Aide-Mémoire

Meeting with Medical Technology Association New Zealand (MTANZ)

Date due to MO:	19 March 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024037501
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health Hon David Seymour, Associate Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

Name	Position	Telephone
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John McGrath	Director, Priority Projects Strategy Policy and Legislation	s 9(2)(a)

Aide-Mémoire

Meeting with Medical Technology Association New Zealand (MTANZ)

Date due:	19 March 2024
To:	Hon Casey Costello, Associate Minister of Health
Security level:	IN CONFIDENCE **Health Report number:** H2024037501

Details of meeting: 4:40-5:10pm 26 March 2024

Purpose of meeting/ proposal: To meet with the Medical Technology Association of New Zealand (MTANZ) and discuss the Therapeutic Products Act (TPA) repeal and implications for the medical device industry

Comment:

Meeting with MTANZ

- MTANZ is the leading industry body representing medical technology manufacturers, importers, exporters, and distributers of medical devices in New Zealand.
- They have requested this meeting with you to discuss the repeal of the TPA, the implications for medical devices and future direction of any reforms.
- This aide-mémoire provides background information relating to the current regulation of medical devices, how this would have altered under the TPA and MTANZ's indicated position on these changes.
- Talking points for your meeting are included, and MTANZ's submission on the TPA is included as an appendix.
- This aide-mémoire discloses all relevant information.

John McGrath
Director, Priority Projects
Strategy, Policy and Legislation | Te Pou Rautaki

Purpose

1. The purpose of this aide-memoire is to provide information for your meeting with the Medical Technology Association of New Zealand (MTANZ) on 26 March 2024. You are meeting with their CEO Cushla Smyth.
2. MTANZ have asked to meet and discuss the repeal of the Therapeutic Products Act 2023 (TPA) and the possible next steps in the regulation of medical devices.
3. **Appendix One** provides a short biography of MTANZ CEO Cushla Smyth. **Appendix Two** provides a copy of MTANZ's Health Select Committee submission on the TPA.
4. Officials attending the meeting will be:
    - John McGrath, Director Priority Projects, Strategy Policy and Legislation
    - Valerie Thompson, Senior Policy Analyst, Strategy Policy and Legislation
    - Chris James, Group Manager Medsafe.

Background and context

5. MTANZ is the leading industry body representing medical technology manufacturers, importers, exporters and distributers in New Zealand. They state their members supply approximately 95 percent of all medical device products used in New Zealand public and private healthcare facilities.
6. MTANZ was a key stakeholder during the development of the Therapeutic Products Bill and were actively engaged in developing secondary legislation to support the TPA.
7. MTANZ has indicated they are interested in talking to you about the repeal of the TPA, the implications for the medical device industry, and any future direction.

Current regulation of medical devices

8. Medical devices are a diverse range of products from simple products (eg, bandages, tongue depressors to complex, implantable devices (eg, pacemakers). Medical devices also include point-of-care manufacturing platforms that produce custom made devices (eg, dental milling tools and 3D printers). Software that is intended to perform a therapeutic activity (such as diagnosing a disease) can also be regulated as a medical device (Software-as-a-Medical Device (SaMD)).
9. Under the Medicines (Database of Medical Devices) Regulations 2003, many medical devices are required to be notified to the Web Assisted Notification of Devices database (WAND database) administered by Medsafe. No pre-market assessment or approval of medical devices occurs, meaning the public cannot be assured of a product's safety, quality or performance, even for higher-risk implantable medical devices. As such, some devices may pose risks similar to some medicines but are not subject to a similar level of assessment and oversight.
10. Medsafe currently engages with the medical devices industry on quality and adverse event complaints and recalls. In 2022-23 Medsafe investigated/managed 562 quality issues or market corrective actions related to devices.

11. On its commencement, the TPA would have modernised the regulation of medical devices using a risk-proportionate approach. The TPA provided mechanisms for assuring the safety, quality and performance of medical devices as well as taking post-market regulatory action.

12. The diversity of medical devices is increasing with technological developments which provides new challenges when considering the future regulation of devices (eg, Artificial Intelligence, advanced implantables).

Stakeholder perspective: MTANZ views on regulation of medical devices

13. MTANZ is generally supportive of 'lighter-touch' regulation for medical devices. Many of their members are sophisticated industry actors, who are familiar with, and meet, international regulatory requirements for medical devices. MTANZ representatives have met with members of the previous government and officials to discuss their perspective on several occasions over the development of the TPA.

14. MTANZ has advised that the number of medical devices to be considered is extensive (they estimate 250,000+ devices) and transitioning these in-market products into any new regime needs to be carefully considered.

15. MTANZ have advocated for reliance on, and recognition of, the decisions of international regulators – for example, a decision to approve a product. This was on the basis that most medical devices imported to and supplied in New Zealand are already approved in other countries with comprehensive medical device regulation such as Australia, USA and/or UK. They also advocate for the costs involved in any regulation to be justified and proportionate.

16. MTANZ was involved in a series of media articles in July 2023 in which they raised concerns that the TPA would lead to delays in the approval of (and thus access to) medical devices in New Zealand. They felt industry concerns about this were being ignored. They cited supply issues of life-saving devices in the European Union that occurred when a new regulatory regime was implemented in 2021.

17. MTANZ were concerned about the requirement in the TPA for manufacturers of medical devices to obtain export market authorisation. They felt that this could lead to two sets of requirements for exporters to meet (New Zealand and the destination country) and a resulting increase in compliance costs.

18. MTANZ may also be interested in discussing the regulation of clinical trials involving medical devices. The TPA had proposed that clinical investigations of devices be managed in a similar way to that of clinical trials for medicines. MTANZ were concerned that this would put up regulatory barriers to innovation in the sector. The Ministry notes that the approach adopted in the TPA reflects standard international practice.

19. MTANZ was engaged in the development of secondary legislation for the TPA. They arranged a workshop in October 2023 to facilitate discussion with the Ministry and various industry representatives. They had also convened a working group with some of their key members to assist in the implementation of secondary legislation for the TPA.

Areas of concern, issues or risk

20. MTANZ are likely to want to discuss the government's approach to the future regulation of Medical devices. You may wish to defer detailed discussion of any reform until after the Social Outcomes Cabinet Committee have considered your paper on 10 April 2024.

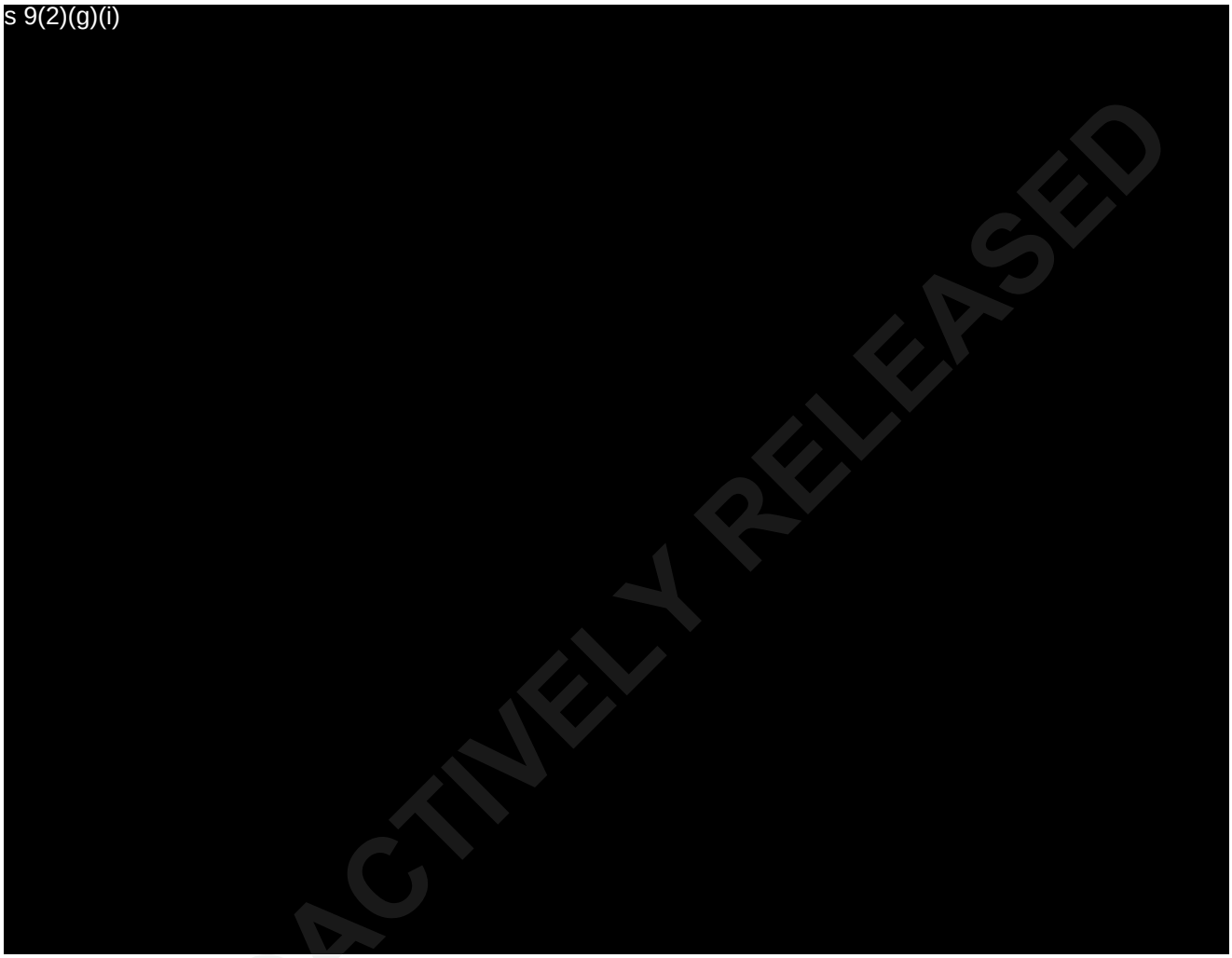
Talking points on meeting with MTANZ

Regulation of Medical Devices

Repeal of the Therapeutic Products Act

- Thank you for taking the time to talk to me about medical devices. I appreciate MTANZ's insights and engagement during the development of the Therapeutic Products Act.

s 9(2)(g)(i)



Appendix One

Biography of MTANZ Meeting Attendee

MTANZ CEO- Cushla Smyth	
	Cushla has been CEO at MTANZ since July 2021. *(Below text extracted from MTANZ website)* "Cushla has a broad experience in the New Zealand health sector through her previous roles as National Manager for OneLink (an EBOS group company), Director Business Development for UniServices and Procurement Specialist for HealthAlliance. Her extensive relationships within multiple sub-sectors of the Ministry of Health, DHBs, ACC and private hospitals, enables her understanding of the current challenges and opportunities the industry members face today and into the future. In addition, Cushla's background with Uniservices ensures her awareness of the important and growing New Zealand MedTech research and development sector."

Appendix Two

MTANZ submission to Health Select Committee on the Therapeutic Products Act

[This document is included as a separate file to preserve the original formatting.]

Submissions on the Therapeutic Products Bill have been published here:
https://www.health.govt.nz/about-ministry/information-releases/general-information-releases/submissions-therapeutic-products-bill