Medical Technology
Association of Australia

Department of Foreign Affairs and Trade
Trans Pacific Partnership

Submission by
Medical Technology Association of Australia

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1. Introduction

The Medical Technology Association of Australia (MTAA) welcomes the development of the Trans Pacific Partnership (TPP) and the opportunity to contribute to the priority setting of issues to be addressed in the TPP.

2. About the Medical Technology Industry

MTAA represents the manufacturers, exporters, importers and distributors of medical technology products in Australia. Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from commonplace, everyday items such as surgical gowns, bandages and syringes, to high technology items such as implantable cardiac and orthopaedic devices, cochlear implants, 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 biomechanical devices, and employ converging technologies in areas such as mobile health.

Sales of medical technology in Australia in 2008/2009 were $7.4 billion, with $1.6 billion earned from exports of medical technology manufactured in Australia. Approximately 80 per cent of the medical technology products used in Australia are imported and nearly all of the products manufactured in Australia are exported. The industry employs over 17,500 people. It is a highly innovative industry which invests heavily in research and development.

3. Issues for inclusion in Trans Pacific Partnership

3.1 Harmonisation of regulatory requirements

Australia is a founding member of the Global Harmonization Task Force (GHTF). Other founding members are the United States, the European Union, Japan and Canada. GHTF is comprised equally of the regulators of medical technologies and representatives of the medical technology industry. It has the stated aim of pursuing harmonization of the regulation of medical devices to ensure that there are no unreasonable barriers to market entry. GHTF is currently chaired by Australia (represented by the Therapeutic Goods Administration) with Australian industry as Vice Chair (represented by MTAA).

Industry acknowledges that there must be well-developed regulatory processes which assess the safety and efficacy of products. However where the regulatory processes are too slow, or where there are multiple varying requirements between countries, barriers are created to the introduction of new medical technologies.

A key feature of medical technology is its rapid innovation cycle. Often a new product can be brought to market in less than two years. Unreasonable delays or inconsistent regulatory requirements therefore serve to delay and at times, stifle, this innovation.

Regulatory controls should be transparent, predictable, efficient, and not unreasonably burdensome. Countries which are still developing regulatory systems might have regard to the work of GHTF to adopt principles which are consistent. The Asian Harmonization Working Party, which has among its members, at least two of the TTP members (Singapore and Vietnam), is actively looking to the guidance material developed by the GHTF to aid in development of regulatory systems. If all TPP parties could follow a similar path we might avoid some of the technical regulatory barriers which often emerge, such as re-registration requirements, prior approval in the country of origin and/or country of manufacture, excessive post-market reporting, and mandatory in-country clinical trials.

These requirements can be particularly burdensome for small and medium sized companies which do not have the resources to comply with multiple requirements and cannot wait long periods with no income for product approval. SMEs compromise the majority of companies in the medical technology sector.

MTAA urges inclusion of regulatory harmonization as an important element in the TPP. In particular MTAA urges commitment to established guidance such as that developed by the GHTF as the mechanism to underpin harmonization.

3.2 Procurement processes

In addition to regulations to assess for safety and effectiveness of medical technology, governments have, or are examining, ways to intervene in the pricing or reimbursement of medical technology. When governments take such action, measures must be implemented in a fair, transparent and non-discriminatory manner. Governmental provisions on pricing should be based on conditions in each market and not on some artificial comparison with foreign markets.

MTAA urges inclusion of language supporting the need for consistent, fair and transparent procurement processes.

3.3 Compliance programs

Many of the national and regional medical technology industry associations have developed codes of practice which provide an ethical compliance framework for the interface between industry, healthcare professionals and health product purchasers. Among the TTP partners, AdvaMed in the US, MTAA in Australia and the Medical Technology Association of New Zealand (MTANZ) have industry codes of practice.

Good compliance programs underpin an ethical and transparent environment which ensures that access to medical technologies is based on the appropriateness of the products for the healthcare system into which they are being sold. Ethical business practices are important in the medical technology sector because of the high level of interaction between medical technology

companies and their partners. The development of new, innovative medical technologies is a collaborative process between companies and healthcare professionals. It is the information from physicians in the course of their practice that identifies new, innovative medical solutions. The medical technology companies work closely with healthcare professionals in providing training on, and demonstrations of, products to ensure effective delivery of medical services.

As a result of these interactions, the medical technology sector requires consistent, predictable and transparent legal frameworks, supported by codes of ethics governing how companies interact with their partners. This not only ensures that medical decisions are based on the best interests of the patient, but that all companies operate on a level playing field.

MTAA urges inclusion of language by which TPP parties commit to consistent principles supporting an ethical framework for business practices within which medical technology companies operate.