Medical Technology Association of NZ

United Kingdom /New Zealand Free Trade Agreement

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Introduction

The Medical Technology Association of New Zealand (MTANZ) welcomes the development of the United Kingdom/New Zealand Free Trade Agreement (UK/NZ FTA) and the opportunity to contribute to the discussions for goods and services to be considered for inclusion in the FTA.

A bilateral FTA should achieve both an ambitious trade liberalisation and expanded cross-border investment in order to enhance productivity and innovation, generate dynamic gains and help create jobs and raise living standards in both economies.

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, invitro 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).

There is a vibrant trade in medical technology between the UK and NZ and while there is no separate data for the UK, NZ imports *$370 million* of its medical technology requirements from Europe (includes UK). Europe (includes UK) is the destination for *$205 million* of New Zealand's manufactured medical technology exports.[1]

Recommendations for a UK/NZ FTA

1 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 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 NZ Therapeutic regulator could have access to the independent audits of the UK conformity assessment bodies to satisfy confidence in the medical technology certification issued in the UK.

Recommendation:

A UK/NZ FTA should include mutual recognition of medical technology standards, conformity assessment and good manufacturing practices e.g CE Certificates.

2 Anti- Corruption and 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.

[1] EMA Business *What the EU free trade deal would mean for NZ* May 2018

Both ABHI (Associated British Health Industry) 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.

Recommendation:

A robust FTA should include language by which UK and NZ parties commit to consistent principles and guidelines supporting an ethical and transparent framework for business practices in all sectors.

3 Government Procurement & Market Access

New Zealand Government is currently assessing and implementing policy changes that could change the way in which the NZ medical technology market operates and transforms what is an open and competitive market into a more closed and controlled market – effectively introducing a new trade barrier for UK companies to access the NZ health market.

The proposed centralisation of medical technology procurement and Health Technology Assessment (HTA) could create a more difficult environment for UK-based medical technology manufacturers to invest and grow medical technology in NZ. It would also act as a major dampener on NZ innovation.

MTANZ supports the pricing/ procurement function to be kept separate from any HTA process. This will ensure that important principles such as transparency, workforce engagement, competition and innovation are fostered alongside NZ public health sector’s regulatory and reimbursement decision making process

A very important market for NZ medical technology manufacturing exporters is access to the UK public National Health Service (NHS). The UK/NZ FTA negotiations represent improved opportunities to ensure a level playing field in each other's markets with the ability to partake in national health tenders for procurement of medical technology and share the exchange of expertise and innovation that will benefit patients and improve lives in both countries.

Access to the UK market could be enhanced by the UK government NHS procurement websites recognising company registration in NZ for eligibility for government contracts.

Recommendation:

United Kingdom and New Zealand medical technology companies would want to see a government procurement process that is transparent with procedural fairness that allows for fair and equitable opportunities for manufacturers to invest in the respective health markets

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