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On behalf of the Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA), I am pleased to submit our comments to help inform the renegotiation of the Canada-United States-Mexico Agreement (CUSMA).

As negotiators prepare for the review of CUSMA in 2025, CPMEA requests that Canada:

1. **Ensure Canada's drug exports are excluded from 232 Tariffs** resulting from the Department of Commerce investigation into Trade in Pharmaceuticals
2. **Codify unfettered access** to the U.S. market for Canadian-made pharmaceutical products through a **Market Access Chapter or side agreement** as part of a national security arrangement
3. **Reject any across-the-board tariffs** or quotas on pharmaceutical exports based other bilateral agreements
4. Ensure Canadian manufacturers are not excluded from any aspect of U.S**. government procurement** including for defense purposes.
5. Be aware of recent "Buy-American" policies that will **give preference in regulatory approval and government procurement for medicines made in the U.S.** and may exclude Canadian exports.
6. Defend and **protect current levels of patent terms and exclusivity periods** for Canadian pharmaceuticals and advocate for mandatory "effective rewards" in Article 20.50
7. Commit to **greater alignment between HC and FDA** through regulatory convergence and Mutual Recognition of Inspections

The CPMEA represents Canadian pharmaceutical manufacturers operating production facilities in Canada, making medicines for Canadian patients and for export. Our members are the **largest manufacturers of medicines by volume** in Canada, include contract manufacturers, and provide innovative, generic and biosimilar pharmaceuticals. The products made by CPMEA members[1] are used to fill more than one third of all prescriptions dispensed in Canada.

Canadian pharmaceutical manufacturers also produce many medicines for export. They rely on access to foreign markets for their medicines and compete successfully against producers from all over the world. According to Statistics Canada, Canadian pharmaceutical exports to the U.S.

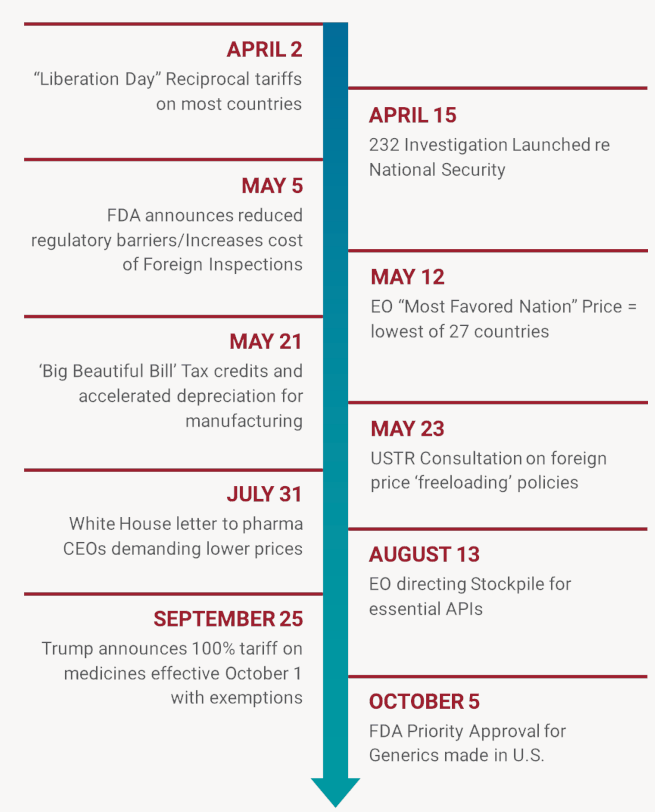
[1] Apotex Limited, Pharmascience, Laboratoire Riva, Teva Canada, Delpharm

exceeded $11 Billion in 2024[2] of which the majority were generic and contract manufactured medicines.

Trade in pharmaceuticals between Mexico and Canada is limited[3], although Mexico is growing as an important source of Active Pharmaceutical Ingredients (API). Trade negotiators for Canada should be mindful as they review CUSMA to recognize the opportunity to foster the interconnectedness of the Canada-U.S.-Mexico pharmaceutical trade relationship.

Section 232 Investigation into Trade in Pharmaceuticals

Like the steel, aluminum, lumber and automobile sectors, pharmaceuticals have been identified by the U.S. as a strategic industry because of high trade deficits. On April 16, 2025, the Trump Administration announced the launch of a Department of Commerce Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients (232 Investigation) to determine if imports of pharmaceuticals and their ingredients threaten U.S. national security[4]. The 232 mechanism is the same used to impose tariffs on the sectors mentioned above and which have been devastating to those Canadian industries.



Actions by U.S. Administration Affecting Trade in Pharmaceuticals

We expect the 232 Investigation will include tariffs and quotas and may provide time-limited exemptions for essential generic medicines or those in short supply. Canada's contract manufacturers that produce brand products under license may be severely impacted. The source of APIs and KSMs is expected to be highlighted in the 232 report.

In addition, on September 25, 2025, President Trump announced 100% tariffs on imports of pharmaceuticals in a social media post with few details provided[5].

As part of the CUSMA review, Canada's negotiators must address impending tariffs on Canadian-made generic and contract manufactured pharmaceuticals because of the 232 Investigation, similar to what have been imposed on other Canadian industry sectors.

[2] https://www150.statcan.gc.ca/n1/pub/71-607-x/71-607-x2021004-eng.htm; Chapter 30 Pharmaceuticals
[3] Canada exported $89 Million in pharmaceuticals to Mexico in 2023; Stats Canada Trade Tables
[4] As of the date of this letter, the 232 Investigation report has not yet been published.
[5] At the time of this letter, to our knowledge, no additional tariffs on pharmaceuticals have been implemented.

The 232 Investigation is a part of a coordinated strategy by the Trump Administration to reshore the domestic production of medicines, address supply chain vulnerabilities, reduce over-reliance on imports from non-allied countries such as China and India, and decrease drug prices for American patients. Between May and October 2025 there have been at least nine announcements from the White House or the FDA affecting trade in pharmaceuticals and access to the U.S. market.

These actions by different agencies are designed to attract new investments in pharmaceutical production to the U.S. and are luring companies to locate production facilities in the U.S. either to avoid costly tariffs, take advantage of favourable tax policy, or to strategically show support for the Trump Administration. In addition, the FDA is moving very quickly to remove regulatory obstacles and to speed up the certification of new manufacturing facilities.

"Buy American" U.S. Government Procurement of Pharmaceuticals

Under the WTO Government Procurement Agreement and echoed in CUSMA, all parties must open government procurement contracts to international competition[6]. The CUSMA negotiations should endeavour to ensure Canadian-made medicines are not excluded under Buy-America provisions.

Two recent policy announcements in the U.S will benefit domestic American pharmaceutical manufacturers over Canadian producers:

- On Oct 3, 2025, the FDA announced a program to provide **faster reviews for generic companies who test and manufacture their products** in the U.S. The program is intended to spur and reward investment in U.S. drug manufacturing and R&D and strengthen the domestic pharmaceutical supply chain. (See link)

- On October 20, 2025, a bipartisan Senate Committee recommended actions to support the government procurement of American-made medicines over imports - actions that would exclude Canadian-made pharmaceuticals unless explicitly identified as part of their FTA obligations with Canada (see link) The committee recommended:

    - establish a **federal buyers' market that prioritizes American-made or nearshored drugs and ingredients** for agencies that directly purchase medications, such as the Department of Defense (DoD).
    - **leverage federal purchasing power by offering long-term contracts** for essential medicines to American manufacturers to help them compete with low-cost foreign producers.
    - **waive penalties** under current group purchasing organization (GPO) contracts **for hospitals that choose to buy domestically manufactured drugs.**

  CUSMA must include a renewed commitment to reciprocity in government regulatory reviews and procurement for pharmaceutical products. It is critical that the definition of 'domestic production' in the U.S. includes Canada so that Canadian generic and

[6] There are procedures to notify parties of products to be excluded from government procurement contracts in certain circumstances. By way of example, the U.S withdrew 227 essential medicines from the GPA agreement in 2020, in violation of several bilateral FTAs, to pursue a Buy American strategy for government procurement of pharmaceuticals.

contract manufacturers are not excluded as suppliers to U.S. entities. CUSMA must ensure that Canadian drug producers can participate in procurement opportunities by the U.S. government for national security and defense purposes and are not disadvantaged in competing in the overall U.S. market.

Tariff Levels in Other Recent FTAs Will Harm Canadian Exporters

Recently concluded bilateral FTAs provide insight into what can be expected at the CUSMA table. Notably, the European Union agreed to an across-the-board tariff of 15% on pharmaceuticals. This is remarkable because the EU is the largest supplier of brand pharmaceuticals to the U.S. The UK successfully negotiated a 'zero-for-zero' agreement on pharmaceuticals which serves as a very helpful precedent.

COUNTRY	PHARMACEUTICAL TARIFFS
UK	"zero for zero" with discussion on market access issues
Japan	Exempt subject to 232 Investigation
EU	15% tariff; with exceptions: not subject to future 232 • drugs on critical medicines list; sterile injectables, ABs • drugs in short supply • possibly biosimilars • $200-300 B USD investment in pharma in U.S.
India	Exempt subject to 232 Investigation

Tariffs on pharmaceuticals in recent U.S. bilateral trade agreements

Canada must not agree to any tariffs on generic and contract manufactured pharmaceuticals including levels of 10-15%. Canada's generic pharmaceutical industry faces extraordinary competition in the U.S. from countries with lower labour costs. Most of Canada's exports to the U.S. are generic medicines, and producers operate with very slim margins. Canada's contract manufacturers also operate on razor thin margins and face stiff competition from local and foreign contract manufacturers. Even a low level of duty will seriously harm Canada's pharmaceutical exports.

Market Access in CUSMA for Canadian-made Pharmaceuticals

The existing CUSMA does not identify pharmaceuticals in its Market Access Chapter because, in the past, there has been no need to do so. Since 1995, Canada and the U.S. have been parties to the WTO Pharmaceutical Agreement, a 'zero-for-zero initiative', which eliminated tariffs on pharmaceutical products and on chemical intermediates used in the production of pharmaceuticals. It is not certain the U.S. will remain a party to the WTO agreements, or even a member of the WTO.

Times have certainly changed and tariff free trade in pharmaceuticals and their ingredients and precursors can no longer be presumed – it must be negotiated as part of CUSMA. It is critical that CUSMA explicitly stipulate barrier and tariff-free trade in pharmaceuticals between Canada, the U.S. and Mexico

> **CUSMA must address Pharmaceutical Market Access (i.e. separate chapter or side letter) to ensure continued reciprocity in pharmaceutical trade for the national security and public health benefit of all three countries.**

The Pharmaceutical Market Access chapter or side letter must also address unfair, market access barriers that restrict Canadian generic pharmaceutical manufacturers from doing business in the U.S. For example:

- 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 complexity of the Biologics Price Competition and Innovation Act (BCPIA) is a formidable market access 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.

<u>Intellectual Property Protection for Pharmaceuticals Under CUSMA</u>

The United States often requires measures to align IP regimes through its bilateral and multilateral agreements. CUSMA is no exception. CUSMA's pharmaceutical provisions aim to balance measures to "encourage innovation and access to medicine," and the IPR chapter reaffirms the WTO Doha Declaration on TRIPS and Public Health. Increases in IP protection under CUSMA may serve to reward innovation, however, expanded IP protections, such as longer patent terms or increased data exclusivity, delay the entry of generics and biosimilars, increase costs for health care systems and reduce patient access.

The U.S on the other hand has many unfair, IP-related barriers that restrict Canadian pharmaceutical manufacturers from doing business in the U.S. For example:

- 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 IP 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 harm to Canadian generic companies. In Canada, all companies including American drug manufacturers, can sue for damages in pharmaceutical cases.

- CUSMA addresses this issue in Article 20.50 through reference to "effective rewards" but falls short of a mandatory obligation. CUSMA sets out Measures Relating to the Marketing of Certain Pharmaceutical Products and allows that parties may also "*provide effective rewards for a successful assertion of the invalidity or non-infringement of the applicable patent"*. To align with Canadian IP law, the CPMEA recommends Canada's negotiators require a change in the text of CUSMA to state that "*parties must provide effective rewards for the successful assertion of the invalidity or non-infringement of the application patent*".

Data Exclusivity for Biologics

During the negotiation of CUSMA, the U.S. brand pharmaceutical industry strongly advocated for Canada and Mexico to adopt longer periods of data exclusivity for biologics, specifically to increase DP to 10 years[7]. At the time. Canada and Mexico agreed to adopt 10 years of DP if the provision was ratified by the U.S. Congress.

This was a contentious issue within the U.S. Congress and was eliminated in the final text. At the time, some Members of Congress argued that if a trade deal includes a defined term of data protection for biologics, it will restrict the ability of Congress to lower that period in the United States in the future. The same would be true for regulators in Canada. Consequently, DP terms were not changed in Canada or Mexico.

It is expected, however, that the U.S. negotiators will push for longer periods of data protection this time again. The pharmaceutical lobby is very strong, the political climate has changed considerably, and the House and Senate are majority-led by Republicans.

The biosimilar market is still developing in Canada, and longer periods of protection for biologics will discourage investment in competing products, delay entry of biosimilars, limit access to these important medications and increase health care costs. CPMEA urges Canada to reinforce its original position in CUSMA on data protection for biologics.

> **As Canada prepares for the review of CUSMA, we encourage our negotiators to resist any new IP obligations that would restrict flexibility in domestic health policy or delay access to generics and biosimilars. We urge our negotiators to defend the current levels of data protection Canada provides for all pharmaceutical products, including biologics. Canada must advocate for a more balanced IP regime in the U.S. aligned with Canadian law including 'effective rewards' or damages for generics.**

Patent Term Restoration and Extensions

Canada has a history of adjusting or extending pharmaceutical patent terms due to the requirements of FTAs with countries where the brand industry is politically strong.

[7] This level does not align with U.S. law which is 12 years of DP for biologics. Mexico provides 5 years of DP for all medicines.

- In 2017, as part of its FTA with the EU, Canada agreed to put in place a patent term extension up to 2 years, known as a Certificate of Supplementary Protection (CSP) to compensate for delays in the regulatory approval of a product.

    - Canada's Patent Term Restoration (PTR) does not include an export exemption, meaning that companies will be prevented from developing and manufacturing a product in Canada during the patent term period for export to a country that does not have a PTR regime, as many do not. This will be a significant barrier for Canadian producers to compete in other markets. It is disappointing that Canada did not seek to provide an export exemption for its PTR period. Yet, Canada's CSP regime includes an export exemption which allows Canadian generics and biosimilars manufacturers to develop and produce a product in Canada and export to countries where there is no extended protection or where protection has expired.

- In 2025, a further revision of Canada's IP regime came because of CUSMA. Under the agreement, parties are required to provide a PTR to compensate for 'unreasonable" delays in the processing of patent applications. The Canadian Parliament subsequently amended the Patent Act, and the new provisions came info force on January 1, 2025. There is no limit on the PTR term.

- This time the U.S. industry association, PhRMA, is asking their government's negotiators to seek **consecutive, not concurrent, patent term extensions**. This is an extraordinary measure beyond what is required in U.S. law. [8]

  Canada's negotiators must be prepared to thwart any efforts to extend patent terms in CUSMA.

U.S. Imports of Canadian Pharmaceuticals Strengthen U.S. National Security

The U.S. Department of Defense (DoD) 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.[9] From a national security point of view, Canada was identified by the DoD[10] as the most trusted partner to the U.S. in provision of pharmaceuticals and their inputs. The DoD evaluated Canada with the lowest level of security risk, second only to the U.S. itself.

Pharmaceuticals manufactured in Canada can be part of a North American Pharmaceutical Security framework. Bilateral trade in medicines is critical for both countries to reduce reliance on imported medicines. This is particularly true for essential generic medicines, on which Canadian and American patients are very dependent.

[8] The U.S. has a maximum 14-year limit on the term of a patent term from the date of product approval by the FDA.

[9] 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)

[10] Renamed the Department of War in 2025

In this context, it is important in its trade relations with the U.S., CUSMA negotiators ensure generic and contract manufactured medicines produced in Canada for export to the U.S. are considered as part of a broad strategy of national security for both the U.S. and Canada. Canadian pharmaceutical exports contribute to American supply security, and any disruption will threaten system resilience.

Mutual Recognition of Inspections (MRA) with FDA

CUSMA is an opportunity for Canada to advance its interest in a MRA for Inspections between Health Canada and the FDA. It is our understanding that initial discussions have been held in the context of regulatory convergence and efforts to reduce inefficiency and redundancy at the agencies. CPMEA supports Canada's efforts to conclude an agreement.

The production facilities of the members of CPMEA are regularly inspected by the FDA as well as Health Canada, with many duplicated activities. All parties agree that both country's regulatory agencies provide exceptional oversight and regulatory rigor. The U.S. has established MRAs for inspections with the European Union as well as the United Kingdom. Canada also has similar MRAs with other countries.

On May 5, 2025, the FDA announced the cost for inspections of foreign facilities will be raised unless they have an MRA with that country. Not only will Canadian drug producers face higher costs, they will also be disadvantaged compared to EU and UK producers who benefit from agreements with the FDA.

A MRA between Canada and the U.S. for mutual recognition of inspections of pharmaceutical production would materially reduce the costs of producing in Canada for the U.S. market, increase efficiency and facilitate trade in medicines between the two countries. It would also reduce costs at Health Canada for conducting its inspections.

Revisiting the CUSMA Review and Modernization Clause

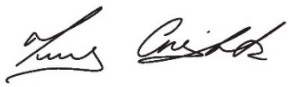
The current review and modernization clause in CUSMA requires a formal review every six years, with parties needing to agree to extend the agreement for an additional 16 years. If no consensus is reached, the agreement enters an annual review cycle until renewed.

This clause remains a double-edged sword: while it enables timely modernization of the agreement to reflect economic and technological developments, it also opens the door to repeated renegotiations that undermine the predictability businesses need to invest and grow with confidence.

To strike a better balance between adaptability and stability, one practical adjustment would be to extend the review interval from six to ten years. This would reduce the frequency of political and economic uncertainty while preserving the agreement's capacity to evolve in response to changing realities.

We wish you well as you start the process leading to the official review of CUSMA with the United States and Mexico.

Sincerely,



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