Submission to the Government of Canada's Consultation on the Review of the Canada-United States-Mexico Agreement

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Executive Summary

Innovative Medicines Canada is the national association for over 40 biopharmaceutical and vaccine companies in Canada. Our sector collectively invests as much as $3.2 billion annually in Canadian research and development (R&D) and contributes approximately $18 billion to Canada's knowledge-based economy. The innovative pharmaceutical sector views the Canada-United States-Mexico Agreement (CUSMA) review as a critical juncture for Canadian economic and health policy. While CUSMA provides a foundational trade environment, Canada must address domestic policy shortcomings—particularly concerning the financing of pharmaceutical innovation, patient access, and intellectual property (IP)—to preserve the benefits of North American economic integration.

To this end, we urge the Government of Canada to prioritize a negotiation and implementation strategy focused on a comprehensive new approach for pharmaceuticals, which includes the following elements:

1. **Protect Canadian supply of medicines and future product launches.** New product launches have been called into question due to Canadian pricing policy and possible U.S. Most Favored Nation (MFN) policy. Canada's supply is also under threat from cross-border commercial diversion.
2. **Increase Canada's financing of pharmaceutical innovation** to a comparable level in leading jurisdictions by establishing a Health Innovation and Resilience Fund (HIRF). This would address the concerns raised by the U.S. government regarding the financing of innovation and provide the financial support needed for Canada to implement related systemic changes in patient access (3), regulatory/pricing (4), and IP (5).
3. **Accelerate public access to new innovative medicines by one year,** adopting the Ontario "FAST" model a pan-Canadian basis with a broader scope and leveraging the Fund noted above.
4. **Address needed regulatory flexibilities** in the Patented Medicine Prices Review Board's (PMPRB) regulations.
5. **Elevate intellectual property standards**, specifically by strengthening regulatory data protection and ensuring a more competitive and meaningful system of patent term restoration to align with U.S. and E.U. peer jurisdictions.

These actions are essential to safeguard the health of Canadian patients, and secure future biopharmaceutical investment, including product launches and clinical trials, which are highly mobile and cannot be taken for granted in the current global and domestic policy environment.

About Innovative Medicines Canada

The innovative pharmaceutical sector is critical to the Canadian economy. Innovative Medicines Canada is the national association for over 40 biopharmaceutical and vaccine companies in Canada. Our sector collectively invests as much as $3.2 billion annually in Canadian research and development (R&D) and contributes approximately $18 billion to Canada's knowledge-based economy. This robust footprint supports critical manufacturing, research, and over one hundred thousand highly skilled Canadian jobs. Canada is a G7 leader in the number of clinical trials per capita, and our industry sponsors the majority of these trials (60-75%).

Maintaining and growing this investment requires a globally competitive and predictable operating environment, which is currently a challenge due to geopolitical uncertainty and the lack of a domestic policy response to significant issues facing the pharmaceutical industry. The CUSMA review offers a timely opportunity to harmonize Canada's policy landscape with its North American partners, ensuring a stable foundation for the industry's continued contribution to national prosperity and public health.

1. **Protecting the supply of medicines: Future launches at risk under U.S. Most Favoured Nation Pricing**

The security and stability of the Canadian medicine supply are paramount to patient safety. Given Canada's smaller, import-driven market for innovative medicines, its supply is based on predictable domestic needs and is particularly sensitive to U.S. policy.

Canada must urgently address U.S. concerns and the Most-Favored Nation (MFN) policy with a coherent, coordinated pan-Canadian response.

In May 2025 the U.S. Administration issued an Executive Order on MFN and has subsequently engaged in a series of bilateral negotiations to ensure "foreign nations can no longer use price controls to freeride on American innovation." This puts significant pressure on Canada to enhance its pharmaceutical system through superior contribution of future innovation.

While details of the MFN continue to emerge, the key issue is that the U.S. will benchmark some U.S. prices to significantly lower prices in Canada and other countries. Significant pricing policy differences put Canada under a high degree of international scrutiny. Future investment, R&D, clinical trials, Canadian jobs, and the launch of new medicines in Canada are already at risk.

Cross Border Diversion

Commercial-scale cross-border diversion of supply, driven by significant differences in pricing policies, also poses a threat to the consistency of domestic supply.

Canada and provincial jurisdictions must commit to the principles of supply chain security and enshrine anti-diversion measures within federal and provincial laws and policy.

Canada must better prevent the unauthorized commercial exportation of Canada's protected pharmaceutical supply, particularly from internet pharmacies and inappropriate volume being driven from increasingly sophisticated U.S.- based Alternate Funding Programs (AFPs).[i] AFPs are commercial actors who target U.S. employers and offer to help import scarce drugs from Canada and other countries, raising a host of trade and safe-supply issues. While data on these commercial actors is limited, it is estimated that approximately 30% of U.S. patients who use AFPs get their drugs from international pharmacies (e.g., Canada) compared to only 15% from U.S. pharmacies.[ii]

As a first step, Canada must obtain and understand detailed cross-border data which is currently lacking. Ultimately, however, Canada must tackle the underlying asymmetry in pricing policy that drive supply diversion and address the U.S. MFN concerns.

2. Renewed commitment to financing of innovation and new medicines

Canada must urgently increase its financing of pharmaceutical innovation to a level comparable to that of leading innovation jurisdictions. This can be accomplished by establishing a *Health Innovation and Resilience Fund* to address current challenges and support governments' goal of improving timely access to medicines. This would be a pro-innovation, pro-trade alternative to single-payer national pharmacare.

This fund would provide the financial support needed for Canada to support provinces and resource CUSMA-related policies that enhance patient access to medicines and vaccines (see 3. below); address regulatory/pricing issues (see 4. below); and enhance intellectual property protections under CUSMA (see 5. below).

The United States has been highly critical claiming that it comprises "less than five percent of the world's population, yet roughly 75% of global pharmaceutical profits come from American taxpayers."[iii]

This has contributed to a perception that Canada and other countries receive unfair discounts on pharmaceuticals which are subsidized by the U.S.: "Americans are subsidizing drug-manufacturer profits and foreign health systems, both in development and once the drugs are sold."[iv] While Canada may not share this view, the U.S. Administration is clearly intent on levelling the playing field.

Canada must prepare for this from a fiscal perspective. According to analysis by accounting firm EY, United States per capita spending on new innovative medicines as a share of GDP per capita is 0.78%, whereas Canada is only 0.32%.[v] This aligns with the situation in Canada where patented

medicine spending is only 4.7% of overall national health expenditure,[vi] although new medicines are essential investments that save lives.

For example, a 2025 study from Columbia University economist Dr. Frank Lichtenberg, found that historic investments in medicines reduced Canadian mortality rates by 49%. Medicines saved 847,000 life years, and reduced hospital utilization by 55%, avoiding potential healthcare costs of $78.7 billion in 2022 alone.[vii] This suggests that accelerated funding of medicines in Canada could offer a win-win for Canadian patients, and ultimately be a cost-effective, long-term investment for the well-being of the country and its citizens.

Canada's ongoing preferential access to the U.S. market under CUSMA can also be protected with investments and policy changes. By establishing a pan-Canadian Health Innovation and Resilience Fund, government(s) can answer U.S. calls while proactively financing their own life science innovation goals and creating a financial buffer against external trade and price volatility. Where these investments support health security, Canada could explore the potential of counting them towards its NATO defense spending obligations.

The proposed Health Innovation and Resilience Fund should be immediately available to provinces to support the cost of timely access to new life-saving medicines and vaccines.

This would help to address concerns from U.S. government officials that specifically cites Canadian pharmaceutical access deficits in the context of "Foreign Nations Freeloading on American-Financed Innovation" and who "support utilizing the full force of the U.S. government to ensure other countries appropriately value American innovation."[viii]

This fund would serve the dual purpose of immediately addressing provincial budget constraints that delay patient access while providing a durable, long-term mechanism to elevate Canada's global competitiveness in the life sciences sector and catalyze private sector investment. By sharing the financial burden, the federal government removes a key provincial barrier to adoption, demonstrating national health and economic leadership.

3. Accelerating Access to Innovative Medicines

Part of the underfunding gap relates to Canada's time-to-patient access for new innovative medicines, which is a widely acknowledged public policy issue. Canadians often wait months or years longer than their U.S. and European counterparts to access innovative therapies due to delays within Canada's cumbersome sequential drug approval and reimbursement system.

Canadians on public drug plans wait over two years following regulatory approval to gain access to new innovative medicines, and Canada ranks last in G7 for medicine availability and time-to-patient. This is a CUSMA trade issue because Canada's trade-related commitments to protect intellectual property rights are significantly eroded due to delays.

The federal government has shown leadership in a future commitment to address this (see 2025 Liberal Platform commitment). Ontario recently launched a bold new pilot program, Funding Accelerated for Specific Treatments (FAST), to help accelerate patients' access seven-10 new cancer medicines per year. These products will reach Ontario patients with cancer 12 months sooner, which could prove lifesaving.

The innovative medicines sector recognizes and applauds provincial efforts, such as the introduction of Ontario's FAST October 2025 program. We urge the federal government to use the CUSMA review to foster national cohesion by **facilitating the adoption of this FAST approach, with a broader scope, on a pan-Canadian basis**. The HIRF referenced above could be used to support provincial efforts to provide medicines where morbidity/mortality is high and there is a significant unmet medical need.

A collective, national commitment to a predictable and accelerated innovative medicine public reimbursement process, benchmarked against G7 peers, could:

- Prioritize patient health by reducing the time it takes for patients to access new cancer, rare disease, and chronic condition treatments (e.g. scope should extend beyond Project Orbis oncology treatments) while recognize the unique value patented medicines bring.
- Encourage early product launches by making the Canadian market more attractive, competitive and predictable.
- Address challenges in Canada's Health Technology Assessment systems that undervalue innovation.
- Help to secure future investment and clinical trial activity. Future clinical trials investment cannot be taken for granted because it is difficult to justify investment where there is no access to the standard of care or if it is not clear if or when trial patients will have access to the medicine after the trial concludes.

In terms of metrics, the central objective of this pan-Canadian acceleration should be to improve the time it takes for a patient to gain access to an innovative medicine in Canada by at least 12 months, consistent with the Ontario FAST program targets, while concurrently valuing the impact of the medicine. This commitment would also serve as leverage for Canada within the CUSMA review and possible renegotiation in that it addresses a U.S. trade issue and could be offered as a 'give' against other Canadian priorities.

4. **Address needed regulatory flexibilities in the Patented Medicine Prices Review Board's regulations.**

The PMPRB was created in 1987 as a trade-off for the expansion of patent rights in Canada. The backdrop for this expansion of patent rights were Canada-U.S. free trade discussions. Patent protection for drugs was one of the key U.S. demands during free-trade negotiations between Canada and the United States in 1985-1987.[ix] The PMPRB has always been tied to Canada-U.S. trade relations because Canada essentially granted patent rights to innovators in exchange for more liberal trade with the United States.

In 2022, Canada unilaterally changed that bargain by removing the United States and Switzerland from the PMPRB's regulatory basket of countries and adding in several lower price countries.[x] These changes run directly counter to U.S. calls for greater international contributions under the "Most Favoured Nation" approach. In June 2025, the U.S. Chamber of Commerce called on the U.S. Trade Representative (USTR) to reconsider PMPRB changes in the context of "Foreign Nations Freeloading on American-Financed Innovation."[xi] Revisiting and reforming Canada's controversial international price-referencing system could help address long-standing bilateral trade frictions and open the door to greater regulatory flexibility for Canada under MFN discussions.

Restoring the United States and Switzerland to the PMPRB's reference basket is essential to re-establish a fair balance among Canada's key trading partners and to safeguard Canadians' long-term access to pharmaceutical innovation.

5. Elevating Canadian intellectual property (IP) standards

A strong and predictable intellectual property (IP) framework is one of the most vital catalysts for attracting and retaining global investment required for drug discovery and development. Despite the high standards set by the U.S. and E.U., Canada's IP environment for innovative medicines remains structurally weaker, creating an IP gap that discourages investment and puts future R&D and clinical trials in Canada at risk.

Canada needs stronger intellectual property protections. Two additional years of data protection for biologics and three additional years of patent term restoration will bring Canada more in line with the U.S. and Europe.

Strengthen Data Protection for Biologics

Regulatory data protection ensures that innovators' proprietary clinical and safety data used to support Health Canada marketing authorization will not be used to support the approval of competitors. It is a well-established intellectual property right, however, the period of protection in Canada lags the U.S. and Europe.

The government should commit to strengthening the duration and scope of Canada's data protection for all innovative medicines, particularly for complex biologics, to bring Canada in line with the U.S. and E.U. standards.

- *The Current Gap:* Canada currently provides eight years of regulatory data protection for biologics. In contrast, the U.S. offers 12 years. This four-year disparity is a major factor in investment decisions as biologics require high levels of capital investment.
- *The Solution:* We urge the government to leverage the CUSMA review to **commit to two additional years of data protection** (to a minimum of 10 years of data protection) for biologics, with a clear intent to work toward full parity with the U.S. 12-year standard.

This is essential to ensure a return on investment commensurate with the investment risk assumed by pharmaceutical companies and to make Canada a preferred launch market. Canada had previously agreed in the first CUSMA negotiation to provide at least 10-years of protection (two additional years), and this unfinished business should be central to the next round of CUSMA discussions.

Ensure Meaningful Patent Term Restoration (PTR)

Canada can also ensure a meaningful system of patent term restoration to align with U.S. and E.U. peer standards and compensate for regulatory delays. Canada must address two major structural shortcomings in its patent legislation concerning the pharmaceutical sector: the limited scope of the Certificate of Supplementary Protection (CSP), and the concurrence of the CSP and the Patent Term Adjustment (PTA) regime.

These policies impose non-tariff trade barriers by weakening IP rights compared to those granted by trading partners.

- *The Current Gap:* Canada's current system for compensating innovators for time lost during the regulatory approval process, the Certificate of Supplementary Protection (CSP), implemented under the Canada-EU Comprehensive Economic and Trade Agreement (CETA), is significantly more limited than those of its major trading partners. CETA sets the maximum patent term restoration at only two years. This is significantly less than the five years permitted in the European Union and the United States' analogous system. The two-year cap does not fully compensate pharmaceutical innovators for lengthy time spent in research and obtaining marketing authorization, thereby effectively reducing the patent's commercial life and discouraging investment in Canada.
- The Solution: Canada should use the CUSMA review to commit to **increasing the maximum term of the CSP from two years to five years.** This will align Canada's market with global standards, help to attract R&D investment, and incentivize the early launch of new medicines in the Canadian market.
- **End the early filing requirement:** The current CSP regulations impose an unnecessary 12-month early filing requirement (the New Drug Submission in Canada must be filed within 12 months of the first foreign regulatory filing in a prescribed jurisdiction). This rigid and often unworkable requirement penalizes companies, is not required by CETA, and can result in the loss of the CSP entirely, even when a drug may be delayed for years in the regulatory system.
- **Canada should eliminate the 12-month early filing requirement for the CSP:** This administrative barrier adds complexity and uncertainty, contradicting the remedial purpose of the CSP.

End concurrence of protections (PTA and CSP)

Canada's relatively recent Patent Term Adjustment (PTA) system, implemented under CUSMA, compensates patentees for delays caused by the patent office (the Canadian Intellectual Property Office - CIPO). However, the government's approach dictates that the PTA term and the existing CSP term must run concurrently, which effectively nullifies the compensation for one of

the delays. The two mechanisms are intended to compensate for delays caused by two different government functions:

- PTA compensates for patent-granting delays;
- CSPs compensate for time spent in research and regulatory approval (by Health Canada), which is currently a significant new issue in 2025, which may heighten the need for appropriate IP offsets.

By making the terms run concurrently, the patentee does not receive the full, intended compensation for both independent delays. This violates the spirit of both CUSMA (PTA) and CETA (CSPs), as it penalizes pharmaceutical patents relative to other patented inventions.

IMC recommends that Canada amend the *Patent Act* to ensure that the terms of the Patent Term Adjustment and the Certificate of Supplementary Protection run consecutively. This will ensure that Canada more fully honours its international trade obligations.

Innovative Medicines Canada is also interested in engaging with the government in a more comprehensive technical discussion on needed improvements to the IP system, including the mechanics of calculation of delays under patent term adjustments, improvements to patent linkage system, and advancing Patent Box incentives with details and timelines.

Conclusion

The CUSMA review is a vital opportunity to align Canada's trade and domestic policy with the requirements of a modern, innovative economy. Innovative Medicines Canada appreciates the opportunity for comment and urges governments to take decisive action to adopt these recommendations. These commitments will ensure Canada remains a competitive destination for investment, a reliable North American trade partner, and, most importantly, a country that provides its citizens with timely access to the world's best medical innovations.

[i] Canada's current regime is insufficient in that the existing framework allows drug establishment licence holders to independently assess export risks without mandatory notification to Health Canada or clear penalties for non-compliance. There are also gaps in provincial legislation and enforcement by pharmacy regulators that support cross-border prescribing and dispensing by some online pharmacies.

[ii] https://www.fiercehealthcare.com/payers/new-wave-middlemen-promise-savings-specialty-drugs-patients-bear-risks

[iii] https://www.whitehouse.gov/fact-sheets/2025/09/fact-sheet-president-donald-j-trump-announces-first-deal-to-bring-most-favored-nation-pricing-to-american-patients/

[iv] https://www.whitehouse.gov/fact-sheets/2025/09/fact-sheet-president-donald-j-trump-announces-first-deal-to-bring-most-favored-nation-pricing-to-american-patients/

[v] https://cdn.aglty.io/phrma/Attachments/NewItems/Report%20-%20High-Income%20Country%20Spending%20on%20Innovative%20Medicines%20-%20June%202025_20250716125138.pdf

[vi] https://canadianhealthpolicy.com/opinions/controlling-drug-costs-doesnt-require-pharmacare/

[vii] https://canadianhealthpolicy.com/wp-content/uploads/2022/01/LICHTENBERG-11-AUG-2025.pdf

[viii] https://buchanan.house.gov/_cache/files/4/2/42b96a0c-a223-4043-8123-c34b578c10fb/CE616BF626F241A5715B7655E6F3A8507CAF8C567A15D23790F7EAC3FDF8E4E2.ustr-pharmaceutical-r-d-letter.pdf

[ix] https://pubmed.ncbi.nlm.nih.gov/8425783/

[x] These changes appear also to run contrary to Canada's obligation under Article 29.6 to acknowledge the need to apply "procedures that appropriately value the objectively demonstrated therapeutic significance of a pharmaceutical product." New guidelines implementing those regulatory changes come into effect January 1, 2026.

[xi] https://www.uschamber.com/health-care/u-s-chamber-letter-to-ustr-request-for-comments-regarding-foreign-nations-freeloading-on-american-financed-innovation