PHARMAC
TE PĀTAKA WHAIORANGA

BRIEFING

TO THE INCOMING MINISTER OF HEALTH

Date **7 July 2020**

To **Hon Chris Hipkins, Minister of Health**

Copies to

Director General of Health
PHARMAC Board
Lead DHB Chief Executive, Pharmaceuticals
Principal Advisor, Governance and Crown Entities, Ministry of Health

Recommendations

It is recommended you:

- **note** the contents of this report

Contact(s)

Sarah Fitt, Chief Executive Withheld

Purpose

This briefing provides a brief overview of PHARMAC's work and outlines some key areas of focus for PHARMAC.

PHARMAC and its role in the health and disability system

PHARMAC, New Zealand's pharmaceutical management agency, is a Crown agent governed by a Board. PHARMAC was established in 1993 and became a Crown entity under the NZ Public Health and Disability Act 2000 PHARMAC's role, as defined in the Act, is:

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

Investing in the health of New Zealanders

Every year PHARMAC makes more medicines available to more New Zealanders. We play an active role in keeping New Zealanders healthy by funding medicines and vaccines During the 2019/20 financial year, PHARMAC approved the funding of 14 new medicines and widened access for 32 medicines. These decisions have benefited over 70,000 New Zealanders.

We know funded access to effective medicines is important to everyone it's important to us too because we strive to get the best health outcomes for all New Zealanders from the medicines we fund in a fair and equitable way

Initially PHARMAC's role was to manage public expenditure on medicines used in the community those dispensed in community pharmacies As PHARMAC established a successful track record in this area it has been progressively tasked with more responsibilities. These now include managing the funding of medicines used in the community and all public hospitals (including all cancer medicines), vaccines and haemophilia treatments as well as some medical devices used in the community.

In 2012 the Government asked PHARMAC to expand our role to hospital medical devices. We are working towards implementing a model for hospital medical devices similar to the current model for all medicines and therapeutic products we manage under the Combined Pharmaceutical Budget.

The Pharmaceutical Schedule now includes over 115,000 contracted hospital medical devices from over 80 suppliers. These contracts cover approximately $296 million (45%) of District Health Board (DHB) annual expenditure on hospital medical devices

PHARMAC continues to support implementation of the DHBs' National Health Finance, Procurement and Information Management System (FPIM) programme with senior PHARMAC staff and PHARMAC's Board Chair participating in FPIM governance arrangements. In addition to this PHARMAC is engaging in the process for the development of the upcoming Business Case for the Health Sector Catalogue to ensure that PHARMAC's requirements for managing DHB hospital medical devices can be delivered.

PHARMAC's 2020/21 2023/24 Statement of Intent

PHARMAC has recently refreshed its Statement of Intent 2020/21 2023/24 and Statement of Performance Expectations (SPE) 2020/21 which reflect PHARMAC's new strategic direction and strategic priorities As part of this work, PHARMAC has developed a new performance framework with a particular focus on equity, timeliness and transparency indicators. We have also included, for the first time, a set of measures to ensure we are holding ourselves accountable under the Treaty of Waitangi.

Refreshed Te Whaioranga strategy

We have refreshed Te Whaioranga, PHARMAC's Māori responsiveness strategy, and this will be embedded across the organisation over the coming year. This will include identifying and engaging with the appropriate Māori organisations to achieve our goals

The refreshed strategy focuses on six areas (Te Tiriti o Waitangi, Māori leadership, Māori Crown partnership, equity, accountability, and building capability), with clear actions and outcome measures over the next three years to deliver for, by and with whānau Māori

Public trust and confidence

PHARMAC is continuing to build on our work to improve the transparency and timeliness of our processes, and further develop our relationships and communication with the public and other stakeholders. Some of the key activity underway, or being planned, includes; upgrading PHARMAC's website based on user feedback and analytics; reviewing and improving our consultation processes; enhancing PHARMAC's social media presence as a channel for consumer engagement; and initiating regular stakeholder engagement surveys.

Equitable access to medicines and medical devices

Not all New Zealanders are gaining the best health outcomes from medicines funded by PHARMAC, particularly Māori, Pacific people, those living in socioeconomic disadvantage and in rural locations. For Māori, the unmet need is highlighted by research showing a shortfall of over one million prescriptions a year in the community. PHARMAC's responsibilities under Te Tiriti o Waitangi also demand a focus on improving outcomes for Māori.

In 2019 we published an evidence based discussion paper Achieving medicine access equity in Aotearoa New Zealand: towards a theory of change. It has been recognised across the sector as a significant step towards identifying the factors that need to be addressed in the health sector if we are to achieve equity of outcomes from medicines for New Zealanders

Equity continues to be a key focus for PHARMAC We have a comprehensive programme of work in this space, aimed at ensuring everyone can have a fair opportunity to access funded medicines and medical devices.

What makes PHARMAC different?

New Zealand is unique in creating a pharmaceutical management agency that combines clinical, economic and commercial aspects, as well as decision making within a fixed budget

Holistic decision-making

All PHARMAC funding decisions are made using the Factors for Consideration, a holistic decision making framework, developed in consultation with the New Zealand public The Factors for Consideration mean that PHARMAC doesn't just look at cost-effectiveness, we also consider evidence relating to health need, health benefits, costs and savings, and suitability. For each of these factors we consider the impacts on the person; the person's family, whānau and wider society; and on the broader health system

Evidence-informed

All PHARMAC's decisions are underpinned by evidence. Objective expert advice on the evidence is provided by the Pharmacology and Therapeutics Advisory Committee (PTAC), and its 20 subcommittees in speciality areas such as cancer, diabetes and mental health. Altogether about 140 New Zealand health professionals provide independent expert clinical advice to PHARMAC through these committees. The Terms of Reference for these committees are currently under review

In addition, our Consumer Advisory Committee is a statutory Committee providing advice to PHARMAC from a consumer or patient point of view. The role and function of this Committee is currently under review.

In conjunction with the Consumer Advisory Committee, we are exploring options for increasing consumer input in our work, including involving consumers during the expert clinical advice stage of our decision making.

PHARMAC has strong relationships with a number of consumer advocacy groups, which we are building on We have completed several planned consumer related activities already in 2020 including; developing a database of consumer advocacy groups; initiating regular meetings with key groups involving consumers in the development of materials for health professionals; and supporting Pacific consumers by developing materials to encourage the Pacific community to keep taking their medicines regularly

Commercial know-how

Globally, New Zealand is a small player, representing just 0.1% of the medicines market. Yet PHARMAC pays some of the lowest prices in the world for medicines. This is because we negotiate with, and encourage competition between, pharmaceutical companies to reduce their prices.

PHARMAC's approach goes well beyond procurement, seeking to actively manage markets for pharmaceuticals so it can seek out opportunities for savings. We employ a wide range of commercial strategies to promote competition amongst suppliers, leading to long-term and sustainable reductions in the cost of medicines This enables PHARMAC to free up funding to create additional "headroom" which, along with any budget increases approved by the Minister of Health, is used to fund more medicines.

COVID-19 response

PHARMAC's two key priorities during the COVID-19 pandemic response have been to support the health sector to respond to the pandemic and to ensure uninterrupted supply of medicines and medical devices.

Supporting the Health Sector

Changes to funding criteria

At the beginning of the COVID 19 pandemic, PHARMAC reviewed the funding criteria for several medicines, with the aim of making changes that would support the health sector and ensure that people could continue to have access to currently funded medicines The nature of these changes was broadly to make it easier for primary care clinicians to initiate (or continue) funded treatment and to facilitate the provision of healthcare away from hospitals

Now that New Zealand has moved out of lockdown restrictions, PHARMAC is consulting with the sector on a proposal to maintain some of these temporary changes indefinitely, and reverse others in a staged approach over the remainder of 2020.

Supply Chain Management

COVID-19 has had global impacts on manufacturing and supply chains. This has affected supply of some medicines and devices in New Zealand and required active management from PHARMAC.

Globally, supply chains are starting to develop more resilience as they pivot to alternative routes, inventory management practices and modes of transport. However, it is anticipated that supply will be unpredictable and more prone to interruption well into 2021

Dispensing frequency rules

On 27 March 2020, PHARMAC put in place Pharmaceutical Schedule rule changes that restricted the dispensing of funded community medicines to just one month's supply at a time. This decision was made in response to the stockpiling of medicines and the closure of borders which may have impacted ongoing supply.

From 1 August 2020, PHARMAC will be easing this restriction so that pharmacists will again be able to dispense three months' supply for most medicines. Following consultation with suppliers, distributors, and wholesalers, we are confident that, for most medicines, there is sufficient stock in New Zealand to support this approach

Temporary one-month-dispensing restrictions will continue for some medicines, and oral contraceptives will continue to be restricted to three month dispensing (not six months as was permitted pre-COVID-19).

Alternate supplies and pricing pressures

There have been a number of stock shortages of funded medicines in New Zealand over recent months. However, PHARMAC has worked closely with suppliers to find alternative supplies of medicines affected This has avoided any scenarios where patients have missed out on treatment, but in some situations, patients may have had to change brands or attend a pharmacy more frequently to collect their medicines.

PHARMAC staff have been communicating regularly with the sector on these issues and keeping the Minister of Health's office informed through "no surprises" notifications

In response to the financial pressures introduced by COVID 19, some suppliers have proposed significant price increases or asked for assistance with freight or exchange rate costs. PHARMAC has negotiated, and continues to negotiate, cost relief proposals with several medicine and device suppliers

Budget bid COVID-19 Relief Fund

DHBs received an additional $35 million from the Government for Combined Pharmaceutical Budget related price impacts to contribute to ensuring supply of essential medicines $25 million has been allocated to the 2019/20 financial year, with the remaining $10 million allocated to 2020/21

PHARMAC has submitted a budget bid to the COVID 19 Relief Fund from 2020/21 for the Combined Pharmaceutical Budget, to provide additional funding to ensure the continuity of supply of medicines and medical devices in response to global supply issues caused by COVID 19

The funding would be used:

- to meet higher medicines prices caused by factors such as cost of freight, exchange rate movements and increased demand
- to fill an anticipated gap in funding that would have been made available by PHARMAC's savings activities. PHARMAC has had to delay a number of savings transactions that were planned over the next two years and beyond, and we also expect that future prices achieved through these are likely to be less competitive than originally envisaged. This means significantly less “headroom” will be available to reinvest in future medicine funding decisions.

COVID-19 vaccine

PHARMAC, in conjunction with the Ministry of Health, Medsafe, MBIE, and MFAT, is on the Task Force set up to oversee implementation of the COVID 19 vaccine strategy The strategy aims to secure a vaccine that is safe and effective, in sufficient quantities, at the earliest possible time.

Other current issues

Funding new medicines

One of PHARMAC’s key ongoing challenges is that New Zealand consumers continue to hold high expectations about access to quality health care, including medicines and medical devices, with consumers often comparing New Zealand unfavourably with other countries.

However, the opportunities for investment in new medicines will always exceed the budget PHARMAC has available PHARMAC often needs to make difficult choices about which new medicines to fund with the available funding. Comparative ranking is an intrinsic part of PHARMAC’s work.

Patient groups continue to advocate for specific medicines, including through the Health Select Committee.

An example is nusinersen (Spinraza), a high cost treatment for the rare disorder Spinal Muscular Atrophy (SMA). PHARMAC has recently advised Biogen, the supplier of Spinraza, that we are not seeking to progress the funding application for nusinersen at this time due to its low priority for funding compared to other medicines awaiting funding Nusinersen remains an option for funding and we have encouraged the supplier to submit an updated proposal to PHARMAC with revised pricing and/or updated evidence if this becomes available

Immune checkpoint inhibitors RFP

PHARMAC has recently postponed the planned Request for Proposals (RFP) for immune checkpoint inhibitors (which includes Keytruda) for lung cancer and other indications. This is due to the considerable uncertainty around the impact of COVID-19 on the 2020/21 Combined Pharmaceutical Budget, and whether there will be sufficient funding next year and beyond for a new investment of this magnitude.

There has been extensive media coverage of the postponement, and there may be further media interest in the impact of COVID-19 on funding applications more generally.

Diabetes medicines RFP

PHARMAC issued a Request for Proposals (RFP) in January 2020 for the supply of a range of oral diabetes agents: SGLT 2 inhibitors, GLP 1 agonists and DPP-4 inhibitors, the first two of which are currently unfunded medicines. The RFP closed on 16 March and staff are currently evaluating the commercial proposals received. We are seeking advice on the bids from PHARMAC's Diabetes Subcommittee. The RFP originally anticipated proposed decisions being announced in July 2020, however the process has been delayed Some diabetes advocacy groups are aware of the delay and may also link this with the recently announced delay to the immune checkpoint inhibitors RFP

PHARMAC hopes to progress this work, however, the extent to which new diabetes medicines can be funded largely depends on the availability of funding in out years to meet the ongoing costs of an investment of this size.

Lamotrigine brand change

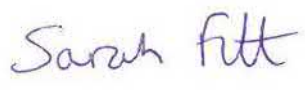
Following intense public scrutiny over its decision to move to one funded brand of lamotrigine in 2019, PHARMAC recently commissioned Jonathan Coates at Claro Law to undertake an independent review of the lamotrigine brand change. The review considered whether the decision-making and implementation processes followed by PHARMAC in relation to the lamotrigine brand change were appropriate It also identified areas in which PHARMAC could improve its processes for future brand changes. The reviewer acknowledged that the PHARMAC Board had sufficient evidence to make the decision to move to one brand of lamotrigine The review noted that it would have been preferable if PHARMAC had sought further input from PTAC and involved its Consumer Advisory Committee in the decision-making and implementation processes. PHARMAC already has work underway to understand how we could better incorporate consumer input into our decision making and review the role of the Consumer Advisory Committee, and the review's findings will influence future work planned in this area.

Response to the Health and Disability System Review

While PHARMAC was specifically excluded from this review, the recommendations will have implications for our work. We are considering opportunities to engage with the sector to support the outcomes of this review

Closing comment

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



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