Briefing

Briefing to the Incoming Minister - Medicines

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To:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: ☒ Māori Health Authority: ☐		

Contact for telephone discussion

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Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Briefing to the Incoming Minister - Medicines

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To:	Hon Dr Shane Reti, Minister of Health		

Purpose of report

1. This paper provides you with information as the incoming Minister of Health on the current operating environment for Medsafe and Pharmac and outlines key issues for medicines policy that may require further advice or decisions in 2024.

Summary

2. Medicines play a key role within the health system to improve outcomes for New Zealanders.

3. As the incoming government, you have outlined proposed commitments and priorities with the aim to further improve medicines access and treatment outcomes, including how new medicines are approved, access to more cancer treatments and reviewing Pharmac processes to ensure they are patient-focussed. These commitments, and others, are briefly discussed in this paper, including when you can expect further advice covering the legal, financial and implementation considerations of the options available. The Government has also committed to repealing the Therapeutic Products Act 2023, and you have been provided separate advice on this commitment [H2023033224 refers].

4. Managing the use of medicines is complex, with the system relying on skilled practitioners and infrastructure to deliver its safe and appropriate use. The responsibility for achieving medicines outcomes is shared and delivered by the different entities within the health system.

5. The Ministry of Health | Manatū Hauora (the Ministry) sets the strategies, policies, and system settings for medicines, working with key stakeholder agencies. As monitor we support the Minister in setting expectations and monitoring performance and outcomes within the system. Medsafe and Pharmac, as regulator and funder of medicines respectively, play visible and public roles in medicines, while other entities (including Te Whatu Ora, ACC and HQSC), health professionals and individuals have crucial roles in service delivery.

6. All entities play a collective role in delivering the best possible outcomes for New Zealanders in respect to medicines. These outcomes include improving access, ensuring quality, safety and efficacy of medicines and its optimal use.

7. While aspects of system generally work as intended, there are always opportunities for further improvements. This includes ensuring that individual processes and the wider

system can adapt to the changes and advancements made in the medicines environment.

8. Pharmac is currently working through commitments they made to meet the Government response to the independent review of Pharmac, released in February 2022. These commitments cover recommendations to improve Pharmac's governance, accountability and decision-making as well as more specific areas of cancer, vaccines, rare disorders, medical devices and the responsible use of medicines.

9. Medsafe continues to provide a high-level of assurance that the supply of medicines is safe and effective. As part of the Government's 100-day plan, you will be provided with a draft Cabinet paper before Christmas setting out proposals to repeal the Therapeutic Products Act 2023 and amend the Medicines Act 1981 to enable faster approval times.

Recommendations

We recommend you:

a) **Note** that Medsafe as the regulator of therapeutics products and Pharmac as the public funder of medicines hold key roles in medicines funding, access and independence of regulatory assessments.

b) **Note** that system changes are underway to medicines and other therapeutic products through the repeal of the Therapeutics Product Act 2023 and the Government response to the independent Pharmac Review.

c) **Note** that the Ministry will coordinate further advice with health entities on your priorities to improve medicines outcomes including access to medicines.

d) **Note** that you will receive briefings further advising you on the options and considerations for your priorities related to these entities including:

   i. improving health outcomes of the funding of specific cancer treatments (late 2023)

   ii. Pharmac's future funding requirements s 9(2)(f)(iv) [redacted]

   iii. coordinating the medicines system to improve outcomes, which will include updating the Medicines strategy, updating the Pharmac decision making model and improving regulatory decision timelines (early 2024).

e) **Advise** if there are any topics on which you would like more detailed advice.

f) **Share** this briefing with the Associate Minister of Health (Pharmac) and other associate Ministers of Health with relevant delegations.

Dr Diana Sarfati

Director-General of Health

Te Tumu Whakarae mō te Hauora

Date: 6 December 2023

Hon Dr Shane Reti

Minister of Health

Date:

Briefing to the Incoming Minister - Medicines

Context

10. Medicines play a critical role in the health system and making significant contributions to the health outcomes of New Zealanders. Medicines are the most common health intervention with over 55 million dispensings in the 2022/23 financial year.[1] Medicines provide the opportunity to enhance the quality of life and independence of individuals.

11. The New Zealand health system has well-established structures and highly skilled practitioners working within it to manage complex access and regulation challenges.

Current state

12. In the New Zealand system, no agency or group holds sole responsibility for delivering medicines system outcomes. Rather, the joint efforts of a range of government agencies, individual health practitioners, consumers and industry stakeholders share this responsibility and collectively contribute to the medicines system.

13. The Ministry is responsible for overall strategy, policy, regulation, and system settings. The Ministry also act as the monitor of the health system, supports the Minister to set expectations and monitors performance and outcomes within the system.

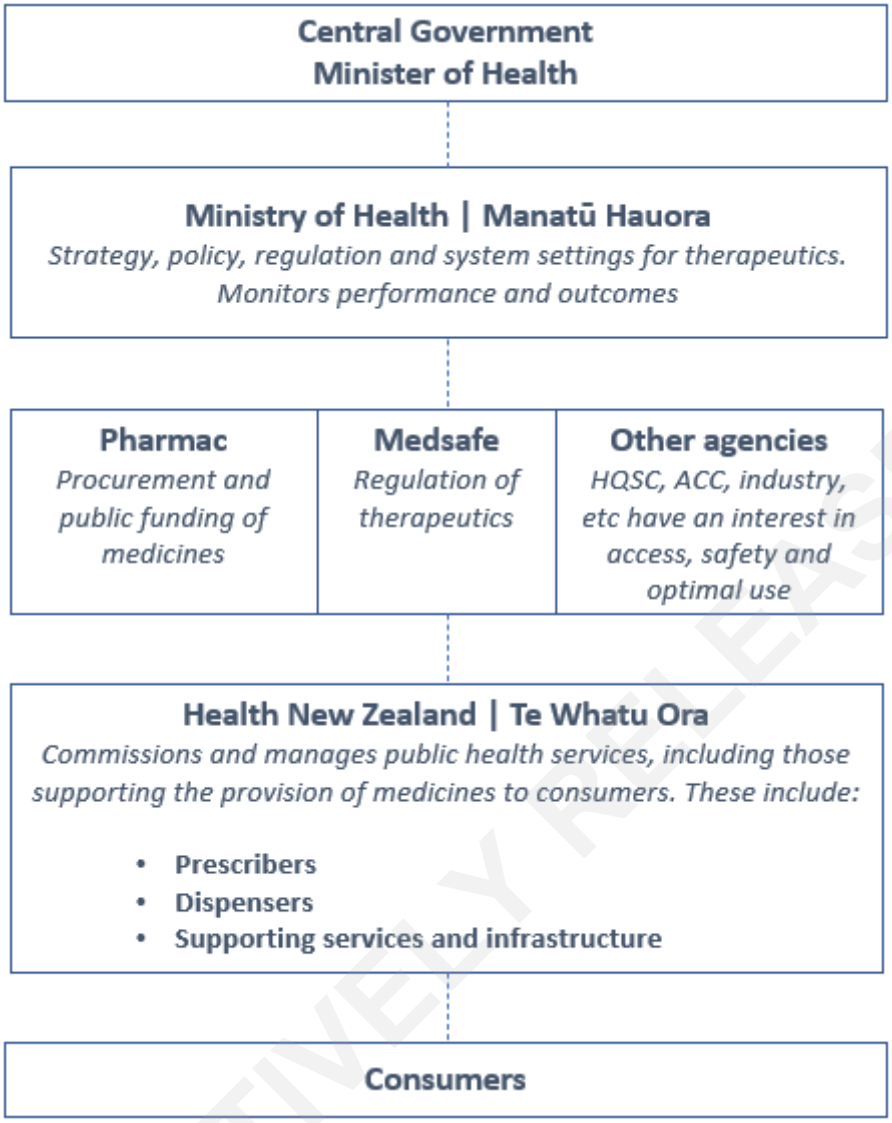
14. A separate briefing advising you on the roles and responsibilities of the Ministry as the monitor of the health system is provided in the briefing: *Performance of the New Zealand health system* [H2023032863 refers].

15. Health New Zealand | Te Whatu Ora (HNZ) commissions and manages public health services, including hospital and specialist services, and primary and community care. The healthcare professionals and services they employ in private, public or community organisations are the prescribers, dispensers and hold other key roles that support the provision of medicines to the public. Other agencies and stakeholders such as ACC and the Health Quality and Safety Commission also have an interest in medicines access and the optimal and safe use of medicines.

16. As the regulator and funder of medicines respectively, Medsafe and Pharmac hold publicly prominent roles in the medicines system and achieving system outcomes. These outcomes include improving access, ensuring quality, safety and efficacy of medicines and optimal use.

[1] **This is based on pharmacy prescription dispensing service claims data (the National Pharmaceutical Collection) for 2022/23**

Table 1: High level summary diagram of the medicines systems



17. Table 1 provides a high-level summary of the medicines system. There are more agencies and groups that manage the range of different responsibilities in the medicine systems, including responsibilities relating to pharmacovigilance and optimal use of medicines.

Challenges and activities within the medicines system

18. There are complex challenges in providing access to effective medicines including:

    a. the number of new, personalised and high-cost medicines and technologies that are being introduced through the medicines approval and procurement processes

    b. medicines prices and delivery costs as public demand for medicines continues with growing and aging population and rising rates of serious and chronic health conditions.

19. Changes to the therapeutics environment aim to help address the complex challenges outlined above. These changes include:

a. legislative reform with the repeal of the Therapeutics Product Act [H2023033224 refers] and to amend the Medicines Act 1981 to enable more approval pathways (including verification) for approval of medicines; and,

b. the implementation of the Government response to the independent review of Pharmac [SWC-23-MIN-0087].

20. Pharmac has been progressing commitments to meet the Government response to the review. These commitments aim to address recommendations on improving patient voice, governance, accountability and decision-making as well as more specific areas of cancer, vaccines, rare disorders, medical devices and the responsible use of medicines.

21. These commitments are ongoing, and are included in Pharmac's strategic priorities in its current Statement of Intent (SOI) and Statement of Performance Expectations (SPE), finalised in 2023, as follows:

a. strategic management of the Combined Pharmaceutical Budget

b. enhanced assessment and decision making

c. strategic management of medical devices

22. The Ministry monitors and advises the Government on Pharmac's delivery progress. Some of Pharmac's commitments have already been achieved, while others are medium to long term and will continue to be actioned over time.

23. The next quarterly report updating you on progress against the Review is due with you in December 2023.

Opportunities for a system approach to improve broader medicines outcomes

24. Medicines errors are recognised as an important cause of patient related harm. Historically, avoidable medicines errors, adverse events and the improper use of medicines have impacted the health of New Zealanders[2]. This can cost the system millions of dollars each year[3], creating ongoing financial and capacity impacts to the health system.

25. Global health systems have recognised the need to coordinate supporting medicine policies, and systems to address the ongoing and complex medicines and prescribing issues (including antimicrobial resistance), reduce medicines errors, and related patient harm. Further system coordination is needed to address broader concerns across medicines quality and safety, as well as ensuring access and optimal use.

26. In New Zealand, the use of medicines relies on complex systems, skilled practitioners and infrastructure to support its timely and appropriate use. Improving medicines outcomes involves identifying the challenges faced by the different agencies, entities,

[2]A historic review estimated this cost to be approximately $222 million. Brown P, McArthur C, Newby L, Lay-Yee R, Davis P, Briant R. Cost of medical injury in New Zealand: A retrospective cohort study. J Health Serv Res Policy 2002; 7(Suppl 1): S29-34.

[3]. A previous study estimated that each year in New Zealand 45,000 people are harmed by medicines with over 2,000 deaths. Robb G, Loe E, Maharaj A, Hamblin R, Seddon ME. Medication-related patient harm in New Zealand hospitals. NZ Med J. 2017; 130(1460): 21-32.

health practitioners and individuals involved at each stage in the delivery of medicines services to the public.

27. There is an opportunity to provide greater direction to the sector on the role of medicines to achieve better health outcomes. The planning, decision-making and delivery actions by Pharmac, Te Whatu Ora, Medsafe and the Ministry collectively effect medicines outcomes. Closer coordination between these key system entities should continue to improve health related outcomes from medicines.

28. The existing medicines strategy (Medicines New Zealand) was established in 2007 to identify where system and broad policy improvements could be made. The strategy identified the following three focus areas where improvements could be made to the:

    a. access to medicines

    b. quality of medicines

    c. rational use of medicines.

Advice on coordinating the direction of the medicines system

29. You have indicated that a priority for this Government is to require the Ministry to publish a Medicines Strategy every three years.

30. The Ministry has begun work with the sector to identify the initial areas to improve health outcomes related from medicines, and to reduce medicines errors and related patient harm. We note, continued engagement with the sector would further identify the areas of work that should be prioritised.

31. We will provide you with further advice on coordinating the direction of the medicines system in early 2024 on options to replace or update the existing 2007 medicines strategy (Medicines New Zealand).

Medsafe assesses medicines for the regulation of therapeutic products

32. Medsafe is a business unit within the Ministry of Health and is responsible for the regulation of therapeutics in New Zealand. Medsafe aims to enhance the health of New Zealanders by regulating medicines and medical devices to maximise safety and benefit by assessing whether they are safe and effective for use.

33. Medsafe's functions include:

    a. making sure medicines meet safety, quality and performance standards

    b. approving clinical trials of new medicines

    c. monitoring reactions to medicines and medical devices

    d. handling complaints, investigations, and recalls of medicines and medical devices

    e. auditing and licensing medicine manufacturers pharmaceutical wholesalers and pharmacies.

34. Medsafe maintains an international reputation as a credible and competent regulator with established processes to efficiently assess medicines. Medsafe is considered an early adopter of reliance pathways by WHO (relying on the approvals of trusted regulators) and this abbreviated pathway makes up a significant proportion of medicine

approvals in New Zealand currently. A verification process is an extension of the reliance model, that provides flexibility for companies who wish to pursue this approval pathway.

35. Medsafe continues to work with trusted international regulators to avoid duplication in medicines assessments, including the below activities.

    a. *Abbreviated (reliance) assessment pathway***.** Under this pathway, Medsafe operates a reliance model to which considers the assessments of trusted regulators such as Australia, USA, UK, Europe and Canada. This provides an efficient process and reduces the duplication of effort. Over half of the applications Medsafe receives are evaluated under this process.

    b. *Involvement in the International Collaboration of Medicine Regulatory Agencies (ICMRA).* As a founding member, Medsafe along with larger global regulators aim to agree and harmonise international regulation requirements, and to share information. During the COVID-19 response, this group agreed on the data requirements and shared information on vaccines and adverse reactions.

    c. *Involvement in various collaborative international groups*. For example, membership in the Pharmaceutical Inspection Cooperation Scheme (PICCS), allows Medsafe to rely on the inspections of other accredited and trusted regulators.

36. Medsafe needs to stay as a credible, full-service regulator that aligns with international best practice to continue to be a member of these groups. Harmonisation of the data required for approvals is key part of Medsafe's ongoing work with medicine regulators internationally.

Advice on regulatory decision timelines

37. You have indicated that a priority for this Government is to improve the regulatory timeframes for the approval of new medicines into New Zealand to closer align with or rely on international counterparts. Specifically, requiring Medsafe adopt a verification pathway in approving medicines that have been approved by at least two overseas regulatory agencies recognised by New Zealand.

38. Through Medsafe, New Zealand maintains a high level of assurance that the supply of medicines is safe and effective. Comparisons with or reliance on international counterparts can be complex, as processes and how those processes are measured vary from country to country.

39. Advice on new approval pathways and timeframes will consider the current settings, resourcing and the level of assurance that is provided so that medicines meet safety, quality and performance standards.

40. We will provide you with further advice and options to take to Cabinet in early 2024.

Pharmac assesses funding and eligibility for medicines and related products within its fixed budget

41. As a Crown agent, the Pharmac Board is accountable to the Minister of Health for its performance in achieving its statutory objective, which is securing pharmaceuticals the best health outcomes that are reasonably achievable from within the funding provided, for the eligible population.

42. Pharmac's functions include:

    a. managing a pharmaceutical schedule[4] that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies

    b. managing incidental matters, including in exceptional circumstances providing subsidies for the supply of pharmaceuticals not on the pharmaceutical schedule

    c. engaging in research to meet its objectives

    d. promoting the responsible use of pharmaceuticals

    e. consulting on matters relating to managing pharmaceutical expenditure.

43. Pharmac plans to provide you a separate briefing further outlining its role, functions, areas of focus and how it will work with you to deliver your Government priorities.

Pharmac decision-making and funding model

44. Pharmac decisions are underpinned by the consideration of evidence on the medicine, recommendations from independent clinical experts, clinical and consumer advisory committees, and public consultation.

45. Pharmac uses a decision-making framework ('factors for consideration') to assess each application for funding. This framework assesses the health need, benefits, costs and savings, and suitability of medicines, considered through the lens of an individual, family, society, and health system.

46. Medicines are publicly funded from one central funding envelope, the Combined Pharmaceutical Budget (CPB). From 2022/23, for the first time, Pharmac was responsible for an appropriation for national pharmaceuticals purchasing. The CPB was previously a notional budget funded from individual district health board budgets.

47. Medicines which are unable to be funded are comparatively ranked and placed on the Options for Investment (OFI) list for when more funding becomes available through savings or uplifts in the CPB. Pharmac publishes that list, unranked for commercial reasons, on its website. Pharmac has estimated that funding all the medicines on the list would cost about s 9(2)(j) [redacted], although the exact value would depend on contracts negotiated.

48. The Ministry acknowledges that Pharmac plays a key role in our medicines system and operates well in ensuring spending does not exceed the CPB. However, it also plays a wider system role in delivering medicines outcomes and maintaining the trust of patients, clinicians and the wider public in reaching its decisions.

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

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

[4] **Under the Pae Ora Act 2022 the pharmaceutical schedule is the list of pharmaceuticals that the Crown intends to supply under a subsidy to eligible persons.**

s 9(2)(g)(i)

Advice on Pharmac's decision making model and funding model

51. You have indicated a priority for this Government is to update Pharmac's decision making and funding model. Specifically, to ensure the decision-making model appropriately takes the patient voice into account and the funding model accounts for positive fiscal impacts on the Crown of funding more medicines.

52. We will work with Pharmac to provide more detailed information on the decision-making and funding models, and options available in early 2024.

Giving effect to policy direction

53. Pharmac gives effect to Government policy when directed by the Minister. Pharmac's strategic direction and targets are set by the Minister through key accountability documents. Pharmac's appropriation for the national purchasing of pharmaceuticals is set through the Budget process (the CPB).

54. To preserve the independence and accountability of Pharmac (and other Crown entities generally), current policy and legal settings do not allow Ministers and/or Crown agents to direct the purchasing of any medicines for specific treatments.

55. Pharmac uses its factors for consideration framework to priorities funding applications. Through this, the Government's and Minister of Health's priorities are considered within its funding decisions.

Advice on funding more cancer treatments and devices

56. You have indicated a priority for this Government is to fund medicines and medical devices to achieve better health outcomes. Specifically, this includes proposals to fund access to 13 more cancer treatments.

57. The Ministry has provided advice in the paper *Options to progress the additional cancer treatments initiative* [H2023033208 refers]. The advice outlines the possible options to progress the initiative, their considerations (including related regulatory, supply, legal and financial (including CPB)) and seeks your preferences for further advice.

58. We note your early direction on these options will support more detailed advice from the Ministry s 9(2)(f)(iv)

Current and future funding of Pharmac

Current level of funding

59. The value of the CPB for 2023/24 is $1.311 billion. It includes all community and hospital medicines, vaccines and medical devices. In 2022/23, Pharmac estimates 365,000 additional New Zealanders benefitted from medicines funding decisions, including:

    a. access to 20 new medicines

    b. widened eligibility to 22 medicines

    c. an estimated $48.9 million was made in savings and reinvested either in new medicines or offsetting cost pressures of existing medicines.

Future funding of Pharmac

60. s 9(2)(f)(iv) [redacted]. Since 2022, there has been a series of short-term funding uplifts to the CPB, which has increased the level of funding up until 2023/24. However, these funding uplifts were time-limited and no funding for 2024/25 or subsequent outyears was provided.

61. The following table highlights the current level of the CPB against an initial Ministry assessment of potential funding requirements to be assessed for Budget 2024.

s 9(2)(f)(iv) [redacted]

62. s 9(2)(f)(iv) [redacted]

63. s 9(2)(f)(iv) [redacted]

Advice on additional funding for Pharmac

64. You have received initial advice on the removal of previous $5 prescription co-payments on medicines and the impact on public demand for prescribed medicines and the CPB

(*Manifesto commitment – Reinstating the $5 prescription co-payment* [H2023033029 refers]). This advice outlines the observed impacts to the CPB and future options on changes to this policy.

65. s 9(2)(f)(iv) [redacted]

Equity

66. Medicines are a key element of healthcare provision, with the potential to make significant contributions to the lives of New Zealanders. There are challenges to ensure that consumers can safely access the appropriate medicines to maintain their independence and improve their quality of life.

67. As a contribution to improving equity of access, Pharmac has undertaken analysis of the inequities for specific patient groups in accessing medicines. For certain medical conditions, Pharmac identified Māori and Pacific people can be disproportionately affected. To address this, Pharmac has used ethnicity as one of the considerations for prescribing to achieve better health outcomes.

Appointments

68. On 30 November 2023, you accepted the resignation of Hon Steve Maharey as the Chair of Pharmac. The current deputy chairperson, Dr Peter Bramley will act as chairperson in the interim. The Ministry provided you a briefing on the acting Chair arrangements in *Pharmac updates* on 30 November 2023 [H2023033285 refers]. We can provide you with advice on the appointment of a new Chair when you are ready to receive this.

Next steps

69. Further supporting advice on specific Government priorities and commitments will be provided as detailed in the table below.

Further supporting advice	
Before the end of 2023	• The funding of 13 more cancer treatments • Pharmac's future funding requirements s 9(2)(f)(iv) [redacted]
Early 2024	In the new year we would like to discuss the timing and advice of: • Coordinating the medicines system to improve outcomes, including options to progress the development of a Medicines Strategy • Improving regulatory decision timelines

70. Officials are available to discuss and can provide further information and advice on other matters raised in this report.

ENDS.

Minister's Notes