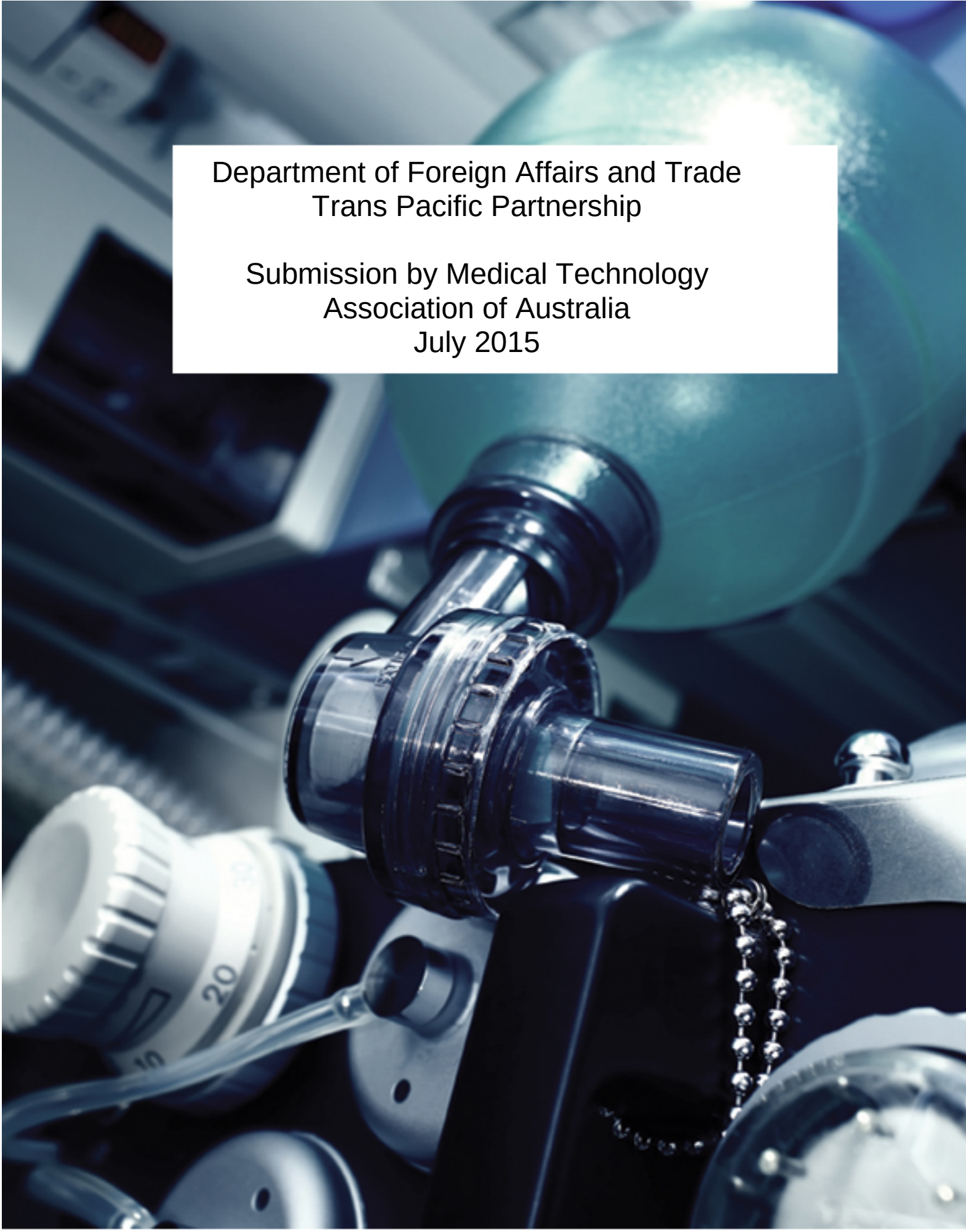

Department of Foreign Affairs and Trade
Trans Pacific Partnership

Submission by Medical Technology Association of Australia
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Medical technology for a healthier Australia

mtaa.org.au

MTAA Medical Technology ASSOCIATION OF AUSTRALIA

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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.

About the Medical Technology Industry

The Medical Technology Association of Australia (MTAA) is the national association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community. The member companies cover the spectrum of the industry in Australia, from subsidiaries of major multinational medical technology companies to independent distributors and small and medium sized Australian innovative companies.

Medical technologies are products used in the diagnosis, prevention, treatment and management of disease and disability. Products range from consumable items such as bandages and syringes, to high technology implantable devices such as cochlear implants, cardiac defibrillators and orthopaedic joints, to diagnostic imaging and operating theatre equipment, to products which incorporate biological materials or nanomaterials. The industry is characterised by a high level of innovation, resulting in short life cycles for many products. Medical technology innovation is characteristically incremental in nature. Many medical devices undergo constant development based on feedback from medical practitioners and advances in other sciences relevant to medical technology.

The Australian medical technology industry[1]:

- had turnover of approximately $10.2 billion in 2012-13 ~$11.8 billion if *in vitro* diagnostic (IVD) and dental products are included
- included over 500 medical technology companies with products listed in the ARTG
- was responsible for ~44,000 medical devices listed on the 2014 ARTG, estimated to represent between 500,000 and one million different devices
- employed more than 19,000 people
- was mainly located in NSW (55%) followed by Victoria (24%) and Queensland (12%)
- imported goods to the value of $4.4 billion and exported goods to the value of $1.9 billion in 2013.

[1] Medical Technology in Australia: Key facts and figures 2014, Occasional Paper Series: Sydney. Medical Technology Association of Australia Limited (2014)

Issues for inclusion in Trans Pacific Partnership

1. Harmonisation of regulatory requirements

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonisation.

It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonisation Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonisation and convergence

The current members are:

- Australia
- Brazil
- Canada
- China
- Europe
- Japan
- Russia
- the United States of America.

The World Health Organisation (WHO) and the APEC LSIF Regulatory Harmonisation Steering Committee are Official Observers. The Asian Harmonisation Working Party (AHWP) and the Pan American Health Organisation (PAHO) are IMDRF Affiliate Organisations.

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, where there are multiple varying requirements between countries and/or there are duplications, barriers are created to the introduction of new medical technologies.

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 IMDRF to adopt principles which are consistent. The Asian Harmonisation 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 IMDRF 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. Those companies that are not able or have no desire to, compromise the majority of companies in the medical technology sector.

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

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, which does not represent or demonstrate the costs associated with supply in a small high cost market.

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

MTAA believes that the main rule regarding government procurement is products are fit for purpose. Most Australian tenders do not overtly discriminate based on country of origin, but we recognise that time to time political directives directing trade away from or to certain regions/groups is required to be respected

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. In 2013, the Kuala Lumpur Principles for Voluntary Codes of Business Ethics in the Medical Device Sector was the first industry-specific initiative in APEC to lay out a series of voluntary, self-regulatory guidelines to assist in the creation and alignment of codes of ethics within the region

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 patient and 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 for patients 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

medical and 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.

4) Temporary Entry/Labor

A process of sharing people across the TPP trading group ensures a greater understanding of what makes each market unique and builds greater understanding across the trading group. A number of the specialist human resources developed in the country of innovation for the health IP can gain critical mass by moving between sovereignties.

MTAA would consider the ability to freely move these skills and expertise around the group essential to the benefit of the whole trading group.