Briefing

Medicines Strategy Scoping

Date due to MO:	21 March 2024	Action required by:	N/A
Security level:	IN CONFIDENCE	Health Report number:	H2024035858
То:	Hon David Seymour, Associate Minister of Health		
Copy to:	Hon Dr Shane Reti, Minister of Health		
Consulted:	Health New Zealand: □ M	lāori Health Authority: □	

Contact for telephone discussion

Name	Position	Telephone
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Minister's office to complete:

☐ Approved	☐ Decline	\square Noted
□ Needs change	□ Seen	\square Overtaken by events
☐ See Minister's Notes	\square Withdrawn	
Comment:		

Medicines Strategy Scoping

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Purpose of report

1. This paper provides you advice on the proposed approach to develop a new Medicines Strategy and seeks your agreement to progress this work.

Summary

- 2. In the context of developing a medicines strategy, the paper provides an overview of the New Zealand medicines system including key stakeholders and their roles.
- 3. Due to the complexity of the medicines system, we advise sufficient time for stakeholder engagement to support development of an informed and well supported strategy.
- 4. The paper sets out the broader strategic context set by the Pae Ora (Healthy Futures) Act 2022 (the Act) and references other medicines initiatives in development, noting that some of these initiatives sit under other Ministers responsibilities.
- 5. The Medicines Strategy needs to align with the strategic direction set by the Act, including key documents under the Act, such as the Government Policy Statement on Health, as well as align with other medicines initiatives.
- 6. The strategy needs to drive collective action towards a strategic vision to be tested with stakeholders *Improved use of and access to medicines to enhance the lives of New Zealanders* with engagement on the strategy proposed to focus on three main areas:
 - a. How can we support increased access to medicines and improved outcomes?
 - b. How can we optimise and realise best value from medicines?
 - c. How can we ensure our medicines system is set up for the future?
- 7. We propose that work on system level changes to primary and community settings and the quantum of medicines funding progresses outside of work on the Medicines Strategy but may feed into strategy development.
- 8. Following your agreement to progress this work, we will provide further advice setting out more detail on the proposed consultation and engagement approach, for your approval.
- 9. We aim to have developed a Medicines strategy for your review by the end of the year.

Recommendations

We recommend you:

- a) **Note** the complexity of the medicines system and the need for the Medicines Strategy to align with the strategic direction set by the Pae Ora (Healthy Futures) Act 2022 and medicines initiatives in development, including those sitting with other Health Ministers.
- b) **Note** our advice on a strategic vision to be tested with stakeholders Improved use of and access to medicines to enhance the lives of New Zealanders - and our proposal for an engagement focus on three main areas:
 - 1. How can we support increased access to medicines and improved outcomes?
 - 2. How can we optimise and realise best value from medicines?
 - 3. How can we ensure our medicines system is set up for the future?
- c) **Note** that officials are available to meet with you to discuss the Medicines Strategy scope, approach, and your involvement, including anything you would like the strategy to include or exclude.
- d) **Agree** that the strategy use the definition of medicines set out in current medicines legislation, that includes vaccines but excludes medical devices and natural health products to manage a timely development process.
- e) Agree that work on system level changes to primary and community settings and the quantum of medicines funding is progressed outside of work on the Medicines Strategy but may feed into strategy development.
- f) **Agree** that the Ministry can progress work on the Medicines Strategy as outlined in this report. **Yes / No**
- g) **Note** that we aim to have developed a Medicines strategy for your review by the end of the year.

Dr Diana Sarfati

Director-General of Health

Te Tumu Whakarae mō te Hauora

Date: 20 March 2024

Hon David Seymour

Associate Minister of Health

Date:

Medicines Strategy Scoping

Context

The New Zealand Medicines Context

- Medicines are essential components of healthcare provision, preventing disease, treating illness, managing chronic health conditions, and enhancing health outcomes for New Zealanders.
- 11. Managing the use of medicines is complex, with the system relying on skilled practitioners, infrastructure, and oversight to enable safe and appropriate medicine use.
- 12. The Ministry of Health (the Ministry) develops the strategies, policies, and supports Health Ministers to set expectations and monitor system performance and health outcomes alongside other health sector partners.
- 13. High profile stakeholders in the public medicines system include:
 - a. Medsafe the medicines regulator who process medicines applications and approve medicines for use in New Zealand
 - b. Pharmac who manage the combined pharmaceutical budget and make decisions on what medicines are funded in New Zealand
 - c. Health New Zealand who commission and manage public health services, including hospital and specialist services, and primary and community care.
 - d. The healthcare professionals employed in private, public or community organisations who prescribe, dispense and hold other key roles that support the provision of medicines to the public.
- 14. Many other stakeholders also play key roles in the medicines system including;
 - a. Medicines development and supply stakeholders including the medicines research sector, the medicines industry and pharmaceutical supply chain actors.
 - b. Medicines information and education providers who support the health workforce deliver medicines in line with best practice including the New Zealand Formulary, He Ako Hiranga, the New Zealand Pharmaceutical Society, the Best Practice Advocacy Centre, Health Pathways and the Health Quality and Safety Commission (HQSC).
 - c. Medicines safety and harm prevention stakeholders including HQSC, the Accident Compensation Corporation, New Zealand Pharmacovigilance Centre alongside Medsafe (CARM reporting), the Health and Disability Commission, Responsible Authorities, alongside the medicines workforce.
- 15. The requirement to develop and implement a medicines strategy is a significant opportunity to bring together key medicines stakeholders alongside the people using medicines, to drive collective action and realise improved medicine related outcomes for all New Zealanders.

The Strategic Context

- 16. You have signalled that improving medicines access and outcomes are priorities and through the coalition agreement with the National party, require the Ministry of Health to publish a Medicines Strategy every three years.
- 17. The Medicines Strategy will sit within a broader strategic context set by the Pae Ora (Healthy Futures) Act 2022 and needs to align with the direction and priorities set by the Pae Ora Strategies and the Government Policy Statement on Health (GPS).
- 18. A new GPS, reflecting Government Priorities for the wider health system is due to be published in July 2024.
- 19. The Medicines Strategy will sit alongside other direction setting health strategies and will inform future iterations of the GPS and health sector monitoring.

The medicines work programme

- 20. The paper on the medicines work programme to address Government priorities [H2024036707] provides an overview of medicines initiatives developing at the same time as the Medicines Strategy.
- 21. We anticipate the strategy will be a key piece of the medicines work programme, complementing broader medicines initiatives and the strategic approach to immunisation to set medicines priorities and direction across the health system.
- 22. With key medicines initiatives developing at the same time, there is the opportunity to ensure alignment through coordination across Ministry teams and across Ministers holding responsibilities for medicines initiatives.

Notes on the Medicines Strategy 2007

- 23. The Briefing to the Incoming Minister: Medicines [H2023032866] previously shared with you provides information on the Medicines Strategy published in 2007.
- 24. The previous Medicines Strategy had a focus on a medicines system that:
 - a. delivers quality medicines that are safe and effective,
 - b. improves access to the medicines people need,
 - c. ensures medicines are used effectively.
- 25. The focus areas of the previous medicines strategy remain relevant, but a new strategy is required to align with the context of the current health system and the rapid changes that have occurred in medicines development.
- 26. While progress was made towards achieving the goals of the previous strategy, a sustained focus on medicines as a priority area is needed to drive collective action across the system and deliver on the strategic vision.

Definition of medicines

27. When we refer to 'medicines' in the context of the Medicines Strategy, our proposed definition is the one used in the Medicines Act (1981) and includes vaccines but excludes medical devices and natural health products.

Our proposals for new Medicines Strategy Scope: Aim, strategic vision and areas for engagement and consultation.

- 28. The strategy needs to motivate and drive collective action towards a strategic vision to be tested with stakeholders *Improved use of and access to medicines to enhance the lives of New Zealanders*.
- 29. To work towards that vision, engagement on the strategy is proposed to focus on three main areas:
 - a. How can we support increased access to medicines and improve outcomes?
 - b. How can we optimise and realise best value from medicines?
 - c. How can we ensure our medicines system is set up for the future?
- 30. The rationale for a focus on these three areas is described in the following sections.
- 31. The strategy will outline deliverables and policy changes required to meet the strategic vision, focused on what is required in the first three years.
- 32. Achieving the overarching aim and strategic vision will require consideration of enablers including medicines leadership, roles and responsibilities, stakeholder capacity, consumer factors and behaviours, as well as the physical and digital infrastructure to support and effectively monitor improved medicines use, access and outcomes.
- 33. Strategy monitoring and measurement of success is proposed to include measurement of increases in medicines access and optimal use, feedback from key stakeholders, including medicines consumers, as well as international comparison, and benchmarking measures.
- 34. We are interested in understanding your views of the Medicines Strategy approach and areas of focus and would welcome an opportunity to meet with you to discuss this.

How can we support increased access to medicines and improved outcomes?

- 35. Access to medicines is crucial for ensuring effective healthcare delivery and improved patient outcomes.
- 36. There are a range of pathways for improved access to medicines, including models used by other countries that could be explored during stakeholder consultation.
- 37. While some improvements in access can be achieved via changes in administrative and professional practices within current system settings, such as changes to prescribing models, others are likely to require system changes, for example changes to the Medicines Act (1981) which regulates how medicines can be supplied in New Zealand.
- 38. Evidence supporting a need to focus on increased access to medicines and improved outcomes includes:
 - a. Research identifying that when adjusted for age and historical disease burden, there appears to be a substantial shortfall for Māori in access to and use of the more recently approved and funded medicines across all therapeutics groups.¹

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¹ <u>Māori uptake of medicines - Pharmac | New Zealand Government</u>

b. Variations in medicines prescribing practice data published on the Atlas of Variation² highlighting that some New Zealanders are not prescribed appropriate medicines approved and funded for their health condition.

How can we optimise and realise best value from medicines?

- 39. It is important to note that while medicines offer enormous potential to improve people's lives, they also can cause harm and cost to people, the health system and wider economy.
- 40. Optimal use of medicines is internationally recognised as an opportunity to both improve medicines outcomes and realise greater return on medicines investment.
- 41. Quantifying the full health and economic costs resulting from preventable adverse medicines events is not possible in New Zealand currently due to a lack of joined up data systems and digital enablers.
- 42. Based on international evidence and limited New Zealand based research and data evidence, Ministry clinical advisors have indicated that there are potentially significant spending efficiencies to be realised through optimised medicines use.
- 43. As part of strategy engagement, we recommend exploring digital enablers, data sharing requirements and prioritising medicines health research to support us to better understand the issue in New Zealand and monitor the success of interventions.
- 44. As we already have a commitment from health sector partners to work towards optimised medicines use and reducing medicines harm, we have an opportunity to make good progress in this area if it is a focus area of the Medicines Strategy.
- 45. There are a range of intervention models to improve medicines practice and medicine adherence to reduce patient harm and realise medicines spending efficiencies that the strategy could explore during engagement.
- 46. New Zealand evidence on medicines system costs and risks of harm includes:
 - a. two studies conducted in the early 2000s that identified the costs of hospital admission and further treatment required because of preventable adverse medicine related events was \$158 million in 2001³
 - b. a study published last year on treatment-related hospital admissions found that medicines caused 54% of all healthcare complications and rates of admissions for treatment injuries were 30% higher for Māori⁴
 - c. polypharmacy⁵ rates are increasing due to our ageing population and more people living with multiple long-term health conditions. Whilst polypharmacy can be beneficial,

² Atlas of Healthcare Variation | Te Tāhū Hauora Health Quality & Safety Commission (hgsc.govt.nz)

³ Briant et al (2004) Representative case series from public hospital admissions 1998 I; drug and related therapeutic adverse events, NZMJ & Brown et al (2002) Cost of medical injury in NZ J. Health Services Research & Policy.

⁴ Svensen G, Hikaka J, Cavadino A, Kool B. Ethnic variation in hospitalisation due to treatment injury and complications of healthcare in older adults residing in New Zealand. N Z Med J. 2023 Jul 21;136(1579):70-85.

⁵ Polypharmacy is defined as the simultaneous use of four or more prescription, over-the-counter or traditional medicines at the same time. Polypharmacy increases the likelihood of a patient having side effects, due to the increased risk of interactions between medicines, and with foods or herbal products.

- the risk of an adverse medicines event has been estimated to increase with the number of medicines used concurrently.
- d. a report by an independent expert panel finding that prescription drugs make a significant contribution to road traffic accidents and driver deaths recommended more understanding is needed of driving impairment that might be caused by all types of prescription medication.⁶

How can we ensure our medicines system is set up for the future?

- 47. Whilst current medicines challenges are significant, there are also longer-term medicines challenges that require key stakeholders to come together and consider.
- 48. Evidence supporting a focus on the future medicines system includes addressing:
 - a. increasing medicines demand due to the ageing population,
 - b. considerations for high quality medicines access as part of pandemic preparedness and in response to global supply chain issues,
 - c. how we ensure timely and affordable access to new and innovative medicines that are more diverse and personalised.
- 49. Looking to the future horizon and determining what medicines will be required for our population, and how and where is best to deliver them is needed to support better access and system sustainability in the longer-term.
- 50. The Ministry recently published a Long-Term Insights Briefing (LTIB) on Precision Health⁷ that sets out opportunities and challenges to be considered in the New Zealand context related to precision health, including precision medicines that could be used to inform the strategies.

Recommended out of scope of the Medicines Strategy

- 51. There are some things we recommend as keeping out of scope of work to develop the Medicines Strategy, both recognising work already underway and keeping scope narrow enough to enable us to develop a strategy for your review by the end of the year.
- 52. This includes:
 - a. System level changes to primary and community settings there is significant policy work underway reviewing primary and community system settings that can feed into the medicines strategy, and so we recommend system level changes to primary and community settings is out of scope of the medicines strategy development process.
 - b. Quantum of medicines funding there is also policy work on medicines funding that can feed into strategy development and so we recommend medicines funding work is out of scope of the medicines strategy development process.
 - c. A broad definition of medicines our proposed definition of medicines aligns with current medicines legislation and therefore medical devices and natural health products are recommended out of scope of the Medicines Strategy. Using a broad definition of

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⁶ IndependentExpertPanelonDrugDrivingFinalReportApril2021.pdf (transport.govt.nz)

⁷ <u>Precision health: Exploring opportunities and challenges to predict, prevent, diagnose, and treat disease more precisely in Aotearoa New Zealand. | Ministry of Health NZ</u>

- medicines would add an additional layer of complexity for strategy consultation and development and increase timeframes.
- 53. The Ministry can provide you further information on these topics outside the development of the strategy if requested.

Proposed process overview

- 54. Medicines are an important contributor to the health of many New Zealanders, and we anticipate a high level of interest from the health sector, industry, and consumers. We recommend ensuring sufficient time and opportunity for consultation.
- 55. It is important for the Ministry to lead a well-managed and a balanced engagement and consultation process across all stakeholder groups to hear all voices.
- 56. There is no budget for engagement on the medicines strategy, so engagement will be led and managed by Ministry officials from within existing operating budget.
- 57. We anticipate a wide range of different viewpoints will be gathered during consultation and there is a risk that the strategy will not be able to reflect them all.
- 58. Consultation on the previous Medicines Strategy lasted approximately eight months and involved a three-to-four-month period for written submissions on the proposed content followed by a similar period for follow up stakeholder meetings.
- 59. Our recommendation is to provide a shorter period of for engagement that would still ensure adequate time for both public and more targeted stakeholder consultation and provide adequate notice to stakeholders to support successful engagement and any follow up required.
- 60. We also plan to include stakeholder views gathered from past medicines engagement and the multistakeholder summit on medicines access planned for 29 to 30 April 2024 to inform development of the strategy.
- 61. Our aim is to provide you with a draft of the Medicines Strategy to review by the end of the year followed by Cabinet approval and planned publication early in 2025.
- 62. Our recommendation for a phased approach to Medicines Strategy development is set out in the high-level overview below. We will provide you further detail on our consultation and engagement approach once we have your feedback and agreement to progress work.

Figure 2. Overview of proposed strategy development time frame



Equity

- 63. Equity of access to medicines and equity of medicines related outcomes have been key considerations during development of this advice.
- 64. Pharmac defines medicine access equity as 'the absence of avoidable, unfair, or remediable differences in funded medicine access among groups of people. Those groups can be defined socially, economically, demographically, geographically, or by other means of stratification.⁸
- 65. We are aware inequity of access to medicines exists for some groups of New Zealanders including Māori, Pacific people, older people, and women. Our recommendation is to include a focus on equity of medicines health outcomes for all New Zealanders.

Next steps

- 66. Officials are available to meet with you to discuss the Medicines Strategy including:
 - a. the Medicines Strategy scope proposed aims, vision, and focus areas for engagement,
 - b. your expectations for involvement in strategy development,
 - c. your progress reporting preferences,
 - d. anything else you would like included in the Medicines Strategy.
- 67. We can also provide you any additional information you require.
- 68. Following your agreement to progress this work, we will provide further advice setting out more detail on the proposed consultation and engagement approach, for your approval.

ENDS.

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⁸ Access equity: What it means for Pharmac - Pharmac | New Zealand Government

Minister's Notes