultimately subjects the health and safety of Americans and Canadians, and the related national security interests, to greater vulnerabilities.

Pharmaceutical manufacturing will always depend on a significant number of raw materials and inputs from around the world, including from Canada. U.S. manufacturing can be protected and enhanced by continuing to maintain and improve our trusted North American supply chains. A 2023 U.S. Department of Defense report highlights Canada as a reliable partner in the supply chain of

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<sup>5</sup> [Trade Tariffs on Canadian Pharmaceuticals—Implications for US Drug Supply and Costs](#)

<sup>6</sup> [Nom de la société](#)

<sup>7</sup> [Health products international activities - Canada.ca](#)

<sup>8</sup> [ICH Official web site : ICH](#)

<sup>9</sup> [Pharmaceutical Inspection Co-operation Scheme website](#)

<sup>10</sup> [Canada-United States Regulatory Cooperation Council \(RCC\) - Canada.ca](#)

<sup>11</sup> [Building Resilience into the Nation's Medical Product Supply Chains](#)

medicines.<sup>12</sup> This provides the basis for further collaboration and alignment for boosting industrial capabilities across our countries.

## **E. TRADE ACTIONS RISK ACCESS TO CRITICAL MEDICINES IN THE U.S.**

Any disruptions to supply chains could lead to shortages of critical medicines and prevent patients from receiving the medicine they need, when they need it. Tariffs and/or other trade restrictions would increase risks to the timely access of medicines as well as the functioning of hospitals and monitoring of patients with chronic conditions. Additionally, some manufacturers could face decisions to discontinue the manufacturing of critical medicine as the cost of production increases, potentially above what can be passed on to patients or payers.<sup>13</sup>

This is particularly concerning for the generic medicines industry. Generic medicines account for approximately 90 percent of prescribed medicines in the U.S. and operate on very tight profit margins.<sup>14</sup> Trade actions would add financial risks to generic pharmaceutical manufacturers, consequently leading them to reassess production capacity of critical medicines. Consequently, this would increase the risk of drug shortages.

In 2023, the U.S. FDA identified almost 100 ongoing drug shortages from previous years as well as more than 30 new drug shortages.<sup>15</sup> Historically, even minor shifts in pharmaceutical supply chains create shortages, particularly when manufacturers lack rapid production scalability to meet demand; any trade actions could exacerbate these effects.<sup>16</sup> Additionally, the threat of such action could lead to market volatilities and irrational stockpiling that would undermine the objectives pursued. Therefore, policy approaches which support stable and predictable markets and collaboration, such as with reliable partners like Canada, would mitigate drug shortages. Our collaboration would also enable manufacturers to reliably meet market demand, ensuring the health and safety of Americans and the national security interest to be able to respond to health emergencies.

Additionally, natural disasters can aggravate supply chain vulnerabilities, further compromising access to critical medicines. Promoting our regional integration for the sourcing of medicines ensures the resilience of our pharmaceutical supply chains, and the contingent capabilities of pharmaceutical manufacturers in case of disruptions to the supply chain due to natural disasters.<sup>17</sup> The CARES Act, signed into law in March 2020 in the U.S., amended the Federal Food, Drug, and Cosmetic (FD&C) Act to manage risks in the drug supply chain.<sup>18</sup> It requires certain manufacturers, particularly those producing critical drugs or APIs<sup>19</sup>, to develop and maintain a redundancy risk management plan, ensuring a more secure and resilient supply of essential medicines during public health emergencies.<sup>20</sup>

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<sup>12</sup> Office of the Under Secretary of Defense for the Acquisition and Sustainment November 2023

<sup>13</sup> [AAM-tariff-actions-should-ensure-access-to-lower-cost-generic-and-biosimilar-medicines.pdf](#)

<sup>14</sup> Office of the Under Secretary of Defense for the Acquisition and Sustainment November 2023

<sup>15</sup> [Drug Shortages Infographic | FDA](#)

<sup>16</sup> [Trade Tariffs on Canadian Pharmaceuticals-Implications for US Drug Supply and Costs - PubMed](#)

<sup>17</sup> [Building Resilience into the Nation's Medical Product Supply Chains](#)

<sup>18</sup> Ibid

<sup>19</sup> [Notifying FDA of a Discontinuance or Interruption in Manufacturing of Finished Products or APIs Under Section 506C of the FD&C Act](#)

<sup>20</sup> [Coronavirus Aid, Relief, and Economic Security Act \(CARES Act\) Drug Shortage Mitigation Efforts | FDA](#)

According to the FDA, having more than one supplier is an example of a risk management strategy to ensure continuity and resilience in the face of potential disruptions.<sup>21</sup> Close regional proximity and strategic diversification across U.S. and Canada offer significant benefits, which would protect against national security risks due to these disruptions and provide a stable pathway to critical medicines.

## **F. CONCLUSION**

Canada is a stable and reliable source of pharmaceuticals to the United States. It contributes to a strong and resilient North American pharmaceutical supply chain. Further, continued and uninterrupted access to Canadian pharmaceuticals can ensure that Americans have access to critical medicines and other drugs that protect the health of Americans and help preserve U.S. national security.

Canada-U.S. collaborations on pharmaceutical manufacturing help maintain and improve trusted North American supply chains to advance regional industrial capabilities, build complementary capacity to mitigate global dependencies, and decrease risks associated with the production of critical and innovative medicines outside of North America.

Combined efforts will not only enhance resiliency against emerging national security threats in North America such as chronic diseases and emerging pathogens, but they will also ensure the availability, affordability, and accessibility of life-saving medicines for Americans.

In conducting this Section 232 investigation, we urge the Department of Commerce to reflect upon the advantages of the longstanding and mutually beneficial trade and security relationships between the U.S. and Canada and the importance of securing and maintaining the reliable and integrated pharmaceuticals supply chain in North America. Further, the Department of Commerce should recognize the strategic importance of the integrated Canadian and U.S. pharmaceutical sector to the U.S. economy, as well as for our bilateral national security relationship. Finally, we urge the Department of Commerce to recognize that pharmaceutical and pharmaceutical ingredient imports from Canada do not threaten or impair U.S. national security, but rather enhance it.

Canada stands ready to continue to advance strategic collaborative solutions that are beneficial to both nations.

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<sup>21</sup> [Risk Management Plans](#)