

Medtech Canada Written Submission

2026 Review of the Canada-United-States-Mexico Agreement (CUSMA)

Introduction

Medtech Canada, the national association representing Canada's innovative medical technology (Medtech) industry, is pleased to provide input to Global Affairs Canada as part of the consultation process on the 2026 joint review of the Canada–United States–Mexico Agreement (CUSMA).

The medtech sector is an integral part of North America's health and life sciences ecosystem. It supports hundreds of thousands of high-skilled jobs, drives cutting-edge innovation, and provides the technologies that enable effective, equitable, and sustainable health care. Our members manufacture and distribute a wide range of medical technologies including, but not limited to, medical imaging, diagnostic equipment and robotic surgical solutions, orthopaedic and cardiac implants, software and AI enabled devices, remote monitoring, mobility aids and wound care products.

The medtech supply chain is deeply integrated across North America. Components, sub-assemblies, software, and finished devices routinely cross multiple borders before reaching hospitals, clinics, and patients. CUSMA has been instrumental in facilitating this integration by reducing trade barriers, ensuring regulatory cooperation, and enabling efficient cross-border trade. Medtech Canada strongly supports the preservation and strengthening of CUSMA as a framework for trade stability, supply chain resilience, and regulatory cooperation in health technologies.

I. PRESERVATION AND CONTINUITY OF CUSMA

Medtech Canada strongly supports the preservation of existing tariff-free access for medical devices and health technologies under CUSMA. Most tariffs in our sector were eliminated under NAFTA and the sector remains duty-free under CUSMA, provided origin requirements are met. It is essential that this continuity be maintained in any future review to ensure uninterrupted access to life-saving technologies across North America.

The Canadian health care system heavily relies on US imports of medical devices. The United States accounts for over 40% of Canada's medical technology imports, resulting in a consistent trade surplus for the U.S. in this sector. Preserving zero-for-zero tariffs through CUSMA secures Canada--the 8th largest medical device market globally—as a stable, accessible and strategic export market for U.S. medical technologies. Additionally, roughly 70% of Canada's medtech exports are to the U.S. market—making this a critically important jurisdiction for Canadian companies in this sector.

Tariffs on either side of the border, threaten the profitability of Canadian and U.S. medtech companies and destabilize the North American supply chain of critical health products which puts this sector at risk for exploitation by other non-allied nations.

II. GENERAL PRINCIPLES

To strengthen Canada's position within the North American medtech ecosystem, it is essential that the Government of Canada reinforce its commitment to open, rules-based trade under CUSMA. This includes maintaining tariff-free and barrier-free access for essential health technologies, safeguarding against export restrictions and protectionist measures—particularly during public health emergencies—and addressing emerging national security concerns such as cybersecurity and supply chain integrity. By explicitly recognizing medical technologies as critical goods and ensuring stable, predictable market access, Canada can enhance health system resilience, support innovation, and secure its strategic role in a globally competitive sector.

III. STRENGTHENING CUSMA PROVISIONS

Chapter 2 – National Treatment and Market Access for Goods

It is critical to ensure that imported CUSMA-compliant medical technologies and raw materials used in the manufacturing of medical technologies continue to receive treatment equal to domestic products, preserving fair competition and patient access to optimal care. The Canadian medtech sector depends on highly integrated, cross-border supply chains, making predictable and barrier-free market access essential for operational continuity and innovation. Strengthening these provisions will encourage investment in Canadian manufacturing and R&D by reinforcing a stable, rules-based trade environment across North America.

Recommendations:

1. Explicitly recognize medical devices and health technologies as essential goods deserving of continued tariff-free and barrier-free treatment under CUSMA.
2. Avoid new non-tariff barriers including duplicative regulatory requirements or discriminatory procurement practices.
3. Ensure consistent application of National Treatment across all levels of government, including provincial, state, and sub-national entities.
4. Establish a trilateral monitoring mechanism to identify and address emerging market access issues in the medtech sector.
5. Develop CUSMA guidelines to discourage export bans or restrictions on medical technologies during public health emergencies.
6. Create a trilateral emergency coordination framework to ensure continued access to critical medical technologies in crises.
7. Simplify customs procedures and reduce compliance costs for all medtech organizations, particularly small and medium-sized enterprises.
8. Provide technical assistance to help Canadian medtech innovators navigate market access provisions in U.S. and Mexican markets.

Chapter 4 – Rules of Origin

The medtech sector depends on multi-jurisdictional manufacturing and sourcing. Components often come from several countries, including high-value electronics, precision-engineered parts, and specialized plastics.

Recommendation:

1. Maintain medical technology import tariffs at a “zero-for-zero” reciprocal level for originating goods in medical technology product categories. Maintain CUSMA Rules of Origin.

Chapter 12 – Sectoral Annexes

Medtech Canada supports strengthening and operationalizing Article 12.E.4 of CUSMA to improve regulatory alignment and mutual recognition in the medical device sector. Enhanced cooperation under this chapter can accelerate patient access to optimal technologies, reduce duplication in compliance, and increase system efficiency.

Recommendations:

1. Definition of Alignment: Each Party should define “medical devices” in a manner consistent with the 2012 Global Harmonization Task Force (GHTF) definition. Alignment in terminology promotes regulatory coherence and predictability for manufacturers operating across CUSMA jurisdictions.
2. Mutual Recognition of Quality Management System Audits (MDSAP): Each Party should recognize audits conducted under the Medical Device Single Audit Program (MDSAP) as evidence of compliance with quality management requirements.
 - Where manufacturers are not yet certified under MDSAP, Parties should allow temporary recognition of audits conducted by MDSAP-authorized organizations during a defined transition period, conditional upon intent to obtain certification.
 - This approach would support continued market authorization, prevent shortages, and ensure timely patient access to safe and effective medical devices.
3. Use of International Guidance: Each Party should consider relevant international scientific and technical guidance documents when developing or implementing marketing authorization requirements. This would ensure global best practices are consistently applied across the region.

Chapter 13 – Government Procurement

The trade landscape has evolved and shifted considerably since the last round of CUSMA negotiations. Some concerns that were front and center never materialized, and the global COVID-19 pandemic affirmed Canada’s high dependency on the global medical technology supply chain. The pandemic made it abundantly clear that governments around the world,

including Canada, have not made adequate investments in public health and pandemic preparation. Steps taken by various countries during the crisis to restrict exports were highly disruptive and indicate the risks of growing global protectionism to Canada's health care systems.

We urge the Canadian government to commit to Canada's inclusion in Chapter 13 – Government Procurement, currently applicable only between the U.S. and Mexico. Canada's exclusion from this chapter has created barriers to fair and transparent procurement processes, particularly at the sub-national level.

It's also critical to ensure that government contracts—particularly in sensitive sectors such as medical technology—are awarded not solely on cost, but also on strategic risk assessments. This includes the exclusion of foreign state-owned enterprises (SOEs) from participating in procurement processes where national security may be compromised. The proposal aligns with growing trilateral concerns over cybersecurity, supply chain integrity, and the protection of critical infrastructure.

Recommendations:

1. Reinstate trilateral government procurement commitments by including Canada in Chapter 13.
2. Align CUSMA procurement obligations with those under the WTO Government Procurement Agreement (GPA), including coverage of all provinces and territories.
3. Establish a Canadian approach to transparent, rules-based procurement across all jurisdictions, reinforced by clear accountability mechanisms and post-award transparency to ensure fair market access for Canadian medtech suppliers and safeguard strategic interests in sensitive sectors.
4. Encourage alignment of monetary thresholds between CUSMA and the GPA to enhance access for small and medium enterprises.
5. Strengthen North American trade policy by embedding national security considerations into public procurement practices.

Chapter 26 – Competitiveness

A key addition to CUSMA was the establishment of the North American Competitiveness Committee (Article 26.1). This trilateral body, composed of government representatives from Canada, the United States, and Mexico, is tasked with promoting deeper economic integration and enhancing the global competitiveness of North American exports.

To date, the Committee has primarily focused on workforce development and emergency coordination mechanisms to safeguard trade flows during crises. However, its mandate offers far greater potential. The Committee should evolve into a strategic platform for advancing a broader competitiveness agenda—particularly by fostering resilient, innovation-driven supply chains that underpin North American economic and national security.

The Competitiveness Committee should prioritize strategic sectors that underpin North American innovation and resilience—namely critical minerals and life sciences. Critical minerals are essential to advanced technologies, including medical devices and semiconductors, and Canada’s resource base positions it as a key supplier; however, continental collaboration is needed to reduce dependence on non-aligned global actors. Similarly, the life sciences sector—including medical devices, diagnostics, imaging, and digital health—is a high-value, innovation-intensive industry with direct implications for public health and economic security. Strengthening these sectors through coordinated policy, investment, and supply chain integration will enable the Committee to drive a resilient, secure, and innovation-led North American economy.

For Critical Minerals, the Committee should prioritize:

- Continentalizing critical mineral supply chains.
- Aligning regulatory and investment frameworks to de-risk projects.
- Ensure tariff-free, reciprocal market access for inputs and finished goods.

For Life Sciences, the Committee should:

- Develop a policy framework that incentivizes the commercialization and adoption of health innovation.
- Streamline pathways to accelerate the movement of medical goods across North American borders.
- Eliminate tariffs and non-tariff barriers on essential medical products.
- Support regional capacity to reduce vulnerabilities and improve access.

Chapter 28 – Good Regulatory Practices

Regulatory inconsistencies are a barrier to trade and economic growth in North America. To enhance North American competitiveness and economic security, all parties should reduce compliance costs and ensure better regulatory alignment.

Recommendations:

1. Actively engage the Committee on Good Regulatory Practices: The three parties should make fuller use of the Committee on Good Regulatory Practices, established under Chapter 28.
 - This Committee could serve as a central coordinating body for enhancing dialogue, collaborating on standardized Regulatory Impact Assessments (RIAs), improving transparency, and setting priorities for deeper regulatory cooperation in areas not specifically addressed elsewhere in CUSMA.
 - The Committee should also conduct regular reviews of regulatory practices and harmonization efforts—adapting to evolving market conditions and technological advancements—and maintain close engagement with industry and other stakeholders across all three countries.

2. Regulatory Collaboration: The Parties should deepen collaboration through international and regional initiatives such as the International Medical Device Regulators Forum (IMDRF) to improve regulatory convergence and reduce redundant requirements.

Chapter 32 – Exceptions and General Provisions

Medtech Canada supports dedicated supply chain provisions in CUSMA to safeguard access to essential medical technologies and services during emergencies. Building on its leadership in the WTO Ottawa Group and lessons from the COVID-19 pandemic, Canada can promote policies that protect an open procurement market and strengthen global supply chains through trusted international partnerships, ensuring economic security and health system resilience.

As global trade dynamics shift, particularly with the rise of non-market economies and foreign state-supported industrial policies, CUSMA provisions could be leveraged to develop a coordinated approach to economic security. Without aligned policies, foreign state-owned manufacturers may exploit investments in one CUSMA country as a gateway to others, undermining domestic competitiveness and distorting market access. The increasing use of national security exceptions in trade further underscores the need for clear, trilateral mechanisms to manage these challenges.

Recommendations:

1. Establish a trilateral “Health Supply Chain Resiliency” framework under CUSMA to coordinate emergency responses, prioritize critical health-related components (including medical devices), and prevent export restrictions among partner countries during crises.
2. Establish CUSMA provisions to prevent non-aligned, state-backed OEMs from using one partner country as a gateway to access others, including measures to ensure such products are not classified as originating goods under the agreement.
3. Establish trilateral guidelines and enforcement mechanisms to protect North American supply chain integrity and economic security.

Conclusion

CUSMA is foundational to the success and stability of Canada’s medical technology sector. As governments prepare for the Agreement’s review, Medtech Canada urges the Government of Canada to prioritize the following:

- Preserve duty-free access for all medical technologies
- Canada should join Mexico and the U.S. as a signatory for Chapter 13 on Government Procurement
- Reinforce commitments under Chapter 2 to maintain open, rules-based trade
- Modernize rules of origin to reflect today’s supply chains
- Enhance regulatory alignment under Chapter 12
- Strengthen trilateral cooperation on supply chain resiliency through measures to strengthen trade, security and economic risks

Strengthening CUSMA in these areas will bolster Canada's innovation ecosystem, ensure patient access to cutting-edge technologies, and enhance health system resilience across North America. Medtech Canada and its members welcome the opportunity to work with the Canadian, U.S. and Mexican governments to strengthen the medtech industry's global leadership and competitiveness.

We would be pleased to provide any additional information or support as needed. For further discussion, please contact Raj Malik, Vice President of Federal Affairs & National Strategic Partnerships at rmalik@medtechcanada.org.