

BRIEFING TO THE INCOMING MINISTER OF HEALTH

Date **5 February 2025**

To **Hon Simeon Brown, Minister of Health**

Copies to

Hon David Seymour – Associate Minister of Health
Director-General of Health – Ministry of Health
Manager System Planning & Accountability, Regulation & Monitoring – Ministry of Health
Principal Advisor, Regulation and Monitoring – Ministry of Health
Pharmac Board

Recommendations

We recommend you:

- a) **note** the information contained in the attached BIM **noted**
- b) **note** that this BIM will be publicly released in due course, and we provide further detail about this once known **noted**



Dr David Hughes
**Acting Chief Executive
Pharmac**

Date: 5 February 2025

Hon Simeon Brown
Minister of Health

Contact

Dr David Hughes, Acting Chief Executive

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Purpose

This briefing provides an overview of Pharmac's role and function and outlines some key areas of focus, including how we will work with you to deliver on the Coalition Government's priorities. We would be pleased to provide more detailed information on any specific area or issue.

Part one: Pharmac's role and function in the health and disability system

Therapeutic products are the most common intervention in health care. Ensuring that New Zealanders have timely and equitable access to a wide range of effective medicines, vaccines, medical devices, and related products, and can use these well, is the main way Pharmac contributes to improved wellbeing and quality of life.

Our work

Pharmac's core objective as outlined in section 68 of the Pae Ora (Healthy Futures) Act 2022 (the Pae Ora Act) is:

“to secure for eligible people in need of pharmaceuticals¹, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided”.

Pharmac are a Crown entity under the Crown Entities Act 2004 and are accountable to the Associate Minister of Health, Hon David Seymour. The Associate Minister of Health appoints Pharmac's Board, which has the powers necessary for the governance and management of Pharmac.

Pharmaceutical Appropriation

Pharmac manages the medicines budget (also referred to as the Combined Pharmaceutical Budget). The level of medicines budget for 2024/25 is \$1.689 billion rising to \$1.794 billion in 2027/28.

The medicines budget comprises government expenditure for all medicines that are administered in public hospitals as well as medicines, some medical devices, vaccines, and related products dispensed through community pharmacies. It also includes vaccines, haemophilia treatments, and other health products provided in other primary care settings (such as nicotine replacement therapies). We do not hold the budget for hospital medical devices this is held by Health NZ.

Our operating budget (circa \$30 million) is used to meet the day-to-day costs of running Pharmac. The operating budget is separate to the medicines budget, and we cannot use medicines budget funding to meet our operational costs.

We manage medicines, vaccines, medical devices and related products

Pharmac helps people live better, healthier lives by deciding which medicines, vaccines, and related products, should be funded for New Zealanders, in a way that is affordable and easy to access.

¹ 'Pharmaceuticals' means substances or things that are medicines, therapeutic medical devices, or products or things related to pharmaceuticals (section 74 of the Pae Ora Act).

We manage contracts with suppliers and work with them to ensure there are sufficient supplies available nationwide. We also establish and manage contracts for medical devices.

We manage New Zealand's fixed budget for pharmaceuticals, including securing savings for reinvestment in therapeutic products and manage the Pharmaceutical Schedule (the Schedule). The Schedule lists all government-funded therapeutic products and related products in New Zealand and includes:

- all nationally funded medicines and related products and some medical devices used in the community
- all nationally funded medicines that can be used in public hospitals
- most government-funded vaccines
- all public hospital medical devices with national contracts
- the rules for dispensing or giving medicines
- the price and subsidy (the amount that it is funded for) of each medicine
- any rules or limits on access to funding for specific medicines or groups of medicines to ensure that the medicines are targeted to the right people.

Pharmac's decision-making process

Because Pharmac operates according to a fixed budget, decisions need to be made as to what pharmaceuticals can be funded and for whom. Pharmac has robust processes in place for evaluating evidence, using our network of specialist advisors to help inform funding decisions. We consider and assess all funding decisions using the [Factors for Consideration](#), the framework used by Pharmac when making funding decisions.

This allows for careful evaluation of clinical and other evidence for the benefits and suitability of a proposal, and to identify and understand the people who will be affected by it.

While our main task is to allocate pharmaceutical funding, we consider the benefits and costs across the whole health and disability system both now and in the future, including the impacts for primary care and hospitals, and we consider direct costs to consumers as well as to all health sector budgets.

Pharmaceutical suppliers, clinicians, consumers and any other interested parties may approach Pharmac to request possible amendments to the Pharmaceutical Schedule (generally referred to as a 'funding application'), using the process described in Pharmac's [funding application guidelines](#).

Pharmac staff and expert advisors consider evidence and perform assessments of funding applications with reference to the Factors for Consideration. The diagram in Appendix One provides a simplified indicative guide to the process that Pharmac will usually follow when assessing a funding application and progressing it for listing on the Schedule. Pharmac is not bound to follow the process set out below and may vary this process or adopt a different process where appropriate.

We also use this same process to review and amend what products are already listed, as we continuously update the Schedule and access criteria for medicines to ensure they are reaching those with the highest health need.

Our current processes already enable us to be responsive and rapid when required. Pharmac is used to working quickly and flexibly to respond to changing landscapes.

We seek expert advice

We undertake evidence based critical appraisal of new products and requests for expanded access to existing funded products. Our expert advisory network provides critical input to Pharmac's funding decision making processes.

We have a range of advisory committees that provide us with expert advice on many topics. These are required under section 71 of the Pae Ora Act. It is difficult to overemphasise the size of this network, breadth of experience and mana of the individual members.

The network advises on new funding applications, therapeutic group/category management issues (such as supply, changes in practice, horizon scanning), and exceptional circumstances funding.

Pharmacology and Therapeutics Advisory Committee (PTAC) is our primary advisory group. PTAC provides objective clinical advice to ensure Pharmac makes the best possible funding decisions. It provides and promotes critical appraisal of the strength and quality of evidence for funding applications. This is applied rigorously, systematically, and consistently across all clinical areas.

Its members comprise experienced health practitioners from a range of specialities, who also regularly work with patients and their families. There has been a consumer member on PTAC since July 2022. Members bring an evidence-based perspective and provide insight on how Pharmac's decisions apply to all people across New Zealand. Information on PTAC members can be found [here](#).

We have 21 further specialist advisory committees (SACs) which provide Pharmac with objective specialist knowledge and expertise within specific clinical areas, such as diabetes, cancer, and mental health.

The SACs have a different, but complementary role from PTAC and their expertise and perspectives can differ from PTAC. When recommendations differ between PTAC and SACs, Pharmac considers the recommendations provided by all our advisory committees when assessing applications.

While long term structures are being developed for expert advice for hospital medical devices, we have established several *ad-hoc* advisory groups to support our medical device category management activities. We have also recently established an interim Medical Device Advisory Group. This group will provide objective, multidisciplinary advisory support to inform and develop explicit, robust and evidence-based frameworks for medical device health technology assessments and other advice required by Pharmac.

The Consumer Advisory Committee (CAC) gives Pharmac a consumer perspective on its work. It advises Pharmac on areas like:

- our strategies, policies and operational activities around funding, access to, and optimal use of medicines

- how we can best communicate our decisions, policies and strategies with consumers, and
- how and when it is best for Pharmac to engage with consumers on its work.

We also work with advisory groups who give targeted advice on specific issues. These advisory groups are *ad hoc* to meet specific needs as and when they arise. This allows for us to move quickly and flexibly to respond to any possible changing landscape.

We manage vaccines in New Zealand

Vaccination is one of the areas where Pharmac plays a major role in wellbeing by preventing illness from starting or spreading in our communities. We manage the funding, purchasing and distribution of most government-funded vaccines in New Zealand. This includes vaccines on the Aotearoa Immunisation Register and COVID-19 vaccines.

Health New Zealand is responsible for delivering the vaccination programme. We work with the Immunisation Outcomes Collective and other cross agency groups to coordinate immunisation activities and services in New Zealand.

We fund treatments for people with exceptional circumstances

We may approve funding of a medicine, vaccine, or related product for an individual through our Exceptional Circumstances Framework.

In this framework, a prescriber may want to prescribe a treatment for someone with exceptional clinical circumstances that is not funded, or that is funded but not for the particular health condition they want to treat. In these situations, we make decisions through a process called a Named Patient Pharmaceutical Assessment (NPPA), where a person's prescriber applies for them to access funding for these treatments. In 2023/24 we received a total 1,824 individual NPPA applications. Numbers have been steadily increasing over the last five years.

Another scenario can occur where a prescriber may want to prescribe a funded treatment for someone who does not meet the funding criteria but meets the intent or 'spirit' of the funding criteria. In these situations, we make decisions regarding whether to waive the criteria for access to the funded medicine. We received 547 waiver applications in 2023/24.

We are working on hospital medical devices

We are applying our expertise and processes to drive better value, more consistent and equitable access to hospital medical devices.

We use the term 'medical devices' to cover a range of things that are used in public hospitals or provided by a hospital service for people to use at home. Medical devices are products, equipment and consumables that are used to diagnose, monitor, treat, modify, prevent or support a health need. This includes things like clinical diagnostic instruments, implants (such as pacemakers), hospital beds, software, robotic surgery machines, surgical products and more. Items such as bandages, continence support products and rehabilitation equipment are also included. While there is a wide range of medical devices, they all support the health and wellbeing of New Zealanders.

Responsible use

We promote the responsible use of medicines, vaccines and related products in New Zealand. We do this by providing information and educational material to health professionals and the public.

Research

Pharmac collaborates with other agencies and organisations to contribute to research projects that are mutually beneficial, including providing funding and sharing data and information. We acknowledge the importance of data sovereignty and will only use data for the purpose for which it was collected.

Part two: Contributing to Government Priorities

Pharmac is guided by legislative, strategic and Ministerial documentation that directs the way we work and what we prioritise. We have received direction on government priorities and objectives through the [Government Policy Statement](#) (GPS) 2024 – 2027 and our [2024/25 Letter of Expectation](#) from the Associate Minister of Health, Hon David Seymour. Pharmac will give effect to relevant actions in the GPS and support, where relevant, delivery of targets and actions across priority areas.

There are three specific actions in the GPS for Pharmac.

Improve the availability of and access to cancer medicines

In June 2024 the Government provided additional funding of \$604 million over four years for the medicines. To date, Pharmac has funded 38 medicines for different health conditions and is currently considering 18 more.

Summary of our progress as of 24 January 2025

Status	Cancer medicines	Non-cancer medicines	Total medicines
Funded	19	19	38
Considering feedback	3	3	6
Consultation open	7	5	12
Total	29	27	56

Currently, the number of people estimated to benefit in the first year of funding so far from the funded medicines or medicines we are consulting on is about 50,000. This number will continue to increase as more consultations are released and decisions are made over coming months.

Enable faster access to medicines by improving the timeliness of processes related to accessing new medicines

We are working to enhance the efficiency of our advice and assessment process. Our key areas of focus are:

- undertaking initial assessments of all proposals to identify rapid assessments and proposals that can be advanced without extensive evaluation
- piloting a rapid clinical advice process in one or two therapeutic areas for lower-risk proposals, exploring the feasibility of seeking expert advice to inform assessments via email outside the formal committee setting
- exploring options to increase capacity and efficiency to manage a high volume of applications reviewed by the Cancer Treatments Advisory Committee (CTAC)
- continuing to review and improve expert advice processes.

We have also expanded our parallel assessment process so we can assess a funding application at the same time Medsafe is assessing the application for regulatory approval. This means that medicines can be considered for funding sooner.

We are continuing to develop Pharmac's model to ensure patient voice and wide-ranging societal consequences are taken into account

Increasing consumer input and patient voice

Since 2019 we have implemented various activities to increase consumer input and patient voice into our assessment and decision-making processes. Whilst progress has been made, as highlighted by the 2022 Pharmac Review, there is more to be done to incorporate consumer advice and lived experience into many aspects of Pharmac's work.

We are required under the Pae Ora Act to act in accordance with the Code of expectations for health entities' engagement with consumers and whānau (the Code). To assess progress against the Code the Consumer Quality Safety Marker (CQSM) Self-Assessment was developed by the Health Quality and Safety Commission as a self-assessment mechanism. We have completed three self-assessments against the CQSM. Work to give effect to expectations in the Code is a key focus for our Engagement Strategy, Engagement Implementation Plan and Equity Policy, all of which are finalised.

The Board Chair commissioned two consumer workshops in November 2024, that ran independently of Pharmac with Dame Kerry Prendergast as the Board appointed Chair. These workshops aim to reset relationships with key consumer representatives and provided an opportunity to hear and work through what representatives consider Pharmac's issues and opportunities from a consumer perspective. An independent report of the meetings will be presented to the Pharmac Board in late February 2025.

Giving effect to the 2024/25 Letter of Expectations

Our [2024/25 Letter of Expectations](#) from Hon David Seymour, Associate Minister of Health contained 21 actions under the four focus areas below that we are working to give effect to:


- organisational culture
- the role of Pharmac
- methods and processes, and
- broader health system priorities and accountability.

We provide regular progress reports to Minister Seymour, which are also provided to your Office, as part of our performance monitoring arrangements.

Part three: Current and emerging issues

We will provide you and the Associate Health Minister with regular reporting or no surprises progress updates on funding transactions or management of supply issues and other items that would be of interest. We have identified a few current and emerging issues to mention below.

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Managing medicines supply issues

Pharmac staff work closely with suppliers on a daily basis to manage demand versus supply and to ensure that risks and challenges are managed (Appendix Two provides a simplified, indicative guide to the process). Pharmac staff also work with Medsafe on supply issues which are impacted by regulatory requirements. We communicate regularly with the health sector to provide information on potential and actual issues and risks of supply through a number of mediums, such as our website, weekly supply issues mailouts and stakeholder meetings.

Annually we manage over 200 supply issues with the significant majority of these being resolved with no patient impact. There are times as part of our management of supply issues, where there is significant public interest. Recent examples include methylphenidate for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and oestradiol patches, a hormone replacement treatment commonly used as part of menopausal hormone therapy. We will provide you and the Associate Health Minister with regular reporting or no surprises progress updates on management of supply issues.

Part four: Who we are and how we work with you

Pharmac is a Crown agent and must give effect to Government policy when directed by you as the Minister of Health or the Associate Minister of Health. Under section 66 of the Pae Ora Act, no direction may be given by the Minister of Health that would require Pharmac to purchase a pharmaceutical from a particular source or at a particular price or provide any pharmaceutical or pharmaceutical subsidy or other benefit to a named individual. This underpins the objective and 'arms-length' role that Pharmac plays in decision-making about funded medicines, devices, vaccines, and related products.

The Government's participation in the process of setting and monitoring Pharmac's strategic direction and targets is formally done by Letters of Expectations, Statements of Intent and Performance Expectations and Output Agreements.

Pharmac's current decision-making framework, the [Factors for Consideration](#), requires us to take account of 'Government health priorities'.

This framework informs all our decisions, and so through this, the Government and Minister’s health priorities (generally communicated through the Letters of Expectations) are embedded into all our work.

Pharmac Board

As a Crown entity, we are governed by a Board of Directors (the Board) whom Hon David Seymour appoints as Associate Minister of Health. The Pharmac Board consists of up to six members – the Chair and up to five directors. The current Chair of the Board is Hon Paula Bennett.

The current Board members are:

Member	Date Appointed	Current Term	Term expiry	Status
Hon Paula Bennett (Chair)	13 May 2024	13 May 2024	30 April 2027	First term
Dr Peter Bramley (Deputy Chair)	10 April 2023	10 April 2023	9 April 2026	First term
Talia Anderson-Town	4 December 2021	4 December 2021	3 December 2024	First term
Diana Siew	23 March 2022	23 March 2022	22 March 2025	First term
Dr Margaret Wilsher	3 July 2023	3 July 2023	2 July 2026	First term

The Board, through its governance arrangements with management, ensures compliance with the law and is the ultimate point for accountability to you for all aspects of the Organisation’s performance. In addition to enacting its legal responsibility, the Board ensures compliance with internal policies and governance documents, modelling and reinforcing the behaviours that it expects the Chief Executive and staff to demonstrate in both in-house and in public settings.

Pharmac Senior Leadership Team

The Pharmac Senior Leadership Team is as follows:

- Sarah Fitt, Chief Executive
- Catherine Epps, Director, Medical Devices
- Dr David Hughes, Director Advice and Assessment and Chief Medical Officer
- Michael Johnson, Director Strategy, Policy and Performance.
- Geraldine MacGibbon, Director Pharmaceuticals
- Dr Nicola Ngawati (Ngāpuhi, Ngāti Hine), Director Equity and Engagement
- Trevor Simpson (Tuhoe, Ngāti Awa), Kaituruki Māori – Director Māori
- *Under recruitment*, Director of Corporate Services and Financial Services.

Pharmac is a small agency with approximately 175 staff with an operational expenditure of circa \$30 million. We manage a budget of nearly \$1.7 billion and funding flows of close to \$2.5 billion for medicines and approximately \$636 million of contracted medical devices spend.

Risk and mitigation

We continuously monitor risks and mitigations. A risk and mitigation list is taken to the Pharmac Board monthly and included as part of our quarterly performance reports to the Associate Minister of Health.

Accountability and monitoring

The Ministry of Health monitors Pharmac's performance on your behalf. The Ministry of Health ensures that the government's priorities and expectations are reflected in Pharmac's governance and accountability documents and ensures each expectation as set out in the Letter of Expectations for Pharmac is appropriately progressed.

Pharmac also provides monthly reports to the Associate Minister of Health that are also provided to your office and reports quarterly on progress toward actions as set out in our Statement of Performance Expectations.

The Board Chair and Chief Executive will meet with you on a regular basis, as you see fit.

Closing comment

We would be pleased to provide more detailed information on any specific area or issue and are looking forward to meeting soon.

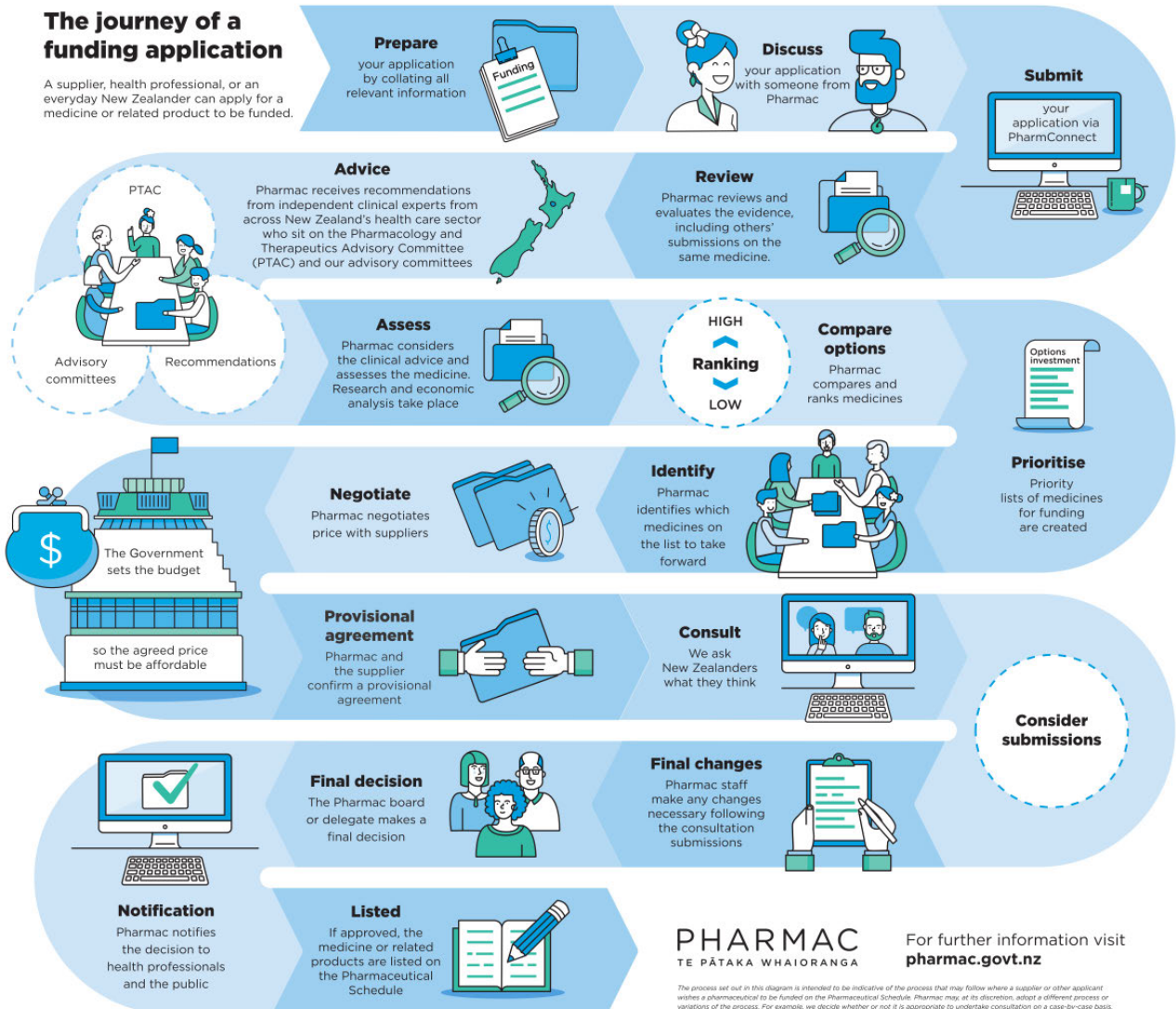


Dr David Hughes
Acting Chief Executive

Appendix One – The journey of a funding application

The journey of a funding application

A supplier, health professional, or an everyday New Zealander can apply for a medicine or related product to be funded.



Appendix Two – The journey of medicines arriving in New Zealand

The journey of medicines arriving in Aotearoa New Zealand

