Aide-Mémoire

Meeting with the Digital Health Association

Date due to MO:	9 March 2026	**Date of Event**	10 March 2026
Security level:	IN CONFIDENCE	**Reference:**	H2026079556
To:	Hon Casey Costello, Associate Minister of Health		
Consulted:	Health New Zealand: ☒		
Proactive release:	This **title** is proposed by the Ministry of Health for proactive release: ☒		

Contact for telephone discussion

Name	Position	Telephone
James Oughton	Chief Advisor, Precision Health Strategy and Policy Group	s 9(2)(a)

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About the Meeting

Purpose of Meeting	Update on the Medical Products Bill (assumed, based on prior engagement with the Digital Health Association)	
Details of Meeting	**Date:**	10 March 2026
	Time:	5:00 pm – 5:30 pm
	Venue:	3.305 EW
Attendees	Stella Ward, Chief Executive, Digital Health Association (DHA)	
Organisation	The DHA is an industry body representing the digital health sector in New Zealand.	
Ministry representatives	Not currently attending - officials can attend at your request.	

Comment/ Summary:

- The Digital Health Association (DHA) is a long-standing peak body (est. 2002) representing over 200 digital health organisations and plays a key role in structured engagement between government, Health New Zealand, and industry.
- You have previously met with the DHA to discuss potential regulation of software as a medical device (SaMD) in July 2024.
- Cabinet has agreed that the Medical Products Bill will modernise regulation of medicines, medical devices, and digital health technologies. Innovation is a core principle of the Bill and tailored approval pathways for innovative products, including AI enabled medical devices and Software as a Medical Device (SaMD).
- The Bill will regulate only AI and software used for therapeutic purposes (ie, SaMD), aligned with international definitions, while excluding general purpose and administrative AI. This will provide certainty for industry, support exports, and enable the safe uptake of digital health tools across the system.

Background and context

1. The DHA was established in 2002 and has a membership of more than 200 organisations across the public and private sectors, including technology providers, health service organisations, research bodies, non-government organisations, and Māori and iwi led digital health companies.

2. The DHA works with Health NZ to facilitate structured engagement between government and industry. This includes advising industry on digital health priorities and direction, promoting adoption of digital standards, supporting consultation on major digital initiatives, and hosting sector events and forums to support alignment across the system.

Previous meetings and other background

3. You previously met with the former CEO of the DHA, Ryl Jensen, on 17 July 2024 (H2024045138 refers). This discussion focused on the regulation of SaMD in the, now repealed, Therapeutic Products Act and in future legislation.

4. You also attended the DHA Parliamentary Reception on 23 July 2024 in Wellington.

5. The DHA have advised that the current CEO of DHA, Stella Ward, will be meeting Hon Simeon Brown on 12 March 2026.

6. DHA is planning a Parliamentary event for 12 May 2026, described as a formal sit-down dinner for DHA members and Members of Parliament. The DHA has advised that Sam Uffindell MP is the sponsoring Member. Stella Ward may invite you to attend the 12 May event. As we understand, no formal invitation, agenda, or supporting information has yet been received by your office.

Update on the Medical Products Bill

7. In July 2025, Cabinet agreed on key policy decisions to support innovation through the forthcoming Medical Products Bill (the Bill), which will replace the Medicines Act 1981. Relevantly, Cabinet agreed that the Bill will enable tailored and appropriate approval pathways for innovative products (eg gene therapies and AI-enabled medical devices).

8. The Bill is intended to modernise New Zealand's regulation of medicines, medical devices (including) SaMD and digital health technologies. It will also ensure patient safety and international alignment. Supporting innovation, including digital and data-enabled health technologies, is a core principle of the Bill.

9. The Bill will enable flexible and adaptive approval pathways for innovative medical products, including advanced digital products. For example, the Bill's framework will enable:

    a. conditional and time-limited approvals, supported by iterative evidence submission

    b. Risk-proportionate regulation of clinical trials, including a notification pathway for trials approved by trusted overseas regulators

    c. pilot programmes to test new regulatory pathways

    d. enhanced regulatory support such as pre-submission engagement.

10. These regulatory tools are designed to help innovative products reach patients faster while maintaining appropriate safeguards. The Bill will be flexible and future focused, so that when new types of products are developed, the legislation will accommodate them if safe and appropriate to do so.

11. The Bill will regulate AI tools that are intended for a therapeutic purpose, rather than regulating AI more broadly. Specifically, the Bill will apply to software and AI that meet the internationally accepted definition of a medical device, ie SaMD. Examples include AI systems used to screen for conditions, deliver therapy, or provide AI-driven diagnostics.

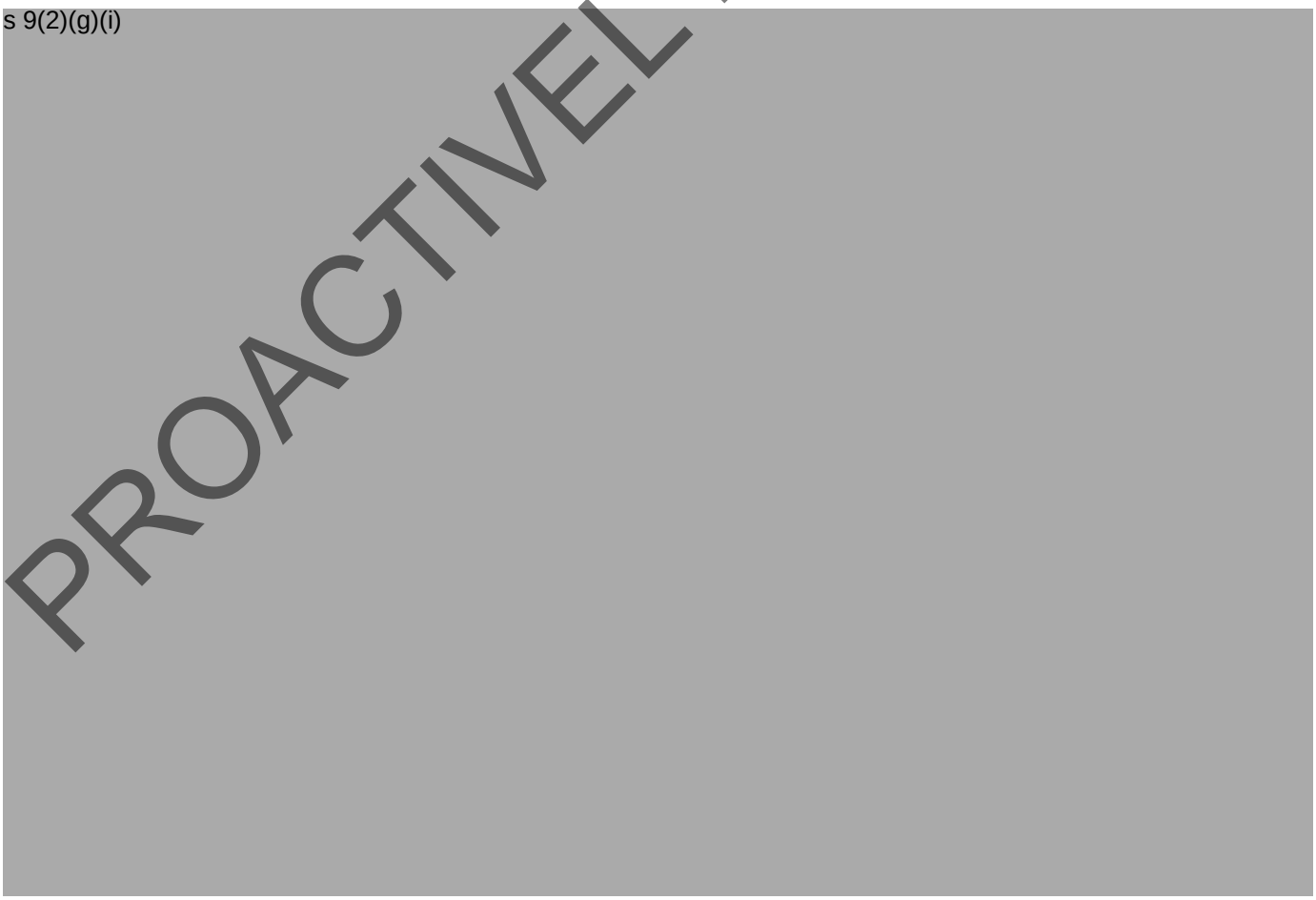
12. AI tools used for administrative and operational purposes (such as AI-scribes and patient management systems); or for research or general informational purposes, will not be regulated under the Bill.

13. The approach is risk-based and proportionate and is consistent with the Government's broader position of regulating AI through existing sectoral frameworks rather than a standalone AI Act.

14. Clear SaMD regulation will provide greater certainty for developers, purchasers, clinicians and patients, including expectations around safety, clinical validation, cybersecurity and data protection. The Bill will also enable reliance on overseas approvals and participation in international regulatory initiatives, supporting export opportunities for New Zealand digital health companies and uptake of high-quality digital tools across the health system, including in rural and underserved communities.

15. There is an intention to introduce the Medical Products Bill to Parliament in 2026. Ongoing engagement with industry, including the digital health sector, will continue as the legislation is developed and implemented.

s 9(2)(g)(i)



s 9(2)(g)(i)

James Oughton
Chief Advisor, Precision Health
Strategy and Policy Group

Appendix 1: Attendees

 Stella Ward, Chief Executive, Digital Health Association	Stella is a Christchurch-based health sector leader with experience across digital health, system governance, and advisory roles. She currently serves as the part-time Chief Executive of the Digital Health Association, alongside a portfolio of governance and consultancy work. Stella brings a pragmatic, system-level perspective informed by working with health organisations, technology providers, and public sector stakeholders across Aotearoa New Zealand.