PHARMAC
TE PĀTAKA WHAIORANGA

Briefing

Date:	28 03 2025	**Reference:**	DS-013
Briefing:	Pharmac Medical Device Programme		
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To:	Hon David Seymour, Associate Minister of Health		
Copy to:	Pharmac Board: ☐ Ministry of Health: ☐		

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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** yourself and the Hon Simeon Brown, Minister of Health have asked for further clarification of the 2025 medical device review's recommendations.	**Noted**
c)	**note** Pharmac disagrees with the recommendations of the 2025 medical devices review, and have in addition to providing clarification, outlined their proposed directions.	**Noted**
d)	**note** the definition of a medical device in Appendix A.	**Noted**
e)	**note** Pharmac's request for funding to continue its medical device obligations as part of its pharmaceutical portfolio statutory duties.	**Noted**

Sarah Fitt	Hon David Seymour
Chief Executive	**Associate Minister of Health**
Date:	Date:

Pharmac Medical Device Programme

Purpose of report

1. This paper outlines Pharmac's work in hospital medical devices and delivery of benefits for the health and disability system to support Ministerial consideration of recommendations from the 2025 Medical Device Review.
2. What constitutes a medical device and established definitions is outlined in Appendix A.
3. Other questions posed by Ministers are responded to in Appendix B.
4. An A3 2-page presentation is included in Appendix C which provides a visual summary of the high-level points from this briefing and further details: the organisational areas of Pharmac investment, initiatives to address the problem and positive progress made by Pharmac's medical devices work.

Summary

5. With an incremental investment in Pharmac of $100.94 million over 10 years, we can realise increasing benefits over time of between $51 million to $88 million savings per annum. We estimate minimum return on investment is $466.65 million over 10 years (1:3.33 / 333%).
6. This will be delivered by continuing to scale the accessibility, practices, and benefits of Pharmac's medical devices programme.
7. Pharmac currently delivers a system that works for medicines that can also work or be modified for medical devices. Pharmac already manages contracting for the majority of devices and can scale this across the whole portfolio, extending the benefits of the Pharmac model to all medical devices currently procured by Health NZ.
8. There are significant opportunities across the health sector as well as other crown agencies (who have considerable medical device expenditure) to recognise further increased cost reductions and savings.
9. Our vision for medical devices is to drive better value through nationally consistent access to medical device technology and delivering the best health outcomes for New Zealanders from within operating budgets.
10. 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 health sector and other stakeholders to improve value from hospital medical devices.
11. Ministers are requested to reconfirm Pharmac's enduring role in leading medical device procurement and funding.
12. 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.

13. 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.

14. Aside from resource requirements to be able to deliver effectively, Pharmac are "delivery ready" as we have built considerable momentum and already have many of the processes in place that are needed.

Background

15. In August 2012, the Government approved a plan for transitioning the management, assessment, standardisation, prioritisation and procurement of hospital medical devices to Pharmac, based on Pharmac's successful track record in managing medicines and controlling pharmaceutical cost growth.

16. As part of this transition plan Pharmac advised Government that three key elements were required to effectively manage medical devices and achieve procurement savings and benefits:

    a. A schedule of products and prices from which hospitals must order,

    b. access to data about actual spending in hospitals, at the item level of detail and ideally linked to or able to be reported against the schedule of products and prices

    c. a mechanism to support hospitals compliance with the schedule

17. To meet the above requirements, a common national Financial Management Information System (FMIS) as developed. At the time, District Health Boards selected the National Oracle Solution (NOS) – now referred to as the National Finance Procurement and Information Management (FPIM) and Health Sector Catalogue (HSC).

18. The original timeframes were for Pharmac to be managing medical devices in 2017, following delivery of FMIS in 2015. Delays in delivery of FMIS/FPIM meant Pharmac progressed developing a standardised schedule of devices which now covers over $700 million in Health New Zealand expenditure.

19. In 2021 the Government commissioned an external review of Pharmac into how well it performs against its current objectives. In February 2022 the review panel delivered its final report to the Minister of Health. The main outcome of the review was that Pharmac is doing an important job and performs well against its objectives but there are improvements to be made. One of the recommendations of the 2022 review was to transfer all responsibility for medical devices from Pharmac to Health New Zealand. The government decided at that time to not accept nor action this recommendation.

20. You outlined in your 2024/25 letter of expectations information to determine 'the role that Pharmac is playing in the value assessment and procurement of medical devices'.

21. In late 2024, the Ministry of Health commissioned Martin Jenkins to undertake an external review of the Medical Devices Programme (the Review). Since release of the Review and Pharmac's response, your office and the Minister of Health have asked for additional clarification of Pharmac's role, the definition of medical devices, and potential value options.

Why Pharmac?

Pharmac has clear performance and delivery

22. The statutory objective of Pharmac is:

    a. to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided; and

    b. any other objectives it is given by or under any enactment, or authorised to perform by the Minister by written notice to the board of Pharmac after consultation with it.

23. Pae Ora (Healthy Futures) Act 2022, Section 4, defines 'pharmaceutical' to mean a medicine, therapeutic medical device, or related product or related thing.

24. Pharmac's budget management has been exemplary with over 30 years of meeting budget with no overspend. In the sustainable delivery of Pharmac's functions, it has consistently managed within 1% of its now $1.694 billion medicines budget.

25. Since Pharmac's inception it is estimated that Pharmac has created in cost avoidance and cost reduction savings of approximately $6 billion in value to the Crown and New Zealand. All this while prioritising investment towards treatments that offer the best health outcomes within available funding.

26. Pharmac's clear performance success is achieved by delivering on its legislated functions and via its core activities of strategic procurement, contract and supplier lifecycle management, stakeholder engagement, health technology value assessment and commercial leverage of funding choices, management of schedules, subsidy (and associated processes), and fiscal management against available budget activities. These are core Pharmac activities which contribute to a sustainable medical device ecosystem.

27. Pharmac is a stable and trusted government agency which is responsive, agile, and adaptable in a rapidly evolving sector.

Pharmac medical device delivery performance and expertise

28. In relation to medical devices; cumulative net savings of approximately $120 million has been achieved by Pharmac from medical device contract activities to date while the primary focus has been establishing systems and consistent practices rather than savings per se.

29. Pharmac's work has brought structure and focus to hospital medical device management and procurement that was limited prior to Pharmac's involvement.

30. Pharmac has expanded and improved medical device contract management and managed price pressures to under 1% per annum across contracted products for 2023/24 and is on track again for 2024/25, despite significant cost pressures across the economy in recent years.

31. Pharmac has completed two commercial market share pilots returning an average of 22% and 30-40% price reductions for approx. $13 million total spend. We are currently doing a similar process for personal protective equipment (PPE).

32. Pharmac has specialist expertise in and is internationally recognised for its health technology value assessment and commercial leverage of funding choices.

33. Pharmac's expertise and resources have assisted Health NZ with engagement of stakeholder groups on the value of health technology assessment and demonstrated how national health technology assessment functions can work.

34. Building on Pharmac's expertise and existing processes minimises the cost burden to the Crown. Health NZ has recognised that Pharmac undertaking health technology assessments on its behalf best utilises the specialist expertise held by Pharmac and already invested in to achieve the improved health outcomes desired.

35. Any removal of hospital medical device responsibilities from Pharmac will not remove Pharmac's dependency on specialist expertise or reduce costs to the Crown where Pharmac' responsibilities for managing pharmaceuticals (medicines, vaccines, community devices and related products) remains. Investment to augment and expand Pharmac's current advice network is planned to support activities associated with engaging medical device expertise, suppliers, and key stakeholders including populations of high health need, advocacy groups, and the New Zealand public.

36. As Pharmac is a small entity with a centralised governance structure, it has used its specialities internally as a shared resource to efficiently support both medicines and medical device functions and activities, thereby reducing possible duplication of resources and costs to the health sector.

37. Pharmac manages a range of medical devices/products dispensed through community pharmacies. These medical devices are funded during and as part of processes for the associated medicines. They are listed on the Pharmaceutical Schedule and are funded from the Medicines Budget (formerly the Combined Pharmaceutical Budget, CPB). Examples include blood glucose meters and test strips, continuous glucose monitors, insulin pumps, contraceptive devices, pregnancy tests, and drug delivery systems (e.g. autoinjectors). They also reflect the growth of the integration of medicines, vaccines and medical devices- as increasingly, medical devices are used to monitor, test the need for, and administer medicines (e.g. insulin pumps, autoinjectors Point of Care Testing in the community etc.)

38. For hospital medical devices, Pharmac has historically been restricted (by operating budget and direction) to focus its scope of activities to public hospitals however its legislation has no such boundaries beyond achieving best health outcomes.

39. Pharmac currently has 180 active contracts with 154 suppliers (covering close to $700 million of Health NZ expenditure and approximately 174,000 individual products). Pharmac has completed 70,000 adjustments (e.g. pricing, additions, removals) to these contracts in the past 12 months. Currently, hospitals do not have to purchase from the listed medical devices but if they do, they must use the Pharmac contract, including pricing.

40. Pharmac is now poised to further mature the medical devices work by completing the process of national contracting used to build a single national list of medical devices. This marks the end of the current stage of the programme and will enable us to move to a new phase with a marked step up in savings,

and acceleration of the value-add to health and social outcomes through managing the contracts and suppliers to generate greater competition.

41. Pharmac can give clear focus and accountability to medical device management outcomes that is unlikely in organisations that have both operational and funding decision roles across the full scope of health care delivery.

42. Health New Zealand's role is predominantly to deliver healthcare services to the population across the country; balancing the health needs of the population, with efficient spend, and effective delivery. For this purpose, Health New Zealand will need to purchase goods and services, including medical devices.

43. Medical Devices are a specialist element of healthcare procurement, and globally are treated as separate from non-clinical procurement – due to their size/ scale, impact on patient safety, and rapidly evolving nature. Appendix A sets out the established definitions for Medical Devices.

Future opportunities

44. Pharmac currently delivers a system that works for medicines that can also work or be modified for devices. Pharmac already manages contracts for the majority of medical devices and can scale this across the whole portfolio to extend the full benefits of the Pharmac model to medical devices currently procured by Health NZ.

45. As part of the 2019 Finance, Procurement, and Information System (FPIM) business case, it was assumed that a long-term **average cost reduction of 6% per annum** was possible[1], equivalent to the realised savings for medicines. This analysis was updated in 2022 when medical device expenditure was estimated to be $850 million per annum, which would translate to Pharmac achieving **$51 million per annum of undiscounted savings across the estimated $850 million expenditure** by Health NZ hospitals. It is estimated that benefits would accrue gradually (due to change effects and current pricing pressures).

46. There is some uncertainty about the precise spend on medical devices, as it is not consistently recorded by Health NZ. A recent review of Health New Zealand spend data by Pharmac produces a range of $920 million to $1.26 billion per annum. Health New Zealand has reported spend of approximately $1.5 billion, though we have not been able to validate this. It would suggest that the spend is more likely at the upper end of our range.

47. In the event spend was closer to the Health NZ estimated spend, the projected **savings increase up to $84 million per annum** (based on the original estimate of a 6% return).

48. There are significant opportunities across the health sector as well as other crown agencies (who have considerable medical device expenditure) to recognise further increased cost reductions and savings.

[1] As estimated in the Health NZ FPIM Business Case with all benefits from the investment to be recognised by Pharmac

49. Further benefits from Pharmac's standardisation of medical devices would mean increased transparency of funding choices about medical devices and better health outcomes would be gained for New Zealanders from:

    - earlier access to medical devices through faster decision-making, listing the right devices for our public hospitals and population needs,
    - consistency of supply chain and therefore consistency and reliability of care – having the right device in the right place at the right time.
    - consistency of devices used between hospitals – healthcare workers are comfortable using medical devices meaning less error and increased patient safety as well as decreased costs such as overall device training costs for budget owners and from increased flexibility of clinician scheduling (e.g. surgeons).
    - Over time, healthcare workers having assurance that the medical devices they choose will have been through a process of selection, including the use of expert advice, so they can give optimal patient care.

50. Pharmac's medical devices work could also enable improved staff mobility using devices in different areas of the health and government sectors dependent on Pharmac's breadth of operating scope. It could also enable improved asset management meaning assets last longer and savings can be spent on other needs.

51. Having greater certainty about future funding growth would allow Pharmac to develop longer-term strategic planning for investing in medical devices, and to:

    - more proactively seek out medical devices and new technologies to address health needs of New Zealanders
    - support long-term population health strategies and goals
    - engage earlier with the wider health sector on future investments, to better inform their long-term planning and prepare for the likely impacts to service delivery.

Delivery dependencies

52. In order for the future opportunities to be realised, **operational funding would** need **to be continued for Pharmac medical devices activities for 2025/26 and increased as outlined**. This would mean that prior fixed-term investment outcomes can be embedded as a foundation for medical devices management going forward.

53. s 9(2)(g)(i) [redacted]

54. Pharmac leads all negotiation of contracts for medical devices once the Pharmac national list of devices is comprehensive and engagement on this

transition is complete (estimate late 2025). Purchasing activity would remain with Health NZ under Pharmac contractual arrangements.

55. Pharmac leads a single national process for assessment and decision-making for medical devices funding informed by Health NZ requirements and expert advice. Pharmac assists Health NZ with implementation of value creation. Health NZ makes choices about what specific funded devices to use from the Pharmac national list to deliver it services. Pharmac is guided by Health NZ and Health Strategy priorities when valuing new clinical technology.

    a. 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

56. The next stage of maturity of the model is the movement of budget from Health to Pharmac to manage funding via a medical devices appropriation (similar to medicines) and this would be required to continue to deliver increasing value.

57. Government commitments to a longer-term funding pathway, where the medical devices budget grows at an affordable rate over time to keep pace with growing demands (i.e. increasing costs, growing population, increasingly diverse health needs, emergent technology) and the increasing availability of good value investment options.

58. Duplication in procurement functions are removed between Health NZ and Pharmac. Any overlapping functions and operational funding transferred to Pharmac to consolidate capacity for clinical product funding and procurement, not including supply chain functions.

59. 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.

Resource requirements and return on investment

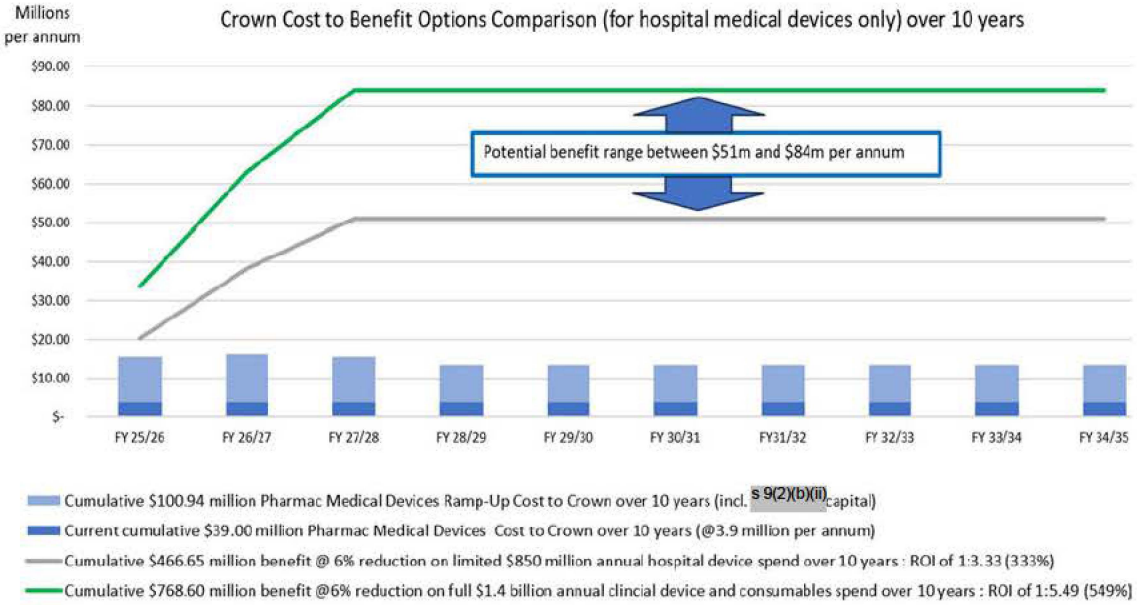
60. To deliver this scaled up approach, Pharmac requires:

    - Additional Full-Time Equivalent (FTE) permanent roles, to be recruited over the next three years
    - Investment in IT systems capabilities.
    - Investment for associated activities to engage medical device advice network expertise, suppliers, and key stakeholders including populations of high health need, advocacy groups, and the New Zealand public.
    - Investment in fixed-term change-management and engagement resources for transition to next steps and embed prior medical device fixed-term investment outcomes.

61. With an incremental investment in Pharmac of $100.94 million over 10 years, we can realise increasing benefits over time of between $51 million to $88 million savings per annum. We estimate minimum return on investment is $466.65 million over 10 years (1:3.33 / 333%).

62. The following graph and tables illustrate the total cost over 10 years and potential for cost avoided / cost reduction benefit returns for the associated investment. Calculations are based on baseline ($3.9m) plus ramp-up (to max $9.41m) per annum and capital s 9(2)(b)(ii), s 9(2)) costs vs. possible returns.

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



$million	25/26	26/27	27/28	28/29	29/30	30/31	31/32	32/33	33/34	34/35	Total 10 Yrs
s 9(2)(b)(ii)											
Operating Budget (Opx and Cpx) Total	11.45	12.20	11.42	9.41	9.41	9.41	9.41	9.41	9.41	9.41	100.94

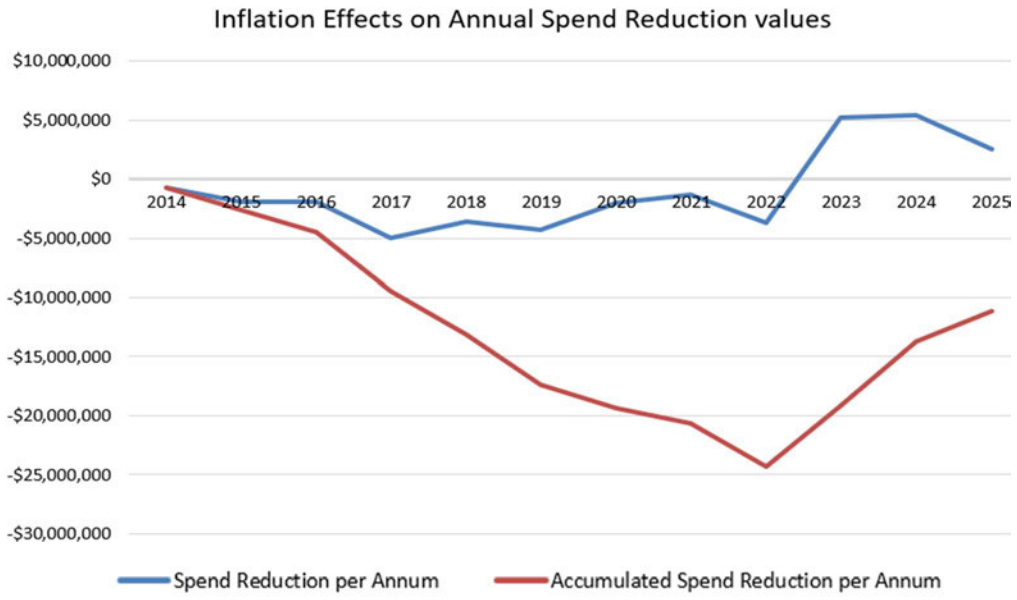
Table 1: New funding to fully resource and deliver projected benefits of Pharmac Medical Device Management

$million	25/26	26/27	27/28	28/29	29/30	30/31	31/32	32/33	33/34	34/35	Total 10 Yrs
Pharmac current costs	3.90	3.90	3.90	3.90	3.90	3.90	3.90	3.90	3.90	3.90	39.00
Pharmac Medical Devices Ramp-Up cost s 9(2)(b)(ii), s 9(2)(g)(i)	11.45	12.20	11.42	9.41	9.41	9.41	9.41	$9.41	9.41	9.41	100.94
Total cost to Crown over 10 years	***15.35***	***16.10***	***15.32***	***13.31***	***13.31***	***13.31***	***13.31***	***13.31***	***13.31***	***13.31***	***139.94***
Return on $850 million clinical hospital device spend @6%	20.40	38.25	51.00	51.00	51.00	51.00	51.00	51.00	51.00	51.00	466.65
Return on $1.4 billion clinical hospital device spend @6%	33.60	63.00	84.00	84.00	84.00	84.00	84.00	84.00	84.00	84.00	768.60

Table 2: Funding profile (fully resourced) against Returns on Investment to the Crown.

Risks to achieving benefits

64. The combined effects of COVID-19, global supply disruptions, and pandemic inflationary effects have driven up the cost and pricing of medical devices as contracts are negotiated or reviewed (see below graph). While Pharmac has managed price pressures to under 1% per annum across contracted products for 2023/24 and is on track again for 2024/25, these pressures remain.



65. The combined pressures and effects may be further impacted or exacerbated as new technologies emerge and older devices are retired.

66. Pharmac has over 30 years of sustainably managing a national pharmaceutical budget as a portfolio with no overspend or underspend. When taking on a new portfolio there are a range of risks and uncertainties. Pharmac has successfully managed these risks and uncertainties for the various additions that have been made to the pharmaceutical portfolio over the years including:

- Uncertainty about uptake of new investments makes annual budget management more difficult where, for example, the rate and number of patients is hard to predict for a previously untreated patient group. For high-cost items, small volume movements can have a significant budget impact.
- New technologies can emerge that would have significant impacts on delivering good health outcomes but would cost hundreds of millions of dollars over a number of years. Pharmac may have difficulty committing to such significant long-term investments without certainty of a long-term budget pathway.
- New investments sometimes result in ‘lumpy’ expenditure, such as for a new vaccine initial roll out where associated consumables and physical devices are required to administer new medicines; or where practitioners are required to apply and administer new technologies but there are

delays due to health staff capacity to apply the new technology, training to attend, and new procedures to implement.

- Pharmac's historical budget position and 'limited ability to invest' has contributed to a market response where suppliers sometimes decide not to bring their products to New Zealand, as they assume Pharmac will say no.
- Supply chain disruptions are becoming increasingly common and can put pressure on pricing (either directly or indirectly), and/or require Pharmac to list alternative devices.
- External shocks (e.g. disease outbreaks as demonstrated by COVID-19, economic (local and global) shocks) have put significant pressure on the global supply chain, and this has had flow on impacts on Pharmac's ability to create savings.

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

Consideration of possible transfer from Pharmac to Health NZ

68. No analysis has been done on the implementation issues should the government decide that Pharmac not continue to manage hospital medical devices. At a high level this would need to include changes to legislation to remove such responsibilities from Pharmac given medical devices is explicitly included in Pharmac's scope under the Pae Ora Act.

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

s 9(2)(g)(i)

70. There would also be additional costs associated with the transfer of operating expenditure and staff between entities.

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 – Definition of Medical Device:

The definition of Medical Devices has adapted to reflect the evolution of this field and is traversed below.

The Medicines Act 1981 defines a medical device as —

(a) means any device, instrument, apparatus, appliance, or other article that—

(i) is intended to be used in, on, or for human beings for a therapeutic purpose; and

(ii) does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and

(b) includes a material that—

(i) is intended to be used in or on human beings for a therapeutic purpose; and

(ii) does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means (but may be assisted in its function by such means); and

(c) also includes—

(i) anything that is intended to be used with a device, instrument, apparatus, appliance, article, or material referred to in paragraph (a) or (b) to enable the device, instrument, apparatus, appliance, article, or material to be used as its manufacturer intends; and

(ii) any device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations to be a medical device for the purposes of this Act; but

(d) does not include a device, instrument, apparatus, appliance, article, or material of a kind or belonging to a class that is declared by regulations not to be a medical device for the purposes of this Act.

The Ministry of Health has further defined medical devices in its Regulatory Impact Statement of product and activity controls for medical devices 22 (August 2024) as:

1. Medical devices work primarily through physical and electronic means. They include a wide range of apparatus, instruments and appliances, ranging from tongue depressors and surgical gloves through to implantable heart valves and machinery (such as ventilators and CT scanners).
2. Medical devices play a critical role in healthcare delivery, as they enable accurate diagnosis, effective treatment and continuous monitoring of diseases and conditions, improving patient outcomes.
3. Medical devices are generally separated into two groups, with distinct regulatory treatment, and are referred to as:

- General medical devices: Devices that are used for a medical purpose such as surgical gloves through to MRI machines and implantable defibrillators. Additionally general medical devices include software that is used for a medical purpose (called Software as a medical Device – SaMD).
- In-vitro diagnostic (IVD) medical devices: Devices that are used for the examination of human specimens to provide information for diagnostic, monitoring or compatibility purposes, such as point-of-care tests (POCTs) to test for pregnancy or COVID-19 infection.

4. Some individuals and communities rely heavily on medical devices to maintain life (such as pacemakers, glucose monitors and dialysis machines) and support daily living (such as hearing aids, wheelchairs and walking frames).

Accepting the statutory definition and the Ministry of Health's interpretation; Health New Zealand in its Future Operating Model for Procurement (31 July 2022) acknowledged the medical devices definition within its included items in the management of procurement categories, being:

Clinical Equipment	**Clinical Consumable Supplies**
ward and general ambulatory equipment	ward and general ambulatory consumables
surgical equipment	surgical services consumables
medical equipment	medical services consumables
imaging equipment	imaging consumables
laboratory equipment	laboratory consumables
	other clinical supplies

Table 3: Medical Devices inclusions - source: Health NZ Future Operating Model for Procurement (31 July 2022)

The Future Operating Model for Procurement also provided a demarcation of *what is not a medical device or associated thing*, being

Outsourced Clinical Services	**ICT / Digital and Data**	**Logistics**	**Support Services Goods and Services**	**Infrastructure, Buildings and Property**	**Commissioning**
Outsourced medical personnel	IT systems and telecommunications	Freight	Passenger transport / motor vehicles / fleet	Construction materials	Mental health services

Outsourced clinical services	Information technology	Warehousing	Cleaning services and supplies	Construction equipment	Public health services.
Outsourced clinical support services	Software	Patient direct	Food and beverage services and supplies	Design and construction services	personal health services
Medical contractors	Hardware (purchases and leases)	Manual handling lifting equipment	Packaging	Building services	Māori health services
Educational clinical services	ICT infrastructure		Print services	Property management	Health Workforce NZ
	Storage		Office supplies	Utilities	Surgical services
	Security and compliance		Soft facilities management	Medical gases, infrastructure and equipment	Primary health care
	Networking		Waste management		
	Cloud computing		Corporate services / non-clinical services		
	Professional ICT services.		Uniforms		
	Note: the categorisation of items does not include SaMD		Accreditation licences		
			Affiliations / associations		

Table 4: Medical Devices exclusions - source: Health NZ Future Operating Model for Procurement (31 July 2022)

Those items as categorised and listed (i.e. not being medical devices) are the activities required to directly house, resource, and deliver day-to-day frontline services by Health New Zealand, regional governing entities (being established), and hospitals and community health providers.

Appendix B – Questions posed by Ministers and responses:

Q1. ***What is the estimated and/or annualised spend on medical devices?***

Response. Due to inconsistent practices in information collection when purchasing medical device by hospitals, the annual spend needs to be estimated. Pharmac estimates this at between $920 million and $1.2 billion per annum.

Health New Zealand in its Future Operating Model for Procurement (31 July 2022) estimated the clinical equipment and supply spend to be $1.4 billion (projected to now be approximately $1.5 billion).

Q2. ***What are Pharmac's savings targets and over what time period?***

Response. As part of the 2019 FPIM business case, it was assumed that a long-term average cost reduction of 6% per annum was possible, equivalent to the realised savings for medicines. Pharmac estimated these savings in 2022 at $51 million per annum. Using HNZ's more recent estimate of $1.5 billion this could be as high as $84 million per annum. We consider savings would increase to fall within this range after a scale up period ($51 million to $84 million per annum).

Possible extension of the access and benefits to the wider health sector (and potentially the Crown – possible under Pharmac's governing legislation) would likely deliver proportional benefits to the amount of spend involved.

Q3. ***In the delivery of devices – what are the least cost / most value fixed and variable costs options?***

Response. Pharmac currently delivers a system that works for medicines and can also work or be modified for medical devices. Pharmac already manages the majority of medical devices and can scale this across the whole health system, extending the benefits of the Pharmac model to medical devices currently procured by Health NZ.

There are significant opportunities across the health sector and other crown agencies, all of whom have considerable medical device expenditure, to recognise further cost reductions and savings opportunities possible under Pharmac's governing legislation.

With incremental investment in Pharmac's medical device capacity and efficient use and investment in its shared services with medicines; for the cost of $46.78 million ($11.70 million baseline plus $25.08 million in new operational expenditure funding and s 9(2)(b)(ii) in capital) over the first 3 years, Pharmac could return $109.65 million in reduced cost savings.

Over 10 years this is $139.94 million in total cost returning a minimum of $466.65 million in cost reduction savings for reinvestment in improved devices, new health technologies, and extending eligibility and/or coverage to improve health outcomes.

Q4. What devices are currently funded in the Medicines Budget (previously CPB)?

Response. The medicines budget includes medical devices/products dispensed through community pharmacies. For example, these include blood glucose meters and test strips, continuous glucose monitors, insulin pumps, contraceptive devices, pregnancy tests, and drug delivery systems (e.g. autoinjectors and transdermal patches).

Q5. What opportunities exist for devices also in ACC / Corrections showing Pharmac as the engine room of the health system

Response. The legislation that governs Pharmac's purpose and functions does not preclude it from acting on behalf of the Crown and/or other agencies accessing Pharmac negotiated contracted. Pharmac has historically not been directed or resourced to extend its scope of interaction or benefits beyond hospitals.

Pharmac sees the opportunity to work with other agencies to manage the procurement of the medical devices they need, and this adding to the value to the Crown.

Appendix C – A3 2-page presentation

Ministerial Briefing on Pharmac Performance – March 2025 (DRAFT)

Why Pharmac?

Clear Performance and Delivery

- Pharmac's legislated purpose is to secure and manage pharmaceuticals, inclusive of medical devices, to improve health outcomes and benefit New Zealand.
- Pharmac's statutory functions and associated core activities including strategic procurement, contract and supplier lifecycle management, and stakeholder engagement contribute to a sustainable medical device ecosystem.
- Pharmac has specialist capability and can accelerate delivery with increased capacity.
- Pharmac has consistently managed within 1% of its now $1.694 billion medicines budget every year.
- Pharmac has specialist expertise in and is internationally recognised for health technology value assessment and commercial leverage of funding choices.
- Cumulative net savings of approximately $120 million has been achieved by Pharmac from medical device contract activities to date without a primary focus on savings.
- Pharmac has expanded and improved medical device contract management and managed price pressures to under 1% per annum across contracted products for 2023/24 and is on track again for 2024/25 despite significant cost pressures across the economy in recent years.
- Pharmac has close to $700 million of medical devices (approximately 70%) now under 180 active contracts, covering approximately 174,000 individual products from more than 150 suppliers.
- Pharmac has managed over 70,000 changes to contracts in the last 12 months (e.g., pricing, additions, removals).
- Pharmac's work has brought structure and focus to hospital medical device procurement that was absent prior to Pharmac's involvement.
- Pharmac has completed two commercial market share pilots demonstrating benefits above Health's estimated 6% savings target:
  - 22% price reduction for wound care products.
  - between 30% and 40% price reduction for drug eluting stents.
- Pharmac is a stable and trusted government agency which is responsive, agile, and adaptable in a rapidly evolving sector.
- Pharmac is now poised to further mature the work by completing the process of national contracting and increasing category management, enabling Pharmac to accelerate the value-add to health and social outcomes.

Future Opportunities

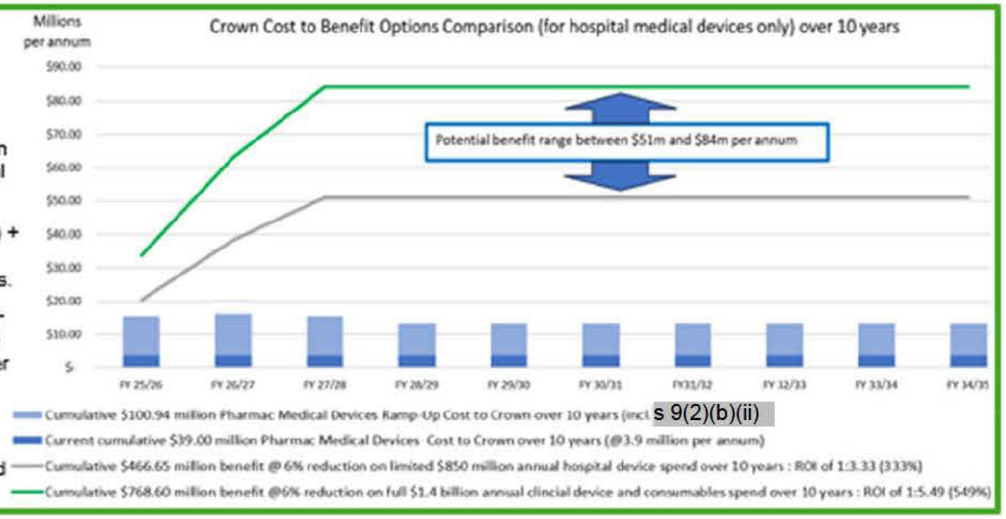
Leveraging Pharmac expertise

Pharmac can give clear focus and accountability to medical device procurement outcomes that is unlikely in organisations that have both operational and funding decision roles.

Calculations based on baseline ($3.9m) + ramp-up (to max $9.41m) per annum + s 9(2)(b)(ii) vs. possible returns.

Assumes new funding of required ramp-up in Pharmac capability being $100.94 million (includes s 9(2)(b)(ii)) over 10 years.

Minimum 6% Return on Investment is 1:3.33 / 333% / $466.65 million over 10 years (inclusive of cost containment and aligned to models used for medicines).



Delivery Dependencies

Operational funding continued for Pharmac medical devices activities for 2025 and beyond.

s 9(2)(g)(i)

Risks to Achieving Benefits

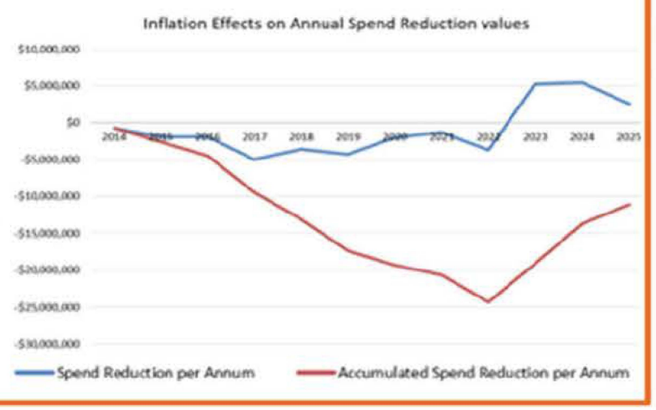
Post COVID-19, global supply, and pandemic inflationary effects.

- The combined effects in recent years have driven up the cost and pricing of medical devices as contracts are negotiated or reviewed (refer Graph).

Poor procurement/purchasing practices hinder progress and compliance.

The state of current processes, data integrity, and lack of compliance within Health systems directly hinder the ability to actively monitor and manage costs.

- 16.64% of devices purchased ($242.840 million) by Health NZ are identified as not from the Pharmac list of medical devices under contract.
- Another 13.37% ($48.869 million) require clarification as to the type and actual products being purchased, and
- 21.17% ($77.344 million) are of unknown spend yet categorized as medical devices or outside the scope of the list.



In Confidence

Ministerial Briefing on Pharmac Performance – March 2025 (DRAFT)

Areas of Responsibility

Pharmac
- Pharmac has a legislated purpose and function to manage medical devices as part of the Pharmaceutical portfolio defined in legislation.

Health New Zealand
- Day to day delivery of health services to New Zealand.

Organisational Areas of Pharmac Investment

Medical Devices
- Pharmac has received $3m to implement Medical Device functions for 2023-2025 and will look to embed learning and improved processes to streamline future Pharmac medical device functions and activities.
- Pharmac will implement improved engagement models with key stakeholders including patient advocacy groups, impacted individuals, medical experts and panels, hospitals, and strategic suppliers.
- Pharmac will scale, with investment, self-contained cross-skilled teams supported by shared services that are aligned to deliver categories and types of medical devices using effective engagement, strategic sourcing, management of contract life-cycles, and responsible fiscal management.

Across the organisation – Direct Support of Medical Devices work and investment to support outcomes
- Advice and Assessment Directorate.
  Triage, applications and assessment functions, management of advisory network, collaborative completion of Health Technology Assessments.
- Equity and Engagement Directorate.
  Engagement facilitation and communications.
- Strategy, Policy, and Performance.
  System level engagement, planning, and performance reporting.
- Māori Advisory.
  Engagement facilitation with Iwi and Māori leaders and advocates.

In-direct Support of Medical Devices work
A range of Corporate functions also indirectly support the efficiency and effectiveness of medical devices activities. These include:
- Roles associated with legal review of national and crown level contracts.
- Roles associated with supporting ICT systems that are critical to medical device ability to function and provide access to contract pricing and benefits.
- Roles associated with analysing spend and environmental impacts to target effectiveness of current and future Pharmac interventions.
- General financial and pastoral care/HR management and reporting.

Initiatives to address the problem

- Create capacity and capability in medical devices proportionate to legislated functions and associated activities to deliver improved health outcomes.
- Utilise capabilities and capacity of functions that are centralised and shared by medicines and medical devices to improve efficiency and reduce cost of effort.
- Due to breadth, variety, and complexity of medical devices – engage a network of experts as required for adaptability and flexibility in preference to employing expertise internally.
- Directly engage clinicians, experts, patients, advocacy groups and suppliers to best understand opportunities, benefits, costs, and impacts of decisions.
- Investigate different funding and revenue/cost models to enable and sustain expansion of medical device access; working with Suppliers and Agencies to achieve the best outcomes.
- Expand access to the Medical Device List or Schedule to the Crown to improve standardisation and mobility of user resources, reduce ownership and product costs, and drive efficiencies.

Maintaining positive progress

The efficiency and effectiveness of how Pharmac delivers its functions and activities are consistently demonstrated from the by-product of the cost reduction savings it generates. No other Crown Agency has shown similar consistent capability to deliver the same level of efficiencies, savings, or effectiveness from their work year–on–year.
Pharmac has demonstrated since 2014 $140m in cost avoided savings from its medical devices work to date where the work was focused on establishing systems and consistent practices rather than savings directly.
The Health sector and government require innovation to break current cycles, which Pharmac, as a stable, low cost, Crown Agency has proven it can be as an effective and efficient circuit breaker to deliver cost reductions and improved health outcomes.

	2023-25	2025 and out-years
Number of suppliers covered by Pharmaceutical Schedule	74%	>90% ↑
Number of devices in (only) hospitals covered by Pharmaceutical Schedule	171,000	>225,000 ↑
Value of devices in (only) hospitals covered by Pharmac national contracts	$830m	>$785m ↑
Estimate of savings per annum from Pharmac medical device activities where fully funded to resource its legislated functions	@$4.7m p.a.	>$45m p.a. ↑

- 2023-25 figures as @ October 2024, out-years based on 90% hospital medical device coverage

Return on Investment from Scope Options

$million	25/26	26/27	27/28	28/29	29/30	30/31	31/32	32/33	33/34	34/35	Total 10 Yrs
Pharmac current costs	3.90	3.90	3.90	3.90	3.90	3.90	3.90	3.90	3.90	3.90	39.00
Pharmac Medical Devices Ramp-Up costs	11.45	12.20	11.42	9.41	9.41	9.41	9.41	$9.41	9.41	9.41	100.94
Total cost to Crown over 10 years	*15.35*	*16.10*	*15.32*	*13.31*	*13.31*	*13.31*	*13.31*	*13.31*	*13.31*	*13.31*	*139.94*
Return on $850 million hospital device spend @6%	20.40	38.25	51.00	51.00	51.00	51.00	51.00	51.00	51.00	51.00	466.65
Return on $1.4 billion clinical hospital device spend @6%	33.60	63.00	84.00	84.00	84.00	84.00	84.00	84.00	84.00	84.00	768.60

s 9(2)(b)(ii)

Given uncertainty in medical device spend, we have modelled savings at the high and low end of the range.

The basis of the return on investment assumes a cost to Crown of the current cost of Pharmac medical devices effort, additional resources as outlined to fully resource the effort to include the overall scope of work, and capital investment in systems needed to support processes.

Actual cost may be funded from new monies or funded through reduction of duplicated effort and cost in Health New Zealand and transferred to Pharmac.

In Confidence