



## **Overview**

The U.S. 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. As the world's largest trade association representing the medical technology industry, AdvaMed represents medtech companies of all sizes, from the smallest to the largest innovators and companies.

The medical technology industry is an American success story, supporting nearly two million U.S. jobs (direct and indirect), and is one of the few remaining domestic manufacturing sectors with a positive net balance of trade. Medtech industry salaries are also nearly 30 percent higher than the average U.S. wage, in part because the industry employs so many highly skilled workers in the areas of research and development, manufacturing, sales and management. Nevertheless, America's highly competitive medtech industry depends on trade to help ensure security, growth, and new opportunities.

Medical technology accounts for three percent of U.S. gross domestic product, and over \$50 billion worth of exports annually. Opening markets and ensuring a level playing field across borders – including through trade agreements with our closest neighbors, Canada and Mexico – are an essential part of ensuring America continues to lead the global medtech industry for decades to come.

## **The USMCA and Key Provisions Impacting the Medical Technology Industry**

The U.S.-Mexico-Canada Agreement (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:

- **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.
- **Temporary Entry:** Remains largely the same as in NAFTA. NAFTA had limitations on Mexican professionals’ use of “TN” visas, but some of these limitations have been eliminated in the USMCA as a small enhancement.

## **Discussion**

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

## **Conclusion**

AdvaMed applauds achievement of this new, substantially improved trade agreement for North America. AdvaMed believes the USMCA represents a significant step forward in terms of transparency, regulatory fairness and ensuring 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. Adoption of the USMCA will therefore strengthen the U.S. medical technology industry, U.S. jobs, the U.S. economy, and the global competitiveness of U.S. medtech exporters.