medical technology
ASSOCIATION OF NEW ZEALAND

Medical Technology Association of NZ

Trans Pacific Partnership Agreement

Submission to Ministry of Foreign Affairs & Trade

March 2016

Background

The Trans Pacific Partnership (TPP) is a plurilateral free trade agreement concluded among 12 countries (U.S., Japan, Australia, New Zealand, Singapore, Malaysia, Vietnam, Brunei, Canada, Chile, Mexico, and Peru), after over a decade of negotiations. Other Asia Pacific countries, including Korea, the Philippines, Indonesia, and Thailand have expressed an interest in possibly joining the TPP after entry into force. The TPP is intended to liberalize trade among its members, leading to increased economic activity and growth. The 6,000-plus page agreement covers manufactured goods, services, government purchases, competition policy, intellectual property, agricultural products, and other areas.

The TPP includes an Annex 8-E: Medical Devices that specifically relates to the medical technology industry. The New Zealand medical technology industry already enjoys business in both directions with several TPP signatories, but the TPP agreement could increase that trade and the awareness of opportunities in each other's markets by removing non-tariff technological trade barriers.

An appropriately implemented TPP will provide substantial improvements over the status quo for patients, workers, manufacturers and the economies of the member countries, and will help ensure that patients in these countries have greater access to safe and effective medical technologies in a timely manner.

About the NZ Medical Technology Industry

MTANZ represents the manufacturers, exporters, importers and distributors of medical technology products in New Zealand. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from common place, everyday items like surgical gowns, bandages and syringes, to high technology items such as implantable cardiac and orthopaedic devices, in-vitro diagnostic products and diagnostic imaging equipment such as ultrasound, computed tomography (CT), magnetic resonance imaging (MRI) and positron emission tomography (PET) machines. Many newer products combine biological products with biomedical products, and employ converging technologies in areas such as mobile health (telemedicine).

Domestic sales of medical technology in New Zealand in 2014 were an estimated $1.5 billion (private & public) with approximately 98% of medical technology imported for the New Zealand market. There are more than sixty companies developing and manufacturing medical technology in New Zealand with export sales of $673 million in 2013. It is a highly innovative industry which invests heavily in research and development with $66 million invested in 2013[1]

United States of America (USA) is the largest medical global medical technology market valued at USD 137 billion[2] (± 40% of global market). Japan is the second largest global medical technology market valued at USD 41 billion[3]

The USA market is New Zealand's largest export market for medical technology valued at approximately $400 million in 2013 (included in this figure is Fisher & Paykel Healthcare's output from their Mexican manufacturing plant)

The majority of New Zealand's medical technology imports are sourced from USA manufacturers.

Key Provisions Impacting Medical Device Industry

The TPP contains the following provisions that will have an impact on the ability of medical device manufacturers to conduct business in TPP countries (please see below for a fuller description of these and other provisions):

- **Regulatory Commitments:** Each TPP country has agreed to provisions that will ensure adherence to important regulatory principles, including consideration of internationally

[1] Reference: NZ Trade & Enterprises Health Technologies Survey November 2013
[2] Statista 2015a Medical Technology Revenues World Regions
[3] Statista 2015a Medical Technology Revenues World Regions

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 healthcare 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 medtech import tariffs, 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.

Description of Relevant Provisions for Medical Device Industry

Regulatory Provisions

The successful inclusion of almost all industry priorities in the regulatory annex of the agreement, with the exception of preventing re-registration requirements.

Key regulatory provisions include:

- improving the alignment of medical device regulations;
- considering relevant internationally-developed guidance documents when developing or implementing laws and regulations on the approval of medical devices;
- using a risk-based approach that distinguishes between classes of medical devices;
- basing approvals solely on information related to safety, effectiveness, labeling, and design/manufacturing quality;
- administering the approval process in a timely, reasonable, objective, transparent, and impartial manner; and
- allowing decisions to be subject to an appeal process.

The inclusion of these provisions in the final TPP agreement will provide substantial benefits for the medical device industry and should be considered a significant win.

Transparency and Procedural Fairness

The TPP agreement includes provisions for procedural fairness in medical device reimbursement. These provisions are designed to provide transparency to the process by which national (but not state or provincial) health care authorities in TPP member countries set reimbursement rates for medical devices. For New Zealand, the annex will apply to the Pharmaceutical Management Agency's (PHARMAC) consideration of applications to fund pharmaceuticals with some new obligations required by PHARMAC.

The procedures require that countries act within a reasonable time period in making reimbursement decisions, that the rules they use to make these decisions are made public, that applicants can provide comments at appropriate times in the decision process, that the basis for decisions is made available to the applicants, and that an appeals process be available to the applicants.

New Zealand has excluded medical devices from the scope of its obligations for transparency and procedural fairness for medical technology reimbursement in this Chapter

In addition to the transparency and procedural fairness provisions, the TPP contains a separate section which applies broadly to the development of regulations and other government decisions across the economy. It is designed to promote good governance through greater transparency, participation, and accountability in the development of regulations and other government decisions. These provisions require governments to promptly publish laws, regulations, administrative rulings of general application, and other procedures that affect trade and investment. It also provides opportunities for stakeholder comment on measures before they are adopted and finalized. These provisions apply to all TPP parties and will assist New Zealand companies entering these markets.

Unfortunately, the final annex falls well short of the New Zealand industry's requirements by failing to include an independent review process, not setting a specific timeframe for making reimbursement decisions, and excluding PHARMAC's decisions on medical devices.

Tariff Elimination

The TPP would yield modest benefits from tariff elimination for the medical technology industry. Import tariffs in most of the TPP participating countries have been eliminated under previous trade agreements, leaving only Brunei, Malaysia and Vietnam with import tariffs. New Zealand has minimal export sales, if any, of medical technology to these countries but with the reduction in tariffs, entry to the potentially larger Malaysian market could be an incentive for New Zealand companies.

Technical Barriers to Trade

To address the challenge of non-tariff trade barriers, the TPP contains provisions to ensure that standards-setting, conformity assessment procedures, and technical regulations are developed in a fair and transparent manner, with opportunities for "bottom-up" participation by stakeholders.

These provisions are designed to reduce unnecessary testing and certification costs and promote greater openness in standards development. They call for the TPP governments to increase public participation in the development of technical regulations, standards, and conformity assessment procedures by government bodies. They also require TPP countries to increase the transparency of government decision-making by publishing new technical regulations and conformity assessment procedures, offering opportunities for public comment, and providing responses to substantive issues raised by comments.

New Zealand exporters often face considerable non-tariff technical barriers when entering international markets and these come in the form of duplication in clinical trials, regulatory time and unnecessary compliance cost

Investment/Local Content Requirements

The TPP contains an extensive set of provisions to ensure the fair treatment of companies that invest in TPP countries. These provisions ensure that investment disputes are handled in a transparent and rules-based manner. They establish rules that provide basic protection against discrimination, such as requirements for national treatment (treatment no less favorable than a TPP country provides to its own investors or investments) and most-favored-nation treatment (treatment no less favorable than a TPP country provides to another country's foreign investors or investments). These provisions also prohibit specified performance requirements, including local content requirements, export requirements, and technology transfer or technology localization requirements.

The investment provisions also:

- provide basic protections against uncompensated expropriation of property so that property may not be seized by a government without the payment of just compensation;
- prevent denial of justice, by which New Zealanders could be denied basic due process in criminal, civil, or administrative proceedings abroad;
- allow for the transfer of funds related to an investment covered under the Agreement, with exceptions to ensure that governments retain the flexibility to manage volatile capital flows;
- ensure that investors have the ability to appoint senior managers without regard to nationality, and that nationality-based restrictions on the appointment of board members do not impair an investor's control over its investment; and

- put in place strong safeguards to raise the standards around investor-state dispute settlement, for example by discouraging and dismissing frivolous suits and by making proceedings more transparent.

Anti-Corruption

The agreement contains provisions to combat corruption and support the rule of law. These provisions seek to discourage corruption including through enforcement of domestic anticorruption laws and regulations as well as through international anticorruption efforts. They also call for the establishment of codes of conduct to promote high ethical standards among public officials.

MTANZ has had a Code of Practice for members since 2005 and this is based on harmonized principles with other trading TPP members' e.g USA, Canada, Australia, Japan. The MTANZ Code is mandated for membership but MTANZ membership is voluntary with the Code being self-regulated

Other TPP members; Peru, Singapore, Malaysia, Vietnam, Mexico, Brunei and Chile are members of the Asia Pacific Economic Communities (APEC) and as such, are subject to the APEC Voluntary Code of Business Ethics for Medical Devices Kuala Lumpur Essential Principles.

Small and Medium-sized Enterprises (SMEs)

The TPP includes the first-ever chapter in a free trade agreement specifically designed to address issues that create particular challenges for SMEs. These are general provisions and are not specifically aimed at the medical device industry. Nonetheless, they could prove helpful to small and medium-sized companies looking to export to TPP countries. With SME's comprising 99% of the New Zealand medical technology manufacturers, TPP's focus on the unique difficulties SMEs face when conducting international business will give much needed assistance for these companies when entering export markets.

The SME provisions are designed to:

- streamline complex technical and administrative barriers that make it hard for small businesses to access new markets;
- promote digital trade and internet freedom to ensure that small businesses can access the global marketplace;
- help small businesses integrate into global supply chains;
- make it easy for SMEs to access to information on utilizing free trade agreements – a problem that SMEs have identified as a disproportionate challenge for them; and
- review how well SMEs are availing themselves of the benefits of TPP and consider recommendations on ways to further enhance the benefits of TPP for SMEs.

Issues for New Zealand Medical Technology Industry

In 2012, the Government agreed to a phased plan for PHARMAC to progressively take on managing hospital medical devices. PHARMAC is working towards full management of hospital medical devices and will build on a base of devices procurement activity that Cabinet has asked PHARMAC to undertake. Eventually PHARMAC will move to full budget management of hospital medical devices with a fixed national budget for devices i.e. reimbursement.

The provisions that are annexed to the TPP Transparency Chapter defines national healthcare authorities for each TPP member. New Zealand's listing includes a footnote which states " for the purposes of the New Zealand, pharmaceutical means "medicine" as defined in the Medicines Act 1981" Section 3, paragraph 1 section (c) of that act indicates that medicine does not include (1) a medical device.

Contrary to this the Medicine Act does not directly apply to PHARMAC's statutory role (which relates to pharmaceuticals "including medical devices")

The TPP arrangements have no provision for New Zealand to include medical devices within the provisions as annexed to the Transparency Chapter which will need consideration with PHARMAC's role extending to reimbursement of medical devices in the future.

The medical technology industry would expect the same obligations by PHARMAC to ensuring procedural fairness and transparency, as required in pharmaceutical applications for funding, for medical devices applications for funding. Also, included in PHARMAC's obligations would be a commitment to consider funding applications within a specified period of time and a review mechanism.

Recommendation:

Currently, New Zealand is in the process of undertaking a review of therapeutic regulations that will replace the Medicines Act 1981 within the next couple of years. This is an opportunity to address the anomaly to ensure that medical devices are treated fairly and equally to pharmaceuticals with transparency and procedural fairness when PHARMAC eventually manages the medical devices' budget.

Report prepared by:

Faye Sumner
Chief Executive Officer
Medical Technology Association of NZ
faye@mtanz.org.nz