Aide-Mémoire

Meeting with Medical Technology Association of New Zealand (MTANZ)

Date due to MO:	13 February 2024	**Action required by:**	N/A
Security level:	IN CONFIDENCE	**Health Report number:**	H2024036005
To:	Hon Casey Costello, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☐ Māori Health Authority: ☐		

Contact for telephone discussion

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

Aide-Mémoire

Meeting with Medical Technology Association New Zealand (MTANZ)

Date due:	13 February 2024		
To:	Hon Casey Costello, Associate Minister of Health		
Security level:	IN CONFIDENCE	**Health Report number:**	H2024036005

Details of meeting: TBC.

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 a 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.
- This aide-mémoire discloses all relevant information.

John McGrath
Director, Priority Projects
Strategy Policy & Legislation

Purpose

1. The purpose of this aide-memoire is to provide information in relation to a request from the Medical Technology Association of New Zealand (MTANZ) to meet and discuss the repeal of the Therapeutic Products Act 2023 (TPA) and the regulation of medical devices.

2. A short biography of potential MTANZ attendees is included in **Appendix 1**. Potential talking points for any future meeting are included in **Appendix 2**. These will be updated should you agree to a meeting with MTANZ and if further information becomes available.

3. A copy of MTANZ's Health Select Committee submission on the TPA is included in **Appendix 3.**

Background and context

4. MTANZ is the leading industry body representing medical technology manufacturers, importers, exporters and distributers in New Zealand. They claim their members supply approximately 95 percent of all medical device products used in New Zealand public and private healthcare facilities.

5. 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.

6. 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.

7. 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.

Current regulation of medical devices

8. Medical devices represent a diverse range of products from simple products (eg, bandages, glasses with corrective lenses) to complex, implantable devices (eg, pacemakers, surgical mesh). Medical devices also include point-of-care manufacturing platforms that produce custom made devices – such as 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, 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 products safety, quality or performance, even for higher-risk implantable medical devices. As such, devices that have a similar risk profile to some medicines 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 perspectives

MTANZ views on regulation of medical devices

13. MTANZ is generally supportive of 'light-touch' regulation of medical devices. Many of their members are sophisticated industry actors, who are familiar with international regulatory norms 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 in any future regime.

15. MTANZ have advocated for advocated for reliance on and recognition of the decisions of international regulations – 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 UK. They are also concerned that the costs involved in any regulation are 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 Europe Union that occurred when a new regulatory regime was implemented in 2021.

17. 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.

Next steps

18. The Ministry suggests you meet with MTANZ, given they are the peak body for the medical device sector. They are an important stakeholder, whose members include large employers. For example, Fisher and Paykel Healthcare employs over 4000 people in Auckland and, in 2023 reported operating revenue of $1.58 billion.

19. As MTANZ represents a significant number of small and large stakeholders in the medical device industry in New Zealand, the Ministry considers that meeting with them would have benefits for their continued engagement with any future work in this area.

20. For similar reasons, we recommended that you meet with the peak body for natural health products (Natural Health Products New Zealand) and, if a request were received by your office, we would recommend you meet with Medicines New Zealand, the peak body for

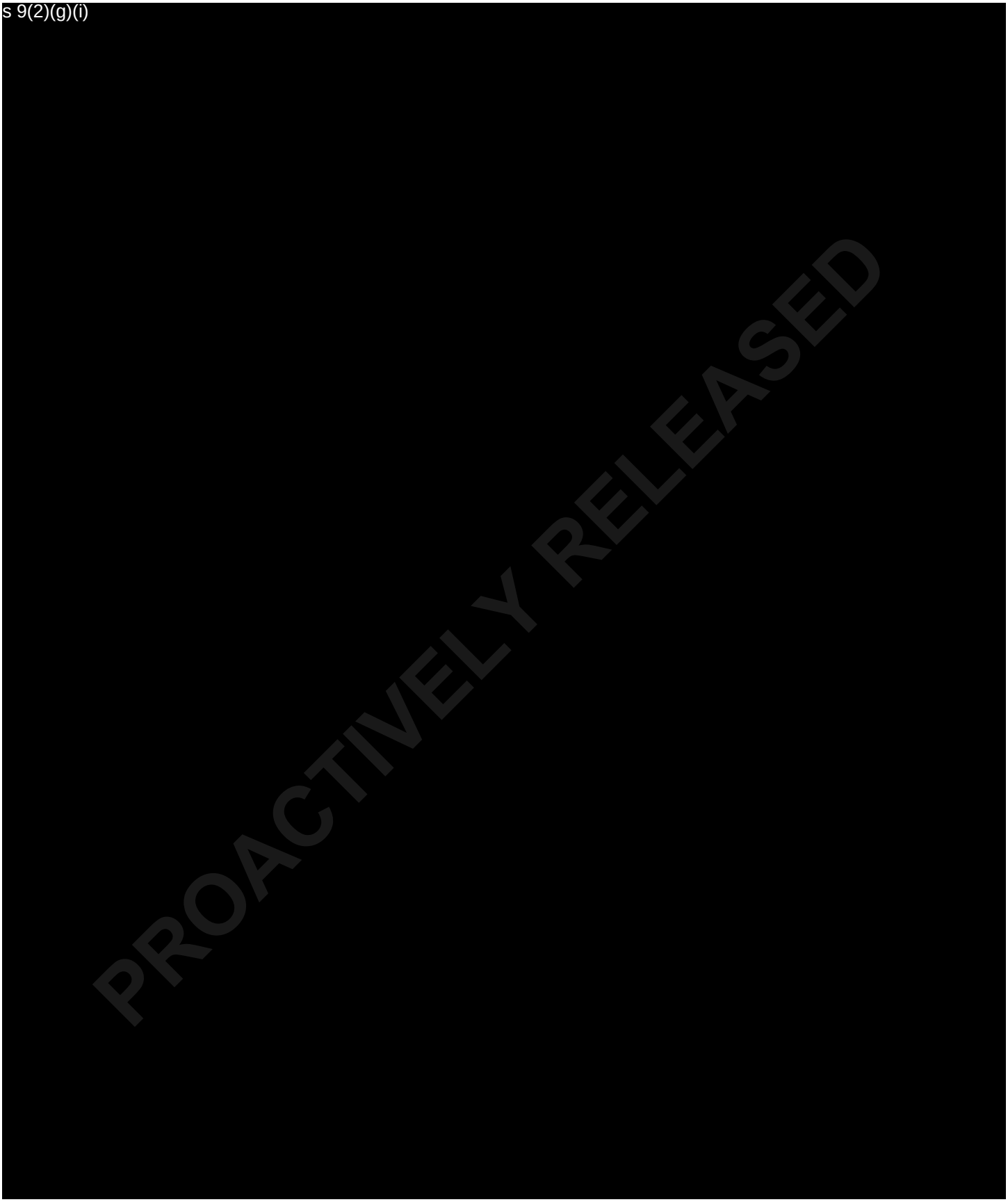
prescription medicine manufacturers. The Ministry could meet with other stakeholders on your behalf.

21. As MTANZ will likely ask about the Government's plans for a replacement to the TPA, we suggest that you defer any meeting until after Cabinet has considered your paper on progressing the repeal of the TPA [H2024035378].

22. The Ministry will be happy to provide further information about specific topics prior to any meeting with MTANZ, if required.

Appendix 1 - Biographies of potential representatives from MTANZ

s 9(2)(g)(i)



Appendix 2 - Talking Points

s 9(2)(g)(i)

Appendix 3 – MTANZ submission to Health Select Committee on the TPA

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