



Tax, Fiscal and Regulatory Measures to *Build Canada Strong* for Drug Production

Canada's 2026 Pre-Budget Consultation

A Submission from the
Canadian Pharmaceutical Manufacturers and
Exporters Alliance (CPMEA) - Alliance fabricants et
exportateurs pharmaceutiques du Canada (AFEPC)

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A Critical Moment for Canadian Biomanufacturing

As Canada prepares its 2026 Budget, the trade war with the U.S. government is top of mind. Many export sectors including Canada's biopharmaceutical, steel, automobile, lumber and aluminum industries in Canada are facing unprecedented Section 232 tariffs on exports, disruption to global supply chains and loss of business.

As of Sept 29, 2026, Canadian pharmaceutical exporters of patented pharmaceuticals will be subject to 100% tariffs to the U.S., a rate so high that it will certainly impact producers and curtail exports to the U.S. Furthermore, President Trump has announced tariffs up to 200% on generics starting in 2028.

The future of Canada's pharmaceutical sovereignty hinges on government leadership and investment in 2026/27. The Canadian biomanufacturing industry produces more than \$16 Billion in output annually, employs 33,000 Canadians and exported almost \$12 Billion to the U.S. in 2024. Canada's biomanufacturers invest hundreds of millions in capital each year to improve productivity, engage a highly trained workforce, and manufacture valued-added health outputs used by Canadians every day.

Canada already has a strong, globally competitive biomanufacturing base. Most pharmaceutical production in Canada is undertaken by generic and contract manufacturers, making domestic production an important component of Canada's supply-chain resilience and public health security.

CPMEA represents these pharmaceutical companies, with facilities located in Canada, manufacturing medicines for Canadians and for export, including innovative, generic and biosimilar medicines. Collectively, CPMEA members provide more than 30% of prescriptions dispensed in Canada.

Tariff uncertainty, however, is putting Canada's pharmaceutical manufacturing base at risk. In 2025, Canadian pharmaceutical exports to the United States declined by \$2.3 billion, even before the tariffs have taken effect. Members of CPMEA are reporting uncertainty among U.S. customers, with companies delaying or declining contract manufacturing orders despite the strong quality, reliability and performance records of Canadian facilities. This is not simply a trade issue - it is a warning sign for Canada's health security, economic resilience and pharmaceutical sovereignty. Once pharmaceutical manufacturing capacity leaves Canada, it is difficult and costly to rebuild. Canada cannot afford to lose the manufacturing capabilities it has today and then discover, in the next supply disruption, that it no longer has the capacity to produce the medicines Canadians depend on.

As the Department of Finance prepares its 2026 Budget, the CPMEA recommends appropriate funding and resources to achieve the following goals:



Competitive Tax Policy

Support investment in manufacturing facilities, equipment, and workforce development



Priority Regulatory Review for Canadian Producers

Establish dedicated pathways to accelerate approvals for domestic manufacturers



Canada-First Procurement

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



Inclusion of Domestic Medicine Production in Canada's Defence Strategy

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

Impact of Reshoring Efforts in U.S. and Europe

The United States has recognized the economic imperative of domestic pharmaceutical production for national security. Over the last 16 months, in addition to tariffs, the U.S. has announced more than a dozen incentives to reshore production and reward domestic drug producers, including:

- tax credits for manufacturing,
- higher rates of depreciation,
- lower user fees and inspection costs,
- preferred procurement,
- fast-track regulatory review, and
- priority market access for domestic generic producers.

U.S. Actions to Reshore Pharmaceutical Production

APR 2025	232 Investigation launched into trade in pharmaceuticals
MAY 2025	FDA Pre-Check reduces regulatory barriers/Increases cost of foreign inspections
MAY 2025	EO "Most Favored Nation" Price = lowest of 27 countries
MAY 2025	"Big Beautiful Bill" tax incentive for manufacturing activity
AUG 2025	EO directing Stockpile for essential APIs
OCT 2025	FDA priority approval for generics made in U.S.
JAN 2026	FDA 3-year waiver for annual facility fees for domestic generic plants
JAN 2026	White House announces price deals with 17 pharma companies; TrumpRx launched
FEB 2026	FDA to accelerate approvals for Gx made in U.S. for 180 Exclusivity
APR 2026	Under 232, 100% tariffs on patented medicines effective July/September
JUL 2026	Trump announces up to 200% tariffs on generics in 2 years
JUL 2026	CMS proposed rule to incentivize domestic essential medicine production

The combination of tariffs, regulatory incentives, tax measures, procurement preferences, and company-specific agreements has created a powerful incentive to expand pharmaceutical production in the United States.

The most significant consequence of recent U.S. policy may be its effect on investment behaviour. PhRMA, the pharmaceutical industry association, reports that there has been over \$550 Billion promised in new investments. Individual companies are making announcements about reshoring production and expanding R&D centres at a rapid pace.

Similarly, the European Union has announced an agreement¹ amongst its members aimed at expanding EU pharmaceutical manufacturing capacity and reducing reliance on suppliers in countries such as China and India. Under the Critical Medicines Act, EU member states are supporting strategic industrial projects to build, modernize, and expand domestic pharmaceutical manufacturing while creating procurement incentives that favour regional production.

To secure Canada's domestic capacity and protect public health, **Budget 2026 must pair regulatory and procurement reforms with targeted tax measures, investment supports, and increased resourcing for Health Canada.** Such actions would recognize the critical national security role of biomanufacturing and are necessary to *Build Canada Strong for Drug Production*.

Key Tax Measures

To create competitive advantage for Canadian manufacturers and to incentivize capacity expansion, CPMEA recommends the following tax reforms and credits.

1. Refundable Manufacturing Tax Credit for Medicines Produced in Canada

Create a refundable manufacturing tax credit specifically for the domestic production of finished-dose pharmaceuticals and APIs. The credit should recognize additional labour, regulatory compliance, and quality assurance costs associated with Canadian production and be large enough to influence location decisions compared to incentives in the U.S. and EU.

2. Enhance SR&ED Support for Generic and Biosimilar Development

Recognize the particular nature of R&D performed by generic and biosimilar producers and adjust SR&ED treatment accordingly:

- Broaden eligible SR&ED activities to include quality control, testing, validation, pre-commercialization activities and manufacturing process development specific to generic and biosimilar production.

¹ EU [Announces](#) Provisional Deal May 12

- Restore pre-2014 program features: 100% credit on amounts paid to Canadian subcontractors (instead of the current 80%) and re-enable eligibility for purchase and rental of equipment.
- Expand eligibility for the enhanced SR&ED rate to Canadian companies with foreign ownership and Canadian public corporations to attract public markets and FDI and encourage headquarters location in Canada.
- Maintain the general non-refundable SR&ED rate at current levels and create an option for a lower refundable general rate for certain small or eligible firms.
- Policy guidelines should explicitly acknowledge the strategic importance of SR&ED activities conducted by generic drug manufacturers. Significant investment is required in R&D activities for generic and biosimilar products - often the same types of activities undertaken by originators for which SR&ED credits are allowed. Generic products are much more complex, testing more extensive, and the technical requirements to bring a generic or biosimilar product to approval have changed over the years. R&D to repurpose, reformulate or combine known molecules can provide value-added medicines with therapeutic improvements for unmet needs.

3. Refundable Tax Credit for Technology Transfer and Onshoring

Provide refundable credits to cover eligible costs of technology transfer and scale-up for products currently produced abroad. Eligible costs should include process transfer, validation, regulatory support, workforce training, and capital modifications required to replicate manufacturing capability in Canada.

4. Interest Deductibility Adjustments for Drug Manufacturing and R&D

Raise or remove the current limits on interest deductibility when interest supports capital used for drug manufacturing or R&D. Alternatively, link permitted interest deductibility to levels of qualifying capital expenditure for manufacturing expansions. This will lower borrowing costs for capacity investments.

5. Accelerated/Full Depreciation for Manufacturing and Onshoring Assets

Introduce immediate accelerated or full first-year depreciation for qualifying investments in manufacturing assets used for drug production (including buildings, production equipment, and onshoring of API/dose-form assets). Consider retroactive adjustments to accelerate depreciation for capacity additions constructed since 2020, recognizing COVID-era investments made to respond to public health needs

6. Restore Preferential Tax Treatment for Pharmaceutical Donations

Reinstate the enhanced tax deduction for corporate donations of medicines to registered charities (reinstating the pre-2017 treatment). This will encourage redirection of surplus product to vulnerable populations, reduce waste, and demonstrate Canada's public-interest leadership without significant fiscal cost.

Health Canada Resourcing to Prioritize Pharmaceutical Products Made by Canadian Biomanufacturers

There is great economic opportunity to retain and build Canada's biomanufacturing sector and support our national and public health security. It is encouraging that Health Canada is taking a "Canada First" approach to regulatory policy and translating the *Build Canada Strong* mandate into policy actions. All policies and processes at Health Canada should be reviewed through the lens of Canada's pharmaceutical sovereignty and self-sufficiency.

This opportunity requires investment by the Government of Canada in appropriate resourcing at Health Canada in four key areas:

- Modernizing Canada's ANDS Review Process to support domestic producers
- Deferral of generics manufactured by Canadian producers from the Ministerial Reliance Order and monitoring the impact on Canadian producers
- Implementation of the Priority Review Program for generics manufactured by Canadian producers.
- Establishment of a 'Canada First' position within Health Canada's Regulatory Management team.

Modernizing Canada's ANDS Review Process

Health Canada has acknowledged delays in the approval of medicines and committed to reform the review process. Compared with regulatory agencies such as the FDA and EMA, Health Canada's review framework is often perceived as less predictable. Sponsors frequently report uncertainty regarding evidentiary requirements, inconsistent interpretations between review teams, and evolving expectations during the review process.

Health Canada frequently relies on reviewer interpretation and case-specific discussions. This can result in information requests, deficiencies, and concerns that were not clearly foreseeable based on existing guidance. Sponsors report instances where similar submissions - even identical submissions - receive materially different questions and review outcomes.

By comparison, the FDA's review process provides product-specific guidance, clearly defined standards, and highly predictable review expectations. Sponsors understand submission requirements before filing applications.

Budget 2026 must include resources dedicated to modernizing the existing ANDS process and to reduce the backlog of submissions in the review queue.

Deferral of Generics made by Canadian Producers from the Ministerial Reliance Order

Health Canada is currently consulting on **Draft Guidance on the Ministerial Reliance Order**. Although intended to speed up regulatory approvals, the Reliance program may inadvertently harm Canada's own drug manufacturers by prioritizing submissions from foreign importers and leaving domestic producers at the back of the queue.

Canadian producers typically submit their files to Health Canada first and therefore cannot necessarily benefit from reliance on an approval by another foreign regulatory authority. The Reliance Order must not create a situation in which the choice to develop and submit a product directly in Canada becomes a competitive disadvantage.

CPMEA has consulted extensively with Health Canada, and we are encouraged by their responsiveness. We support their decision to defer the inclusion of generic and biosimilar products from the initial implementation of the Incorporated by Reference (IbR) framework. CPMEA recommends that Health Canada dedicate resources to establish a Canadian-manufacturing safeguard. CPMEA also recommends that the Guidance explicitly require a public consultation before adding generics and biosimilars to the IbR list.

Implementation of a Priority Review Program for generics manufactured by Canadian producers

On July 15, Health Canada announced a proposed pilot program to prioritize certain generic submissions involving domestic manufacturing. This is a very positive development to speed up approval of medicines made by Canadian producers and to support a 'Canada First' agenda. CPMEA strongly supports continued work in this direction and recommends that the pilot be considered together with the future design of the Reliance program.

The two policies should work together. A domestic-manufacturing priority mechanism addresses the queue position of Canadian submissions; a reliance safeguard ensures that the Reliance Order does not subsequently create a faster alternative route for foreign competitors supplying the same products. CPMEA is consulting with Health Canada on the structure and implementation of the Pilot Program.

'Canada First' position within Health Canada's Regulatory Management team

CPMEA also recommends the creation of a 'Canada First' regulatory project-management function within Health Canada - a 'navigator' so to speak. A central point of coordination could improve communication, manage response timelines and reduce avoidable regulatory delays for domestic producers. This is an important part of the Priority Program for Generic medicines too – the navigator can ensure that submissions from Canadian producers are 'picked up' first through workflow management.

'Canada First' Procurement and Market Access

Canada has launched its *Buy Canada Policy* aimed at supporting Canadian businesses and workers as well as critical industries.

CPMEA recommends using federal procurement levers to create predictable demand for Canadian-made medicines. Directing even a portion of federal public drug spending toward domestic products will create the demand signal needed to justify manufacturing investments without increasing public drug spending and will encourage the provinces to follow the federal lead.

Definition of "Canadian Producer"

At least 30% of manufacturers gross revenue and/or volume from the sale of drug products in Canada generated through the sale of drug products manufactured in Canada.

*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.*

- Implement a 'Buy-Canadian' procurement program for federal drug programs; e.g., NIHB, PSHCP, military, veterans.
- Coordinate with provinces through the Canada Drug Agency to create an exclusivity window (e.g., six months) for Canadian producers when new off-patent medicines are launched.
- Work through pCPA to reduce or waive product listing agreement (PLA) rebates for Canadian producers to improve their competitiveness and market access.

Defence Industrial Strategy and Stockpiles

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"². 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.

The Government of Canada has identified domestic biomanufacturing as critical infrastructure. Budget 2026 should allocate funds to:

- Expand production capacity for medical countermeasures and essential medicines for defence and civilian stockpiles.
- Support stockpiling of essential medicines and APIs.
- Create procurement mechanisms and contracting certainty to ensure capacity is available in emergencies.

² Canada's Defence Industrial Strategy

Canadian Biomanufacturers Face Greater Exposure than Other Jurisdictions

Most major pharmaceutical-exporting countries have negotiated arrangements with the United States that reduce or eliminate the impact of Section 232 tariffs. It is no surprise that Europe, UK, South Korea, Switzerland and Japan rapidly negotiated separate bilateral agreements with the Trump Administration in the months after the 232 Investigation was launched. Recently, the UK government has agreed to increase their National Drug Budget by 25% to pay for U.S. drug price increases to avoid tariffs on their exports to the U.S.

Canada remains the only major pharmaceutical exporter to the United States—other than India³—without a dedicated pharmaceutical agreement. As a result, **Canadian producers face the most severe tariff exposure of any major pharmaceutical-exporting jurisdiction.**

Jurisdiction	Pharmaceutical Tariff Treatment
United Kingdom	0% tariff; agreed to raise prices of US medicines
European Union	15% tariff
Japan	15% tariff
South Korea	15% tariff
Canada	100% tariff on patented products

Risks of Inaction

Without competitive tax and procurement measures, Canada risks losing investment, jobs, and export markets to jurisdictions that are actively incentivizing reshoring drug production. U.S. tariffs and preferential incentives will redirect supply and investment, harm Canadian producers and weaken national resilience in a time of heightened geopolitical risk.

Budget 2026 must move beyond symbolic recognition of biomanufacturing as strategic and provide concrete, targeted, and time-sensitive tax, regulatory, procurement and defence investments to secure Canada's pharmaceutical sovereignty.

³ India does not have a bilateral agreement covering pharmaceutical with the U.S. however the vast majority of its exports to the U.S. are generic and biosimilar product which are currently exempt from 232 tariffs.

About CPMEA

The Canadian Pharmaceutical Manufacturers and Exporters Alliance (CPMEA) represents companies that operate pharmaceutical manufacturing facilities in Canada, including major generic and contract manufacturers. Together our members produce over one-third of all prescriptions used by Canadians, support more than 33,000 skilled jobs and accounted for over \$11B in exports to the U.S. in 2024. We stand ready to work with the Government of Canada to implement policies that secure domestic production, protect public health, and strengthen Canada's economic and national security.

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