PHARMAC
TE PĀTAKA WHAIORANGA

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13 March 2020

Dr Shane Reti MP
Parliament Buildings
Wellington

CC: Hon Dr David Clark, Minister of Health

By email: [redacted]

Dear Dr Reti

Failure to disclose information regarding meningitis vaccines

I am writing to apologise on behalf of PHARMAC for process failings in responding to your 10 December 2018 Official Information Act request for "all information and communications relating to Meningococcal W disease in 2018…".

Prior to PHARMAC's 18/19 Annual Review hearing at the Health Select Committee we were asked a number of written questions as to whether specific information had been disclosed in response to your request. We have also been asked to assist the Ombudsman with an investigation into our response. As a result, we have now completed an internal investigation into this matter.

It is clear that a significant portion of information within scope of the December request was not included in our response. Given the amount and significance of the information which was left out, this was a significant error on our part, especially given the constitutional importance of Members of Parliament being able to access information and scrutinise the actions of government agencies such as PHARMAC. However I can assure you that this was an inadvertent error made by staff under pressure who were acting in good faith.

I set out below some more detail about what went wrong and also the changes we have since made. I have also shared this information with the Chief Ombudsman, and we will be providing updated responses to the Health Select Committee to acknowledge our error.

What went wrong

Your December request was broadly framed and with hindsight PHARMAC should have promptly scoped the request and considered whether it was appropriate to engage with you to narrow or refine it. This was entirely PHARMAC's responsibility, but it did not occur and as a result we attempted to respond to this very large request.

Unfortunately the request also came at a time when we were experiencing significant resource constraints and increased demands on our Communications team, which at the time was responsible for processing OIAs. In addition, subject matter experts responsible for vaccine management were extremely stretched, both responding to the Northland Meningococcal W outbreak itself and a range of other matters.

As a result of these factors, staff responsible for our OIA process at the time found it challenging to assemble and process the relevant information, and in the event relevant information was missed.

Changes we have made

Since the time of our response to your December request we have made a number of significant changes to our approach to handling OIA requests. These include:

- Establishment of a standalone OIA processing function, separate from the Communications team (this is now hosted within our Policy team);
- Recruitment of an OIA specialist to provide overall management of the OIA process;
- A weekly triaging meeting for new requests which is attended by legal, information management, and analysis staff;
- Weekly reporting to the business, including the responsible senior manager, of the status of all current OIAs; and
- An ongoing programme to review and formalise of our business processes in relation to OIAs.

I have a high level of confidence that these steps have addressed the underlying issues that led to our failure to fully respond to the December request.

It is my understanding that, following your subsequent request and written parliamentary questions, you now have all information that you wish to receive – either through your subsequent OIA requests and parliamentary questions, or our appearances before the Health Select Committee. Please feel free to contact me if this is not the case. I would like to close by once again offering my apologies for our process failing in responding to your original request.

Yours sincerely

Sarah Fitt

Sarah Fitt
Chief Executive
PHARMAC

From: Jane Wright
Sent: Tuesday, 17 March 2020 11:47 am
To: [redacted]
Cc: [redacted]
[redacted] Lizzy Cohen
[redacted] Rachel Read [redacted]
Subject: No surprises on the Application Close Out project – tranche two.

Hi [redacted]

This is a 'no surprises' update for the Minister on the Application Close Out project – tranche two.

On Wednesday 18 March we will be publicly notifying 17 pharmaceutical applications that PHARMAC will formally decline as part of the Close Out project. We will be notifying on our website; no proactive media is being planned.

Background

PHARMAC is committed to making our decision-making process faster, clearer and simpler. We have heard from New Zealanders that they want PHARMAC to make definitive decisions on funding applications, so they can have some certainty, even if this is a decision to decline funding.

To give people more clarity about what we may – and may not – fund, PHARMAC is making decisions to decline funding for a number of inactive applications. This will make it clearer to everyone whether a medicine is, or is not, being actively considered for funding.

There are several reasons funding applications may be declined including:

- Our expert clinical advisors recommended that the funding application be declined more than two years ago.
- Other medicines for the same condition are now funded, making the funding application irrelevant.
- The medicine would provide no additional benefits over other treatments we already fund or may be harmful.
- No company is able to supply the medicine in New Zealand.

In July 2019 we declined eight applications as part of tranche one of the Application Close Out project. We notified on our website and prepared reactive messages, but there was no media interest.

We identified a further 20 inactive funding applications for medicines that impact a wide range of people. In December 2019 we consulted widely with interested parties such as suppliers, clinical experts and patients, before making a decision whether or not to decline these applications. We received feedback as part of the consultation process that led us to decide to not decline three of the 20. These three will go back to the appropriate subcommittee for further review.

Applications considered for decline

The pharmaceutical applications that will be declined are:

- Naltrexone hydrochloride (low-dose) for Henoch-Schonlein purpura
- Dipyridamole 200mg for stroke prophylaxis

- Dipyridamole 200mg + aspirin for stroke prophylaxis
- Niacin (nicotinic acid) + laropiprant (extended release) for hypercholesterolaemia and mixed dyslipidaemia
- Prasugrel for percutaneous coronary intervention (PCI) procedure in patients with diabetes
- Aliskiren for hypertension
- Fenofibrate for hyperlipidemia
- Clindamycin for prophylaxis of haematogenous infection of prosthetic joints during dental interventions
- Golimumab as a second-line TNF inhibitor in ankylosing spondylitis
- Golimumab as a second-line TNF inhibitor in psoriatic arthritis
- Omega-3 fatty acids for augmentation of antipsychotics in schizophrenia
- Everolimus as second line therapy in metastatic renal cell carcinoma
- Octreotide (long-acting) for small intestinal neuroendocrine tumours (SI-NETs), metastatic or unresectable
- Bovine lipid extract surfactant for pulmonary distress
- Ciprofloxacin and hydrocortisone ear drops for chronic suppurative otitis media
- Paediatric oral feed (Neocate Nutra) for food allergies
- Oral supplement 1 Kcal/ml to 2 Kcal/ml (Enprocal) for nutrition supplementation

The three that are not being declined and are going back to their appropriate subcommittees are:

- Clodronate for osteoradionecrosis
- Certolizumab for rheumatoid arthritis
- Fluticasone in combination with salmeterol (high dose) for asthma and chronic obstructive pulmonary disease

PHARMAC are preparing reactive messages for any public or media interest we receive.

If you require further information about the Application Close Out project – tranche two please let me know.

Jane Wright

Jane Wright | senior communications advisor

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PHARMAC
TE PĀTAKA WHAIORANGA

BRIEFING

Update on PHARMAC's work in Access Equity

Date: **20 February 2020**

To: **Hon Peeni Henare (Associate Minister of Health)**

Copies to

Minister of Health
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
Alison Hill, Director Engagement and Implementation [redacted]

Purpose

You are meeting with PHARMAC's Chief Executive, Sarah Fitt, on the 2nd of March. This briefing provides an overview of PHARMAC's work in medicines access equity, with particular reference to access to medicines for Māori.

Executive Summary

PHARMAC, Te Pātaka Whaioranga, has for a long time been committed to reducing inequitable access to medicines, including for Māori and Pacific people This commitment is reflected in our organisational strategies and publications.

The current focus of PHARMAC's access equity mahi is ensuring equitable access to funded medicines for the prevention, treatment and/or management of long term conditions that disproportionally impact our priority populations. These include conditions such as cardiovascular disease, asthma, diabetes and gout.

PHARMAC has:

a. identified the key system drivers of equitable access to medicines, and the different levels of impact PHARMAC has on each of these drivers;

b developed a comprehensive Monitoring and Outcomes Framework for medicines access equity, which articulates at the system level what success looks like for equitable access to medicines and proposes measures to track changes in inequitable medicines access

PHARMAC is actively working with a number of key partners in the community to deliver direct support to priority populations, and to better inform our access equity work.

We recently issued a request for proposals (RFP) for a class of new diabetes medicines These proposed treatments are a good example of where PHARMAC has carefully considered the health needs of Māori and Pacific people and adjusted our proposal to better meet those needs.

PHARMAC and its role in the health system

PHARMAC, New Zealand's pharmaceutical management agency, is a Crown entity 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."***

Initially PHARMAC's role was to manage government 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 all medicines used in the community and public hospitals (including all cancer medicines), vaccines and haemophilia treatments as well as some medical devices used in the community

PHARMAC manages the Combined Pharmaceutical Budget (CPB), a nominal budget set by the Minister of Health, by counting expenditure on medicines listed in the Pharmaceutical Schedule by District Health Boards (DHBs)

What makes PHARMAC different?

Most developed countries have a medicines technology assessment agency, separate from the medicines safety and quality regulator In New Zealand the regulator is Medsafe, part of the Ministry of Health, and the technology assessment and funding agency is PHARMAC.

New Zealand is unique in having a management agency that combines clinical, economic and commercial aspects, and decision making within a fixed budget for pharmaceuticals

Other key elements of PHARMAC:

- ***Holistic decision making:*** PHARMAC uses 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 take into account evidence in relation to health need, health benefits, costs and savings, and suitability For each of these we consider impacts on the person with the disease or illness; the person's family, whānau and wider society; and on the broader health system We also take current government health priorities into account.
- ***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 highly skilled New Zealand health professionals provide expert advice to PHARMAC through these committees. In addition, our Consumer Advisory Committee provides us advice from a consumer or patient point of view.

PHARMAC and medicines access equity

Research shows that some population groups, notably Māori and Pacific peoples, don't receive medicines at the same rates as other New Zealanders. This means these people are potentially missing out on the health gains they might get from funded medicines.

PHARMAC commitment to improving access equity

PHARMAC has for a long time been committed to reducing inequities in access to medicines to improve the health of people in New Zealand, including Māori and Pacific people This commitment is reflected in our organisational strategies, including:

- *Te Whaioranga*, PHARMAC's Māori Responsiveness Strategy, which provides a framework for ensuring PHARMAC responds to the particular needs of Māori in relation to medicines. It was first put in place in 2001 and has been refreshed and updated several times since then. We are currently working with a range of public sector Māori leaders on a further refresh of this important guiding strategy. Members of the governance group include Dr Kathie Irwin, Head of Māori and Cultural Capability at ACC, John Whaanga, DDG Māori Health at the Ministry of Health, and PHARMAC's kaumātua Wiremu Kaua Papa Bill
- PHARMAC's *Pacific responsiveness strategy 2017 2026*, which provides strategic direction and a framework for PHARMAC to improve Pacific peoples' health though improved and timely access to, and use of, medicines and medical devices.
- PHARMAC's 2017/18 2020/21 Statement of Intent, which included a 'Bold Goal' to "Eliminate inequities in access to medicines". To support this bold goal, PHARMAC created a new dedicated team of staff to focus on medicines access equity.

We are now updating our strategic direction, in preparation for a new Statement of Intent Equitable access and use of medicines and medical devices will continue to be a key priority. We are also lifting Te Tiriti o Waitangi to sit alongside our organisational purpose at the centre of our strategy. This change will help ensure that achieving equitable health outcomes for Māori is at the core of all our work and that we meet Government expectations.

In 2018 PHARMAC incorporated Te Pātaka Whaioranga the Storehouse of Wellbeing into our identity This refers to the part we play in managing and safeguarding resources that are of great value to the whole community. Incorporating te reo Māori into our name also signalled our commitment to Te Tiriti o Waitangi and the work we're doing with Māori communities and stakeholders to achieve the best possible health outcomes for Māori from funded medicines

Focusing our activities

There is always a lot of discussion in the media about funding new medicines When considering funding new medicines, PHARMAC specifically considers the health needs of our priority populations, including Māori, Pacific peoples and those experiencing deprivation

However, we believe that New Zealand can gain more in overall health by improving access to medicines that we already fund. The focus of PHARMAC's access equity mahi is therefore to ensure equitable access to **funded medicines** for the prevention, treatment and/or management of long term **conditions that disproportionally impact our priority populations**, such as cardiovascular disease, asthma, diabetes and gout.

In line with the Government's priorities, we are focusing on the **primary care** setting Over time, we'll look to improve equity of access to medicines in secondary care and for funded vaccines.

The "drivers" for change

In April 2019 PHARMAC published an important and thought-provoking discussion document on this topic *Achieving medicine access equity in Aotearoa New Zealand: Towards a theory of change* This document brings together expert opinion and evidence to build a theory about how to improve medicines access equity in New Zealand. The publication has been sparking conversations between individuals and organisations with a role in the health sector, about what actions they can take and how they can collaborate to help achieve equity

A key part of this discussion document is the identification of the drivers that facilitate equitable access to medicines. These are:

1 **Availability** how PHARMAC makes and implements funding decisions so that everyone who is eligible can access funded medicines

2 **Affordability** reducing cost barriers so that people can afford funded medicines

3 **Accessibility** – ensuring people don't face challenges getting to see a prescriber or to the pharmacy

4 **Acceptability** the ability of health services to create trust, so patients are informed and engaged enough to accept the medicines they've been prescribed

5. **Appropriateness** the adequacy and quality of prescribing to ensure equitable health outcomes

Each of these has secondary drivers that contribute to it that are outlined in more detail in the diagram in Appendix One.

The diagram in Appendix One also indicates the various levels of impact PHARMAC has While we have direct control over medicines availability, in other areas PHARMAC has a much smaller role (less direct control) or can only influence or provide guidance to other health sector players.

Inequitable access to medicines is a system wide issue it is a manifestation of a health system with inequitable access to services, coupled with structural inequalities in the social determinants of health. While PHARMAC's role in the health system does not extend into related realms such as the social determinants of health, PHARMAC is an active contributor to broader health sector goals, including the Ministry of Health's focus on more equitable health outcomes (of which more equitable medicines access is one part).

Measuring the impacts of our activity

As part of our work in the area of access equity, PHARMAC has been developing a comprehensive Monitoring and Outcomes Framework for medicines access equity. This has included analysis support from external partners Synergia and the National Hauora Coalition.

Appendix two provides a summary of the Monitoring and Outcomes Framework that we have developed. The framework includes both population level measures (for access, persistence and adherence to medicines) and indicators for the medicine access equity drivers. These measures will:

1. Provide baseline measurements of inequity; and
2 Enable changes in inequity to be tracked at a system level

We believe this framework will fill a gap in the health system by providing the first comprehensive, national reporting against indicators relating to equitable medicines access.

We intend to deliver an initial baseline report on this framework in mid 2020. It aims to show the impact of medicine accessibility, affordability and acceptability on equitable access, by ethnicity and by health conditions most amenable to treatment by medicines in primary care which include conditions such as diabetes and cardiovascular disease

The report will analyse data from key national data collections such as the pharmaceutical collection, hospitalisations and the Health Quality and Safety Commission's (HQSC) primary care patient experience survey

Following publication of this report, and a period of internal planning and preparation, we will be seeking to engage further with the key sector stakeholders on the report's contents. This will be a period of "sense making" with the sector and will include examining issues such as Māori data sovereignty. We hope to generate cross sector discussion about how to address health equity challenges and how to close key medicines access equity gaps. This external engagement process will likely involve close collaboration with the HQSC, as we hope to make use of their existing channels to disseminate information and engage with key stakeholders.

Mahi in the community: key partnerships

PHARMAC actively works with a number of key partners in the community to support priority populations, and to better inform our work PHARMAC is also using these partnerships to try to provide influence and guidance in relation to wider system challenges

Whānau Ora collectives

Through *Te Whaioranga*, our Māori Responsiveness Strategy, we have developed enduring partnerships with Whānau Ora Collectives across the country to support their health activities in Māori communities PHARMAC works with its partners to provide annual funding and resources for community-driven initiatives focused on the Hauora Arotahi - Māori health areas of focus.

The Hauora Arotahi were identified through consultation with Māori communities about which areas of health mattered most to them The most recent round of consultation identified the following Hauora Arotahi:

- Mental health (Hauora hinengaro)
- Diabetes (Matehuka)
- Heart health high blood pressure and stroke (Manawa Ora)
- Respiratory health (Romaha Ora)

- Cancer lung and breast (Mate Pukupuku)

He Rongoā Pai, He Oranga Whānau

These wānanga, supported by PHARMAC, are run by our partners throughout the motu to provide support and medicines education for whānau.

Māori and Pacific health workforce

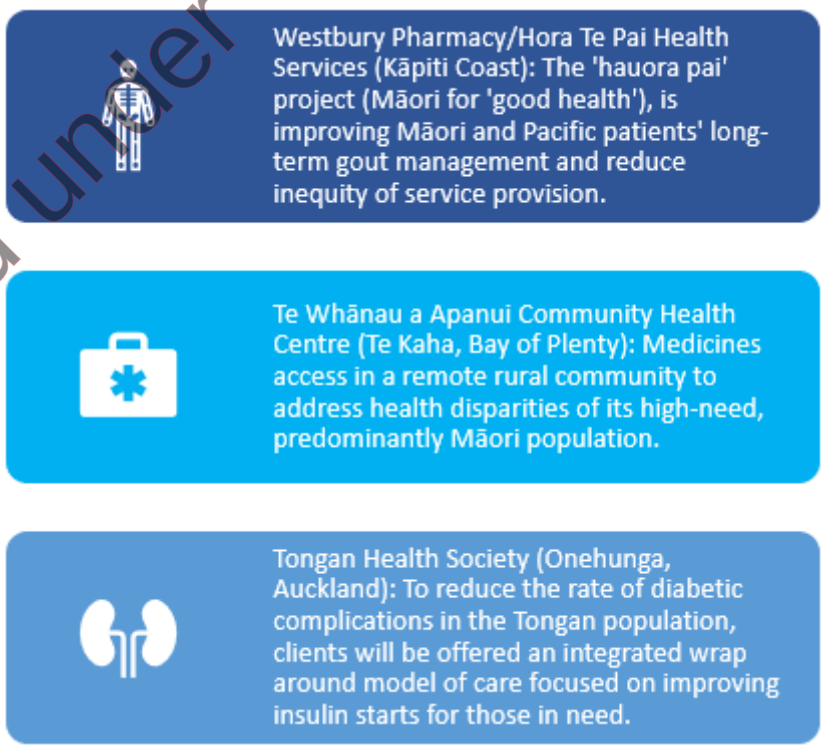
PHARMAC supports the development of Māori Health workforce, through a number of annual scholarships and awards, in partnership with our Māori health professional partners:

- Te ORA (Māori Medical Practitioners Association),
- Ngā Kaitiaki o te Puna Rongoā o Aotearoa (Māori Pharmacists Association),
- Te Rūnanga o Aotearoa,
- NZNO/Tōpū tanga Tapuhi Kaitiaki o Aotearoa (New Zealand Nurses Organisation) and
- Ngā Pou Mana (Māori Allied Health Professionals of Aotearoa).

PHARMAC also supported the formation of the Pacific Pharmacists Association in 2017 Since its establishment, 45 members have signed up to be part of the Association, including interns, technicians and students PHARMAC continues to have a constructive relationship with this group and has used this partnership to engage on access equity issues.

Whakakotahi projects

In partnership with the Health Quality & Safety Commission and Te Tihi o Ruahine Whānau Ora Alliance, PHARMAC has been supporting three community led projects looking at improving equitable access to medicines in their communities These are providing invaluable information about what works on the ground, which we can use to inform larger-scale interventions in the future. The projects are focused on priority conditions and populations:



New diabetes medicines

As the Associate Minister with responsibility for diabetes, you may be aware of PHARMAC's recent activity relating to proposed new treatments for type 2 diabetes and the potential impacts this could have on Māori and Pacific people with this disease.

In January 2020 PHARMAC issued a request for proposals (RFP) for new diabetes medicines, including SGLT-2 inhibitors, GLP-1 agonists and DPP-4 inhibitors. Clinical evidence suggests that these classes of medicines have the potential to improve certain outcomes in those people with type 2 diabetes who are at a high risk of cardiovascular complications They work in different ways to other currently funded options for type 2 diabetes.

It is estimated that more than 240,000 people in New Zealand have been diagnosed with diabetes (mostly type 2) It is thought another 100,000 people have type 2 diabetes, but don't know they have it. Māori, Pasifika and other specific population groups have a higher risk of developing type 2 diabetes, and experiencing complications of the disease, compared to other people living in New Zealand

These proposed diabetes treatments are a good example of where PHARMAC has undertaken activity in relation to the medicines' availability driver of access equity, by carefully considering the health needs of Māori and adjusting our proposal to better meet those needs. Early consultation on the proposed access criteria highlighted concerns that the treatments might not adequately reach the populations facing the most inequitable health outcomes for this health condition This prompted PHARMAC staff to adjust the proposed access criteria, and we are now confident that the medicines, if funded as proposed, will be available to those priority populations.

Concluding comments

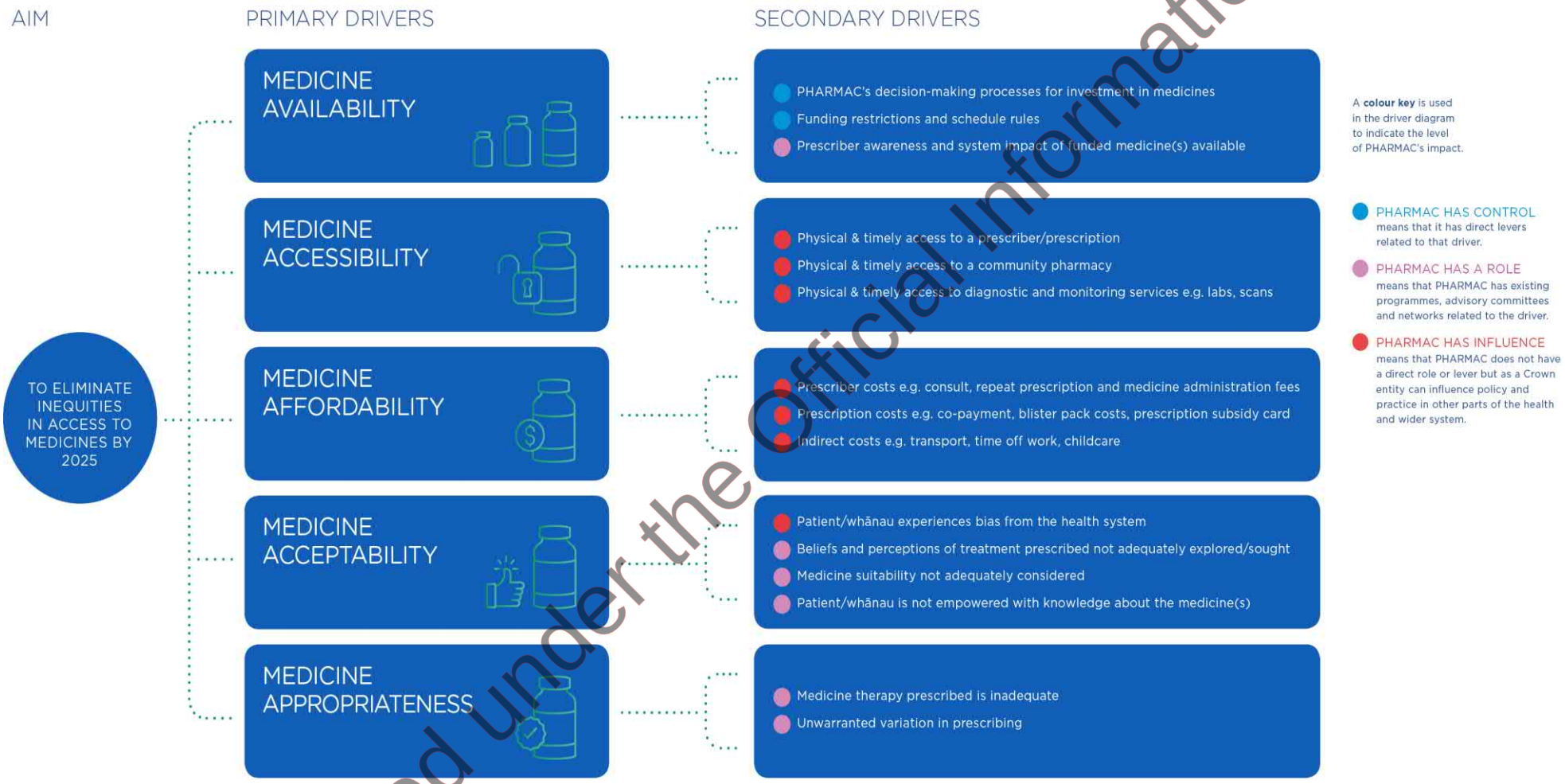
Medicines access equity continues to be a key area of focus for PHARMAC, and we have a wide variety of relevant work underway I look forward to discussing this work with you further

Sarah Fitt

Sarah Fitt

Chief Executive

Appendix One: Medicine access equity driver diagram



Appendix two: Monitoring and Outcomes Framework for medicines access equity

PHARMAC's Medicine Access Equity Monitoring and Outcomes Framework

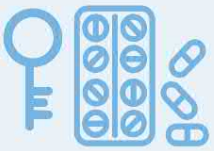
PHARMAC Pharmaceutical Management Agency | National Hauora Coalition | SYNERGIA

INTRODUCTION

PHARMAC's Medicine Access Equity Monitoring and Outcomes Framework (the Framework) presents key outcomes and measures to track PHARMAC's equity work and the journey towards **BOLD Goal One; eliminating inequities in access to medicines by 2025**.

The key outcomes identify the changes that we would expect to see when medicine access equity is achieved. PHARMAC has adopted a system level focus, which means that it does not have control over all the outcomes in the Framework. Tracking system level progress will help PHARMAC to understand where to invest resource and where to seek to influence change with the sector.

MEDICINE ACCESS EQUITY



Everyone should have a fair opportunity to access funded medicine to attain their full health potential, and that no one should be disadvantaged from achieving this potential. In this context, unequal inputs are required to attain a fair opportunity to access funded medicines.

NATIONAL AND STRATEGIC CONTEXT, SCOPE AND FOCUS OF PHARMAC'S MEDICINE ACCESS WORK PROGRAMME

Te Tiriti o Waitangi
NZ Public Health and Disability Act
Government priorities
Te Whaioranga (Māori Responsiveness Strategy)
Pacific Responsiveness Strategy
Medicine access and health inequity in NZ
Potential health gain from medicine access equity

SCOPE
Publicly funded medicines
Primary care
Conditions significantly amenable to medicine

Priority populations and conditions

Māori, Pacific
Low socio-economic status
Refugee, Rural

CVD, Gout, Diabetes, Asthma and COPD

THE MEDICINE ACCESS EQUITY MONITORING AND OUTCOMES FRAMEWORK

Key outcome: Priority populations have equitable access to funded medicines, in line with their health need

POPULATION LEVEL MONITORING MEASURES

- Reduce variation in access to medicine
- Reduce variations in medicine adherence and persistence
- Decrease amenable hospitalisation rates and emergency department presentations
- Reduce variation in amenable mortality rates

MEDICINE ACCESS EQUITY OUTCOME DOMAINS AND MEASURES

AVAILABILITY
Funding decisions and restrictions do not disproportionately impact on priority populations

Key Measures
- Increase influence of health need and system thinking in medicine availability decisions
- Reduce the impact of funding restrictions and schedule rules as barriers to access
- Increase prescriber awareness to reduce availability barriers

ACCESSIBILITY
People have timely and easy access to prescribers and medicine

Key Measures
- Ensure medicines that are prescribed are dispensed
- Increase timely access to prescribers, community pharmacy and diagnostics

AFFORDABILITY
Costs barriers do not prevent access to funded medicines for priority populations

Key Measures
- Reduce costs as a barrier to accessing a GP/nurse
- Reduce unfilled prescriptions due to cost

ACCEPTABILITY
Primary health care system ensures patients and whānau are informed and engaged in their medication decisions

Key Measures
- Increase patient involvement in medication decisions
- Increase patient rating of proper medication explanations
- Increase cultural competence of primary care staff

APPROPRIATENESS
Patients and whānau receive the most appropriate medicine

Key Measures
- Reduce rates of inadequate prescribing
- Increase consideration of suitability in medicine availability decisions
- Reduce adverse events from inappropriate prescribing

INTERNAL CAPABILITY

KEY OUTCOME

PHARMAC becomes an exemplar as a pro-equity organisation

Key Measures
- Health loss and need is consistently identified as an important driver of PHARMAC's work
- Strong organisational leadership for equity
- Increase understanding of equity and cultural competence
- Increase proportion and influence of Māori and Pacific staff with equity expertise
- Increase pro-equity capability through the advisory groups and consumers

DATA AND ANALYSIS CONSIDERATIONS

When tracking progress, the population level monitoring measures will require a systems response and will take longer to change. Changes in PHARMAC's internal capability and some of the medicine access equity outcome domains should change within a shorter timeframe.

A Medicine Access Equity Monitoring and Outcome Framework is new for New Zealand. Many of the measures and associated indicators do not have existing data sources or have not been analysed with a medicine access equity lens before New analytical approaches will need to be applied to existing data sources and new indicators will need to be developed.

IMPLEMENTATION RECOMMENDATIONS

1. Establish the baseline for existing indicators. This could form the basis of a dashboard to track progress.

2. Develop and test analytical approaches for new indicators that can be supported by existing data sources.

3. Explore opportunities for data sharing and integration with the sector. Engaging with District Health Boards and Primary Health Organisations, for example, would support access to prescribing data.

4. Explore options for investing in new data collection. This could be adding questions or indicators to existing data sources or investing in additional data collection processes or systems with the sector.

5. Establish internal review processes to track changes in internal capability.