medical technology
ASSOCIATION OF NEW ZEALAND

Submission to New Zealand's Productivity Commission's "New Zealand firms: Reaching for the Frontier"

February 2021

Thank you for the opportunity to respond to your draft consultation report "New Zealand firms: Reaching for the Frontier" particularly in relation to the identification of the health technologies sector.

I am responding on behalf of the Medical Technology Association of New Zealand (MTANZ) the only industry body representing medical technology manufacturers, importers, exporters, and distributors of medical devices in New Zealand.

New Zealand has a vibrant and efficient medical technology sector populated by many established New Zealand-owned and multinational medical supply companies supporting the healthcare system. The companies who reside in New Zealand are essential for developing and supporting the manufacturing sector with specialized skills and expertise in international market access

MTANZ supports the main findings of the report and the need to develop an innovation focus policy to lift productivity levels in New Zealand that can contribute to economic growth and wellbeing for our people. However, to build capacity and capability in the medical technology sector there needs to be a thriving innovation ecosystem involving researchers, universities, clinicians, hospitals, industry, and government in partnership. The relationships are there but require more collaboration, investment, and support.

There are important areas to consider ensuring the right support from the New Zealand Government to grow the potential of this sector and build economic growth.

1) Access to District Health Boards (DHBs)

The Productivity Commission's Report highlights the huge importance the DHBs could play in supporting healthtech innovation but unfortunately, most DHBs are inactive in this area. Medical devices are developed at the bedside in the clinician's hand, unlike pharmaceuticals which are developed in the laboratory.

To develop a medical device from the idea through to realization for patient treatment requires considerable specialized input from many players along the journey of development. Clinical trials undertaken in a hospital environment are

critical to establish the safety and effectiveness of the device and to produce evaluation data essential for regulatory requirements.

New Zealand's DHBs can play a vital role in the development of medical technology and for the DHBs, this will reward them with improved patient outcomes, clinician retention and provide choice of treatment. DHBs must work in partnership with the medical technology industry, identifying and solving methods of delivering treatment more efficiently and effectively.

DHBs need to be incentivized and supported to encourage investment and involvement in the medical device development which has the potential to create considerable value to the hospital and the healthcare sector while contributing to New Zealand's economic growth.

In 2020, the New Zealand Government released the Health and Disability System Review with recommendations that are now being considered for implementation. This provides an excellent opportunity for a culture of innovation to be embedded in the New Zealand healthcare system and establish a sustainable sector that can contribute and support the growing potential of the medical technology manufacturing and export sector.

MTANZ totally supports the findings of the Productivity Commissions Report "*In pursuing any major reforms, the Government should improve the mandate, funding and incentives for DHBs to work collaboratively with healthcare companies as part of their innovation ecosystem"* (page 7)

2) Government Policy

The right Government policy is critical to support research, development, and timely access to the healthcare system for innovative medical technology to flourish in New Zealand. The international market is the primary focus for New Zealand medical technology manufacturers, but they need to have a robust domestic platform to establish the safety and performance of their product with patient data to support their international launch.

In 2019, the Government proceeded with two significant reforms that will each impose considerable challenges to the sector, namely the introduction of the Therapeutic Products Bill and an expansion of PHARMAC's authority over medical devices. Combined, these changes are a threat to the continued operation of some parts of the industry and the range of products delivered in New Zealand.

The medical technology sector is a crucial plank in New Zealand's health system, as evidenced by the way the sector mobilised during COVID to ensure delivery of essential medical products, despite the severely disrupted global supply chain.

To avoid establishing barriers that add costly delays to market access and inhibit a vibrant innovation ecosystem, Government must consider the implications and impact of both centralized procurement and new therapeutic regulations.

a) Value-Based Approach

One of the approaches that should be urgently considered by Government, particularly consider the future of our health system and the need for innovation, is

how to ensure the procurement system incentivises value for the patient across their interaction with the health and disability system – rather than at a point in time.

Value-based approaches have potential to deliver better outcomes for patients and the health system and introduce innovative medical technology to enable treatment to be delivered in the most highly efficient means.

The PHARMAC reforms as proposed in 2019 will have implications across the health sector, but they currently do not focus on value-based outcomes for patients. It therefore makes sense to pause these reforms and consider any changes as part of a broader approach to the future of our health system with a focus on value-based outcomes for patients. Implementing these changes in isolation, as has been proposed to date, will run counter to the broader objectives of a patient-centric and sustainable health system, and risks undermining the competitive and innovation that currently characterises the medical technology sector. The reforms as proposed could stifle the entry of New Zealand manufactured medical technology into the DHBs.

Currently, New Zealand enjoys an open and competitive medical technology market which supports robust patient outcomes.

There is a real risk to patient outcomes and the competitiveness and innovation of the industry to introduce measures that unintentionally establish a closed and controlled market, creating possible market access trade barriers.

This is what the changes to the regulatory and reimbursement framework, as proposed by Government in 2019, are likely to deliver.

MTANZ supports the aim of ensuring that New Zealand patients have access to cost-effective and innovative medical treatments and this can be achieved by partnering with the local manufacturing, export sector.

MTANZ also supports the introduction of a risk-proportionate regulatory scheme.

However, the changes as announced in 2019 will:

- Erode clinician and patient choice
- Deprive patients of innovative technologies and lifesaving therapies
- Impact on competition and investment
- Undermine clinical training opportunities
- Not reduce total costs to the health care system
- Run counter to a patient-outcomes focussed system that is sustainable over the long term.

b) Reforms to the Therapeutic Products Bill

MTANZ is not opposed to the introduction of a new regulatory regime in New Zealand, but the changes need to be implemented in a way that is sensible and workable for both government and industry to ensure that patient care is not compromised.

It is also critical for a country with a small market by global standards that the regulatory burden, complexity, and timelines are not out of proportion.

New Zealand medical technology manufacturers seek global audits for conformity assessment to recognized international standards for safety and performance to give them access to multiple markets. This is also a requirement to be placed on the New Zealand market and will be mandated by the introduction of the Therapeutic Products legislation.

The complexity and burden of the arrangements proposed by the current draft legislation, will require significant resource requirements for the regulator, as well as for companies who wish to continue their existing operations in New Zealand and inhibit the development of medical technology in New Zealand

We think the Government has underestimated the resources and time it will take to implement the scheme as proposed, and that some elements are lacking in clarity and workability.

The extent of the proposed regulatory changes may make continued investments in New Zealand unsustainable.

The proposed changes regarding clinical trials will also erode investment in research and innovation in New Zealand. This will be an opportunity lost to build capability and capacity for New Zealand's growing and dynamitic medical technology manufacturing and export sector.

c) PHARMAC Reforms

Expenditure on medical devices in New Zealand, as it is globally, is a small percentage of the overall health budget.

The spend on devices in New Zealand is smaller than the spend on pharmaceuticals.

In addition, devices are generally one part of a more complex treatment plan. Focussing on price at one point in a patient's care ignores the potential of ensuring value across the entire care continuum. New Zealand's procurement model needs to move from cost-based to value-based.

Restrictive market share agreements in what is already a small market in global terms would be likely to reduce competition and access to technology and will not lower total health care costs.

In addition, PHARMAC's intention to control all entry of products into the New Zealand public hospital system will likely slow, and halt, the entry of many medical technology innovations which rapidly evolve to deliver safer and more efficient healthcare.

Not only do restrictions in product choice limit patient outcomes, but they also have long term ramifications including the training of medical professionals.

All this, while there is so much uncertainty around the new regulatory regime and the broader health sector reforms are eroding investment confidence in the medical technology sector in New Zealand.

We do not believe the government can deliver its objectives through the proposed PHARMAC reforms without undermining patient outcomes and inhibiting innovation.

A review of PHARMAC's mandate to include the boarder aspect of investing and supporting local medical technology manufacturing will be vital to ensure the potential of this sector is realised for the betterment of New Zealand's economic outlook.

d) Innovation Focus Policy

MTANZ supports the Productivity Commission's Report recommendation to establish a Government innovation focus policy with the main purpose to bring together Government leaders, industry experts and researchers to prioritise areas of the economy and technologies for focused effort.

New Zealand needs to lift its productivity level, but this cannot be achieved without lifting its export performance. New Zealand's healthtech sector, of which medical devices is the biggest sector, is poised and ready for expansive export growth and a Government focus on innovation is a vital ingredient to support this vibrant and fast-growing sector.

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