Briefing for information

Regulatory settings for medical devices

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To:	Hon Simeon Brown, Minister of Health		
Copy to:	Hon Nicola Willis, Minister of Finance Hon David Seymour, Associate Minister of Health		
Proactive release:	This **title** is proposed by the Ministry of Health for proactive release: ☒		

Contact for telephone discussion

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Minister's office to complete:

☐ Noted

☐ Seen

☐ Needs change

☐ Withdrawn

☐ See Minister's Notes

☐ Overtaken by events

Comment:

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Purpose of report

1. This briefing provides an overview of the current and future regulatory settings for medical devices and outlines recent changes to improve New Zealand's approach to procurement.

Summary

2. There are currently no pre-market approvals required for medical devices. Improving access to medical devices is primarily driven by how devices are funded, procured and adopted across the health system. Changes to procurement and system decision-making therefore present the most immediate opportunity to improve access.

3. Although there are few specific regulatory barriers for medical devices, the lack of a regulatory framework does make New Zealand an outlier internationally. This means purchasers of medical devices have limited assurance of safety and are often required to manage safety risks themselves without any regulatory oversight.

4. The proposed Medical Products Bill will introduce approval requirements for medical devices, aligning New Zealand with international practice. Most devices would be approved automatically or through reliance on overseas regulators, with only a small proportion requiring local assessment. These changes are intended to improve safety, reduce duplication across agencies, support innovation, and complement the new procurement approach.

5. Health New Zealand (Health NZ) and Pharmac are implementing a new, coordinated approach to medical device procurement, supported by the Ministry of Health (the Ministry). This model is designed to improve national consistency, value for money and innovation, ensuring procurement decisions better support patient access and health system outcomes.

Recommendations

We recommend you:

a)	**Note** that unlike most other countries, medical devices are not currently regulated in New Zealand	**Noted**
b)	**Note** that the proposed Medical Products Bill will introduce a proportionate regulatory framework that will align with other countries	**Noted**
c)	**Note** that Health NZ and Pharmac are implementing a more coordinated approach to medical device procurement to deliver greater value for money	**Noted**
d)	**Note** that under this approach Pharmac has a specific role to conduct Health Technology Assessments to support innovation	**Noted**
e)	**Note** that the Ministry will be providing a report back on progress with the new approach to medical device procurement in March.	**Noted**

Allison Bennett
Group Manager
Strategy and Policy
Date: 25 February 2026

Hon Simeon Brown
Minister of Health
Date:

Regulatory settings for medical devices

Current regulatory settings are not a significant barrier

6. At present, there is no pre-market assessment or approval requirement for medical devices supplied in New Zealand. Suppliers are not required to demonstrate approval by any overseas regulator. The only requirement is for suppliers to notify Medsafe of the device and product information through the Web Assisted Notification of Devices (WAND) database.

7. As a result, there are effectively no regulatory barriers to introducing medical devices into the New Zealand market, other than supplier or practitioner interest and any funding or purchasing decisions (including the fact that many practitioners directly procure devices themselves).

8. This approach makes New Zealand an international outlier, which the Medical Products Bill (MPB), currently in development, seeks to amend for reasons outlined below.

The Verification Pathway and how it differs to medical device approvals

9. The Verification Pathway or "Rule of Two" has been introduced through the Medicines Amendment Act 2025, which will enable medicines to be approved in 30 working days if the product has approval from two recognised overseas jurisdictions. This removes the need for duplicate approval processes in New Zealand and streamlines the pathway for access to new medicines.

10. The Verification Pathway will be carried over into the MPB when it replaces the Medicines Act 1981, with commencement currently expected in 2030. The Verification Pathway only applies to medicines and not to medical devices, hence the need for an alternative regulatory framework.

Future regulation will improve safety and enable greater access

11. The proposed Medical Products Bill (MPB) will introduce pre-market approval requirements for medical devices, bringing New Zealand into line with international practice.

12. Industry has emphasised that harmonisation will reduce the time and cost for manufacturers to bring new devices to multiple markets thereby ensuring patient access, support greater choice of products, and lead to cost savings that can be passed on to healthcare providers and patients.

Regulation will be proportionate to risk

13. Under the proposed model:

    a. Low risk devices (around half of all devices) will be automatically approved when a sponsor registers the device on the Medical Products Register and declares compliance with applicable standards.

b. Higher risk devices will generally rely on approval by at least one recognised overseas regulator.

c. A small subset of higher risk devices (for example, implantable devices) may require two overseas approvals or direct assessment by Medsafe.

d. Overall, Medsafe is expected to directly assess only a very small proportion of devices each year, largely locally manufactured products without existing international approvals.

14. Under the MPB, almost 75% of medical devices would be approved automatically or through reliance pathways, with some devices excluded from regulation altogether. Only around one percent of new devices – highest-risk products without trusted overseas approval – would require further review.

Alignment with other countries will reduce costs and improve efficiency

15. Bringing New Zealand into alignment with medical device regulations internationally is important for safeguarding the public as well as saving taxpayer and consumer money.

16. Medical devices can cause significant and costly ongoing harm if they are substandard or used inappropriately. ACC has spent more than $77 million on claims relating to harm from surgical mesh alone. It is important that use of medical devices is in line with authorised indications supported by clinical evidence.

17. At present, Pharmac, ACC and Health NZ each undertake their own due diligence on medical devices because there is no regulatory approval system they can rely on, resulting in duplicated effort outside their core capabilities. The regulatory changes proposed under the MPB will reduce this duplication and also support agencies to focus on their core functions such as maximising value, innovation and outcomes through better procurement.

Future regulation will also support innovation

18. There are currently no requirements for manufacturers to meet basic standards on quality, privacy or cybersecurity for software used for medical purposes. This absence creates risks to consumers and purchasers, including Health NZ. Software defects are one of the most common reasons for medical device recalls in Australia, accounting for over 20% of recalls.

19. In order to set risk-proportionate regulations for these products, the MPB will include clear provisions for defining and regulating software for a medical purpose. This definition will include regulating some applications of AI, such as AI that analyses medical images to diagnose cancers, while excluding general use AI or general 'health software', such as note-taking software or patient management software.

20. The aim of regulating software in the same way as medical devices is to ensure that digital tools intended for a medical purpose are clinically validated, safe and function as intended, thereby protecting patients and the public. Requiring software to meet cybersecurity requirements also reduces the risk of patient data breaches.

21. As with other medical devices, the regulation of software will be streamlined and proportionate. Where appropriate we will recognise approvals granted in other

countries, including under current Mutual Recognition Agreements. Appropriate regulation will also enable New Zealand membership of international organisations and initiatives on software and AI.

22. Alongside the regulatory framework ensuring product safety, workforce regulation under the Health Practitioner Competence Assurance Act 2003 (the HPCA Act) will need to be kept up to date to support the safe and capable use of AI software and tools by clinicians. Cabinet recently approved amendments to the HPCA Act which will support workforce regulators to respond to innovative health technologies, including AI.

New approach to Medical Device procurement 2025

23. Following Cabinet confirmation in September 2025, Health NZ and Pharmac are implementing a new, more coordinated approach to medical device procurement. The focus of the new approach is on improving national consistency, value for money, and strategic alignment between clinical and patient need, procurement decisions, and funding.

24. As well as greater coordination of procurement activity, the new approach allocates procurement responsibility to both agencies in a way that best reflects their capabilities and expertise. Under the approach:

    a. Pharmac is leading primary procurement activities for 27 of the 55 device categories. These are primarily devices that have direct therapeutic impacts on patients, for example orthopaedic implants.

    b. Health NZ is leading primary procurement for 28 of the 55 categories, focusing on devices that are less therapeutically intensive and require integration with infrastructure and models of care, for example, beds, imaging and diagnostics.

25. In the short-term, it is expected this will support greater value for money through shared datasets, utilising Health NZ's bulk purchasing capabilities and re-tendering contracts. The benefits derived in the short-term are expected to compound over time as each agency develops capability, builds relationships, and focuses on areas where they add the most value.

26. In the longer term, the coordinated approach aims to support wider productivity and economic growth objectives. By improving system-wide coordination, assurance and market engagement, the approach provides greater certainty to suppliers, reduces duplication across agencies, and enables more effective adoption of innovative products. Together, with the future regulatory settings, this will create an environment that improves patient access to devices while supporting longer-term economic growth.

Health Technology Assessments will support innovative products

27. A key priority of the new approach is to drive innovation in medical device procurement. To achieve this, agencies have agreed a Service Level Agreement through which Health NZ will fund Pharmac to deliver Health Technology Assessments (HTA). This leverages Pharmac's expertise in delivering HTAs, ensuring decisions to adopt new technologies are aligned with health system priorities and drive greater value for the system.

28. Health NZ is introducing a structured national prioritisation process called the Health Technology Evaluation Pathway (HTEP). HTEP aims to support Health NZ to achieve greater efficiency, transparency, and national consistency in patient access to high value health technologies.

Progress report will be provided in March 2026

29. A Letter of Expectations was provided to agencies following Cabinet confirmation of the new approach which makes it clear that the Government expects measurable improvements in innovation adoption, value for money, patient outcomes and supplier experience. The Ministry has been chairing a cross-agency oversight group to oversee the transition and assure delivery.

30. The Ministry is currently preparing a progress report which will be provided to Ministers in March 2026.

ENDS.