

Briefing

Date:	5 March 2025	Reference:	DS-007
Briefing:	Pharmac Medical Device Programme		
Security level:	IN CONFIDENCE		
To:	Hon David Seymour, Associate Minister of Health		
Copy to:	Pharmac Board: <input checked="" type="checkbox"/> Ministry of Health: <input checked="" type="checkbox"/>		

Contact for further information

Name	Position	Telephone
Oliver Whitehead	Team Leader, Government Services	s 9(2)(a)
Catherine Epps	Director, Medical Devices	s 9(2)(a)

Recommendations

We recommend that you:

- a) **note** the Ministry of Health have completed its review of hospital medical devices and have recommended that Health NZ be the single entity responsible for hospital medical devices procurement **Noted**
- b) **note** you are meeting with Hon Simeon Brown, Minister of Health on 10 March to discuss the review report **Noted**
- c) **note** Pharmac disagrees with the recommendations of the medical devices review, and have outlined their proposed direction below **Noted**
- d) **agree** with Pharmac's recommendations listed at the end of this paper **Yes/ No**

Sarah Fitt
Chief Executive
Date:

Hon David Seymour
Associate Minister of Health
Date:

Pharmac Medical Device Programme

Purpose of report

1. To support your meeting with Hon Simeon Brown, Minister of Health on the roles and responsibilities pertinent to medical devices across the health system. It provides an update on Pharmac's delivery of benefits for the health and disability system and outlines the proposed next phases.

Summary

2. Pharmac disagrees with the review's main recommendation that it would be more efficient if the role and related responsibility for hospital medical device procurement is moved to Health NZ.
3. Pharmac considers that the best outcome for the health system and for New Zealanders is for medical devices procurement and funding to sit with Pharmac as dedicated lead agency, working in partnership with the sector and other stakeholders to improve value from hospital medical devices.
4. This is because:
 - a. Pharmac has specialist expertise in assessment of value and commercial leverage of funding choices for clinical technology and is internationally recognised for this
 - b. Pharmac is agile and adaptable in a rapidly evolving sector
 - c. Pharmac's work has brought structure and focus to hospital medical device procurement that was absent prior to our involvement
 - d. Pharmac has specialist capability and can accelerate delivery with increased capacity
 - e. Pharmac can give clear focus and accountability to medical device procurement outcomes that is unlikely in an organisation that has both operational and funding decision roles
 - f. Pharmac's proximity to supply, demand and frontline insights.
5. Ministers are requested to reconfirm Pharmac's enduring role in leading medical device procurement and funding.
6. Ministers are asked to increase resourcing for Pharmac to ensure effective delivery, and a cost-neutral suggested solution is provided.

Background

7. In late 2024, the Ministry of Health commissioned Martin Jenkins to undertake an external review of the Medical Devices Programme.
8. This was in response to an action in your 2024/25 Letter of Expectations to determine 'the role that Pharmac is playing in the value assessment and procurement of medical devices'.

9. Pharmac staff worked with the Ministry of Health, Health NZ, and Martin Jenkins on the development of the review report.
10. The Pharmac Board considered the draft review report on 24 February 2025. The Board is very concerned about the draft report, its analysis and findings, and recommendation to move to a single entity model with Health NZ assuming sole responsibility.
11. The Board discussed its concerns regarding the review recommendations with you when you met with them on 25 February.
12. Following our consideration of the draft review report and discussions with the Pharmac Board our key feedback on the current state and the way forward is summarised below. (Pharmac have recently received a copy of the final review report which has not been substantially changed from the earlier draft.)
13. Your office asked four key questions on the medical devices review report to support your discussion. We have integrated our answers into the paper and cross referenced them for your ease in Appendix A.

Pharmac has specialist expertise in assessment of value and commercial leverage of funding choices for clinical technology and is internationally recognised for this

14. Pharmac is an entity specialised in examining the value of clinical products and managing the funding of these within available budgets to achieve the best health outcomes.
15. Pharmac is a specialist organisation in assessment of value and commercial leverage of funding choices for clinical technology and is internationally recognised for this. It has long experience working across organisations with different regional or service priorities.
16. Our objectives and functions effectively mean that Pharmac's core business is to make decisions about investment in health products, from with a fixed funding pool, and towards products that are likely to generate the best health outcomes.
17. Our budget management is exemplary with over 30 years of meeting budget with no overspend. Currently managing a medicines budget of \$1.694 billion we would apply the same budget rigor to hospital medical devices.

Pharmac is agile and adaptive in a rapidly evolving sector

18. Our organisational specialisation generates a greater focus on the issues and developments in respect of clinical products. This includes regular engagement with industry and end users to stay across future developments, but also relating health priorities to clinical product use.
19. Throughout its history in medicines, Pharmac has adjusted to technology options and funding priorities, such as prioritising cancer treatments that are more expensive but can be used closer to home. Likewise, Pharmac can also

manage medical devices to meet government targets and supports a sector approach for delivering better health outcomes.

20. Through the recent budget uplift, we've demonstrated our ability to move at pace to deliver for all New Zealanders, and likewise aim to do the same for medical devices.
21. Pharmac is focused on new innovations to benefit patients and enable efficiency of healthcare. For devices we want an explicit pathway for suppliers, and end users to provide proposals that deliver these benefits. We want to increase transparency through enhanced partnerships.
22. Pharmac has demonstrated ability to be flexible in establishing ad-hoc advisory groups to support time limited transactions. We took this clinical engagement approach with previous procurement approaches for wound care and stents, returning an average of 22% and 30-30% price reductions for approx. \$13 million total spend. We are currently doing a similar process for personal protective equipment (PPE).

Pharmac's work has brought structure and focus to hospital medical device procurement that was absent prior to our involvement.

23. Pharmac has a dedicated focus on this market that cannot be guaranteed in more general organisations with competing priorities.
24. Pharmac has a specialist knowledge of medical devices.
25. Pharmac has delivered consistent national contractual arrangements that reduce overheads for both suppliers and Health NZ.
26. Pharmac's work to define a medical device dataset allows the expenditure on medical devices can be quantified. Laying strong foundations for, and is enabling, management of devices as a portfolio.
27. Prior to Pharmac management very few coordinated controls on medical devices existed. Basic systems were required to work towards the ideal scenario of reliable and timely funding choices. This was due to no clear information on device use and expenditure.
28. Visibility of medical device funding and clarity of commercial arrangements are much clearer now due to Pharmac's focus on this work, and our plan has always been to build on this.

Pharmac has specialist capability and can accelerate delivery with increased capacity

29. Recent fixed-term FTE increase has enhanced our capacity to:
 - a. Finalise a comprehensive list of medical devices. This is on track for completion and to be available for all public hospitals by 1 July 2025.

- b. Expand and improve contract management and manage price pressures to under 1% per annum across contracted products for 2023/24 and is on track again for 2024/25.
- c. Continue to save through national contracts. Continue our contracting work with another \$85 million by spend of devices under Pharmac's national contracts during the 2024 calendar year. At 1 February 2025, the Pharmaceutical Schedule will include approximately 174,000 contracted line items from over 140 suppliers. These contracts cover approximately \$643 million of annual Health NZ hospital expenditure on medical devices.
- d. Further category management supported by data analysis.
- e. Undertake several health technology pilot assessments.
- f. Augment our extensive expert advice functions and establish a dedicated overarching Medical Device Advisory Group.
- g. Increase sector engagement with suppliers and healthcare organisations.
- h. Accelerate and expand how Pharmac can best integrate with Health NZ processes, and this will improve further with intended digital improvements.

Pharmac can give clear focus and accountability to medical device procurement outcomes that is unlikely in an organisation that has both operational and funding decision roles

- 30. Pharmac has built a comprehensive medical device list/dataset where products are described and categorised in a consistent way that is being used across the sector. Pharmac's focus on this has been a driver for development of what is now the Health System Catalogue (HSC) in Health NZ, with medical devices being the most complete section/category within HSC.
- 31. The fiscal benefits and savings of \$51 million per annum identified and quantified in the 2019 FPIM business case were predominantly modelled on Pharmac applying full budget management for hospital medical devices.
- 32. It assumed that expenditure growth in devices is similar to that of medicines before Pharmac intervened (~7-8%), and that we would be able to modify this to a lower growth path (2-3%) while directing investment to devices that provide the best health outcomes from available options.
- 33. Any decision by Ministers to invest more, or less, in devices from year to year based on its funding priorities can be supported by our portfolio approach. It enables clearer advice on the relative value of different investment levels. While the financial benefits may vary from above, the Government can have confidence it will achieve the desired outcomes.
- 34. Recent examples of our procurement approach and outcomes are:
 - a. Supported by clinical stakeholders Pharmac negotiated savings of \$1 million per annum to supply public hospitals with the latest version of drug eluting stents and updated clinical practice accordingly.
 - b. In 2024 we managed over 70,000 changes to items and pricing for medical devices. Average price movement at or below 1% per annum

across the portfolio. This is a solid foundation for responsible management of a high volume of activity.

35. Pharmac operates transparently by maintaining a publicly available view of what is funded, and what is being considered for funding. It can leverage this list of funded items to generate competition for a place on the list, and the transparency also allows the public at large to understand what is available.
36. With the expected achievement of the comprehensive and closed list for medical devices during 2025, we are poised to move to a next phase of maturity where significant savings can be gained from managing the whole portfolio of medical devices, to realise the most value from each category.

Pharmac has proximity to supply, demand and frontline insights

Pharmac is a system leader who holds trusted relationships

37. Supported by over 30 years of experience of making explicit investment decisions. Guided by expert advice from across the health system. With a strong international reputation for evidence-based decision making.
38. Both medicines and medical devices are health technologies aimed at supporting clinical practice. Pharmac is highly experienced at working with teams/roles we need to at Health NZ and connecting across different entities. This benefit is carefully balanced with the ability to maintain our independence.
39. The operation of our 21 expert advice groups is unique to Pharmac, with membership, agendas and outputs published. It is our view that a much larger organisation with a varied role may not deliver this level of accountability in respect of medical devices.
40. Pharmac has established relationships with clinical leaders and Health NZ clinical networks (many of the individuals are also members of Pharmac's own advice network). Feedback from clinicians we engage with has been consistently supportive of Pharmac's work and role in the sector.
41. In 2024 we hosted a successful supplier webinar, with over 300 stakeholders registered. We actively manage our relationships with suppliers on both an individual and collective basis; including a strong relationship with Medical Technology Association of New Zealand (MTANZ).
42. We also have established relationships with the key professional associations representing the range of healthcare practitioners.
43. Our decision-making framework, the Factors for Consideration, requires consideration of impacts for patients and their families, clinicians, and the wider health system. There is no visible equivalent analysis carried out by Health NZ. The Factors require Pharmac to engage with the upstream and downstream impacts and work with the sector to achieve the best health outcomes.
44. The funding of continuous glucose monitors (CGMs) alongside insulin pumps involved innovation, commercial processes, collaboration, and the input of the

wider health and disability system. So that we understood the needs of consumers, clinicians, advocacy groups, and whānau.

45. Our CGM funding process required public consultation on the proposal. Asking those who would be impacted by the decision to give their feedback. We hosted a webinar attended by over 700 people, and extended timelines to support the best possible outcome for New Zealanders and their access to this device.
46. Pharmac has demonstrated it is able to support the health sector. Through our relationships with Health NZ and Medsafe, we identified a trend in a device that could have been considered isolated failures at different places around New Zealand. We connected with the right groups at Health NZ and worked with them and suppliers to source replacements and help the device changeover.

Preferred way forward

Confirmation of Pharmac's enduring and system leadership role in medical device procurement

47. The benefits and risks of medicines and medical devices can be technical in nature and require a degree of specialisation when it comes to the investment and procurement choices around them. They are different to cars, building management, outsourced services and workforce procurement.
48. Globally, medical devices are seen as a separate and specialist area of healthcare due to the complexity, rapidly evolving nature, impact on the success of the health system delivery, and scale. Pharmac considers medical devices procurement within New Zealand should be seen as a specialist area for procurement.
49. We consider that the split focus of Health NZ across different types of procurement has, and is likely to continue to mean, less emphasis on improving value from medical devices as an area of spend and investment.
50. All parties are agreed that we can not continue with status quo, as the lack of clarity is jeopardising the ability to deliver continued improvements for the medical devices work.
51. Other mixed or hybrid models have not been identified as splitting the portfolio is complex. However, it may be possible to keep some aspects of large capital investment and procurement of medical devices with Health NZ.

Pharmac manage medical devices as part of the pharmaceutical portfolio

52. Pharmac favours a model where medical devices are managed as a complete portfolio by Pharmac, as we do with other pharmaceuticals, and as part of our existing medicines, vaccines, community devices and related products work.
53. Increasingly devices, medicines and vaccines are becoming intertwined to better meet patient need, eg pumps to deliver drugs, monitoring equipment linked to dosage needed, wearables providing diagnostic data etc.

54. Pharmac's role would be to manage a transparent list of funded products, add new technology to the list within funding guidance from Government, use the funding levers to generate good commercial incentives on industry, and direct funding to the products that deliver the greatest value to consumers in terms of health benefits.

Health NZ retain operational focus for service delivery

55. Health NZ is the main provider of health care services in New Zealand, and it is appropriate for day to day operational delivery of healthcare to sit with it. Patient care, clinical expertise, warehousing, and ordering and equipment maintenance should appropriately sit with Health NZ.
56. It is tempting to suggest that, because operational delivery is impacted by the funding framework and decision making, these should be housed in the same place. However, our experience is that where organisations in health have both operational and funding decision roles there is a tendency to focus resources on operational delivery given the demands that come with these.

Role delineation between Pharmac and Health NZ and clear expectations set

57. There does need to be some interaction and coordination across these activities. As described earlier, we have considerable experience navigating the sector and making these connections.
58. Key features of our preferred model are for Pharmac to lead the following functions:
 - environmental scanning in relation to opportunities and for how medical devices (new and evolving) can improve health outcomes
 - advice on clinical efficacy from advice network and other experts (noting the experts would often work in Health NZ)
 - economic evaluation under consistent, internationally recognised methodology
 - explicit prioritisation decisions on what should (and should not) be purchased within the fixed budget, using a transparent decision-making framework
 - negotiation with suppliers, using a range of standard commercial practices
 - category/therapeutic group management to extract value from base expenditure to reinvest in managing product demand and expanding access
 - management of budget of medical devices to be able to maximise value (from 26/27)
 - implementation and optimisation of the contracts effectively within Health NZ so that they are well understood and the maximum value is utilised.
59. Hospitals would manage purchasing, using prices negotiated by Pharmac. Pharmac and Health NZ share contract management to ensure supplier compliance with national contracts.

Creation of a fixed medical devices budget

60. A key feature of the Pharmac model is a fixed budget, as set in Vote Health. The Medical Device Programme has been working toward a mature budget management model similar to medicines. Achieving a comprehensive and then a closed list of medical devices is a significant step in this process. The next step is for management of new investments within an interim fiscal envelope while medical device data quality is improved to a level which allows appropriate forecasting. Timing for budget responsibility would also need to be aligned with sufficient workforce capacity to manage within this fixed budget.
61. We consider that many of the current issues, such as supplier gaming behaviour, are not driven by a disaggregated model but rather a current lack of clarity about which entity does what.
62. The uncertainty of some about Pharmac's ongoing role in medical devices has presented significant barriers to progress, and some duplication of effort, so confirmation of an enduring role is preferred.

Capacity constraints

63. The review report discusses limitations in capacity and capability in the sector and considers some consolidation of this is desirable to avoid competition for resources between Public Sector entities.

Efficiency in Pharmac resourcing due to our specialist expertise, existing processes and use of shared functions supporting our medicines funding work

64. It is mentioned that Health NZ has 160 FTE in its procurement team, against around 34 FTE at Pharmac (18 permanent FTE and the rest fixed term). It is important to recognise the procurement scope of Health NZ is broader than medical devices and includes other products and services that hospitals require for their operations.
65. If Ministers agree not to accept the review recommendation to move medical devices procurement to Health NZ as a single entity, and for example agree for Pharmac to continue to mature its medical devices programme, Pharmac will need additional permanent resources from the 2025/26 year.
66. We anticipate Pharmac's resource requirements are likely to be less than Health NZ for the same work, given our existing processes, systems and expertise and the use of shared functions that support our medicines funding work.
67. Aside from resource requirements to be able to deliver effectively, Pharmac are "delivery ready" as we have built considerable momentum and already have the processes in place that are needed.
68. We provided your office with prior references to the upcoming resource requirements for medical devices in January 2024, End of Q4 2024, and August 2024.

69. s 9(2)(g)(i)

Preferred model

Pharmac has full responsibility for procurement of medical devices

70. Pharmac recommends:

- a. Pharmac take lead on all negotiation of contracts for medical devices once the Schedule of devices is complete (estimate late 2025). Purchasing activity would remain with Health NZ under Pharmac arrangements.
- b. Duplication in procurement functions are removed. Any overlapping functions and funding transferred to Pharmac to consolidate capacity for clinical product funding and procurement. Not including supply chain functions.
- c. Communicating to suppliers, clinicians and consumers so it is clear that Pharmac manages all medical device funding.
- d. Pharmac leads a single national process for assessment and decision-making for medical devices funding informed by Health NZ requirements and expert advice. Health NZ makes choices about what specific funded devices to use to deliver its services. Pharmac is guided by Health NZ and Health Strategy priorities when valuing new clinical technology.
- e. A Health NZ system and policy/process-based compliance mechanism is put in place to reduce off-catalogue purchasing to improve data quality about medical devices to enable forecasting and improve insights for value creation. The system level could be integration of the Pharmac Schedule with FPIM catalogues such that only devices listed on the Pharmac Schedule can be routinely purchased.
- f. We consider the above points can be enforced through current legislative settings, changes to the Pharmac Schedule Rules (to 'close the list') and clear public communication.
- g. Roles and responsibilities for respective entities set out in a formal Memorandum of Understanding.
- h. Ministers may wish to consider setting improved role clarity, expectations and performance metrics for Pharmac and Health NZ.
- i. Setting a fiscal envelope for new investment in budget 25/26 and a medical devices appropriation from Vote Health aligned with operational funding for Pharmac for its management in budget 26/27.

Next steps

71. We will continue to engage with you and your office. As pending Ministerial decisions will need to be carefully managed as they have budget and workforce implications.

Appendix A

The answers to the additional questions have been integrated into the paper above.
Table summarising sections that answer the further questions from Minister's office.

Question	Sections of above Paper
<p>1. *Capacity Constraints*</p> <p>The report notes that Pharmac has made progress in addressing capacity constraints, with your medical devices team growing from 13 full-time equivalents (FTE) in July 2021 to 34 FTE by December 2024. However, it also highlights that Health NZ has a significantly larger procurement team of approximately 140 FTE managing over \$6 billion in annual spending.</p> <p>- How does Pharmac assess its current capacity to manage the complexity and scale of medical device procurement, especially given the sector's diversity and rapid innovation?</p> <p>- Do you believe capacity is sufficient to meet the demands of the sector, particularly in comparison to Health NZ's resources?</p> <p>- Can you provide examples of how recent capacity improvements have enhanced Pharmac's ability to deliver timely and effective procurement outcomes?</p>	<p>62</p> <p>63-67</p> <p>28</p>
<p>2. *Agility and Adaptability in a Fast-Evolving Sector*</p> <p>The review suggests that Health NZ's larger structure and broader responsibilities could make it less agile in responding to the fast-evolving medical devices sector, conversely, Health NZ's size gives it greater procurement opportunities.</p> <p>In contrast, Pharmac's smaller size and focused mandate might offer greater flexibility but might impact on procurement scalability.</p> <p>- How does Pharmac view its ability to be agile and adapt to changes in the medical devices sector, particularly in areas like innovative technologies or emerging product categories?</p> <p>- Can you provide examples of how Pharmac has demonstrated agility in procurement, either for medical devices or medicines, that could be applied to this sector?</p>	<p>17-20</p> <p>21,33,43-45</p>
<p>3. *Proximity to Demand and Frontline Insights*</p> <p>The report emphasises Health NZ's advantage of being closer to the demand of devices with direct access to real-time insights from clinicians and patients. It also notes that Pharmac operates at a distance from day-to-day operations, which can sometimes lead to misalignment with frontline needs.</p>	

<ul style="list-style-type: none"> - How does Pharmac currently incorporate frontline insights from clinicians and patients into its procurement decisions for medical devices? - Are there specific processes or mechanisms in place to ensure that procurement choices align with clinical and patient needs, despite not being directly involved in service delivery? 	<p>36-39</p> <p>42-45</p>
<p>4. Preferred model</p> <p>While the review recommends a single-entity model under Health NZ, it also acknowledges the potential benefits of a hybrid approach. I'm interested in Pharmac's view on the ideal model.</p> <ul style="list-style-type: none"> - A hybrid model seems to allow more opportunities to engage with innovation or more discreet needs of particular areas/hospitals. In practice is this something Pharmac can demonstrate given work to date? - What are your thoughts on a hybrid model where Pharmac focuses on categories that require specialised expertise (e.g., health technology assessments for innovative devices), while Health NZ manages high-volume or less complex procurement? - Is there a better model that Pharmac would recommend? (Is there a way to lean further towards a single entity with Pharmac as the lead?) 	<p>49</p> <p>50</p> <p>51-61</p>