



On the Front Line of Canada's Pharmaceutical Sovereignty

Submission to the Standing
Committee on Health

Canadian Pharmaceutical Manufacturers
and Exporters Alliance (CPMEA)



Executive Summary

Over the past two decades, domestic drug manufacturing has steadily declined in Canada. Today, Canada imports more than 80% of its medicines, leaving our healthcare system increasingly vulnerable to global supply disruptions, geopolitical instability, and foreign policy decisions beyond our control. This level of dependence is not only a public health concern - it is a national security risk that demands policy action and leadership.

At the same time, the United States is moving rapidly to reshore pharmaceutical production and secure its domestic supply chain. In April 2026, the U.S. announced Section 232 tariffs on pharmaceutical imports, including potential 100% tariffs on patented medicines from countries without bilateral agreements. Canada is directly exposed, putting more than \$9 billion in annual pharmaceutical exports at risk.

The 232 tariffs are being reinforced by a coordinated set of domestic incentives designed to attract pharmaceutical manufacturing, including:

- Regulatory prioritization for U.S.-based manufacturers
- Reduced user fees, lower inspection costs, and market access priority for domestic producers
- Targeted tax and investment incentives
- Procurement policies favouring domestically produced medicines

Canada now faces a critical inflection point. Without a clear and immediate policy response, investment will continue to shift to jurisdictions that offer stronger incentives and more predictable market conditions. Under current conditions, Canadian pharmaceutical manufacturers will face increasing pressure to move production out of Canada. Canada must act with equal focus and urgency.

To build and secure Canada's pharmaceutical sovereignty, CPMEA recommends a Five Point Action Plan.



Canada-First Procurement

Prioritize Canadian-made medicines in public drug plans to create stable, long-term demand



Priority Regulatory Review for Canadian Producers

Establish dedicated pathways to accelerate approvals for domestic manufacturers



Competitive Tax Policy

Support investment in manufacturing facilities, equipment, and workforce development



Inclusion of Domestic Medicine Production in Canada's Defence Strategy

Recognize pharmaceutical manufacturing as critical infrastructure within Canada's defence strategy



Strategic Trade Alliances with Trusted Partners

Strengthen partnerships with trusted countries while maintaining strong domestic capacity

Canada's Pharmaceutical Manufacturing: Capacity and Decline

We want to thank the Committee for recognizing that Canada's pharmaceutical sovereignty is at risk. Strong domestic drug manufacturing is essential for Canada to ensure its own pharmaceutical sovereignty.

The Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA) is a coalition of biopharmaceutical companies with manufacturing facilities based here in Canada. Our members are the largest producers of medicines in Canada and collectively represent more than 30% of all prescriptions dispensed in Canada. Our sector is also an important driver of economic activity. Canadian producers exported more than \$9 Billion¹ in pharmaceutical products to the U.S. in 2025.

In the past, Canada had a significant number of multinational pharmaceutical companies producing medicines for Canadians and for export. Over that last two decades, most have diminished their investment in Canada; pharmaceutical production that takes place in Canada is mostly generics and contract manufacturing, without which we would be even more vulnerable.

During this time of increasing geopolitical tensions, Canada must depend on domestic drug production to meet our needs, or we are facing a looming national security and public health crisis.

U.S. Section 232 Tariffs on Canada's Pharmaceutical Exports

The U.S. government's recent actions directly threaten Canada's biopharmaceutical sector and its pharmaceutical sovereignty. On April 2, 2026, the U.S. imposed Section 232 tariffs on pharmaceutical imports, which will create unprecedented export barriers, disrupt supply chains, and threaten jobs and investment in Canadian biomanufacturing. Canada must assess the damage to domestic producers, exporters, and its own drug supply resilience.

On April 2, 2026, the Trump Administration announced the results of their 232 Investigation into Trade in Pharmaceuticals with a Presidential Proclamation² imposing 100% tariffs on patented medicines for companies and countries that have not negotiated separate agreements³. Although generics and biosimilars are exempt, this decision will be reviewed in one year⁴.

Canada does not have a separate agreement for pharmaceuticals and will be subject to 100% tariffs on pharmaceutical exports to the U.S. We anticipate that pharmaceutical exports from Canada will not be protected under CUSMA rules.

This announcement follows a series of regulatory policy actions taken by the FDA in the past year offering incentives to reshore pharmaceutical production and lure investment away from other countries. See Appendix for a list of U.S. incentives to domestic producers.

¹ Statistics Canada. Canadian International Merchandise Trade Web Application

² [Presidential Proclamation](#)

³ The countries with negotiated agreements on pharmaceuticals are Japan, South Korea, EU, Switzerland, Lichenstein and the UK. In addition, 17 global pharmaceutical companies have entered into confidential agreements and will be exempt if they invest in reshoring production and offer their 'most favoured nation' price on products sold in the U.S. At this time, generics and biosimilar imports are exempt subject to a review in one year.

⁴ Discussions with the Dept of Commerce suggested sliding scale tariffs on generics over time in the future.

CPMEA Five-Point Action Plan to Secure Canada's Pharmaceutical Sovereignty

To secure Canada's Pharmaceutical Sovereignty, CPMEA recommends a Five-Point Action Plan for Canadian Domestic Pharmaceutical Production:

1. **“Canada First” regulatory policy to support investment here including a priority regulatory review** for domestic biomanufacturers to incentivize production in Canada while accelerating access to essential medicines; as well as common sense solutions to **avoid patent evergreening** which benefit foreign companies and prevents fair competition from Canadian producers.
2. **Canada-First procurement.** Federal drug programs and public plans should prioritize medicines manufactured in Canada. Directing even a portion of public spending toward Canadian-made medicines would create stable demand and support long-term investment.
3. **Competitive tax policy.** Pharmaceutical manufacturing is capital-intensive. Canada's tax framework must support investment in facilities, equipment and workforce development.
4. **Under Canada's Defence Industrial Strategy,** investments in the production of medical countermeasures and stockpiling to ensure access to essential medicines. Domestic manufacturing must be treated as critical infrastructure within national security and defence planning.
5. **Strategic trade alliances with trusted partners** to strengthen supply chain cooperation while ensuring Canada maintains robust domestic capacity.

Health Canada Must Prioritize Pharmaceutical Products Made by Canadian Biomanufacturers

It is time for Health Canada to take a “Canada First” approach to regulatory policy and translate the *Build Canada Strong* mentality into actions. All policies and processes should be reviewed through the lens of Canada's pharmaceutical sovereignty and self-sufficiency.

Health Canada has acknowledged delays in the approval of medicines and committed to reform the review process. The recent Reliance Program⁵ may help address bottlenecks for importers of speciality medicines, however, the Reliance program will harm Canada's own drug manufacturers by prioritizing submissions from foreign importers and leaving domestic producers at the back of the queue. The unintended consequences of speeding up approval for importers must be addressed or this will undermine Canada's industrial and health policy goals.

⁵ [Reliance Program](#)

CPMEA recommends Health Canada:

- Implement a Priority Review process for submissions from Canadian producers. building on the existing priority review guidance. (see Appendix A)
- Ensure resources are available to review new drug submissions from Canada's own producers in a timely manner.
 - Appoint a Regulatory Project Manager to act as a central point of coordination between Health Canada and domestic biomanufacturers, responsible to ensure submissions are directed to reviewers expeditiously.
- Tackle the inefficiency of the current approval pathway on which Canadian producers rely and which is not being addressed under the Reliance program.
- Match cost reduction programs offered to domestic U.S. producers such as lower user fees, and reduced inspection fees.
- Address the anti-competitive consequences of 'patent evergreening' and allow carved-out indications (skinny labels) for generic products made by Canadian producers.


"Canada First' Procurement

In December 2025, the Canadian government launched their *Buy Canada Policy* aimed at supporting Canadian businesses and workers. New procurement rules will help create stronger Canadian supply chains by prioritizing Canadian suppliers and Canadian-made goods and services and make Canadian industries more self-sufficient and resilient to changes in the global economy. This is particularly important for pharmaceuticals where our supply chain is so vulnerable to geopolitical and public health events.

Canada's public drug plans spend over \$18 Billion⁶ annually to provide comprehensive drug coverage for eligible Canadians. Most of this spending is used to reimburse imported medicines produced by global pharmaceutical companies.

As it stands today, there is no preference in public drug plan formularies for Canadian-made medicines. The absence of policy direction inadvertently favours imported products.

By directing procurement to domestic pharmaceuticals through formulary management, Canadian public payers can support local production and reduce dependency on imported medicines **without incurring any additional cost.**



A "Canada First" procurement policy will reinforce Canada's pharmaceutical sovereignty.

⁶ CIHI

There are several areas where the federal government can direct its procurement to support Canadian pharmaceutical producers:

- Implement a “Buy-Canadian” procurement policy for federal drug programs, e.g. NIHB, federal Public Service Health Care Plan (PSHCP), military, and veterans’ programs.
- Establish clear guidance to NIHB, Provinces and Territories that pharmaceutical procurement from Canadian producers is necessary for Canada’s national security.
- Coordinate with provinces through the Canada Drug Agency ‘Canada First’ Formulary Exclusivity listings, so when a new drug off-patent medicine is launched, a six-month period of exclusivity on provincial formularies will be provided for Canadian producers.
- As member of the pCPA, work with other jurisdictions to eliminate or reduce rebates on pCPA-negotiated product listing agreements (PLA) for Canadian producers.


Economic incentives to Support Domestic Pharmaceutical Production

Canada must offer incentives like those in the U.S. to retain manufacturing here at home and attract foreign direct investment. Tax and economic policies are needed to ‘level the playing field’ and compete against benefits offered elsewhere. Incentives are needed to recognize it costs more to manufacture in Canada compared to countries where labour costs are much lower. Economic incentives can have a positive effect on securing Canada’s pharmaceutical sovereignty.

Biomanufacturing as Part of Canada’s Defence Industrial Strategy

It is an uncomfortable fact that access to pharmaceuticals can be weaponized, and supply disrupted by geopolitical events. Canada’s recently announced *Defence Industrial Strategy* acknowledges that “our allies have explicitly linked biodefence and medical countermeasure readiness to their economic and national security”⁷. The unprecedented actions of the U.S. to levy tariffs on pharmaceutical imports is in reaction to the national security and biodefence risks they face. Many countries are developing new strategies and mechanisms to use their defence budgets to build biomanufacturing resiliency.

Canada’s strategy recommends “*investments to establish and expand critical biodefence and medical countermeasures capacity*”. It also proposes stockpiling of critical medicines and active pharmaceutical ingredients (API) and other medical countermeasures, as well as funding programs to increase investment in Canadian producers of essential biodefence products.



Canada’s domestic drug manufacturers are ready, willing and able to step up to participate in Canada’s national security and defence.

⁷ [Canada’s Defence Industrial Strategy](#)

Strategic Trade Alliances with Trusted Partners

It has never been more important to align with allies to support Canada's pharmaceutical sovereignty. Canada's pharmaceutical supply chains are facing disruption when the U.S. 232 tariffs are implemented this summer. Uncertainty about CUSMA negotiations and border measures prevail. The impact of 'Most Favoured Nation' pricing is unclear.

We urge the Standing Committee on Health to recognize the need for Canada to secure access to the U.S. market and reject any across-the-board tariffs or quotas on pharmaceutical exports based other bilateral agreements. The CUSMA review must defend current levels of patent terms and exclusivity periods for Canadian pharmaceuticals and address recent America-First protectionist policies that will exclude Canadian exporters.

About the CPMEA

The Canadian Pharmaceutical Manufacturers and Exporters Alliance – Alliance fabricants et exportateurs pharmaceutiques du Canada (CPMEA) is a coalition representing pharmaceutical manufacturing companies operating production facilities in Canada. Our members are the largest producers of generic and contract manufactured medicines in Canada Together, we supply more than 33% of all prescriptions used by Canadians to treat illness and improve their lives.

The CPMEA unites the pharmaceutical manufacturing sector here at home, to ensure we retain what we have, and to strengthen our capacity to produce essential medicines, reduce dependence on imports and ensure long-term public health security.

Canada's pharmaceutical producers support more than 33,000⁸ highly skilled and technical jobs, making medicines for Canadians and for export. The largest volumes of biopharmaceuticals manufactured in Canada are made by generic and contract manufacturers.

Canadian pharmaceutical exports to the U.S. in 2025 exceeded \$9⁹ in value; this is remarkable given the relative size of our economies and the vast U.S. pharmaceutical industry. It is estimated most of this production – between \$6-7 Billion – are finished dose products manufactured in Canada by generic and contract manufacturers.

⁸ Stats Can Sources: Principal statistics for manufacturing industries, by NAICS Code 3254 Pharmaceutical Manufacturing.

⁹ Statistics Canada. Canadian International Merchandise Trade Web Application

Appendices

Appendix A

Health Canada's existing Priority Review process grants fast-track status to eligible drug submissions with a shortened review target of 180 days, in comparison to 300 days for non-priority. Priority Review submissions are inserted into Health Canada's drug submission queue with a shortened review target ahead of non-priority submissions¹⁰.

To provide a meaningful incentive to formulate and manufacture pharmaceuticals in Canada, CPMEA recommends the following amendments (in italics) to the Health Canada Priority Review Guidance¹¹:

This policy applies to a New Drug Submission (NDS), ***Abbreviated New Drug Submission (ANDS)*** or Supplemental New Drug Submission (S/NDS) that:

- i. are for a serious, life-threatening or severely debilitating disease or condition for which there is substantial evidence of clinical effectiveness....
- ii. ***is submitted by a "Canadian producer"***

Definition of "Canadian Producer"

- At least 30% of manufacturers gross revenue from the sale of drug products in Canada generated through the sale of drug products manufactured in Canada.
- For a DIN to contribute towards the value of gross sales manufactured in Canada, the finished goods must be manufactured in Canada.
- Packaging of finished goods manufactured outside of Canada should not count towards the value of gross sales manufactured in Canada.

¹⁰ <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/priority-review-drug-submissions-therapeutic-products.html>

¹¹ https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/prodpharma/priordr-eng.pdf

Appendix B

U.S. ACTIONS TO RESHORE PHARMACEUTICAL PRODUCTION



APR 15, 2025	232 Investigation Launched into Trade in Pharmaceuticals
MAY 5, 2025	FDA reduce regulatory barriers/ Increase cost of Foreign Inspections
MAY 12, 2025	EO "Most Favored Nation" Price = lowest of 27 countries
MAY 21, 2025	'Big Beautiful Bill' tax incentive for manufacturing activity
MAY 23, 2025	USTR Consultation on foreign price 'freeloading' policies
JUL 31, 2025	White House letter to CEOs demanding lower prices
AUG 13, 2025	EO directing Stockpile for essential APIs
OCT 5, 2025	FDA Priority Approval for Generics made in U.S
JAN 7, 2026	FDA 3 yr waiver for annual facility fees for domestic Generic plants
JAN 16, 2026	WH announces price deals with 16 pharma companies; TrumpRx launched
FEB 1, 2026	FDA opens applications to speed up plant approvals
APR 2, 2026	Under 232, 100% tariffs on patented medicines effective July/September