PHARMAC
TE PĀTAKA WHAIORANGA

BRIEFING TO THE INCOMING MINISTER OF HEALTH

Date **29 November 2023**

To **Hon Shane Reti, Minister of Health**

Copies to

Pharmac Board
Director-General of Health – Manatū Hauora
Manager System Planning & Accountability, Regulation & Monitoring – Manatū Hauora
Principal Advisor, Regulation and Monitoring – Manatū Hauora

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**
c)	**Agree** to share the attached BIM with Hon David Seymour, Associate Minister of Health	**Yes/No**

Sarah Fitt
Chief Executive
Pharmac
Date: 29 November 2023

Hon Shane Reti
Minister of Health

Date:

Contact(s)

Sarah Fitt, Chief Executive 021 529 954

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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

Since its inception, the Pharmac model has worked well, making more medicines, medical devices, vaccines and related products available for New Zealanders, while efficiently managing a fixed budget. This was reaffirmed by the 2022 Pharmac Review and Government response, albeit with improvements to be made (refer to Part Three).

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 pharmaceuticals[1], the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".*

We are guided in all our work by the Pae Ora health sector principles and other key health strategies and plans. An integrated health and disability system will support improved access to and use of, medicine and medical devices. A strong collective focus on te Tiriti o Waitangi and health equity is essential to delivering better and fairer health outcomes. This was also highlighted in the Pharmac Review.

Pharmaceutical Appropriation

Pharmac manages the Combined Pharmaceutical Budget (CPB). The CPB for 2023/24 is $1.497.6 billion[2]. The CPB comprises Government expenditure for all medicines that are administered in public hospitals as well as medicines, medical devices, vaccines and related products dispensed through community pharmacies, and vaccines, haemophilia treatments and other health products provided in other primary care settings (such as nicotine replacement therapies).

Since 1 July 2022, the CPB has been directly managed by Pharmac via a Vote Health Appropriation. We sought this change as part of the health reforms. The appropriation alongside the proposed new multi-year funding arrangements for the health and disability system, due to come into effect from July 2024, bring significant opportunities for Pharmac to better plan and manage the CPB in the medium term. Further detail about CPB outyear cost pressures are outlined in Part Five.

[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).

[2] This figure does not include a one-off payment of $240 million that we have to make in 2023/24 for Novavax COVID-19 vaccines.

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 CPB and we cannot use CPB funding to meet our operational costs. Further detail about operating budget cost pressures is outlined in Part Five.

We manage the Pharmaceutical Schedule

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.

Pharmac manages the Pharmaceutical Schedule (the Schedule) which lists all government-funded medicines and related products in New Zealand. The Schedule includes:

- all funded medicines in the community
- all funded medicines that can be used in public hospitals
- 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) each medicine
- any rules or limits on access to funding for specific medicines or groups of medicines.

Managing the Schedule includes managing continuity of supply of medicines, vaccines and related products. Minimising the impact of supply issues is a collective effort involving us working with the health sector and other agencies.

The Schedule does not provide information about medicines that are not funded, nor whether an unfunded medicine is approved for use in New Zealand or its classification. This information is available on Medsafe's website. The New Zealand Formulary helps identify products that may be used in New Zealand that are not Medsafe approved (and therefore won't be visible on the Medsafe website).

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. The network includes the Pharmacology and Therapeutics Advisory Committee (PTAC), Specialist Advisory Committees and our Consumer Advisory Committee (CAC).

Specialist Advisory Committees

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

The 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 senior 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 (the Chair of the Consumer Advisory Committee). 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 22 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. Three consumer members were appointed to the Specialist Advisory Committee's in March 2023.

The specialist advisory committees 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 specialist advisory committees when assessing applications.

The Consumer Advisory Committee (CAC) gives Pharmac a consumer perspective on its work. CAC 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
- 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 (like we have used for COVID-19) 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.

Te Rōpū

We established Te Rōpū in 2021 to provide Māori leadership and high-level advice and guidance to the Pharmac Board and Senior Leadership Team in respect of Pharmac's commitment to achieving best health outcomes for Māori. We are currently undertaking a planned progress review of Te Rōpū.

We manage vaccines in New Zealand

We manage funding, eligibility criteria, purchasing and distribution of the majority of Government-funded vaccines in New Zealand. This includes all vaccines on the National Immunisation Schedule (NIS), which includes the childhood immunisation programme and the annual influenza vaccine, which is free for eligible people.

Since July 2023, responsibility for decisions about COVID-19 vaccines and management was transferred to Pharmac. Also, funding for COVID-19 vaccines (and treatments) become part of the Combined Pharmaceutical Budget at this time.

Unlike other products we manage, implementation programme management for vaccine funding decisions is managed by Te Whatu Ora. We work across the health and disability system working closely with Manatū Hauora, Te Whatu Ora, Te Aka Whai Ora, the Public Health Agency and other health entities on implementation of vaccine programmes. A cross-agency steering group has been established to support and strengthen immunisation activity. We work collaboratively within the new cross agency immunisation governance arrangements to support the delivery and priorities of immunisations in New Zealand, as members of the Immunisation Oversight Board to exercise strategic governance and an Immunisation Outcomes Collective to exercise operational governance.

We fund treatments for people with exceptional circumstances

We may approve funding of a medicine, vaccine, device or related product for an individual with exceptional clinical circumstances. For example, a prescriber may want to use a treatment that is not funded, or that is funded for other uses but not for their patient's particular health condition. The main way we make decisions in these situations is through a process called a Named Patient Pharmaceutical Assessment (NPPA), where a person's doctor applies for funding to enable their patient to access these treatments.

We also use Special Authority waivers. If a person's clinical circumstances meet the spirit or intent of a Special Authority criteria – but not the exact technical requirement – the person prescribing the medicine can ask Pharmac to waive certain criteria.

We promote funded treatments being used in the right way

We promote the responsible use of medicines, devices and related products in New Zealand. This means making sure funded treatments are not under, over, or mis-used. We do this by providing information and educational material to both health professionals and the public. We are committed to ensuring equitable access to the treatments we fund and to ensuring everyone uses treatments in the best way, so they get the health benefits those treatments offer.

We are also focussed on priority population groups, especially Māori and Pacific peoples, to support them to live healthy lives through improved and timely access to and use of treatments.

Research

We have a statutory function to engage in research as appropriate. We are involved in supporting and/or initiating research that supports our core functions and aligns with our strategic priorities. Pharmac collaborates with other agencies and organisations to contribute to research projects that are mutually beneficial, including providing funding and sharing data and information.

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 to 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 (refer to Appendix One).

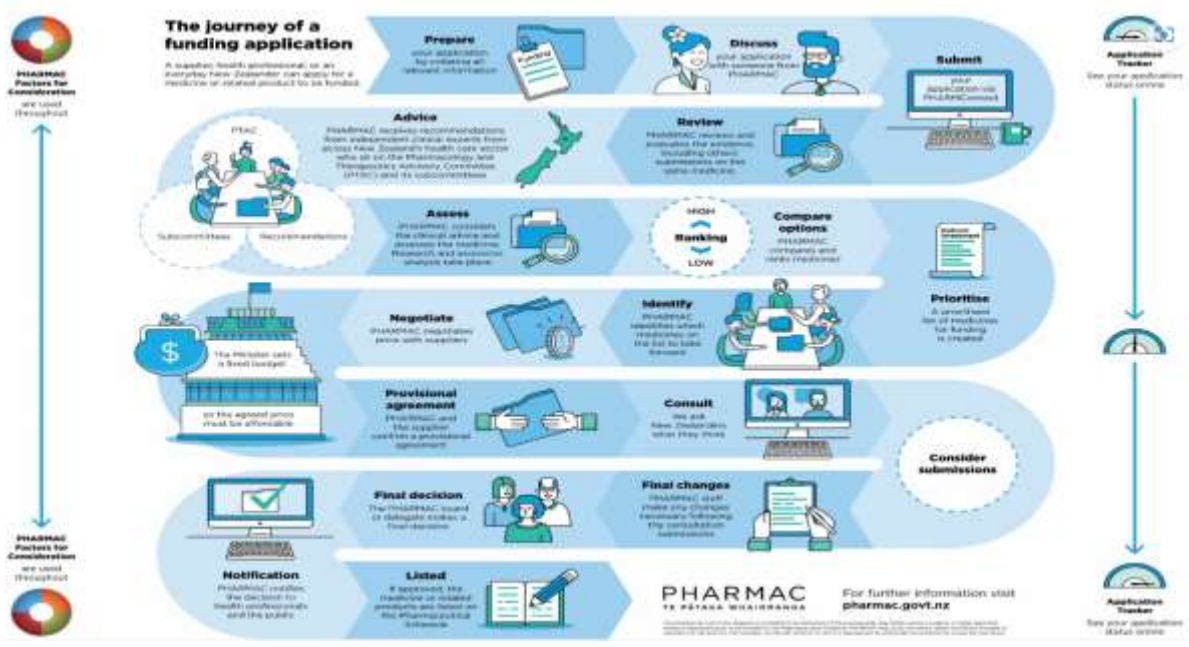
This allows for careful evaluation of clinical and other evidence for the benefits and suitability of a proposal, and to identify and understand the people who will be affected by it. The Factors for Consideration included detailed consideration of the impact on Māori health areas of focus and Māori health outcomes, and equity considerations more broadly.

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 specialist advisors consider evidence and perform assessments of funding applications with reference to the Factors for Consideration. The diagram below 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 is already listed, as we continuously update the Schedule and access criteria for medicines to ensure they are reaching those in need and helping to achieve our equity and te Tiriti goals.



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.

The 2022 Pharmac Review suggested that we revise the Factors for Consideration. Further work and resources are required to consider a revision and we will keep you updated as work progresses.

Part Two: Medical Devices Programme

We are working towards applying the full Pharmac model to hospital medical devices. To date, Pharmac has taken a staged approach to applying our management model due to the significant change involved with transitioning to a centralised model and the lack of any national formulary of devices currently used in public hospitals. Our programme is structured to deliver changes and benefits in three sequential levels of Pharmac management, as capacity and capability is built over time.

Phase One

The first phase has been building a national list of medical devices purchased by Te Whatu Ora (formerly District Health Boards) using national contracting as a tool.[3] This has brought benefits including:

- creating a platform for consistency of access and improved efficiency for both hospital and suppliers
- improving transparency of medical devices market
- delivering cumulative savings of approximately $102 million since it began in 2014 (while savings has not been the key focus of the national contracting phase); and
- establishing good working relationships with all key medical device suppliers as well as building good relationships with key clinical and technical groups.

Once complete, we estimate there will be around 250,000 line items listed covering an estimated expenditure of $850 million in public hospitals. As of 1 November 2023, the Pharmaceutical Schedule includes approximately 163,000 contracted line items from over 100 suppliers. These contracts cover approximately $547 million of annual Te Whatu Ora hospital expenditure on medical devices.

Phase Two

We have completed significant preparatory work for the next phase of our management model which will enable more explicit, robust and evidence-based decisions on what new medical devices are added to the Pharmaceutical Schedule, the generation of market tension to improve public value from expenditure on medical devices and improve consistency, transparency and fiscal sustainability in relation to funding choices across medical devices.

Pharmac currently aims to move to phase two from mid to late 2025 with some dependencies.

[3] Originally it had been anticipated that the Health Finance, Procurement and Information Management System (FPIM) and the Health Sector Catalogue would be the vehicle to achieve this national list, however significant historical delays to delivery of these ICT programmes required Pharmac take this alternate approach.

Phase Three

The final phase will see expenditure on existing medical devices and investment in new medical devices be managed within a fixed funding allocation (likely to be determined by the Coalition Government, as with the Combined Pharmaceutical Budget).

As we have reached key points in the Programme, we have consulted on where we've got to and the feedback is helping us as we progress our devices work. Moving to a new approach will involve a change for Te Whatu Ora, suppliers, people who use hospital medical devices, and Pharmac. We're committed to maintaining a collaborative approach as we keep developing the new way of working together.

Health Sector collaboration on Medical Devices

As with medicines, vaccines and related products funded via the Combined Pharmaceutical Budget, Te Whatu Ora will play an important part in Pharmac's medical devices activities including, but not limited to, technical expertise (clinicians and other professionals) for the assessment of new technology, local and regional sourcing, logistics, distribution and stock management activities.

Recent changes across the health and disability system have brought the management of hospital medical devices, roles and responsibilities, delivery options and the cadence/opportunities for change to the fore. These include:

- the health and disability system reforms, including the establishment of Te Whatu Ora as a single national entity replacing the 20 District Health Boards
- the Government response to the Pharmac Review
- the significant progress made with the roll-out of the Health Finance, Procurement and Information Management System (FPIM) and the development of the Health Sector Catalogue (HSC)
- the recent passing of the Therapeutics Products Act.

These changes present significant opportunities and benefits for accelerating progress for the management of hospital medical devices. We are working closely with Te Whatu Ora to maximise health benefits for New Zealanders from hospital medical devices, drive better value and more consistent and equitable access. We would be happy to provide you with further detail on our medical devices programme.

Part Three: The Pharmac Review and our response

The Independent Review

In March 2021, the Government commissioned an independent review of Pharmac. The Pharmac Review Panel provided its final report[4] to the Minister of Health on 28 February 2022 with findings and recommendations on:

- how well Pharmac performs against its current objectives and whether and how its performance against these could be improved
- whether Pharmac's current objectives (with emphasis on equity for Māori and Pacific peoples) maximise its potential to improve health outcomes for all New Zealanders as part of the wider health system, and whether and how these should be changed.

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, including:

- securing equitable outcomes for all New Zealanders, especially for Māori, Pacific peoples and disabled people
- engaging with and promoting participation and sharing decision-making for Māori and honour Te Tiriti o Waitangi
- making Pharmac's processes, decisions, and the information it holds, more open and accessible to the public, consumer groups and people needing accessible information
- incorporating consumer advice and lived experience into many aspects of Pharmac's work and decision-making including for people with rare disorders
- strengthening collaboration with other health agencies to achieve more equitable health outcomes
- explaining the highly technical work Pharmac does and the impacts it has on people's health and doing this with equity of health outcomes clearly visible.

The Government response[5] to the Pharmac Review was released on 1 June 2022. The Government accepted most of the 33 recommendations made by the Review Panel, noting that the Pae Ora Act addressed many of the directional changes recommended by the Review. We welcomed the review's findings and agreed with key areas for improvement. The findings aligned well with our priorities and work that we had underway or planned or aspire towards.

As well as Pharmac being required to progress actions, Manatū Hauora are also responsible for some actions including developing a rare disorders strategy and contributing to wider Government work on supply chain resilience. We are aware that work on the development of a national rare disorders strategy is well advanced and have provided input and support to this work. We recently called for funding applications for medicines to treat rare disorders.

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[4] https://www.health.govt.nz/publication/pharmac-review-final-report.

[5] https://www.health.govt.nz/about-ministry/information-releases/general-information-releases/government-response-independent-review-pharmac

These will be considered at the next meeting of the Rare Disorders Advisory Committee meeting in May 2024.

One of the recommendations from the Review was for Manatū Hauora to develop an updated Medicines Strategy. We note the Coalition Government's commitment to require Manatū Hauora to publish a Medicines Strategy every three years. We look forward to contributing to next steps for this important work and would be happy to provide any further information you require.

Pharmac's Response

We set out in our interim response to the review in July 2022 where we will work to make initial improvements, making a total of 30 commitments for 2022/23. We have reported progress against these commitments quarterly. We publish our quarterly performance reports on our website. Our upcoming 2022/23 Annual Report will have further detail.

We provided our final response to the previous Minister of Health in mid-November 2022. This provided a long-term view of improvements and changes required which we have outlined in our 2023/23 - 2026/27 Statement of Intent (refer to Part Four below) and 2023/24 Statement of Performance Expectations. We would be happy to provide you with further information on any aspect of the Review or our response.

Part Four: Pharmac's strategy

Our 2023/24 - 2026/27 Statement of Intent (SOI), which came into effect from 1 July 2023, sets out our vision, our strategic priorities and outlines our contribution to the principles and outcomes of the health and disability system. Our new SOI seeks to build on our previous 2020 - 20223 strategy and priorities, with a stronger emphasis on responding to the Pharmac Review and how we embed the expectations of the Pae Ora Act.

Our strategy is built around shaping improvements in the way that we manage and invest in medicines and medical devices. These improvements will be centred in three key areas.

1. ***Strategic management of the Combined Pharmaceutical Budget (CPB)***: There are significant opportunities to better plan and manage the Budget over a medium-term horizon to ensure that we achieve the best health outcomes and health equity for New Zealanders from medicines, vaccines, and related products, while staying within the fixed budget set by Government.

2. ***Enhanced assessment and decision making***: Making improvements to ensure that we make high-quality, evidence-based, and timely funding decisions that achieve equitable health outcomes. We need clear and consistent processes for assessment and decision making, including clarity of how equity considerations and te Tiriti are embedded throughout our work.

3. ***Strategic management of medical devices***: We have built strong foundations for medical device contracting and procurement. With our sector partners there are significant opportunities to maximise health benefits to New Zealanders by implementing an integrated approach to hospital medical devices, which drives better value and more consistent and equitable access.

We intend te Tiriti o Waitangi, health equity, and collaboration and engagement to be key components of Pharmac's activities and initiatives. Underpinned by organisational excellence, they are integral to everything that we do.

The following framework outlines our strategic priorities and the key factors that are woven throughout our work.

Our planned commitments for 2023/24 and how we intend to measure performance are outlined in our 2023/24 Statement of Performance Expectations. This includes improvements that we want to make generally and in response to the Pharmac Review and Government response. We would be pleased to provide more detailed information on any specific area or issue.

We will provide you with regular updates on progress with implementation of our strategy as part of our regular performance reporting to you.

Part Five: Current or emerging issues

We will provide you through our regular reporting or no surprises progress updates on funding transactions or management of supply issues. We are currently working through the procurement process for two significant transactions for continuous glucose monitors, insulin pumps and insulin pump consumables and multiple myeloma treatments.

Continuous glucose monitors (CGMs), insulin pumps and insulin pump consumables procurement

We issued a request for proposal (RFP) in July 2023 to seek bids from suppliers for CGMs, insulin pumps, and insulin pump consumables. The RFP allows us to look at all available products and how they'd be used side by side, comparing them to ensure we fund the best possible products. The RFP closed on 18 August.

We are currently evaluating the proposals received as a result of the RFP and are planning to publicly consult on a preferred proposal in early 2024. Following this consultation process we will take a proposal to the Pharmac Board for approval. We will keep you updated through our regular reporting on progress.

Treatments for multiple myeloma

We understand there is a high unmet health need for people with multiple myeloma. We issued a request for proposal (RFP) on 24 August 2023 seeking bids from suppliers for two medicines, lenalidomide and pomalidomide, for use in the treatment of multiple myeloma. Lenalidomide is currently funded for people with relapsed/refractory multiple myeloma and as maintenance therapy following first-line autologous stem cell transplant. Funding for these people will continue regardless of the outcome of this process. Pomalidomide is not currently funded.

In addition to seeking to secure future supply of lenalidomide for the currently funded group, we are asking suppliers to submit bids that could result in one or both of the following new funding scenarios:

- funding wider access to lenalidomide, for people with previously untreated multiple myeloma
- funding of pomalidomide for people with relapsed/refractory multiple myeloma.

The RFP closed on 11 October 2023. The next steps are for us to evaluate the proposals received and then to publicly consult on a preferred proposal in early 2024. Following this consultation process we will take a proposal to the Pharmac Board for approval. We will keep you updated through our regular reporting on progress.

Access to 13 new cancer treatments

The Coalition Government has made a commitment to increase access to cancer medicines by investing $280 million over four years to fund 13 treatments for solid cancers with that are available in Australia but not in New Zealand. We have been working closely with Manatū Hauora, who we understand intend to provide advice on options for how this could be progressed. We are happy to discuss any aspects of this advice with you.

Budget 2024

Manatū Hauora will provide you with advice on Pharmac's funding at Budget 2024 as part of the wider programme of work on the development of the next 3-year Government Policy Statement. There are a number of Pharmac-specific issues that you will receive advice on in relation to the Combined Pharmaceutical Budget and Pharmac's operating budget.

Combined Pharmaceutical Budget

Recent funding uplifts for the Combined Pharmaceutical Budget (CPB) have been for fixed-term duration:

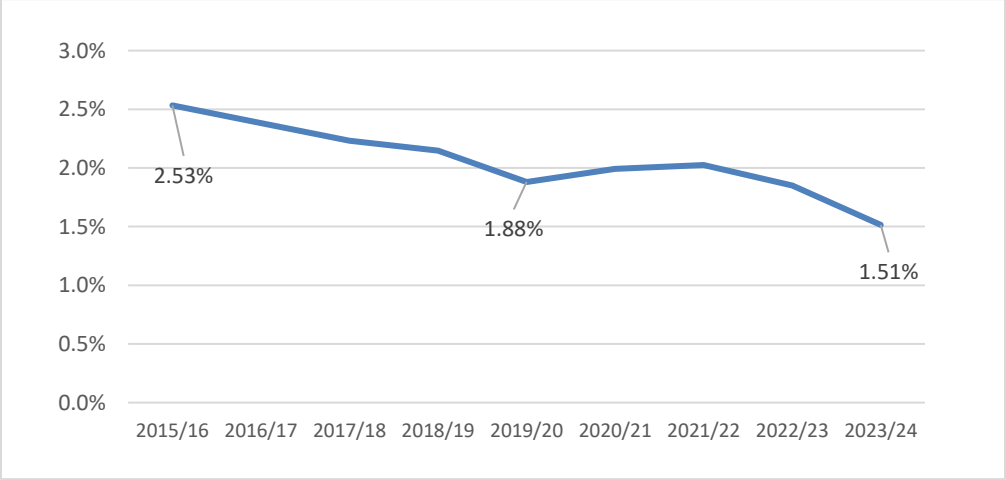
- Budget 2022 provided a CPB uplift of $191 million over two years and a further CPB uplift of $66 million was made in December 2022. No funding was provided for subsequent outyears.
- The addition of COVID-19 vaccines and treatments and the cost impact of the removal of the $5 prescription co-payment, have a combined impact to the CPB of nearly $200 million per year. The CPB was adjusted for 2023/24, but not for outyears.

Operating Budget

Whilst we have grown as an organisation to deliver additional responsibilities over time, our existing operating baseline budget is not sustainable in the medium-term. There are five factors facing us:

- over recent years we have been using cash reserves to maintain operations and these reserves will be nearly exhausted in a few years
- the need to increase capacity, capability and systems to accelerate progress and deliver on next steps for our medical devices programme
- there has been a significant increase in the level of the CPB in recent years and the need to deliver new investments and other associated work and activity. As the CPB has grown our operating budget has not kept pace (refer to Graph One below). We also received one-off operational funding of $1 million in 2022/23 to support COVID-19 work and this was not baselined from 2023/24 despite work being ongoing to manage COVID vaccine and treatments
- the health and disability system reforms, alongside the Government response to the Pharmac Review, mean there are new expectations of Pharmac's work and performance and improvements that we need to make, for example the review of our decision-making framework the Factors for Consideration
- as many organisations experience through growth, IT systems that were once fit for purpose are no longer well-suited to new business needs.

Graph One: Operating costs as % of total funds/contracts we administer (CPB + Medical Devices)



Work on timeliness of assessment and decision-making of funding decisions

We have had a programme of work since 2018 to increase transparency and make our funding assessment and decision-making processes faster, clearer and simpler – while continuing to ensure the robustness of our decisions. We heard from the Pharmac Review that we need to do better to develop clear and consistent practices in our work, including our methodologies, processes and documentation.

There is more that we need to do to improve the timeliness and efficiency of our processes, and this is one of the key focusses of our enhanced assessment and decision-making strategic priority. We would be happy to provide with further detail on current and planned activity.

Increasing consumer input

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

As part of the Pae Ora (Healthy Futures) Act, we are required 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 Te Tāhū Hauora (Health Quality and Safety Commission - HQSC) as a self-assessment mechanism.

We recently completed and reported its first self-assessment against the CQSM for the period from 1 March to 30 September 2023. For this first self-assessment we gave ourselves a CQSM score of 2 consultation (out of 4) which signals that as an organisation, we strive to do more and better with consumer and whānau engagement. As previously highlighted, we have added consumer representatives to our expert advisory committees and we have had patient advocacy groups present to PTAC and SACs.

Work to give effect to expectations in the Code will form a significant part of Pharmac's strategic priorities and our Engagement Strategy, Engagement Implementation Plan, and Equity Policy, all of which are currently under development. We would be happy to provide you with further detail on our work to increase consumer input.

Rule 8.1b of the Pharmaceutical Schedule

Rule 8.1b of the Pharmaceutical Schedule provides a unique exception to usual processes for accessing medicines, allowing clinicians to prescribe off-Schedule medicines to children with cancer and for them to be automatically funded by Pharmac without going through the usual assessment process.

We are looking at the rule as concerns have been raised around its fairness when compared with other groups of people and conditions, such as children with rare diseases, and the growing costs of new cancer medicines. We need to carefully consider if there are good reasons why paediatric cancer medicines should be treated differently to everything else.

Between November 2022 and March 2023, we invited submissions on our review of rule 8.1b. We received a large amount of feedback, in response to this public consultation. Before publicly releasing the summary of feedback, we have re-engaged with the submitters to check that we have conveyed their perspectives accurately and that they are comfortable with the quotes included. This was released to submitters on 23 August 2023.

The 'Summary of Submissions to the Review of Rule 8.1b of the Pharmaceutical Schedule' is now complete and following consideration by the Pharmac Board at its meeting on 27 October, is ready to be publicly released. Prior to any public release, we would provide you with a briefing on the review, next steps and information to support the public release of the Summary.

Emerging new medicines / treatments

In order to ensure the best, most equitable health outcomes for all New Zealanders Pharmac needs to consider emerging medicines and medical technologies and international benchmarks for best practice.

Pharmaceutical companies continue to innovate. Development of new medicines is evolving and changing at a fast pace. The advent of advanced therapy medicinal products (ATMPs) such as cell and gene therapies, pan-tumour anti-cancer agents and new high cost treatments for common conditions such as dementia, cardiovascular disease and diabetes present exciting and challenging opportunities for Pharmac and the health sector.

The unique characteristics of ATMPs – often single-administration treatments with great therapeutic potential, high upfront costs, and incomplete evidence at the time of launch – create challenges for health technology assessment and pricing and reimbursement. In addition, advanced therapy medicinal products often have workforce and service-related implementation issues that require a multi-agency approach.

A relevant example is CAR T-cell therapy, a fast-growing precision medicine that is improving outcomes for people with blood cancer as well as showing potential to improve the treatment of people with solid tumours.

CAR T-cell therapy involves modifying a person's immune cells and reintroducing them back into the person's body so they can attack and destroy cancer cells. At present we are engaging with agencies across the health sector to understand the development and implementation opportunities and challenges with introducing CAR T-cell therapy to New Zealand.

Another example is gene therapy. Gene therapy involves using genes to fight or prevent diseases. It might mean replacing a gene that isn't working properly, adding a "good" gene into a person who has a disease, or blocking a gene that is causing a problem. We have already received funding applications for two gene therapies, onasemnogene abeparvovec (Zolgensma) and voretigene neparvovec (Luxturna). Zolgensma is a gene therapy given as a one-off treatment for babies and children born with spinal muscular atrophy, a rare genetic neuromuscular disorder. Luxterna is a gene therapy that is injected into a person's eyes as a one-off treatment for inherited retinal dystrophy (an inherited disorder that causes severe vision loss or blindness).

We expect that new technologies, including gene therapy and other cell therapy (including CAR-T) will be submitted, assessed and prioritised during this next three-year budget window.

These treatments are likely to be some of the most expensive we have seen to date. These new technologies would require investment in workforce and infrastructure early on, and therefore would require a collaborative effort with Te Whatu Ora and other sector stakeholders.

Part Six: 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. Under section 66 of the Pae Ora (Healthy Futures) 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.

Your participation in the process of setting and monitoring Pharmac's strategic direction and targets is formally done by Letters of Expectation, Statements of Intent and Performance Expectations and Output Agreements. The Statement of Intent is done three-yearly with the most recent one commencing in July 2023.

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 Letter 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 you appoint as 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 Steve Maharey. The current Board members are:

Member	Date Appointed	Current Term	Term expiry	Status
Hon Steve Maharey ((MA (Hons), CNZM)) (Chair)	1 August 2018	4 December 2021	3 December 2024	Second term
Dr Peter Bramley (BSc (Hon), LL.B, PhD) (Deputy Chair)	10 April 2023	10 April 2023	9 April 2026	First term
Dr Anthony Jordan (BHB, MBChB, FRACP)	4 December 2021	4 December 2021	3 December 2024	First term
Talia Anderson-Town (BBS, PG Dip Professional Accounting, CA, CPP)	4 December 2021	4 December 2021	3 December 2024	First term
Dr Diana Siew (PhD)	23 March 2022	23 March 2022	22 March 2025	First term
Dr Margaret Wilsher (MD, FRACP, FRACMA)	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
- Kathryn McInteer, Director of Corporate Services and Financial Services
- Dr Nicola Ngawati (Ngāpuhi, Ngati Hine), Director Equity and Engagement
- Trevor Simpson (Tuhoe, Ngāti Awa), Kaituruki Māori – Director Māori.

Pharmac is a small organisation of approximately 160 staff that manages over $2 billion of health expenditure.

Risk and mitigation

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

Accountability and monitoring

Manatū Hauora monitors Pharmac's performance on your behalf. Manatū Hauora ensures your priorities and expectations are reflected in Pharmac's governance and accountability documents and ensures each expectation as set out in your Letter of Expectations for Pharmac is appropriately progressed.

Pharmac provides monthly reports 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.

Sarah Fitt
Chief Executive

Appendix One – Factors for Consideration

The Factors for Consideration help us assess each funding application against Pharmac's statutory objective. They help us answer the question:

> *'Does the proposal or decision help Pharmac to secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceuticals treatment and from within the amount of funding provided?'*

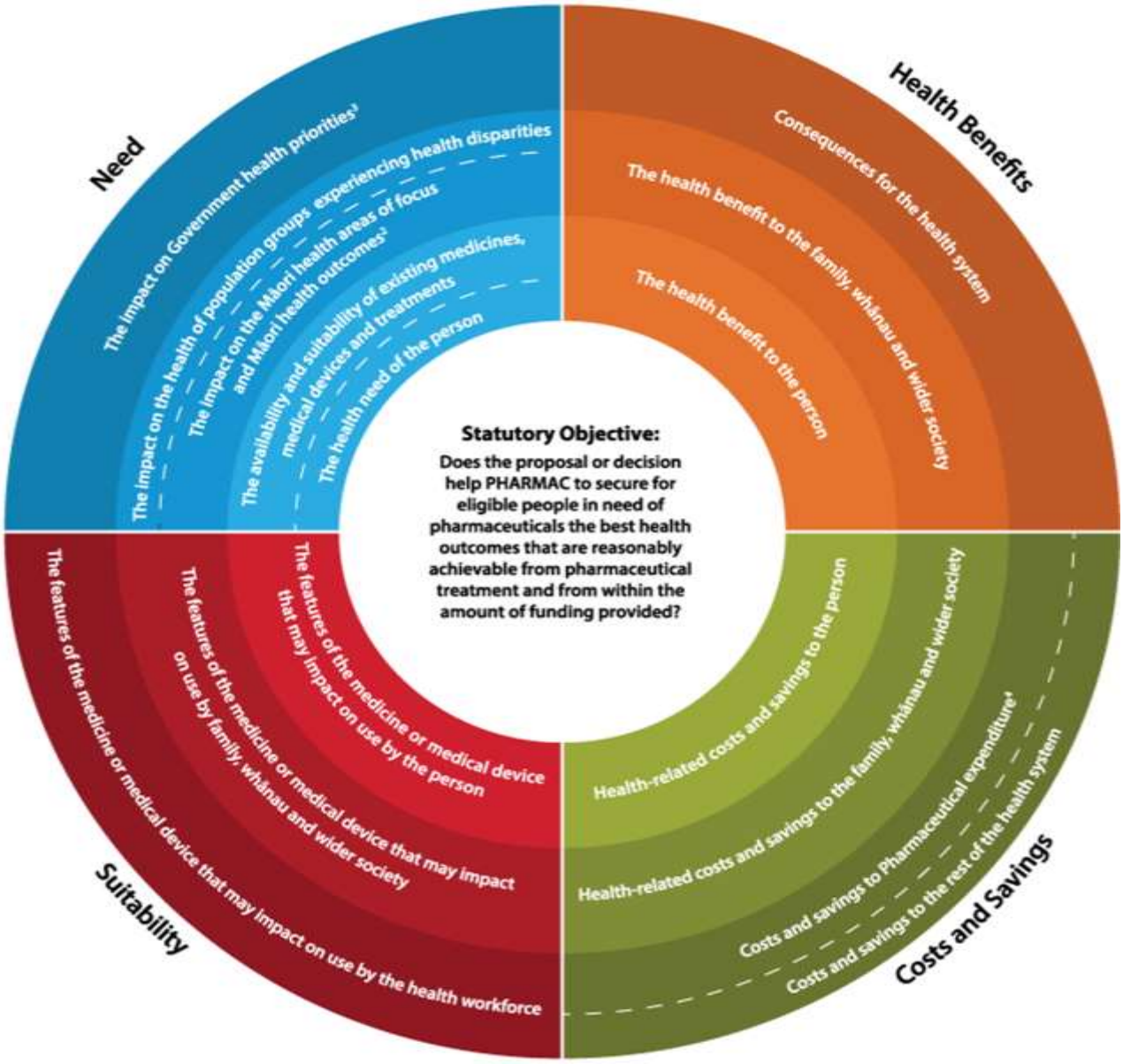
We mainly use the Factors for Consideration when we're making funding decisions, both decisions relating to treatments being listed on the Pharmaceutical Schedule, and also for decisions for individual patients through Pharmac's Named Patient Pharmaceutical Assessment Policy.

The four Factors for Consideration are:

- Need
- Health Benefits
- Costs and Savings
- Suitability.

Each factor has 3 different aspects:

- the individual
- the family, whānau and society
- the health system.



Need

To work out what the level of 'need' is we consider the impact of the disease, condition or illness on the person, their family or whānau, wider society, and the broader New Zealand health system.

The health need of the person:

- *How unwell is a person compared to the average healthy New Zealander?*

One major way in which we consider this is by comparing life expectancy and quality of life at full health and with the disease, condition or illness.

The availability and suitability of existing medicines and treatments:

- *What options are currently publicly funded to treat the population with this condition?*
- *How well do the current options work?*

The 'suitability' of available medicines and treatments includes the practicality, effectiveness or appropriateness in the patient population group.

The impact on the health outcomes of population groups experiencing health disparities

What is the impact of the disease, condition, or illness on other population groups, including Pacific peoples, experiencing health disparities?

This Factor enables us to consider the impact of a decision on those that are facing health disparities as a result of an underlying disadvantage, separately from the illness itself. They may be characterised by ethnicity, culture, location, or socioeconomic status.

The impact on the Māori health areas of focus and Māori health outcomes

- *What is the impact of the disease, condition or illness on Māori health outcomes?*

Has the disease, condition or illness been identified as a Māori health area of focus in our Māori health strategy Te Whaioranga?

Pharmac is committed to improving the health outcomes of Māori and being a great Te Tiriti/The Treaty partner. We work with Māori to identify specific health areas that are important to Māori communities.

Health System

- *Is the disease, condition, or illness a Government health priority?*

The Government chooses some health problems for the whole health sector to focus on. You can find the current health priorities in the Ministry of Health's Statement of Intent, Pharmac's Statement of Intent, Output Agreement and/or Letter of Expectations.

Health Benefits

Health benefit is about the potential health gain from the medicine being considered.

The Health Benefit to the person

We consider, for example, if the treatment will make the person healthier, or help them live a longer life.

The Health Benefit to family, whānau and wider society

A medicine may have health benefits beyond the person receiving the treatment. For example, reducing antibiotic resistance will have positive health benefits for all New Zealanders.

Consequences for the health system

- *If the medicine were funded, what would be the consequences for the health system?*

Pharmac's decisions can have flow-on impacts for the rest of the health system. For example, if support services are required to administer a new treatment.

Costs and savings

We consider the costs and savings to the person and their family, whānau and to wider society. The cost and savings to the health system covers both the pharmaceutical budget and the wider health system.

Health-related costs and savings to the person

For example, the amount a person pays for a GP visit to be able to access the medicine.

Health-related costs and savings to the family, whānau and wider society

Funding a medicine may result in health-related costs and savings to family and whānau of the person receiving the treatment. For example, family and whānau may be caregivers, and a treatment may reduce the need for the level of care and the costs associated with this.

Costs and savings to pharmaceutical expenditure:

- *How would the funding of the medicine or related product impact on pharmaceutical expenditure?*

- *Would funding this medicine result in some savings due to people switching from another pharmaceutical that is already funded?*

Te Whatu Ora have limited funding available for pharmaceuticals used in the community or in hospital, so we need to consider the health outcomes that can be achieved from the limited amount of money available.

Costs and savings to the rest of the health system

Funding medicines or related products can have flow-on impacts for the rest of the health system (the health system refers to New Zealand's health and disability system). For example, if a treatment can be given at home rather than in hospital it would free up a hospital bed for someone else to use.

Suitability

Suitability considers the non-clinical features of the medicine or medical device that might impact on health outcomes.

The features of the medicine or medical device that impact on use by the person

We may consider non-clinical features such as the size, shape and taste of a medicine, or its method of delivery (e.g. oral vs injection) that may affect health outcomes. For example, if a capsule is very large, some people may not be able to swallow it. This could affect their health outcomes.

The features of the medicine or medical device that impact on use by family, whānau and wider society

When family, whānau or members of wider society are the primary caregivers of a person receiving a medicine or medical device, the features of the medicine or medical device may affect their ability to administer the treatment. This in turn may affect the person's health outcomes. For example, it may be easier for caregivers to give a sick person a pill than to give an injection.

The features of the medicine or medical device that impact on use by the health workforce

How the health workforce uses the medicine or medical device may affect the health of the person, for example, a medicine that is easy to use may reduce the likelihood of error or accident.