

APACMed supports the Trans-Pacific Partnership (TPP) agreement as a driver for economic growth and access to quality healthcare in the region.

SINGAPORE, 29 January, 2016 – The Asia Pacific Medical Technology Association (APACMed) announced its support today for the Trans-Pacific Partnership (TPP) agreement.

The TPP contains many provisions that will contribute to raising the standards of healthcare in Asia-Pacific, aligned with the mission of APACMed. These include provisions to strengthen regulatory systems, promote codes of conduct in business practices, and address the challenges faced by small- and medium-sized enterprises (SMEs) when conducting international business. Provisions in TPP will also foster investment in the region, reduce tariffs and technical barriers to trade, and promote transparency and procedural fairness in government reimbursement decisions.

APACMed believes TPP will have an overall positive impact for economies, patients and the broader healthcare ecosystem in Asia Pacific. We urge participating governments and other stakeholders to work together to quickly address specific remaining concerns and approve the agreement. We also urge all parties to commit to full and faithful implementation to ensure that patients and economies realize the benefits of TPP.

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KEY PROVISIONS OF THE TRANS PACIFIC PARTNERSHIP (TPP) IMPACTING THE MEDICAL DEVICE INDUSTRY IN ASIA-PACIFIC¹

The TPP contains the following provisions that will have an impact on the ability of medical device manufacturers to conduct business in TPP countries:

- **Regulatory Commitments:** Each TPP country has agreed to provisions that will ensure adherence to important regulatory principles, including consideration of internationally developed guidance, use of risk-based systems, basing approvals solely on safety and effectiveness, and following reasonable timelines for reviews.
- **Transparency and Procedural Fairness:** The agreement provides for 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 setting and technical regulations are developed in a fair and transparent manner.
- **Anti-corruption:** Contains provisions to combat corruption and support the rule of law, and calls for the establishment of codes of conduct to promote high ethical standards;
- **Investment:** Ensures fair treatment of companies that invest in TPP countries and prohibits local content and other performance requirements.
- **Tariff Elimination:** Eliminates all med tech import tariffs, with an estimated impact of under ten million dollars annually after five years, because tariffs have already been eliminated for US exports, except to Brunei, Malaysia and Vietnam;
- **Small and Medium-sized Enterprises (SMEs):** Includes provisions designed to address issues that create particular challenges for SMEs when conducting business internationally.

¹ Adapted with permission from an AdvaMed analysis.

Background:

The TPP is a trade agreement among twelve member countries: Australia, Brunei Darussalam, Chile, Canada, Japan, Mexico, Malaysia, New Zealand, Peru, Singapore, the United States, and Vietnam. Collectively, they represent nearly 40% of world GDP. TPP is open for other countries to join in the future providing they agree to the provisions set out in TPP, and Indonesia, the Philippines and Thailand have expressed interest in joining. Negotiations of the content of TPP were concluded on Oct 5, 2015 and the full text was released on Nov 6, 2015. The scope of the TPP is broad and covers areas such as market access, supply chain management, intellectual property, free movement of information, labor standards, workers' rights, and environmental protections.

Each participating country must ratify the agreement according to their country-specific process. The governments of Malaysia and Vietnam have expressed support. Japan's ratification is seen as critical to establish credibility of the agreement with other countries in Asia-Pacific. The Abe Administration is supportive of TPP and the Diet in Japan currently plans to debate TPP in April and May, with possible passage before the end of the Diet Session in June. In the US there is support among broad coalitions and concerns by some stakeholders over certain provisions, such as data protection for biologics and inclusion of some sectors (e.g., tobacco) in investor-state dispute settlement provisions. The politics of the US Presidential election will also affect the timing and substance of the debate. Many believe TPP will not be introduced for US Congressional debate until after the November elections.