



Medical Technology Association of NZ
Proposed European Union/New Zealand Free Trade Agreement
Submission to Ministry of Foreign Affairs & Trade
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1 Introduction

The Medical Technology Association of New Zealand (MTANZ) welcomes and supports the intention to explore the opportunities of a European/New Zealand Free Trade Agreement (FTA) and the potential to contribute to the priority setting of issues to be addressed in the FTA.

New Zealand and the European medical technology sector already enjoy considerable business in both directions but a FTA could increase that trade and the awareness of opportunities in each other's markets.

2 About the 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).

3 European / NZ Medical Technology Sector

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 \$700 million in 2013. It is a highly innovative industry which invests heavily in research and development with \$66 million invested in 2013¹

New Zealand imports approximately \$450 million (30%) of its medical technology requirements from Europe. While Europe is the destination for approximately \$220 million (30%) of New Zealand's manufactured medical technology exports. Europe is New Zealand's second largest market for both imports and exports.

In Europe, an average of 10.4% of gross domestic product (GDP) is spent on healthcare. Of this figure, around 7.5% is attributed to medical technologies with expenditure per capita around €195 (weighted average), compared with €380 in the US².

The European medical technology market is estimated at roughly €100 billion, 31% of the world market. It is the second largest global medical technology market after the US (\pm 40%)

The global medical technology industry is dominated by what is considered small / medium sized companies with an estimated 80% in this category and this is reflected in the New Zealand market too.

New Zealand medical technology manufacturers use the European Notified Bodies to audit their manufacturing process to a recognised international ISO standard for quality systems. This allows for applications of CE Mark Certification for market access to Europe and a recognised global standard for entry into other jurisdictions.

EU Notified Bodies and Competent Authorities

This European-style model works well to cater for the enormous diversity of life-improving medical treatments and technologies provided to patients. Europe's current medical device legislation makes a more targeted and effective use of competent authority and regulator resources.

In the EU conformity assessment of medical devices is undertaken by Notified Bodies (NB). These bodies are impartial, independent third-party commercial organisations specifically designated to monitor and review conformity assessment procedures applied by medical device manufacturers. Each member state of the EU has a Competent Authority (e.g. in the United Kingdom the Competent Authority is the Medicines and Healthcare Products Regulatory Agency (MHRA)), which is

¹ Reference: NZ Trade & Enterprises Health Technologies Survey November 2013

² Reference: The European Medical Technology Industry *In Figures 2015*

responsible for implementing the European laws ('Directives') nationally, and designating Notified Bodies (e.g. in the UK BSI and SGS are Notified Bodies) within their respective nation.

The member state Competent Authority will assess a resident Notified Body's organisational structure, operational policies and procedures, and particularly the skills and competence of personnel involved in activities related to medical device assessments.

The European Commission has established a new framework for the designation and supervision of Notified Bodies operating under the EU Medical Devices/Active Medical Devices Directives and partnering with a Competent Authority will provide the greatest insight into the competence of a range of Notified Bodies.

In September 2013, regulation on the designation and supervision of notified bodies was adopted, examples of new measures include:-

- A Member State shall only designate or re-designate a Notified Body after a joint assessment conducted with experts from the Commission and other Member States. The assessment reports shall be made available to all other Member States.
- Member States are required to carry out surveillance and monitoring of the Notified Bodies at certain intervals to ensure that they continuously live up to the requirements. If this is not the case, the Member State must withdraw the designation as Notified Body.
- Knowledge and experience requirements of the staff of the Notified Bodies are clarified.

New Zealand has a Mutual Recognition Agreement (MRA) with the EU which may also support the reliance by Medsafe (the current NZ Ministry of Health therapeutic regulatory authority) on the conformity assessment procedures undertaken by European Notified Bodies. Under a FTA with Europe there could be an additional benefit for Medsafe to have access to the audit reviews of the Notified Bodies.

These recent "improvements" to the European system provide additional confidence in the way that Notified Bodies fulfil their responsibilities.

4 Harmonisation of Regulatory Requirements

The medical technology industry acknowledges that there must be well-developed regulatory processes which assess the safety and efficacy of products. However, where 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 the market in less than two years. Unreasonable delays or inconsistent regulatory requirements therefore serve to delay and at times, stifle this innovation and add unnecessary cost.

Regulatory controls should be transparent, predictable, efficient and not unreasonably burdensome. The proposed New Zealand medical device regulations will be based on the GHTF Essential Principles and will underpin the new Rules in legislation to replace the Medicines Act 1981 in 2017.

Global Harmonisation Task Force (GHTF)

The GHTF was a voluntary group of representatives from national medical device regulatory authorities and the regulated industry founded in 1992. At its inception GHTF was comprised of representatives from five founding members (Australia, Canada, European Union, Japan and United States), each of which actively regulated medical devices using their own unique regulatory framework. The GHTF was established to address global issues:

- The need to harmonise national standards in order to minimize regulatory barriers
- Facilitate trade and improve access to new technologies
- Reduce the cost of implementing regulations for Governments and local industry

The purpose of GHTF was to encourage convergence in regulatory practices related to ensuring the safety, effectiveness/performance and quality of medical devices, promoting technological innovation and facilitating international trade, and the primary way in which this was accomplished was via the publication and dissemination of harmonised guidance documents on basic regulatory practices, which could be adopted/implemented by member national regulatory authorities.

The GHTF system encourages manufacturers of medical devices to apply internationally harmonised standards to the design and manufacture of their product to demonstrate compliance with the Essential Principles. This includes compliance with the international QMS standard (ISO13485), for all but the lowest risk (Class I) medical devices. This standard requires manufacturers of medical devices to establish and maintain the high quality of design, manufacturing and post-market monitoring necessary for medical technology.

In 2012, the International Medical Device Regulators Forum (IMDRF) was launched to build on the foundation of the GHTF to achieve further convergence of medical device regulations from around the world.

5 Business Ethical Compliance Programmes

Many of the national and regional medical technology industry associations have developed codes of practices which provide an ethical compliance framework for the interface between industry, healthcare professionals and health product purchases.

Both MedTech Europe (the European medical technology association) and MTANZ, have industry codes of practice based on harmonised self-regulatory principles.

Good compliance programmes 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 the healthcare professionals. The development of new, innovative medical technologies is a collaborative process between companies and healthcare professionals. It is the information from clinicians in the course of their practice that identifies new, innovative medical solutions that benefit patients.

The medical technology companies work closely with healthcare professionals in providing training on, and demonstration of, products to ensure effective and safe 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 interest of the patient, but that all companies operate on a level playing field.

Recommendations:

- 1 MTANZ urges inclusion of therapeutic regulatory harmonisation as an important element in an EU/NZ FTA. In particular, MTANZ urges commitment to establish guidance such as that developed by the GHTF as the mechanism to underpin harmonisation.
- 2 New Zealand's therapeutic regulatory authority (Medsafe) needs to have confidence in the European CE Mark certification and the European Notified Bodies conformity assessment process. Therefore, MTANZ recommends that access to the audit information of the Notified Bodies for Medsafe be incorporated within the FTA.
- 3 MTANZ urges inclusion of language by which European and New Zealand parties commit to consistent principles supporting an ethical framework for business practices within which medical technology companies operate.

Paper prepared by:

Faye Sumner
Chief Executive Officer
Medical Technology Association of New Zealand
email: faye@mtanz.org.nz