



ADVAMED, AMID, MEDEC SUPPORT FOR USMCA PASSAGE

- The medical technology¹ associations of the U.S., Mexico and Canada recognize the importance of the NAFTA renegotiation among the three countries not only for its economic impact but also to help ensure appropriate access to life-saving and life-enhancing health care products across borders for the benefit of patients.
- We applaud achievement of the USMCA as a new, substantially improved trade agreement for North America, replacing NAFTA, which has been a landmark for commercial integration of the region that favors its country members and strengthens them competitively with the rest of the world.
- The USMCA represents a significant step forward in terms of transparency and regulatory fairness, and to help ensure open access to the markets of all three countries.
- The agreement includes new provisions that apply to medical devices that will foster greater patient access to the latest medical technology innovations and further regulatory harmonization.
- We urge legislative approval of the USMCA in all three countries to strengthen the medical technology industry, jobs, economies, and the global competitiveness of U.S., Mexican and Canadian medtech exporters.

Overview

The medical technology industry is focused on developing advanced medical devices and diagnostics that allow people to live longer, healthier, more productive and independent lives. Such advancements in medical technology yield savings across the health care system by replacing more invasive procedures, reducing hospital stays and allowing people to return to work more quickly. The medtech sector includes companies of all sizes, from the smallest to the largest innovators and companies, but most are small and medium-sized enterprises. We are also a research-intensive industry, spending as much as 20 percent of revenue on R&D to help provide innovative new treatments and cures to patients, support well-paying jobs and continue to lead in an intensely competitive global market.

The USMCA and Key Provisions Impacting the Medical Technology Industry

The USMCA is a trilateral trade agreement concluded among the three countries to replace the 1994 North American Free Trade Agreement. The USMCA includes modernized and high standard provisions intended to support mutually beneficial trade leading to freer and fairer markets, increased economic activity and growth between the parties. The USMCA provisions address the following priority objectives for medical device manufacturers' operations in and between USMCA countries:

¹ "Medical technology" includes medical devices and in vitro diagnostics.

- **Good Regulatory Policies:** Trilateral commitments to follow important principles on how regulations are developed – including open and transparent practices, advance planning, regulatory impact assessments and retrospective reviews.
- **Medical Device Annex:** Ensures consideration of internationally developed guidance, use of risk-based systems basing approvals solely on safety and effectiveness, following reasonable timelines for reviews, and mutual recognition of quality management system audits that conform to the Medical Device Single Audit Program (MDSAP).
- **Transparency and Procedural Fairness:** Requires transparency and fairness in the process by which programs operated by national health care authorities set reimbursement rates.
- **Technical Barriers to Trade:** Ensures that standards and technical regulations are developed in a fair and transparent manner and based on international standards; also ensures non-discriminatory conformity assessment.
- **Tariffs and Customs Facilitation:** Keeps medical technology import tariffs at their previous NAFTA levels – zero for originating goods in medical technology product categories – with a customs facilitation chapter to improve and streamline customs clearance in the region.
- **Anti-corruption:** Combats corruption and supports the rule of law.
- **Investment:** Ensures non-discriminatory treatment of foreign investors and prohibits local content and other performance requirements.
- **Small and Medium-sized Enterprises (SMEs):** Addresses challenges for SMEs when conducting business internationally.
- **Intellectual Property Rights:** Reinforces IPR and strengthens WTO provisions, expanding the scope of IP, patent, trademark and trade secret protections and enforcement.
- **Cross-Border Trade in Services:** Includes familiar provisions also present in other U.S. trade agreements; these provisions could be helpful as members move toward providing more services functions.

Discussion

The USMCA has achieved almost all of the industry priorities identified when the NAFTA renegotiation was launched in 2017. The agreement meets the medtech sector’s overarching goals of: 1) meaningfully upgrading NAFTA to serve as a benchmark for 21st century FTAs while “doing no harm”, including maintaining existing commitments with Mexico and Canada, and 2) preserving the trilateral nature of the agreement.

Conclusion

We urge legislative approval of the USMCA in all three countries to strengthen the medical technology industry, jobs, economies, and the global competitiveness of U.S., Mexican and Canadian medtech exporters.

Sincerely,

AdvaMed	Advanced Medical Technology Association – United States
AMID	Mexican Association of Innovative Medical Device Industries – Mexico
MEDEC	Canada’s Medical Technology Companies – Canada