



**PHARMAC REVIEW**  
Te Arotake i Te Pātaka Whaioranga



**Te Kāwanatanga o Aotearoa**  
New Zealand Government

# Pharmac Review Interim report

September 2021



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# Message from the Chair

Easy access to medicines – whether for lifesaving or more routine purposes – is critical to a well-functioning health system. The task of procuring publicly funded medicines in Aotearoa New Zealand falls to medicine-buying agency Pharmac. Over the past 20 years it has played an increasing role in the procurement of publicly funded medicines and it prides itself on the savings it has achieved. A central question for our review is whether that claimed achievement has come at the cost of equitable outcomes for all.

This interim report assembles much of what the review has heard from patient advocates, clinicians, industry lobbyists, pharmaceutical companies, consumers, Māori and Pasifika health providers and Pharmac itself. Our most grateful thanks go to those who shared deeply personal stories about the struggle – either their own or those of whānau – with rare disorders or disabilities and attempts to get public funding for their medication. No review member was left unmoved.

The stories brought home the complexity of the health system but also the simple need for each of its arms (and there are many) to link back to a centre. Our review comes at a time when the entire health and disability system is to be more fully integrated. We know any recommendations the review makes must fit within those new structures – the Ministry of Health, Health New Zealand, and the Māori Health Authority. It sounds obvious, but the review has continually reminded itself that access to medication, while important, is just one part of what determines a “healthy outcome”.

We have also been mindful Pharmac can never fund all medicines on people’s wish lists but rather must work within a budget set by the Government. It is what determines Pharmac’s allocation of that budget that the review is assessing.

We have met frequently since March and heard voices from across the health spectrum. Our discussions have been vibrant and respectful. As chair, it has been a pleasure to be part of such an informed and committed group. We have also received 213 submissions – a sign of how deeply people feel about the issue of public medicine funding.

This is the first independent look at Pharmac’s systems and processes since its inception. There is much of which the agency can be proud. It is a unique model which combines medical assessment with procurement and budget holding. This integration is responsible for much of its success but there are problems. Few submitters commented favourably on their experience with Pharmac or on the outcome of their dealings with Pharmac. The review is conscious that many New Zealanders benefit from Pharmac’s work every day and many may not even be aware of the work Pharmac does. The review also accepts that submissions by their very nature are not necessarily reflective of Pharmac’s overall impact on the lives of New Zealanders. But none the less it was concerning that almost without exception, the feedback contained many elements that were critical, particularly of the timeliness and transparency of Pharmac’s decision-making processes. To compound matters, we were sometimes unable to independently verify the information the agency supplied to us.

This interim report considers Pharmac's systems and processes and whether they help achieve equitable health outcomes for all New Zealanders, but in particular for Māori, Pasifika and disabled people. We also met with groups representing people with rare disorders, and our final report will look further at the important issues of equitable access that they raised. It also considers whether Pharmac's more than 20-year-old legislation remains suitable, particularly considering the major impending legislative reform of the entire health and disability sector. We have commissioned further analysis to test some of what we have heard. The outcome of that work will help provide evidence for our recommendations in the final report early next year.

The review is indebted to its head of secretariat, Sarah Davies, and the consultants and writers it has worked with in bringing this report to life. And, of course, the review could not have reached even this interim stage without the hard work and dedication of its members – Sue Crengle, Tristram Ingham, Leanne Te Karu, Frank McLaughlin and Heather Simpson.



Sue Chetwin CNZM  
September 2021

# Preliminary observations

In this interim report, we have largely focused on:

- what we have learned from submissions and stakeholder meetings
- Pharmac's role in assessing medicines for public funding
- whether Pharmac's current objectives and processes provide for equitable outcomes for Māori and Pacific people and disabled people
- how and to what extent Pharmac is supporting the Crown in meeting its Te Tiriti o Waitangi obligations.

In the next phase of our work, we will:

- continue to develop the issues raised in this report
- address other aspects of Pharmac's functions, including the role it plays in assessing medical devices and vaccines
- look more closely at Pharmac's governance arrangements
- address outstanding aspects of our terms of reference
- look further at funding for people with rare disorders.

## Part 2: Pharmac's operating environment

- There is nothing new about the struggle to keep pace with the rising cost of medicines, but the sharp rise in the number of new medicines under development, including those for cancers and rare disorders, is a new and not easily overcome challenge. All countries are struggling to fund this increased range of medicines, which sometimes have lower evidential standards, and this is making decision-making less straightforward. These new medicines can be expensive, often costing tens of millions a year to fund.
- Aotearoa New Zealand is a small part (0.1 per cent) of the world's pharmaceutical market.
- No publicly funded health sector can afford to fund all the medicines available. Determining which medicines to fund within a capped budget is complex.

## Part 3: What Pharmac does

- It is timely, given the legislative overhaul of the health system, for the Government to also consider Pharmac's enabling legislative provisions to ensure they are consistent with the legislative framework of the new system and share the same set of objectives.

- The responsibilities of Pharmac’s prime advisory body, the pharmacology and therapeutics advisory committee (PTAC), its 21 specialist subcommittees and its consumer advisory committee (CAC) are sometimes muddled. For example, there is some confusion amongst stakeholders whether PTAC should consider cost when giving advice. And CAC is rarely asked for strategic advice on communicating Pharmac decisions. Nor, indeed, has this committee any real involvement in Pharmac’s day-to-day activities.
- It is difficult to measure Pharmac’s performance other than in relation to the cost savings it says it has made, and then only at a high level. Pharmac’s performance monitoring is limited and does not report against its objective of “best health outcomes”.
- Pharmac closely guards its information, leaving the public poorly informed about the decisions it makes. In part, Pharmac does this to maintain leverage in price negotiations. Nonetheless, it is not clear to us how Pharmac weighs the trade-off between public transparency and commercial leverage, and whether anyone is maintaining oversight of this trade-off.
- The lack of information from Pharmac has made it difficult to assess the extent to which Pharmac tries to anticipate trends and scenarios that might affect future investment decisions. Regular projection work for each of the large therapeutic groups would give the public confidence that Pharmac’s funding framework is regularly and systematically reviewed, and not put in a “set and forget” mode.
- Pharmac’s ability to work within the new integrated health system will require a greater commitment to co-ordination, data-sharing and accountability to achieve better health outcomes for all New Zealanders.

#### **Part 4: How Pharmac makes funding decisions**

- Pharmac uses what it calls a Factors for Consideration framework to prioritise what medicines it will or may fund. It says it applies the four elements of this framework – need, health benefits, costs and savings, and suitability – at each stage of the decision-making process. Pharmac provides guidance on the Factors in its application process and has guidelines for how staff should consider them when they make their assessments. However, it is not clear how the framework is used in practice, or how it weights each of the four elements, if indeed it does weight them. The review was concerned Pharmac involved its staff – as a proxy for all New Zealanders – when reviewing the order in which medicines are ranked for funding.
- Stakeholders expressed deep concerns about the transparency and timeliness of decisions. There are no formal benchmarks for timeliness other than to publish PTAC minutes on the website within 70 working days of a meeting.
- There is considerable scope to broaden the involvement of consumers in the decision-making process.

## Part 5 and 6: Equity

- Pharmac has made various commitments to improving equitable outcomes for Māori and Pacific people and disabled people, but it is a long way from achieving this goal, just as it is a long way from having a fair representation of Māori and Pacific people and disabled people within its own ranks, or systems, processes and structures that facilitate equitable outcomes.
- Pharmac needs to incorporate equity considerations in all stages of its assessment processes. Equity considerations need to be an everyday part of the work of Pharmac's board, leadership team and various committees and subcommittees.
- Pharmac needs to work more closely with other parts of the health system to better achieve equity outcomes. There is some data on access to medicines, but it is held in different parts of the system and needs to be better integrated.
- Stakeholders raised concerns that Pharmac's clinical advisory subcommittees have few Māori or Pacific people or disabled people on them. Very few of its staff are Māori.
- Pharmac talks about equity engagement and equity outcomes, but there is little of this in practice.
- We intend looking more closely at how and when Pharmac applies its Factors for Consideration framework in relation to such issues as burden of disease, distributional impacts and other equity outcomes.
- The review is concerned to look at whether the prioritisation approach in decision-making disadvantages Māori and Pacific people, disabled people, those with rare disorders and other groups.

## Part 7: Stakeholder engagement

- Pharmac must act from a position of strength against the weight of the pharmaceutical industry, but this tough stance has translated into defensiveness and an extreme reluctance to share information with stakeholders and the public. Stakeholders observed a fortress mentality that permits little transparency and openness, increasingly disconnected from other parts of the health system.
- Better communication with stakeholders, particularly Māori and Pacific people, disabled people and those with rare disorders, would help foster authentic, rather than purely transactional, relationships.
- External communication is clumsy and not patient- or consumer-centred.

## **Part 8: What other countries do**

- Submitters believe Pharmac's excessive focus on containing costs and using generic medicines as much as possible is causing New Zealand to fall behind other comparable countries. Australia and England are often cited as examples of how things could be better. Both countries' decision-making processes are broadly consistent with Pharmac's (as are those of two other countries we looked at, Canada and Norway). Larger countries devolve decision-making to more agencies and split the assessment and purchasing elements. We will look at whether these countries' systems are producing better or different outcomes, and whether any aspects of their decision-making processes might better enhance public trust and confidence. We will also look at how other countries consider equity, including when considering medicines for cancer and rare disorders.

## **Part 9: Pharmac's place in reformed health system**

- Any review of Pharmac needs to be understood within the context of the health system. Medicines are an important intervention, but they must be viewed as part of an integrated health system, along with public health and preventive, primary and secondary care.
- Pharmac may be operating too independently of the wider health sector and its decisions not adequately guided by overall system oversight and values. If Pharmac is to be able to operate effectively within the new health system, it will need to be guided by the overall NZ health plan, a modern medicines strategy, and be bound by the proposed health charter.

# 1 Introduction

Pharmac was set up in 1993 as a joint venture with what at the time were the country's four regional health authorities. In 2001, it became a Crown entity under the New Zealand Public Health and Disability Act 2000. Its purpose was 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".<sup>1</sup> Pharmac saw its task as deciding which medicines (and later, medical devices and vaccines) should be publicly funded from its capped budget, and negotiating the best possible prices on those technologies, with savings used to fund more medicines.<sup>2,3,4</sup> At that time, medicines accounted for 15 per cent of the health sector budget, so the prime focus was on getting pharmaceutical spending under control to fund more medicines.<sup>5</sup> A report in 1992 by the Office of the Auditor-General raised serious concerns about the rising cost of medicines, noting that 58 of the 74 medicines then subsidised, cost more than they did in Australia, and that 27 of the 58 were more than 50 per cent dearer.<sup>6</sup>

Pharmac says it has achieved the objective of procuring medicines at lower prices through its negotiations with pharmaceutical companies and the high use of generic medicines (those no longer protected by patent). But containing costs is only part of the picture. Today, people are asking whether Pharmac is funding the right range of medicines, whether those in need are getting equitable access to medicines, and whether Pharmac's funding decision model follows a fair process to meet the health needs of all New Zealanders.

Our description of the environment in which Pharmac operates aims to promote further discussion of what a modern medicines management agency might look like. There has been no previous review of its activities on this scale, or any real opportunity for the public to scrutinise its operations.

Many submitters said Pharmac's processes were opaque. Pharmac's response was that it had become more open about how it made decisions but had to balance this increased transparency against its need to be a strong, consistent, and effective negotiator. Revealing too much, it said, would undermine its negotiating position. It also said drug companies did not want other countries knowing how cheaply this country was buying its medicines.

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<sup>1</sup> Cummings, J. Mays, N. Daube, J., How New Zealand has contained expenditure on drugs. British Medical Journal, 2010.

<sup>2</sup> 2019 Report Funding Medicines for Rare Disorders, Appendix 1: Explaining New Zealand's Health System, p23.

<sup>3</sup> Other responsibilities have been added over the years, such as hospital medicines and vaccines.

<sup>4</sup> Pharmac, History of Pharmac: <https://pharmac.govt.nz/about/what-we-do/pharmac-history/>.

<sup>5</sup> Pharmac, 1993–2018 Pharmaceutical Management Agency 25-year history, 2018, p7.

<sup>6</sup> The Audit Office (1992), Department of Health: Administration of the Pharmaceutical Benefits Scheme.

Nonetheless, critics have grown more vocal in their opposition to this perceived secrecy in recent years. They also say New Zealand is falling behind other countries in the funding of new medicines. We found most clinicians supported the continuation of Pharmac’s existing mandate, but, like other stakeholders, questioned various aspects of the agency’s responsibilities. Stakeholders had different motivations and levels of dissatisfaction – from the deeply personal when a loved one had been refused life-saving medication to the strictly commercial – but there was a remarkable consistency about their complaints.

Our task is to determine whether these criticisms are just unfounded “noise” and Pharmac continues to be what some, including the Ministry of Health (with some caveats), regard as a high-performing agency making tough decisions in an inevitably sensitive area, or whether something has gone awry, and it needs reforming to fit into a modern-day health system. Central questions in our review are whether Pharmac’s systems, structures and decision-making processes are achieving the best health outcomes that are reasonably achievable from pharmaceutical treatment within the funding available.

In assessing Pharmac as a Crown entity, we have also had to consider how and to what extent it is supporting the Crown’s Te Tiriti o Waitangi obligations. Our approach has been to look at guidance to government organisations on building Te Tiriti capability<sup>7</sup> and the findings of the Waitangi Tribunal in stage one of its Kaupapa inquiry into health services and outcomes (specifically Te Tiriti principles as they apply in the context of primary healthcare).<sup>8</sup> We also examined government strategy documents,<sup>9</sup> published approaches to Te Tiriti analysis<sup>10</sup> and work by Māori scholars.<sup>11</sup>

Additionally, we have in places looked at how Pharmac has supported the Crown’s Te Tiriti commitments. In examining questions of equitable access to medicines, for example, we have looked at how Pharmac has put into practice the principles of equity, active protection, and options.

Our terms of reference also require us to consider Pharmac’s legislative objectives, whether they should be broadened or reduced and, importantly, whether they result in equitable outcomes for Māori and Pacific people, disabled people, and those with rare disorders.<sup>12</sup>

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<sup>7</sup> Te Arawhiti (2018) Māori Crown Relations Capability Framework for the Public Service – Organisational Capability Component: <https://www.tearawhiti.govt.nz/assets/Tools-and-Resources/Maori-Crown-Relations-Capability-Framework-Organisational-Capability-Component.pdf>.

<sup>8</sup> Waitangi Tribunal. Hauora: Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry, WAI 2575. Wellington, New Zealand: Legislation Direct; 2019.

<sup>9</sup> These include: Ministry of Health (2014) He Korowai Oranga: <https://www.health.govt.nz/our-work/populations/maori-health/he-korowai-oranga>; and Ministry of Health (2020) Whakamaua: Māori Health Action Plan 2020–2025: <https://www.health.govt.nz/our-work/populations/maori-health/whakamaua-maori-health-action-plan-2020-2025>.

<sup>10</sup> These include: Came H, O’Sullivan D, McCreanor T. Introducing critical Tiriti policy analysis through a retrospective review of the New Zealand Primary Health Care Strategy. *Ethnicities*. 2020 Jun;20(3):434–56: <https://doi.org/10.1177/1468796819896466>.

<sup>11</sup> These include Mikaere A. (2011). *Colonising myths – Maori realities: He rukuruku whakaaro*. Huia Publishers.

<sup>12</sup> New Zealand Public Health and Disability Act 2000, ss 47 and 48.

Everyone on our review committee is keenly aware that our eventual recommendations must fit within the health system as it undergoes the reforms outlined by the Government in April this year. We met the transition agency responsible for implementing these reforms and will do so again before delivering our final report.

This interim report reflects the fact-finding phase of our review. We have met as many stakeholders as possible to help us gather those facts, and we have examined 213 submissions. In this interim report we raise issues and make preliminary observations which we want to explore further, before arriving at recommendations for our final report.

## Scope

We are required to make recommendations on two key matters:

- how well Pharmac performs against its objectives and whether and how its performance against these could be improved
- whether those objectives maximise its potential to improve health outcomes for all New Zealanders (in particular, equitable outcomes for Māori and Pacific people) as part of the wider health system, and whether and how these should be changed.

In considering equity questions, we use the Ministry of Health's definition of health equity: "People have differences in health that are not only avoidable but unfair and unjust. Equity recognises different people with different levels of advantage require different approaches and resources to get equitable health outcomes." This is in line with the World Health Organisation definition of health equity, which is "the absence of avoidable, unfair, or remediable differences in funded medicines access among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other means of stratification".

In examining in this report whether Pharmac's model for assessing and managing the pharmaceutical budget remains suitable (and if not, what should change), we have framed a series of questions to help us reach our conclusions. These include:

- How well placed are its processes to take it into the future? Are they able to take account of the significant social, economic, and technological developments that have occurred since it was established?
- Does its Te Whaioranga strategy reflect Te Tiriti principles?
- Do its processes allow for equitable outcomes, particularly for Māori and Pacific people, disabled people, and those with rare disorders?
- How and where should Pharmac sit within the health system?
- Do its processes foster trust and confidence among stakeholders, such as patients, advocates, clinicians, the pharmaceutical industry, and the Government?

## Out of scope

The terms of reference exclude any consideration of:

- the commercial arrangements Pharmac negotiates with pharmaceutical companies
- whether Pharmac should remain a separate Crown entity
- the size and fixed nature of its budget
- the day-to-day operations of Pharmac
- the appropriateness of specific decisions made by Pharmac.

## Our approach

We have drawn on input from patients and patient advocacy groups (including Patient Voice Aotearoa) and Māori and Pacific health experts, pharmaceutical industry organisations and companies, clinicians, medical colleges, economists, consultants, the Ministry of Health, and comparable medicine-buying agencies overseas. We also sought input from Pharmac's consumer advisory committee, its pharmacology and therapeutics advisory committee (PTAC) and its specialist cancer subcommittee. We also heard the views of Pharmac's board and leadership team and examined many papers prepared by Pharmac for us.

In this interim report, our focus has been on the funding of medicines. Our final report will look further into the funding of medical devices (everything from swabs to MRI machines) and vaccines. It will also look in more detail at the funding of medicines for people with rare disorders and the other functions the legislation requires Pharmac to perform.

The Human Rights Commissioner Paul Hunt has asked us to consider his view that Pharmac is bound under a body of international human rights law to take into account wider societal benefits in its decision-making. Director-General of Health, Dr Ashley Bloomfield, has asked us to recommend a response to this issue. Time did not permit us to do so for this report, but we intend to meet Mr Hunt, Disability Rights Commissioner Paula Tesoriero and the Children's Commissioner Judge Andrew Becroft before making any human-rights-related recommendations in our final report.

## 2 Pharmac's operating environment

Any review of Pharmac must necessarily examine the broader context in which it operates, notably the global pharmaceutical market and Pharmac's role within the new health system. But first, we set out some of the factors that influence how and why it operates as it does.

Medicines have the potential to cure, control or prevent the development of illness. For rare critical conditions, medicines can offer the promise of saving or prolonging life. The decision to fund a particular medicine has a direct, and at times painful, impact on individuals, their whānau and their community. Those deciding what medicines to fund are rightly held to a high standard of professionalism and transparency for the reasoning behind those decisions, the process by which they make them, and how they explain their decisions to the public.

Pharmac assesses medicines through an evidence-based process that considers whether the benefits can be demonstrated to a sufficient level to justify public funding. This is Pharmac's core function. It requires analysis against scientific, technical and "social utility" criteria. The number of medicines – including personalised medicines and new medical technologies – has been growing rapidly, and this poses a challenge for Pharmac, which must work to maintain high-quality analysis in the face of this growth. It must also work to ensure the public trusts its decision-making processes and is confident they lead to the best possible health outcomes.

No publicly funded medicine-buying agency anywhere in the world has enough money to fund every available medicine. Pharmac is no exception. One unique characteristic of Pharmac is that it must operate within a legislatively capped budget. Another is that it combines the assessment and procurement processes under one roof – these functions are kept separate in other countries.

Public funding of medicines at low or no cost to consumers began in the 1940s, and the country has grappled with the problem of relentlessly rising medicine costs ever since. Even as early as the 1960s, one of the country's top medical officials, Dr Hayes, assistant director of the Clinical Services Division, lamented the lack of success in curbing rising costs, which they attributed to the high cost of new drugs, and questioned whether "we are paying too much for [these] newly discovered drugs".<sup>13</sup>

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<sup>13</sup> For Health or Profit?, Peter Davis (ed), Oxford University Press, Auckland, 1992.

## Global context

The world spent \$NZ1.950 trillion on medicines in 2020,<sup>14</sup> of which the New Zealand market accounted for just 0.10 per cent of those sales.<sup>15</sup> To illustrate the size of the sector, the prescription sales of the world's top five pharmaceutical companies in 2020 were more than this country's GDP of \$NZ325 billion (or \$US221 billion) in the same year (Table 1).<sup>16</sup>

**Table 1: Top five pharmaceutical companies in 2020 by prescription sales**

Company	Sales (NZD)
Roche (Switzerland)	\$73.04 billion
Novartis (Switzerland)	\$72.59 billion
AbbVie (US)	\$68.19 billion
Johnson & Johnson (US)	\$66.36 billion
Bristol Myers Squibb (US)	\$64.44 billion
<b>Total</b>	<b>\$344.63 billion</b>

Source: Pharmaceutical Executive 2021 Pharm Exec 50.

Despite their considerable size and profitability, pharmaceutical companies are strongly focused on getting new medicines listed for public funding because it enables early and rapid market uptake of those medicines and maximises profits while protected by patents.<sup>17</sup> To take an example, heart medication such as ACE inhibitors, statins and omeprazole were originally innovative, but competitors developed other medicines with the same or similar therapeutic effect, and eventually the originals lost their intellectual property protection and became generic medicines that could be copied by others. In the process, medicines that might once have commanded hundreds of dollars a dose could be purchased for a dollar or two – or even a few cents – a dose.

Pharmaceutical companies generate large profits from relatively few products. The top 10 medicines in New Zealand, for example, had gross sales of \$NZ501.53 million in the 12 months to 30 June 2020.<sup>18</sup>

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<sup>14</sup> Based on the Reserve Bank of New Zealand's published average NZD/USD exchange rate across the 2020 calendar year.

<sup>15</sup> Before off-invoice discounts and rebates.

<sup>16</sup> <https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=NZ>.

<sup>17</sup> Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies Ledley et al. Bentley University 2020.

<sup>18</sup> We do not have access to the net price of pharmaceuticals so must rely on the gross price.

**Table 2: Top 10 medicines in New Zealand by gross sales**

Rank	Medicine	Therapeutic group	2019–20
1	Glecaprevir and pibrentasvir (Maviret)	Antivirals	\$129,320,000
2	Adalimumab	Immunosuppressants	\$98,720,000
3	Dabigatran	Antithrombotic agents	\$45,480,000
4	Pembrolizumab	Immunosuppressants	\$42,160,000
5	Trastuzumab	Immunosuppressants	\$35,740,000
6	Insulin glargine	Diabetes	\$34,150,000
7	Pneumococcal vaccine	Vaccinations	\$33,300,000
8	Etanercept	Immunosuppressants	\$30,910,000
9	Human papillomavirus (6, 11, 16, 18, 31, 33, 45, 52 and 58) vaccine [HPV]	Vaccinations	\$26,300,000
10	Abiraterone acetate	Oncology	\$25,450,000

Source: Pharmac top 10 reimbursed medicines by gross spending, Pharmac Online Pharmaceutical Schedule and Medsafe product/application search.

Actual prices paid by buyers are difficult to establish. Pharmaceutical companies ask very high prices and then typically agree to rebates which buyers are required to keep confidential. Quite apart from being a good negotiating tactic by allowing buyers to feel they have struck a good deal, this approach also obscures actual prices paid, thereby keeping each market in the dark about what other markets have paid or may pay. This means every market represents a fresh opportunity for pharmaceutical companies to negotiate the highest possible prices for their medicines. Obscured pricing makes it difficult for health systems to gauge whether they have paid a fair price that is comparable to that paid by other health systems.

To date, Pharmac has not given us access to information about the value of rebates, merely indicating that they may be in the range of between 25 per cent and 75 per cent of the gross cost. We do not, therefore, know the true cost of listed medicines. What we do know is that these funding decisions amount to very significant investments.

Another feature of the pharmaceutical sector – but a more recent one – is the sharp rise in the number of medicines under development or entering the market. The number of pharmaceutical companies with medicines under active development has increased 27 per cent worldwide between 2017 and 2021, while the number of pharmaceutical medicines under development has risen 25 per cent during the same period.<sup>19</sup> Cancer medicines account for 38 per cent of all medicines under development in 2021. The next three biggest areas of focus are infectious diseases, neurology, and endocrinology.

<sup>19</sup> Intelligence Informa Pharma, Pharma R&D Annual Review 2021.

The biotechnology sector is behind a lot of this development. According to The Economist magazine, newly started biotechnology firms are responsible for 64 per cent of the medicines in the final stages of development, and nearly all are built around a novel technology derived from recent advances in cell and gene therapies.<sup>20</sup> The magazine said money was “flowing into firms developing treatments for cancer, illnesses of the immune system or the brain, and even infectious diseases. Everyone is vying to be the next Moderna, whose market capitalisation has jumped from \$5 billion when it went public in late 2018 to \$US156 billion”.

Another significant development is the regulatory changes in the United States that have allowed an increasing number of cancer medicines on to the market that have a lower regulatory threshold and require less evidence of being effective against cancer. This increase in cancer medicines in turn raises expectations that New Zealanders, too, should have access to such medicines. A recent OECD report expressed concern about the sustainability of member countries’ health budgets in the face of the growing number of new, high-priced cancer medicines entering the market.<sup>21</sup> It noted that spending on such medicines had been steadily rising as a result of higher launch prices and increases in the number of patients being treated, which in turn was due to more cancer cases, new treatment options and longer treatment times.

Development of medicines for rare diseases also continues to grow. Regulatory incentives and fast-tracked approval processes, particularly in the United States, have allowed an increasing array of medicines for rare diseases to become available much faster. At the start of 2021, manufacturers had more than 5,600 medicines under development to combat rare diseases, a 6 per cent increase on the same time in 2019. Most resulting medicines still treat only a single rare disease (or a genomic subset of a rare disease), even though more generally it is becoming common for medicines to be able to treat a variety of conditions. This is most evident in cancer and autoimmune diseases where a better understanding of biological processes allows a single drug to treat numerous diseases.<sup>22</sup>

Precision medicine is an area of promise because it allows individualised treatment based on a greater genetic understanding of diseases and environmental variations among patients. This minimises the side-effects experienced during broad treatment approaches. To date, precision medicine has mostly targeted cancers (accounting for 90 per cent of such approved treatments in 2018).

Working out how to fund expensive new medicines is a challenge all countries continue to face. Pharmac’s ability to foster competition in this area, while also encouraging a shift to generic equivalents, is likely to diminish in the face of this increase in new medicines. Biological medicines, as opposed to traditional synthetic chemical medicines, are expected to dominate the industry by the end of the decade.<sup>23</sup> They currently account for 43 per cent of medicines under development. Importantly, these biological medicines may not fall in price over time in the same way traditional pharmaceutical medicines do because they cannot be copied or manufactured as easily.

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<sup>20</sup> The Economist, August 2021 <https://www.economist.com/business/american-biotechnology-is-booming/21803495>.

<sup>21</sup> OECD, Addressing Challenges in Access to Oncology Medicines, 2020.

<sup>22</sup> Intelligence Informa Pharma, Pharma R&D Annual Review 2021.

<sup>23</sup> Ibid.

## 3 What Pharmac does

We briefly outline here Pharmac's core objectives and functions because this is necessary for understanding later parts of this report. We note, by the way, that we found many people had little knowledge about much of what Pharmac does.

### Purpose and functions

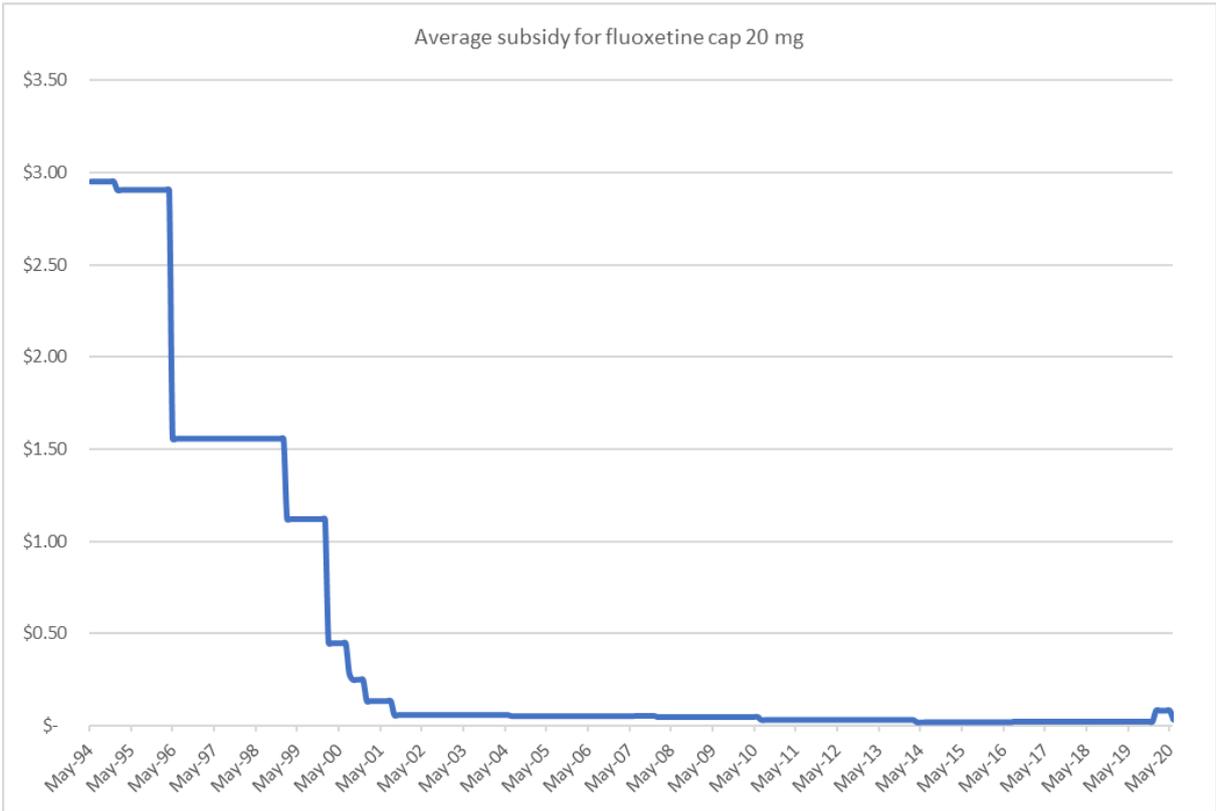
As previously noted, Pharmac became a Crown entity in 2001 under the New Zealand Public Health and Disability Act 2000. Its purpose, as set out in section 47, was to "secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

Section 48 says one function is to "maintain and manage a pharmaceutical schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies". This involves evaluating medicines, comparing them with any already available, assessing need, negotiating a subsidy, and then making those subsidised medicines available. Once a medicine is on the schedule, it tends to stay there.

Day-to-day responsibility for this work rests with Pharmac's therapeutic group managers. They work with pharmaceutical companies, liaise with relevant specialist committees and work with analysts to decide on the relative need and benefits of medicines. They also negotiate prices and subsidies and manage the allocation of funds among their therapeutic groups. The pharmaceutical schedule is split into 23 therapeutic group areas covering such conditions as cardiovascular disease, diabetes, mental health, musculoskeletal conditions, cancer, and rare disorders. Despite the critical role played by therapeutic group managers, we heard from stakeholders of high turnover in these roles. The review also noted Pharmac had been without a medical director, who is responsible for medical leadership, for more some time. We understand that the role has now changed to a chief medical officer and a person has been appointed to the role.

Pharmac negotiates on the price of a medicine as long as it has patent protection. When the patent expires, Pharmac runs a rolling tender to secure the lowest price from several suppliers. Figure 1 shows how dramatically prices drop when a drug is no longer covered by a patent and generic equivalents become available. In this case, it is the well-known anti-depression drug Prozac and its generic equivalent fluoxetine. The subsidy has fallen from \$2.95 a capsule to less than 5 cents a capsule.

**Figure 1: Change in subsidy levels of Prozac/fluoxetine**



A second function is to evaluate medicines that are not on Pharmac’s schedule (or are not funded for the specific use sought by people with urgent or unusual clinical circumstances) but may warrant public funding in exceptional circumstances. Pharmac uses what it calls an exceptional circumstances framework to help with this evaluation. Prescribers, not patients, make applications for public funding of these medicines. Applications under this framework are intended to be a mechanism to complement, not bypass or queue jump, the national Pharmaceutical Schedule funding process. When considering an application Pharmac needs to consider all other patients with similar clinical circumstances. If the patient’s clinical circumstances are different to those who would be eligible through the normal funding application process, then they can be considered. If not, then the application will not be considered, and the patient will need to wait to access the medicine if and when the treatment is funded through the Pharmaceutical Schedule.

A third function is to conduct research and a fourth is to promote the responsible use of medicines.

The responsible Minister can give Pharmac other functions after consulting the agency, and this has happened over the decades (see Table 3) with the addition of vaccines and medical devices. As Pharmac has taken on new or expanded areas of work, its workforce has grown accordingly. Pharmac says assessing new medicines and assessing the expanded use of existing medicines takes up about 30 per cent of its time. As already noted, we will look at medical devices and vaccines in our final report.

**Table 3: Additions to Pharmac activities and functions**

Year	Addition
2003	Some hospital medicines added to schedule (contracts only)
2004	Influenza vaccine added to schedule
2008	A separate fund for hospital cancer treatments added (subsequently combined with community pharmaceutical to form the Combined Pharmaceutical Budget in 2011)
2012	All other vaccines added to schedule <sup>24</sup>
2013	Recombinant (manufactured) blood products added to schedule All hospital medicines now added to the schedule
2014	Some contracts for hospital medical devices added to schedule
2018	Hospital and community pharmaceutical budgets merged

Pharmac is governed by a board that is accountable to the responsible Minister for all aspects of the organisation’s performance. The board ensures compliance with internal policies and governance documents and reinforces the behaviour it expects from the chief executive and staff. Like the boards of many other Crown entities, it has considerable independence to act, within the objective and functions specified in legislation. This independence means politicians are kept at arm’s length from the decision-making processes. Monitoring of Pharmac’s performance is undertaken by the Ministry of Health on behalf of the Minister.

As a Crown entity, Pharmac reports directly to the Minister of Health and liaises with district health boards, whose appropriations include a medicines budget. Pharmac passes on rebates it negotiates with pharmaceutical companies to district health boards. From a budget management perspective, these transfers are opaque and will need updating, along with the underlying legislation, during the health reform process.

## Expert advice

Section 50 of the Act requires Pharmac to have two advisory committees – a pharmacology and therapeutics advisory committee (PTAC) and a consumer advisory committee. Their chairs attend the Pharmac board meetings in an advisory capacity. PTAC is Pharmac’s primary clinical advisory committee. It provides independent, objective advice on the clinical evidence that pharmaceutical companies provide as part of their application for Pharmac funding. It uses Pharmac’s “Factors for Consideration” framework as part of its deliberations before making a recommendation to Pharmac (see Part 4). All its members are clinicians. Pharmac publishes PTAC minutes on its website within 70 days of each meeting.

<sup>24</sup> <https://pharmac.govt.nz/assets/2014-09-12-FINAL-Vaccines-MOU-between-PHARMAC-DHBs-and-the-MoH.pdf>.

We heard from stakeholders a concern that PTAC has no mandate to assess cost as part of its clinical advice as Pharmac has a separate evaluation process for this. Pharmac has clarified that PTAC, through its terms of reference, is asked to consider cost as part of its use of the Factors for Consideration.

If PTAC or Pharmac considers it needs more detailed specialist clinical advice, it refers an application to one of Pharmac's 21 specialist subcommittees, each of which deals with a particular type of disease or condition. A PTAC member chairs each of these specialist subcommittees, which generally meet only when called upon in this way.

Some clinicians told us they believed Pharmac hand-picked PTAC members according to whether they followed Pharmac's approach of "cost above all else". They also said a conformist group mentality prevailed in all Pharmac committees. However, Pharmac says it is a big and difficult task to find individuals with the necessary levels of expertise and time to sit on its various committees. It further said it expected committees to provide impartial, independent advice, and without such advice there was little point in establishing them.

Pharmac does not consult the consumer advisory committee on specific funding applications, but rather, in its words, on how best to get consumer views and how to consider these views in its work.<sup>25</sup> Specifically, it says it seeks the committee's advice on:

- its strategies, policies, and operational activities regarding the funding of, access to, and best use of medicines
- how it can best communicate its decisions, policies, and strategies
- how the committee can engage with consumers to ensure it gives quality advice to Pharmac.

Pharmac says it does its best to seek the views of those potentially affected by its decisions by meeting consumer advocacy groups and by encouraging people to respond to any consultations it releases.

These are laudable objectives. However, we found the tenor of all Pharmac's communications, whether written or verbal, to be guarded and defensive. We found little evidence Pharmac used the consumer advisory committee, or indeed its other specialist advisory subcommittees, to help with its communications efforts.

Members of the consumer advisory committee told us Pharmac called on their services in a reactive, ad hoc manner, and they wanted the mandate and the necessary support to act strategically and proactively. They said Pharmac provided no feedback about whether and how it used their advice in any of its decisions. This made it difficult to keep communities informed and involved and fostered the impression that in seeking their views – and, indeed, those of the public – Pharmac was merely going through a box-ticking exercise. They cited the example of Pharmac's announcement in May this year to review access to cancer medicines for children – a decision made without any reference to them. They said such actions made them feel undervalued, even irrelevant. Finally, they said they considered the consumer voice had only minimal influence on Pharmac's decision-making processes.

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<sup>25</sup> <https://pharmac.govt.nz/about/expert-advice/consumer-advisory-committee-cac/>.

Pharmac told us it was in the process of introducing new terms of reference for the consumer advisory committee which were updated following public consultation. Our impression is that there is still further room to consider the role of the consumer advisory committee.

## Measuring performance

We are not currently in a position to make meaningful comment about how well or otherwise Pharmac is performing. The reason is this: Pharmac zealously guards information about a host of operational and financial matters, making it difficult to measure the extent to which it is meeting its objectives. What information it has given us limits meaningful analysis. This lack of information extends to such basic facts as the cost savings on listed medicines; as noted, Pharmac has only provided indicative ranges for rebates, not actual figures.

At the outset, we sought a range of data from Pharmac, such as its investment profile, including historical investment against a range of indicators (ethnicity, geography, and specific diseases) and what the forecast investment profile might look like. Pharmac would not supply much of this data, citing concerns about our inadvertently revealing commercially confidential information. This lack of information prevents us from being able to identify the risks, systemic or otherwise, arising from the current and forecast schedule of publicly funded medicines.

Rather than reporting on bench-marked performance measures, Pharmac relies on a “savings” methodology based on what the country would have spent on public medicines if Pharmac had not secured price reductions and rebates. The defence for this approach is the supposed difficulty of finding truly comparable countries and the need to report at a level that does not compromise the commercial confidentiality of its agreements with pharmaceutical companies. This approach, whether justified or not, makes any assessment of performance extraordinarily difficult.

We are unable to see and measure the links between inputs, impacts, outcomes, and the long-term objective of achieving the best health outcomes possible from its budget. Getting a clear line of sight between its activities and this objective will be one of the priorities of the next stage of our review.

Without more information, we cannot assess the extent to which Pharmac actively scans for emerging trends that might influence investment decisions. We do know, however, that board minutes available on Pharmac’s website reveal no such scanning, beyond Pharmac’s four-yearly “pipeline report”. Regular review of information, including emerging trends and scanning of issues pertaining to each of the large therapeutic groups and funding provided, would give public confidence that Pharmac’s decision-making was underpinned by a systematic review and refresh cycle and not a “set and forget” formula.

It need hardly be said that the public is in even less of a position to assess Pharmac’s performance or understand how or why it makes the decisions it does. We will be pressing Pharmac more on this issue of performance monitoring and will be examining reporting and governance arrangements to assess whether it is meeting its overall objective of getting the best possible health outcomes from its limited budget. We will be taking a particularly close interest in how Pharmac’s board and the Ministry of Health monitor its performance.

We conclude here by noting that Pharmac’s “fortress mentality” – a phrase borrowed from more than a few submitters – does not bode well for Pharmac in the new health system where greater co-ordination, data-sharing and accountability will be expected of all participants.

## Consultation and communication

Pharmac is legally obliged to consult those likely to be affected by its funding decisions and to communicate any decisions it makes about the pharmaceutical schedule. Specifically, section 49 of the Act requires Pharmac to “consult on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups, or individuals that, in the view of Pharmac, may be affected by decisions on those matters; and take measures to inform the public, groups, and individuals of Pharmac’s decisions concerning the pharmaceutical schedule”.

Consultation is required if it intends switching from one medicine brand to another, or if it intends declining an application to fund a medicine. Good communication is essential if it is to carry out this consultation effectively, just as it is necessary in carrying out its statutory function of promoting the responsible use of medicines. However, many stakeholders felt strongly that Pharmac was not meeting its obligations in this respect. They said Pharmac communicated neither clearly nor frequently enough. We will be looking more closely at Pharmac’s consultation and communication performance. Our initial impression is that Pharmac relies too heavily on its website and social media as communication tools and not enough on building relationships and working alongside patient groups and special interest clinical groups.

## 4 Decision-making and transparency

For the interim report the review has focused on understanding Pharmac's decision-making processes for pharmaceuticals. The review has focused on publicly available information including:

- how easy the public-facing information is to understand
- whether it gives the level of information you would expect to be shared (from both a consumer and industry point of view)
- how long it takes to access information
- whether this would be considered timely.

### Deciding whether to fund a medicine

Pharmac's funding decisions are based on evaluating pharmaceuticals, comparing them with what is already available, assessing need, negotiating subsidies, and then listing subsidised medicines on the pharmaceutical schedule. As illustrated in Figure 2 below, this funding decision process incorporates a *clinical assessment* of medicine, assessing its *relative priority* for funding compared to other medicines, *negotiation of the price* with the medicine supplier and *consultation* with the public before a final *funding decision* is made by Pharmac and the medicine is listed on the pharmaceutical schedule.

### The decision-making process

We describe here the principal elements – but not every element – of Pharmac's decision-making process.

After receiving an application to fund a medicine, Pharmac assesses the medicine from a clinical and economic perspective, compares it with what is already available, assesses the need for it, negotiates a subsidy, consults the public, makes a funding decision, and lists it on the pharmaceutical schedule. Most applications come from pharmaceutical companies, although anyone, including a patient, can make an application. Pharmac itself can, and does, initiate applications, too.

Once an application is received there is a triage process and this, among other factors, can influence when it is considered by the different stages of the assessment processes. How long consideration of an application takes varies greatly and is influenced by the relative priority of the medicine being considered; the timing of meetings of the relevant advisory groups; and whether additional information is needed to complete the assessment stages.

The assessment process starts with the clinical assessment of the individual medicine or medicines under consideration. This involves Pharmac staff providing a summary of the application, with some comment, to the Pharmacology and Therapeutics Advisory Committee or a relevant subcommittee. We understand this summary includes the health need of the patient group, whether existing medicines are already available, the medicine's effectiveness (based on clinical trial data and other available evidence), the suitability of the medicine and the size of the population it will treat. PTAC and/or the subcommittees give advice to Pharmac particularly around efficacy and clinical treatment alternatives and make a recommendation to Pharmac about its view of priority. The subcommittees are particularly important in considering applications relating to some therapeutic areas. For example, cancer treatments will be considered by the Cancer Treatments Subcommittee (CaTSoP).

Once PTAC or an expert specialist committee recommends a medicine receive funding (whether on a low, medium, or high-priority basis), Pharmac conducts an economic assessment of the medicine. Pharmac evaluates the health benefits of supplying the medicine compared to the cost of subsidising it. To do this, Pharmac staff undertake a cost-utility analysis that weighs up the extra quality of life for the net extra cost of the medicine.<sup>26</sup> This analysis measures some, but not all, elements contained in a decision-making framework that Pharmac employs to help decide which medicines to fund (see Factors for consideration framework below). Pharmac staff document this analysis in a report called a technology assessment report.

The pharmaceutical or proposed extension of pharmaceutical use is then compared against all the other funding applications received to decide which ones will get the best health outcomes for New Zealanders within the available budget. At that point, Pharmac looks at whether the prices being offered represent good value overall. Pharmac uses several voluntary price negotiations and supply contracts to control prices and expenditure.

A pharmaceutical may be fully funded without conditions or may have conditions attached (e.g., a particular disease or tumour or an age limit or other clinical indicator). Such conditions on subsidisation are called Special Authorities.

Pharmac does decline applications outright, but not often because new clinical data may emerge. There is also the risk of legal action if an applicant feels the decision has been made unfairly. Pharmac consults publicly on every medicine it places on this decline list and those it intends to decline. It has on rare occasions reversed its decision after such consultation and sent a medicine back for further evaluation.

Once an application has been assessed (noting that it can take many months or even years to complete all the steps in the process) Pharmac allocates the pharmaceutical to one of three lists:

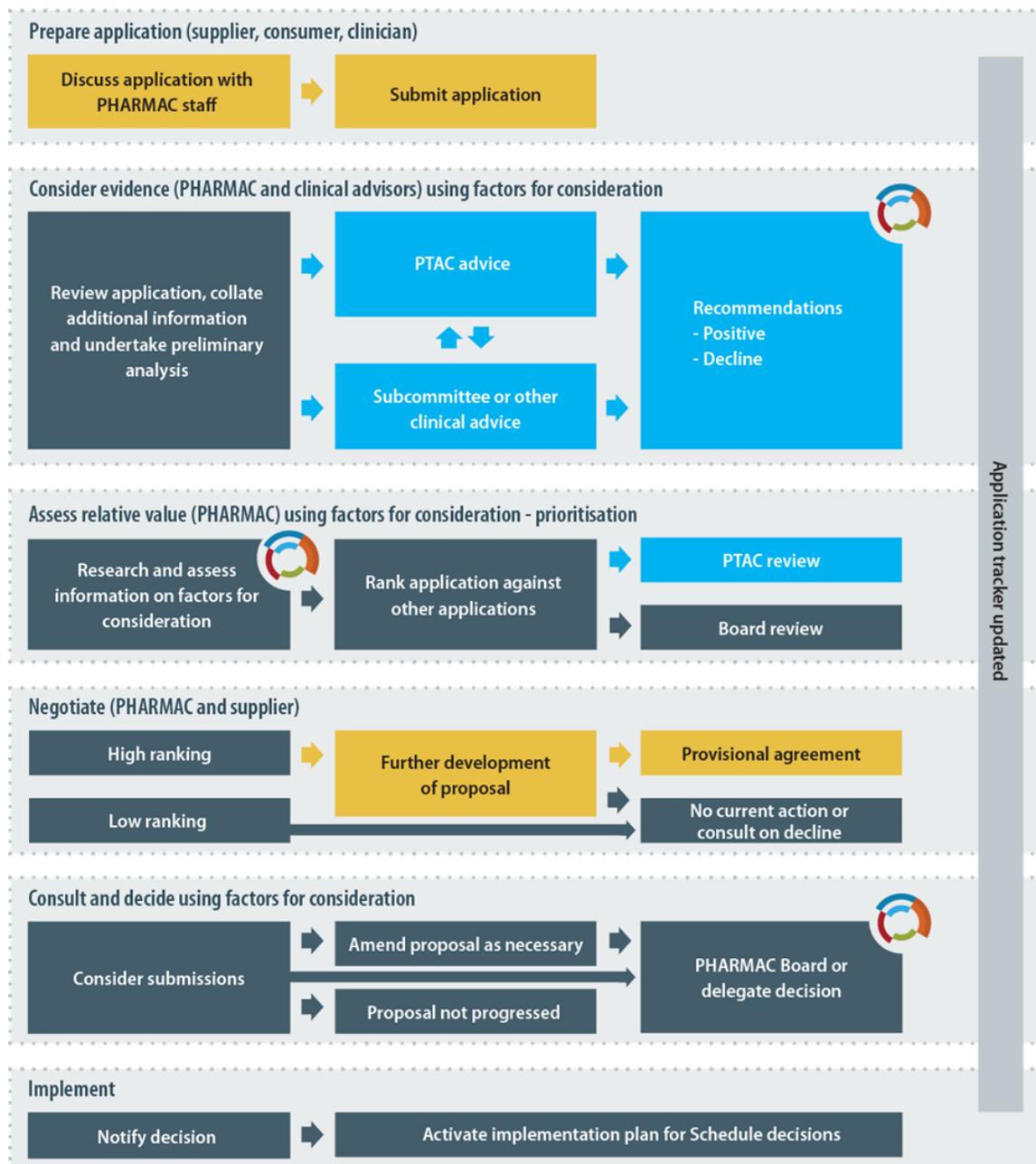
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<sup>26</sup> A medicine's net cost takes account of the cost of any medicines that are no longer needed, plus any extra health system costs, such as those for infusions, imaging, laboratory tests and so on during a patient's lifetime, less health system costs avoided.

- Recommended for decline: Pharmac places applications on this list once the clinical and economic assessments have been completed and the application is not considered fundable. Pharmac now consults with the applicant and the public before a decline is confirmed.
- Fund where cost-neutral or cost-saving: Pharmac may consider funding the medicine if the cost is no greater than funding an equivalent medicine already on the pharmaceutical schedule.
- Options for investment: Pharmac will look at funding the medicine if its budget allows it.

This process of consideration drawn up for us by Pharmac is shown in Figure 2 below.

**Figure 2: Pharmac’s decision-making process**



## Factors for consideration framework

Pharmac says it draws on this framework at every step in the decision-making process. The four factors for consideration are illustrated in Figure 3 below.

The four factors incorporate:

- 1 **Need** – consideration of the disease, condition or illness and the impact of the disease, condition or illness on individuals, wider society and the health system.
- 2 **Health benefit** – consideration of the potential health benefits that can be gained from the medicine being considered for funding.
- 3 **Costs and savings** – consideration of the costs and savings that would result from a decision to fund the medicine
- 4 **Suitability** – consideration of the non-clinical features (for example how it is administered) that might impact on health outcomes.

Figure 3: Factors for consideration



Consideration of these factors happens:

- at the beginning when the funding application is made. How to incorporate the factors into an application is part of the information on how to apply provided for suppliers, prescribers, and patients
- in the cover papers to PTAC so members can see the factors alongside their clinical advice
- after the economic assessment has been completed and applications are prioritised
- as advice provided to the board or executive on the funding of a medicine.

When Pharmac staff are using the factors to provide advice to the board, PTAC or a specialist committee, they use the Factors Internal Guidance document which Pharmac advises is reviewed and updated regularly, for example they were last updated to reflect changes in the Government's health priorities.<sup>27</sup> Whilst the Factors for Consideration do appear to be considered at all stages of the application process and may underpin all its decision-making, information about much of the decision-making assessment process is not widely available, and the guidance suggests the factors themselves are open to a level of discretion in how they are applied.

Pharmaceuticals on the options for investment list are prioritised using the Factors for Consideration. The ranking is established through, we understand, a meeting open to all Pharmac staff.

We understand Pharmac reviews and re-ranks the medicines quarterly. To confirm the rankings, Pharmac runs a process open to all staff using an approach called 1000minds, which it says acts as a proxy into what New Zealanders think.<sup>28</sup> It adds staff views cannot make a significant difference to the rankings. It says it amends rankings in response to changes identified in the framework, including the outcome of price negotiations, any new evidence about a medicine's benefits and any changes in health priorities.

Until July 2021, Pharmac did not make the contents of lists public, citing commercial confidentiality. But in that month, it reversed that position, saying "people are interested in what applications we are actively considering, and we want to be more transparent". The lists are released in alphabetical rather than priority order. It said funding everything on the lists would cost more than \$400 million a year. This is a step in the right direction and one we applaud. However, Pharmac still has a long way to go before it can claim to be truly open about how and why it makes funding decisions.

We talk more about the Factors for Consideration and the manner in which equity is considered in decision-making, in Part 6 on Equity.

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<sup>27</sup> Pharmac Factors for Consideration, Internal Guidance document 2020.

<sup>28</sup> <https://www.1000minds.com/>.

## Testing transparency of decision-making

Transparency of its decision-making was raised consistently when the review heard from stakeholders. Pharmac has tried to provide a level of transparency by publishing information on the decision-making process and timeline on its website through its application tracker (<https://connect.pharmac.govt.nz/apptracker/s/>).

We examined the information Pharmac made public about two medicines during its deliberations to explore how transparent Pharmac’s application processes are. One was empagliflozin (a diabetes drug) and the other pembrolizumab (a cancer drug). Appendix A lays out the information in chronological order. These two case studies illustrate that while Pharmac does provide information on the *clinical assessment* through the minutes of the pharmacology and therapeutics advisory committee meetings during the funding decision process and notifications of decisions, it does not provide specific information on the *economic assessment*. In addition, it appears to confirm that Pharmac does not communicate how it incorporates the Factors for Consideration in its final decision to fund these two medicines. So, stakeholders do see some material around clinical effectiveness, and might not be expected to see its commercial analysis, but we believe there is room for greater disclosure of material relating to the Factors for Consideration.

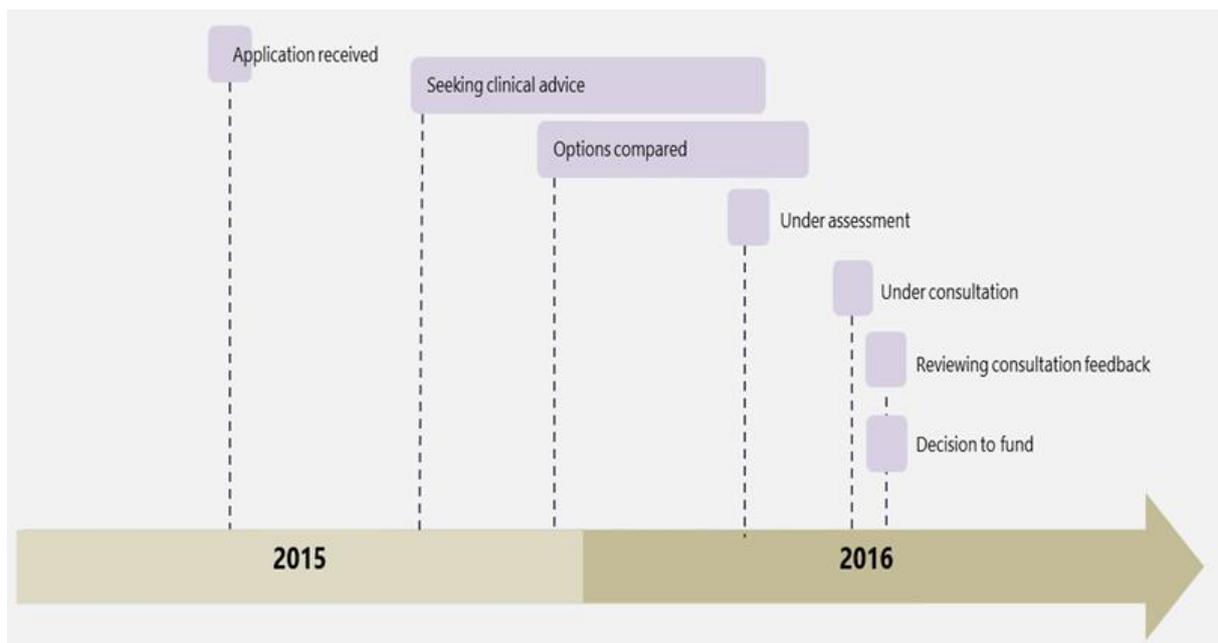
## Timeliness of decisions

Pharmac has no formal benchmarks on timeliness of decisions. It does require PTAC and the various specialist committees to publish their minutes within 70 days of meeting. The review notes the application assessment process is complicated, applications often need further information to be supplied which can take time, and applications rarely follow a linear timeline. It appears each funding decision “takes as long as it takes”. We note that empagliflozin took nearly five years from receipt of application to approval of funding, while pembrolizumab took a little over a year. Figures 4 and 5 set out the timelines we documented from the application tracker.

**Figure 4: Timeline for the funding decisions on empagliflozin**



**Figure 5: Timeline for the funding decisions on pembrolizumab**



## What we heard from stakeholders

There was a long list of concerns from stakeholders, some about specific pharmaceuticals, and some about more general issues, but all feeling marginalised.

- Stakeholders expressed a range of concerns about the way Pharmac made and communicated decisions. A lack of openness and long delays were common sources of complaint, along with an excessive focus on cost at the expense of health outcomes. Some said Pharmac's cost-saving culture had got so out of hand it was having a detrimental effect on the health of New Zealanders.
- Submitters complained Pharmac would give no indication of how long a decision might take. There is some justification for this reluctance because of variables such as the relative priority of the medicine under consideration and when specialist committees meet, but even this does not account for the huge variation in decision times. Even an indicative timeframe would be of some use. We heard of applications taking anywhere from nine months to ten years.
- Submitters also complained Pharmac published detailed information on the mechanics of the decision-making process and the range of factors it said it considered but disclosed minimal information about how it applied its decision-making criteria in individual cases and on what basis it made its final decisions. One industry submitter said the way Pharmac decided which medicines should receive priority funding was "completely lacking in natural justice and public accountability".
- Stakeholders expressed frustration at Pharmac's failure to explain how it applied the Factors for Consideration framework, including the weighting it gave to each factor, and in fact whether it applied them at all.

- Others said Pharmac was highly selective about what it made publicly available, and that its default position was to withhold information and force interested parties to rely on Official Information Act requests to obtain the information they were seeking.
- Consumers often spoke of feeling ignored or marginalised by Pharmac’s approach. They questioned the level and quality of consultation by Pharmac and said there was a lack of meaningful input from consumers. Said one: “The consumer voice appears to be secondary and undervalued.” Said another: “You very quickly realise you are the least important element of that system. The sole driver of Pharmac’s actions is reducing costs. All other factors – aside from managing PR – are secondary”.

The review considers that some of these submissions, including industry submissions about their own drug applications, are to be expected, but we note lack of transparency appears to be reducing trust and confidence in pharmaceutical decision-making. For the review, this is summarised in the following quote from a medical college. The college was among those voices calling for a more inclusive and collaborative approach by Pharmac, saying it would increase public participation and input into decision-making: “If Pharmac used processes that are sensitive to inconsistency and context to inform fairness when making difficult decisions to achieve equity, there would be greater transparency and trust in the process”.

## **What the review observed and next steps**

The review notes that since Pharmac’s inception the processes of pharmaceutical assessment, costing, and defining and measuring health outcomes have become more complex. There will be new institutional arrangements in the new health sector, including a health charter, and the review will consider further how a more comprehensive medicines strategy might assist in providing more equity guidance. The review will also observe how Factors for Consideration are used in practice and will make suggestions about a more transparent process. We will also make specific comment on broadening and strengthening consumer involvement.

## 5 Equitable outcomes in the new health and disability sector

Pharmac’s statutory objective does not explicitly require it to secure equitable health outcomes for all, but rather the best outcomes reasonably achievable within its budget for “eligible people”. Nonetheless, successive governments have expressed their desire to eliminate the unjustifiable differences that have arisen in health outcomes for Māori and Pacific people. Pharmac’s own enabling legislation defines one of the Act’s purposes as “reducing health disparities by improving health outcomes for Māori and other population groups”.<sup>29</sup> Later health legislation refers to “reducing inequalities”.<sup>30</sup> Today, it is called “achieving health equity”.

### Importance of equity

The Crown has accepted the advice of the Waitangi Tribunal that equity as a Treaty principle should apply throughout the health system.<sup>31</sup> Table 4 sets out details of this principle and other principles from the tribunal’s Hauora report in 2019. Our terms of reference are very clear on the importance of equity. One of the two key issues we must investigate and make recommendations on is whether Pharmac’s objective to improve health outcomes for all New Zealanders facilitates its potential to achieve equity for Māori and Pacific peoples. That requirement extends to health inequities faced by disabled people and those with rare disorders.

**Table 4: Principles and guarantees of Te Tiriti o Waitangi, from Waitangi Tribunal’s Hauora report (2019)**

Guarantee of Tino Rangatiratanga	There is Māori self-determination and mana motuhake in the design, delivery and monitoring of services.
Principle of equity	The Crown unequivocally commits to achieving equitable health outcomes for Māori.
Principle of active protection	The Crown acts, to the fullest extent practicable, to achieve equitable health outcomes for Māori and be fully informed of Māori health outcomes and inequities.
Principle of options	The Crown ensures all health services are provided in a culturally appropriate way that recognises and supports the expression of Māori models of care. The Crown also supports Māori health and disability providers to participate fully in the provision of services.
Principle of partnership	The Crown and Māori work in partnership in the design, delivery, governance and monitoring of primary healthcare services.

<sup>29</sup> New Zealand Public Health and Disability Act 2000, s 3.

<sup>30</sup> Ministry of Health, 2002. Reducing Inequalities in Health: <https://www.health.govt.nz/publication/reducing-inequalities-health>.

<sup>31</sup> Waitangi Tribunal, Hauora report, 2019.

## Defining equity

As already noted, we have adopted the Ministry of Health’s definition of health equity, which is based on the World Health Organisation’s definition. Its essence is that different people have different levels of advantage and require different approaches and resources to get equitable health outcomes. A one-size-fits-all approach to health delivery does not satisfy the requirements of this definition. We have drawn on academic and overseas sources, including Māori and Pacific communities and scholars, to give context to what health equity should look like and how inequities arise and can be eliminated.

We note at the outset that different population groups:

- have different degrees of access to the things that help them stay healthy
- have different degrees of exposure to the things that put their health and wellbeing at risk
- have different degrees of access to healthcare services (including medicines), depending on such factors as location, physical access to services, the availability of services, the cost to patients of receiving care, and eligibility and funding rules
- receive different levels of care, including unjust or unfair differences in the kinds of referrals they receive, and are subject to differences in prescriber behaviour.<sup>32</sup>

While we are concerned with any unfair and unjust differences in outcomes between different population groups, health inequalities based on ethnicity are the most marked and persistent. This fact has been well established by the Waitangi Tribunal in the first stages of its inquiry into health services (WAI 2575), and by the Health and Disability System Review in both its interim and final reports.<sup>33</sup> In other words we are keeping an eye on how the potential for racism and ableism play out in Pharmac’s work and how this in turn impacts on inequity.

## Submitters’ concerns at decision-making

Through submissions, we heard equity-related concerns<sup>34</sup> with the way Pharmac made decisions on available funding for pharmaceuticals:

- A sense that Pharmac was not working to achieve equitable outcomes from the perspective of Māori and Pacific peoples or other disadvantaged populations.
- Pharmac looks at medicines in an isolated way and does not consider the shortcomings of the overall health and disability system which have a particular impact on Māori and Pacific populations and disabled people and those with rare disorders.
- A sense that despite needs of population groups, including Māori and Pacific people with significant metabolic disease, pharmaceuticals are not funded quickly enough.

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<sup>32</sup> This framework is based on Jones (2001) as quoted in Reid et al: Understanding Health Inequities, 2006, Hauora IV, University of Otago.

<sup>33</sup> Health and Disability System Review, Final Report Pūrongo Whakamutunga, 2020.

<sup>34</sup> We note that there were also a number of submissions that related to perceptions of “unfairness” in the way Pharmac makes pharmaceutical funding decisions. These are discussed elsewhere [chapter reference].

Submitters also identified that the balance of clinicians and “expert” voices on one hand and consumer voices (particularly Māori and Pacific groups and disabled people) was weighted too heavily in favour of health professionals, leading to decisions that did not take the impacts of equity into account sufficiently.

In the last year Pharmac has introduced ethnicity as a Special Authority criterion for empagliflozin (with or without metformin) and dulaglutide (for treating diabetes). Pharmac says it is developing a policy to guide decisions on inclusion of ethnicity in Special Authority criteria.<sup>35</sup> This shows promise, but it only came because of concerted advocacy from Māori stakeholders.<sup>36</sup>

## Factors for consideration and equity

In undertaking its funding role, Pharmac starts with a utilitarian approach, in that it seeks to achieve the best use for society of available funding. As discussed in Part 4, Pharmac applies a set of four Factors for Consideration. Equity considerations are included most explicitly in the first factor, need, which looks at consideration of the disease, condition or illness, and the impact of the disease, condition or illness on individuals, wider society, and the health system.

The need dimension includes the following elements:

- the impact on Government health priorities
- the impact on the health of population groups experiencing health disparities
- the impact on the Māori health areas of focus and Māori health outcomes
- the availability and suitability of existing medicines, medical devices, and treatments
- the health need of the person.

These elements have the potential to balance the classical utilitarian economic focus (on the greatest good for the greatest number) with a view about the impact on those with the greatest health need. Therefore, the need dimension might reasonably be expected to bring an equity element to the prioritisation decision.

But as discussed here and in Part 4, the review was concerned at how the factors were applied and when. The review will explore this more for its final report, by looking at several pharmaceutical decisions, supporting analyses and how Pharmac has considered issues such as burden of disease, distributional impacts, and other equity outcomes that we are interested in.

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<sup>35</sup> Pharmac Equity Briefing (for Review Panel) (2021), p4.

<sup>36</sup> Verbal briefing by Te Whakakaupapa Urutā to review committee, 22 July 2021.

## Adopting different analytical perspectives to achieve equity

The inequities across the health and disability system mean there is not a universal health and disability system experience in Aotearoa New Zealand. A clinician group told the review that “Equity should be one of the primary considerations for all funding applications, applications should have to outline what benefits the medication or device has to priority population, and what engagement and partnership they have undertaken in their process (if any). Applications that have a higher equity focus and bigger potential for gains in achieving health equity should be prioritised. This may also result in some positive research and engagement of our priority populations”.

The standard approach to assess the degree of health gain that can be achieved for a given cost is Quality Adjusted Life Years (QALY) and is commonly used for medicines investment decisions internationally. However, while the average benefit to cost ratio of an individual health intervention (whether that is prescribing a medicine or some other activity) may be high, whether such an investment moves the population towards equitable health outcomes depends upon distributional considerations.

Assessing health investment is more complicated than people might think. It is possible to fund services or pharmaceuticals with positive cost-benefit ratios that will improve health for some while at the same time increasing inequity. Bowel cancer screening illustrates this point. Screening is highly cost-effective compared to other healthcare interventions. But since the disease had a relatively lower incidence among Māori, this could increase inequity by focusing on a disease less common among those with the greatest health needs.

We need to make investment decisions in such a way that they move the population towards equity, rather than away. That means thinking meaningfully about the overall burden of disease and what difference an intervention will make for people with different starting points in terms of their burden of disease and their health need.

## Balancing different perspectives in decision-making

Many stakeholders and submissions noted a widespread perception that Pharmac’s processes were opaque, and it took an unreasonably long time to reach decisions (as discussed in Part 4). One industry stakeholder noted “Pharmac’s processes are not patient-centred. It does not formally involve or capture the perspectives of patients, patient groups, hard to reach communities or different ethnic groups in its decision-making or in the design of its methods.” We have also heard concerns raised about the gender, ethnicity, and disability breakdown of Pharmac’s clinical advisory groups. An early indication from the numbers we have been provided by Pharmac is that only around 4 per cent of clinical advisory group members identify as Māori,<sup>37</sup> but ethnicity data was not available for all group members.

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<sup>37</sup> Numbers provided by Pharmac: 6 Māori clinical advisory group members out of 152 people who have provided ethnicity data (a further 53 have not provided data).

However, what we have seen warrants further investigation and we will continue to investigate the range of skills and expertise included in decision-making processes and the balancing of clinical and consumer voices and perspectives, including equity, Hauora Māori, Pacific health, and disability expertise.

We are also aware the focus in this report has been equity implications for Māori as a population group. However, we have been asking questions about Pacific health outcomes and the health and wellbeing of disabled people and those with rare disorders and will continue to do so. We understand Pharmac has also identified groups with low socio-economic status, refugees and people who live in rural areas as priority groups.

To date the review has come up against substantial data limitations, particularly around disability-related information. Also, there is limited data on medicine access equity for Pacific people in relation to their health needs. We are also unable to get data on the numbers of disabled people employed by Pharmac or on Pharmac committees because it is not collected routinely. Pharmac is not alone in this regard – disability data is poorly collected across the health and disability system – but it is certainly something that works counter to a pro-equity approach.

## 6 Building a culture of equity

Pharmac states its focus on equity started with the work undertaken on the first Māori responsiveness and Pacific responsiveness strategies.<sup>38</sup> In 2017 this extended to identifying “medicines access equity by 2025” as one of three bold goals,<sup>39</sup> which more recently evolved into identifying “equitable access and use” as one of six strategic priorities.<sup>40</sup> This goal risks being rhetoric if there is no evidence of how it is operationalised throughout Pharmac’s:

- Te Tiriti o Waitangi commitments
- implementation of funding decisions
- organisational-level policies and strategies
- staffing and team structure and advisory committees
- internal decision-making
- partnerships in the health and disability sector and in the wider community – particularly for Māori whanau, hapū and iwi, Pacific communities and disabled people.

### Pharmac’s role in equitable use of pharmaceuticals

Across all iterations of its equity commitments Pharmac is clear its focus is to change what is in its direct control and positively influence prescribing and use of medicines.<sup>41</sup> A hui participant told the review “It’s not about Pharmac, it’s about our people. How do we shift an entire health system built on silos?”.

In its 2019 document *Achieving Medicines Access Equity in Aotearoa New Zealand – Towards a Theory of Change*, Pharmac excludes unfunded medicines from its work on equity.<sup>42</sup> Removing consideration of unfunded medicines is in itself inequitable. The document (while acknowledging wider determinants of health, racism and colonisation play a role in creating inequitable health outcomes) narrowly defines and articulates the barriers to accessing funded medicines in the community. Pharmac classifies barriers as either patient-centred or health system. These barriers don’t fully incorporate the drivers of inequity or the pathways that contribute to inequity, such as differential access to the determinants of health, differential access to healthcare and differences in quality of care. Nor do they capture the pervasive impacts of racism on differential health outcomes.<sup>43</sup>

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<sup>38</sup> Pharmac Equity Briefing (for Review Panel) (2021), p1.

<sup>39</sup> Ibid, p2.

<sup>40</sup> Pharmac (2020) Statement of Intent, p31.

<sup>41</sup> Pharmac Equity Briefing (for Review Panel) (2021), p2.

<sup>42</sup> *Achieving Medicines Access Equity in Aotearoa New Zealand – Towards a Theory of Change* Pharmac (2019) p7.

<sup>43</sup> Racism and health in Aotearoa New Zealand: a systematic review of quantitative studies. Talamaivao (2020),

A comprehensive approach to the determinants of health is seen as core to organisations taking equity commitments seriously.<sup>44</sup> In this case, Pharmac’s narrow approach to understanding barriers to health equity in medicines access, coupled with its narrowly defined equity obligations, compromises a pro-equity approach.

## **Operationalising equity commitments is mixed**

Pharmac’s record of practically addressing inequity is mixed. When asked, Pharmac has pointed to initiatives such as One Heart Many Lives, and Space to Breathe / He Tapu Te Hā, as good examples of social marketing campaigns seeking to eliminate inequity. Pharmac was out there on the marae and the sports fields, with health champions, seeking to ensure medicines were used in the right way. We find these examples compelling, but both programmes ended (in 2015 and 2013 respectively) and have not been replaced. The rationale for ending those programmes is not clear and the job of improving medicines access for Māori and Pacific populations and for disabled people remains.

More recently Pharmac has funded He Ako Hiringa to support the responsible use of pharmaceuticals in primary care. Its primary focus is to drive medicines access equity for Māori and Pacific peoples with long-term conditions by providing free education and analytics to primary care clinicians.

From the evidence presented to us, from Pharmac’s review of itself, and from the organisational mechanisms and other evidence, we see pro-equity engagement talked about but lacking in practice. For instance, although the organisation has grown considerably, the number of Māori employed has fallen (discussed below). There is no evidence of a Māori responsiveness strategy being enacted at governance level, at management level, through specialist and other committees, or through any other mechanism.

## **Case study: building a Pharmac workforce with equity capability and increasing the number and influence of Māori staff**

Pharmac’s Te Whaioranga / Māori responsiveness strategy has been in place since 2002, with different iterations. The fourth iteration was released in 2020 with the dual purposes of giving effect to Pharmac’s Te Tiriti o Waitangi obligations and understanding and supporting whānau Māori to achieve best health and wellbeing through access to, and optimal use of, medicines and medical devices. A Hui participant told the review: Pharmac’s “Te Whaioranga strategy, it’s light on detail. I can’t see the core values from a Māori perspective. Just the words but not the next step. What does it mean for Pharmac?”.

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<sup>44</sup> Achieving Health Equity: A Guide for Health Care Organizations. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; Wyatt et al. (2016).

Pharmac has in particular emphasised the focus of this strategy on strengthening Māori leadership and advice. Recently it appointed an inaugural Chief Advisor, Māori role (part of the Pharmac executive team). Previous Māori-specific roles have not been this senior. This is a positive development. However, as a review we cannot ignore the fact this is only one position in the context of nearly 150 people and is not proportionate to the level of commitments to building the influence and number of Māori staff Pharmac has made in the past. A stakeholder told the review Pharmac “should look at who they are employing. There seems to be a high turnover of staff, lack of ethnic variety to reflect society. They have done better at engaging the community a bit more, but they also work a lot behind closed doors and emails. Need more Pacific and Māori staff and clinical staff not just clerical”.

Table 5 summarises the Māori workforce commitments made in Pharmac’s four Māori responsiveness strategies over this time.

**Table 5: Pharmac’s commitments to building a Māori workforce (2002–2020)**

Document	Commitment to building a Māori workforce
<i>Te Whaioranga Pharmac Māori Responsiveness Strategy, 2002</i>	“Improve human resources development by nurturing culture within Pharmac that is responsive to Māori requirements and to develop and implement a training and development programme” (p11).
<i>Te Whaioranga Pharmac Māori Responsiveness Strategic Action Plan, 2007</i>	Māori staff training and development plan to be developed, implemented and funded (p5 and p6), which is noted as “in progress”.
<i>Te Whaioranga Pharmac Māori Responsiveness Strategy, 2013</i>	Recruiting and retaining key staff with strong links with Māori communities (p9), although this is something that is seen to have been a strength from previous years (p6).
<i>Te Whaioranga Pharmac Māori Responsiveness Strategy, 2020</i>	Pharmac increases and supports Māori participation in governance, leadership and management decision-making at all levels of the organisation (p8).

We assume Pharmac aims to have a workforce reflecting the wider population – which means Māori would make up 16.5 per cent of Pharmac’s employees.<sup>45</sup>

Pharmac has provided ethnicity breakdown of its staff annually since 2015. Table 6 below shows there has been both a slight decrease in the number of Māori staff employed and a drop in the proportion of staff who identify as Māori, and at 2.2 per cent it is well short of 16.5 per cent.

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<sup>45</sup> Statistics NZ (based on 2018 Census data).

**Table 6: Pharmac Māori staff numbers 2015–2021<sup>46</sup>**

Year to 30 June	Number of Māori staff	Total number of staff	Percentage of Māori staff
2015	6	115	5.2
2016	6	127	4.7
2017	4	120	3.3
2018	5	126	4.0
2019	5	127	4.0
2020	3	132	2.3
2021	4	146	2.2

The workforce data presented in Table 6 suggests Pharmac has not yet created or “nurtured” an environment that attracts and retains Māori staff and raises questions about the level of priority given to the commitments made towards improving Māori health generally and in implementing Te Whaioranga specifically.

Pharmac also needs to build the overall capacity and capability across all its staff to be more responsive to Māori and to build the organisation’s capability to address inequity and the elimination of inequity in its work. We understand this still requires considerable work by Pharmac, some of which is planned for the 2021/22 year.

In 2020, Pharmac commissioned its own independent Te Tiriti o Waitangi review focused on how it was doing as an organisation.<sup>47</sup> This highlighted gaps in staff understanding, capability, and ability to respond to Te Tiriti. This translated to a lack of understanding and analysis in the advice included in board papers, significant policy processes and development, funding decisions, operating procedures and processes. Also, the Factors for Consideration did not comply with Te Tiriti. This lack of understanding impacts Pharmac’s ability to eliminate inequities for Māori.

We have heard similar themes in feedback from submitters and Hui participants on the way Pharmac operationalises its Te Tiriti o Waitangi commitments and will continue to look into this further.

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<sup>46</sup> Pharmac Annual Reports. A caveat to the staff ethnicity data provided in this table is that it is unclear whether and to what extent the *Ethnicity Data Protocols* have been applied by Pharmac. These guidelines describe the procedures for the standardised collection, recording and output (reporting) of ethnicity data for the New Zealand health and disability sector and extend to information on employees of organisations (i.e., health workforce statistics). The outputs used, especially in 2015 (before the current protocols came into place), indicate that a standardised question has not always been asked. It is also unclear whether prioritised ethnicity is used in analysing ethnicity data.

<sup>47</sup> Maihi, C. (2020) Pharmac Te Tiriti o Waitangi Review.

## Māori Advisory Rōpū

Following the 2018 pro-equity Pharmac-commissioned review, a Māori advisory rōpū is being established (Te Pātaka Whaioranga Māori Advisory Rōpū) to provide the organisation with access to external Māori health capability. Its terms of reference identify the kaupapa as being: to provide Māori leadership and high-level advice and guidance to the Pharmac board and the senior leadership team in respect of Pharmac's commitment to achieving the best health outcomes for Māori. The rōpū will also provide guidance to Pharmac on its commitment to upholding Te Tiriti articles and principles.

This is a positive step. However, the amount of action and speed with which things are implemented are disproportionate to the level of Māori health need. At the time of writing this report membership of the rōpū was not yet confirmed and while it was meant to meet in July, as of early September this had not happened. The review also heard from submitters there was a fatigue factor around more advisory groups with a perception that advice given was rarely acted on.

## Implications for the review

The review will spend more time considering Pharmac's approach to equity and how it is discharging its responsibilities. The review will talk more with affected groups and with Pharmac about how different approaches could be taken to improve outcomes for those groups.

## 7 Stakeholder engagement

The review received 213 submissions, held over 40 face-to-face interviews and three group sessions with industry representatives and advocacy groups to get more detailed views on issues raised by the review. We also held a series of meetings with Pharmac to get its perspective on what was working well, and what was not with the current arrangements, as well as its views on where improvements could be made to the medicines assessment process. We structured all engagement around a series of pre-prepared questions and have incorporated the views expressed to us in the body of this report.

### Interviews and workshops

As well as receiving formal written submissions, the review (or the secretariat acting on our behalf) met with a wide range of stakeholders, held focused workshops with some groups and met with Government officials and Pharmac (staff, board, and advisory group members).

Most of those we met acknowledged the role Pharmac played in the health system and that the role was needed to ensure New Zealanders had access to reasonably priced medicines. However, they also felt that a review was long overdue and welcomed the opportunity to share their experience of Pharmac and thoughts about how Pharmac needs to change to become an organisation that delivers a broad range of health outcomes as well as providing cost-effective medicines and medical devices.

The themes from the interviews and workshops were consistent with the content of the written submissions and many of those we met also followed up with a written submission. A feature of the interviews and workshops that the review noted was the level of consistency both within and between the stakeholder groups. Most of those we talked to, for example, acknowledged the complexity of the assessment process but criticised the length of time taken to make a decision to fund a particular medicine. They also said poor communication with stakeholders at the different stages of the process exacerbated matters.

In the workshops held with the industry members and with advocacy and consumer groups, we were able to spend more time hearing what people felt was good about Pharmac, and where there was room for improvement. We also asked their views about the role Pharmac needed to play in forthcoming health reforms. The key themes from the workshops, overall, aligned with the themes from the submissions. A common thread running through feedback, albeit one outside Pharmac's scope, was the need for a strategy and policy settings applicable across the entire health sector. Submitters also raised the need for an updated medicines strategy and a strategy for patients with rare disorders.

## Submissions

We received written submissions from a wide range of individuals, academics, clinicians, consumer groups and pharmaceutical industry members.

**Table 7: Submitter types**

Submitter type	Description	Number of submitters	Percentage of total
Individuals	Submitted a personal account generally based on their individual experience of Pharmac	86	40
Consumer groups	A group that is representing the interests of a particular condition requiring medicines (e.g., cystic fibrosis) or that advocates for patient rights (e.g., Patient Voices Aotearoa, Human Rights Commissioner)	51	24
Clinicians	Medical professionals, including pharmacists, who submitted stating a professional view, and groups representing clinicians	46	22
Industry	Pharmaceutical company or industry association	28	13
Academics	Individuals submitting an academic view, who had an affiliation with an academic institution	2	1

With 213 responses from a broad range of submitters, we are confident, given the consistency of the responses, that the results are robust.

In the following section, we have summarised the principal themes to emerge from submissions. These were consistent with the results of our interviews and workshops. Most interviewees and workshop participants:

- were in favour of the role Pharmac played in the health system, although they were clear that changes are needed to make it an effective – but less cost-driven – organisation that funds a broad range of medicines and medical devices
- accepted that the assessment and funding process is inherently complex, but even allowing for that fact, it still takes too long to decide whether to fund particular medicines, and matters are made worse by the poor communication with stakeholders throughout this process
- workshops reiterated these points. Participants also emphasised the need for Pharmac to develop better strategies – including for patients with rare disorders – and better high-level policy settings, including an updated medicines strategy.

## Themes

### Te Tiriti o Waitangi principles largely unseen in decision-making, operating methods

Many submitters said Pharmac did not reflect Treaty principles well – or, indeed, at all – in the way it made decisions and functioned. This could be seen in a number of ways, including: a lack of funding for medicines for diseases and conditions that disproportionately affected Māori; a lack of Māori representation in Pharmac leadership positions at both governance and operational levels, including on Pharmac committees; and a lack of partnership and engagement with Māori in the decision-making process. They said Pharmac could turn around this state of affairs by:

- prioritising medicines and medical devices that have the greatest benefit for Māori
- adopting a te ao Māori perspective in funding decisions
- monitoring and reporting on the outcome of funding decisions
- explaining how it intends to uphold the principle of partnership and guarantee tino rangatiratanga.

A few submitters said Pharmac was aware of the need to reflect Te Tiriti principles more in the way it worked and was taking steps in the right direction.

### Pharmac is underperforming in helping to fix inequitable health outcomes

Some submitters said Pharmac needs to improve its consultation and engagement with the public – particularly Māori, Pacific, rural communities, disabled people, and other vulnerable groups. They identified that Pharmac needs to understand equity needs better, feed informed advice into its decision-making, and help achieve more equitable health outcomes for these population segments. There was a view that equity is not considered as one of the questions that Pharmac or its committees tries to answer, and that equity should be one of the very first questions that are brought to the table.

Submitters had various suggestions about how Pharmac could help correct health inequalities. They suggested Pharmac:

- set clear equity targets and monitor how funding decisions contribute to more equitable outcomes
- explain how it intends to correct inequalities in under-served populations in the community
- put the end-user foremost in its approach to funding medicines and medical devices for disabled people, such as considering bespoke services and medical equipment
- improve the equity capability and capacity of the board, committees and staff, including having Māori, Pasifika and disabled people's voices at the table and part of the decision-making processes

- prioritise funding of medicines that could be taken orally or administered at home, rather than in hospitals or at GPs' premises
- align its existing Māori health strategy with that of the Ministry of Health's Māori Health Strategy, He Korowai Oranga, and other work by their Māori Health Directorate.

### **Prioritisation approach disadvantages those with rare disorders or conditions**

Many submitters – particularly individuals, consumer groups, and industry submitters – indicated that taking a cost-savings approach to decision-making means Pharmac largely relies on an assessment of cost-effectiveness to decide what medicines and devices to fund. These submitters suggested Pharmac makes funding decisions primarily based on achieving the best outcome for the largest number of people. These submitters argued this 'one-size-fits-all' approach disadvantages those who require an individualised approach – such as those with rare disorders – due to their smaller population size.

Submitters who commented on this 'one-size-fits-all' approach considered it to be a major constraint to Pharmac's responsibility to provide the best health outcomes for all New Zealanders. They explained that a lack of consideration of the needs of those with rare disorders or conditions has resulted in inequitable outcomes for these groups as they are unable to access the high-cost treatment that they need to live well.

Submitters also found it unfair that Pharmac has no alternative assessment pathway for medicines or devices to treat diseases or conditions that affect small population groups.

### **Excessive focus on containing costs**

Many submitters said Pharmac's fixed budget makes it unnecessarily focused on containing costs. They said its concentration on short-term cost savings means it does not consider the long-term impact of its funding decisions on consumers or the health system. An example was Pharmac's failure to consider the opportunity costs of not funding certain medicines, opting instead for cheaper alternatives. Some submitters argued Pharmac's emphasis on costs is at odds with its legislative mandate to provide the best health outcome for all New Zealanders. Said one clinician: "It seems that cost is the driving force, not patient need". However, a few submitters said this cost-saving approach has been beneficial, adding that Pharmac's strong negotiating powers have improved access to affordable medicines and medical devices.

### **Funding decisions don't consider all available evidence and advice**

Many submitters said Pharmac does not consider the latest available evidence or expert advice, or give appropriate weight to overseas research, when making funding decisions. They were baffled when Pharmac refused to fund medicines or medical devices considered safe and effective in other countries on the grounds there was insufficient evidence about their efficacy. A few submitters, however, considered Pharmac's approach to funding decisions to be well-researched and evidence based.

## **Decision-making opaque and slow**

Many submitters were frustrated at how long Pharmac takes to consider, prioritise, and fund medicines and medical devices. The opaqueness surrounding how it makes decisions – and when it will make them by – was another source of frustration. The lack of information about how Pharmac prioritises the funding of medicines or medical devices greatly concerned consumer groups and pharmaceutical industry members. These submitters said they often did not know the basis for prioritising one medicine over another, how Pharmac applied decision-making criteria, or how long it would take to reach a decision. More than a few mentioned Pharmac’s failure to communicate to the public or clinicians the reasons for switching medicine brands. They said this omission has potential consequences for patient health. A few submitters, on the other hand, said Pharmac’s processes work well and are relatively open to outside scrutiny. They also said Pharmac makes information about funding applications available in a timely manner.

## **Engagement with consumers and advocacy groups not meaningful**

Pharmac’s decision-making processes lack meaningful consultation with, or involvement from, the public and advocacy groups, according to many submitters. They said there is a lack of consumer representation, including of vulnerable communities, on its subcommittees.

Without meaningful input from consumers, they said, Pharmac sometimes fails to prioritise or fund medicines and medical devices that meet consumers’ needs. The patient’s voice is absent from the decision-making process, too, said one patient/consumer group, and this results in a “lower quality of data and information provided to decision-makers”. A few submitters considered that Pharmac’s public consultation process works well.

On a related note, a few submitters considered Pharmac does not seek meaningful input from clinical experts during the decision-making process. They also considered relevant clinical experts to be poorly represented on subcommittees. Other submitters, however, spoke positively of Pharmac’s performance in seeking input from various clinical experts on specialist subcommittees.

## **“Two-tier” health system has developed for haves and have-nots**

Some submitters argued a “two-tier” healthcare system has evolved in response to Pharmac decisions to fund some medicines and medical devices and not others. Those who are well off can afford to buy more modern and effective medicines and medical devices, leaving the rest to rely on publicly funded medicines and medical devices, which are generally fewer in number and older, offering suboptimal treatment and outcomes. This two-tier system flows down even to GP visits, according to some submitters, especially clinicians, who said many individuals cannot afford to go to a doctor to get a prescription for cheaper medicines. One clinician group said subsidies that reduce the cost of prescription medicines are pointless if people cannot afford the cost of a GP visit to get them.

## **Convolut ed procurement processes put off pharmaceutical companies**

Some industry submitters and consumer groups said international pharmaceutical companies are discouraged from registering new medicines in New Zealand because of Pharmac's lengthy and complicated procurement processes, along with the limited prospects of Pharmac eventually funding their medicines. This acts as a significant barrier to the availability of a greater range of medicines in New Zealand, they said. One industry submitter said, "Fewer pharmaceutical companies [are] doing business in New Zealand because the environment is not economically viable".

## **New Zealand falling behind other developed countries**

Many submitters said New Zealand is falling behind other developed countries in providing public access to a range of modern medicines and medical devices. They said a big factor is the size of New Zealand's pharmaceutical budget, which is well below that of other OECD countries. Some of these submitters suggested that limited access to medicines and devices has also contributed to poorer health outcomes for New Zealanders compared to other developed countries.

Submitters also said that New Zealand takes considerably longer to assess, prioritise, and fund medicines and medical devices than other OECD countries.

Some submitters, particularly patient and consumer groups, said other OECD countries – unlike New Zealand – offer alternative routes to assessing and funding medicines for those with life-threatening or rare diseases or conditions. They cited Australia's Life Saving Drugs Program and the United Kingdom's NICE assessment process. A few submitters said other OECD countries, such as Canada and the United Kingdom, have more transparent decision-making processes.

## **Suggested improvements from submitters**

Submitters suggested a range of measures to improve Pharmac's performance, which we have grouped under the following headings.

### **Emphasise health outcomes more in funding decisions**

Many submitters said Pharmac should adopt a funding model that puts more weight on health outcomes than on making cost savings. Specifically, submitters suggested:

- The Government should amend Pharmac's statutory objective to make health outcomes the paramount consideration in funding decisions.
- Pharmac should separate its assessment and procurement functions when making funding decisions.

- Pharmac should develop a medicines strategy that clarifies their approach to prioritising health conditions, is aligned with international clinical guidelines, and considers equity, innovation, and New Zealand-specific areas.
- Pharmac should amend the incremental cost per quality-adjusted life year measure to put greater weight on quality of life.

### **Undertake meaningful stakeholder engagement**

Many submitters said Pharmac needs to undertake more meaningful engagement with stakeholders beyond the pharmaceutical companies. They said Pharmac’s pharmacology and therapeutics advisory committee as well as its various subcommittees should have a greater representation of Māori, Pacific and disabled people and other vulnerable groups. They also urged Pharmac to bring in disease experts to offer their expertise to the pharmacology and therapeutics advisory committee during its decision-making.

### **Make decisions faster and in a more open manner**

Many submitters said Pharmac needed to make decisions more quickly, more efficiently and in a more open manner. They said Pharmac should:

- give clear explanations about why it has declined funding for medicines and medical devices, including which of the “Factors for Consideration” it applied when rejecting funding and how it weighted each of these factors<sup>48</sup>
- adopt clearly defined and reasonable timeframes for each stage of the assessment and decision-making process
- introduce a rapid assessment process for medicines for individuals with life-threatening conditions who have no recourse to other suitable treatments
- hold meetings of the Pharmacology and Therapeutics Advisory Committee and its various subcommittees more frequently, publish their agendas online beforehand, and publish meeting minutes in a timely manner.

### **Consider the latest evidence**

Many submitters said Pharmac needs to give more consideration to the latest evidence – usually in the form of overseas research – when making funding decisions. Advocacy groups and submitters from the pharmaceutical industry also urged Pharmac to actively search out innovations in medicines and medical devices that could benefit New Zealanders.

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<sup>48</sup> <https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/factors-for-consideration/>.

## **Work more with the wider health system**

Some submitters suggested the health and disability system reforms provide an opportunity for Pharmac to work in a more integrated way with the wider health system and contribute to better health outcomes for New Zealanders. A few submitters talked about opportunities to place a greater emphasis on achieving equitable access to medicines and devices when making funding decisions. A few other submitters suggested that changes to the health and disability system could mean changes to Pharmac's funding model. This included the potential for greater flexibility of funding, a greater proportion of funding allocated to Pharmac, or a shift from a cost-savings approach to one that is health outcomes focused.

## **Review observations and next steps**

The submissions we received have been a good source of information to help inform the interim report. They also have a level of detail and areas of suggested improvement that we are still working through. We will continue to engage with stakeholders in the coming months.

## 8 What other countries do

Many submitters said Pharmac's excessive focus on containing costs and using generic medicines is causing New Zealand to fall behind other comparable countries. They said this contrasts with Australia, where decisions about what to fund rest with politicians, and the United Kingdom, where the focus is on assessment while funding decisions and trade-offs are left to the public health service. Some stakeholders said New Zealand's approach limits opportunities for innovation, reduces the opportunity for medical trials to gather and test population-specific data, and risks losing technical expertise if medical professionals feel they cannot access the latest treatments. One industry submission argued New Zealand's approach has significantly reduced the number of medicines available across a range of therapeutic areas compared with most OECD countries, saying this has "undoubtedly resulted in, or contributed to, poorer health outcomes for New Zealanders".

We selected four countries with similar healthcare systems so we could compare their operating methods to Pharmac's. They are Australia, England, Canada, and Norway. Specifically, we looked at how each country:

- makes decisions about which medicines to subsidise
- negotiates prices with pharmaceutical companies
- manages exceptional individual cases
- conducts and promotes research
- promotes the responsible use of medicines
- procures hospital medicines
- procures medical devices
- procures vaccines.

### Broad consistency

We found decision-making processes are broadly consistent with Pharmac's processes. Larger countries devolve decision-making to more agencies and split the assessment and purchasing elements of decisions. We have not yet been able to determine whether these processes, and applicable policies, are producing different outcomes to those achieved by Pharmac. Discussions with relevant agencies in these countries will clarify how stakeholder consultation, review mechanisms and equity considerations feed into their decision-making processes. Our final report will provide these details.

Table 8 summarises the four countries' various Pharmac functions.

**Table 8: How other countries carry out comparable functions**

Functions	Australia	England	Canada	Norway
Making funding decisions	Pharmaceutical Benefits Advisory Committee makes recommendations on funding decisions to Minister of Health, who makes final decision. If net cost of medicine to the Pharmaceutical Benefits Scheme is more than \$A20 million a year, Cabinet makes decision. Scheme's schedule lists all subsidised medicines.	National Institute for Health and Care Excellence makes recommendations on medicines. Local health authorities select medicines for use in their regions based on these recommendations.  Department of Health publishes National Health Service Drug Tariff, which lists reimbursement prices for generic medicines paid to contracted dispensers.	Drug plans operate independently at federal, provincial, and territorial level. Canadian Agency for Drugs and Technologies in Health co-ordinates assessment of medicines for all drug plans (except in Quebec) to reduce duplication. Recommendations are advisory only. Each body responsible for own drug plan. Body makes own final decision on whether to list a drug.	Norwegian Medicines Agency assesses and approves outpatient medicines for reimbursement under National Insurance Scheme.  No national reimbursement is available for inpatient medicines.
Negotiating prices	Department of Health manages negotiations and statutory price disclosures and reductions, which together control prices of reimbursed medicines.	A complex system of profit regulation, price rebate schemes and decision-making by local health authorities manages prices.	Statutory regulations and voluntary price negotiations determine prices. Bodies responsible for public drug plans negotiate prices, typically resulting in patented medicines priced below allowed maximum.	Statutory price limits, supply contracts and tendering determine prices. Norwegian Medicines Agency sets prices of all market-authorised medicines.
Managing exceptional cases	Department of Health funds and administers relevant programmes and schemes.	National Health Service considers exceptional individual cases. National Health Service clinician asks, on behalf of patient, to fund a treatment not usually offered to such a patient. Early Access to Medicines Scheme gives people access to medicines that do not yet have a marketing authorisation.	The Access to Drugs in Exceptional Circumstances regulatory route enables access to medicines authorised for sale in certain other countries but not in Canada. Health Canada manages the List of Drugs for an Urgent Public Health Need, which sets out medicines eligible for importation and sale in this way	
Conducting and promoting research	Pharmaceutical Benefits Advisory Committee undertakes research.	National Health Service promotes and conducts research.	Canadian Health Evaluation Forum undertakes health research. Canadian Agency for Drugs and Technologies in Health is a member of the forum.	Norwegian Medicine Agency facilitates research and innovation.

<b>Functions</b>	<b>Australia</b>	<b>England</b>	<b>Canada</b>	<b>Norway</b>
Promoting responsible use of medicines	Department of Health and other agencies promote responsible use of medicines.	Medicines and Healthcare Products Regulatory Agency promotes safe use of medicines.	Health Canada ensures safe use of medicines.	Norwegian Medicines Agency monitors appropriate use of medicines.
Procuring hospital medicines	State and territory governments have central purchasing arrangements for medicines for public hospitals (except Australian Capital Territory public hospital, which has access to New South Wales state contract arrangements with suppliers). Public hospitals procure medicines they need.	National Health Service oversees and allocates funds to 191 clinical commissioning groups, which govern and pay for care delivery at the local level. National Health Service commissions acute trusts that administer hospitals. These trusts usually carry out procurement.	Hospitals and other healthcare providers procure their equipment, supplies, and services individually or as part of group purchasing or shared services organisation.	National Insurance Scheme covers public hospital medicines.  Procurement is the responsibility of hospitals. Regional health authorities' hospital medicines committees supply advisory lists to guide procurement.
Procuring medical devices	Medical devices must be on Australian Register of Therapeutic Goods to be sold in Australia. States administer their procurement.	Medicines and Healthcare Products Regulatory Agency regulates medical devices market, including decisions on marketing and supply of devices.  National Health Service negotiates prices, which are listed on Drug Tariff.	Health Canada regulates sale of medical devices.  Healthcare systems in Canada use tenders to buy devices.  Procurement processes depend on individual provinces. Each hospital generally conducts procurement.	Norwegian Medicines Agency has administrative and advisory responsibilities for medical devices, including supervisory authority over manufacturers, distributors and notified bodies.
Procuring vaccines	Pharmaceutical Benefits Advisory Committee makes recommendations about whether to include vaccines in National Immunisation Program. Federal government supplies vaccines and states deliver them.	Public Health England buys and distributes vaccines for children's programmes. GPs and pharmacists buy and supply vaccines for everyone else eligible for vaccines through National Health Service's vaccination programme.	Public Health Agency of Canada helps co-ordinate and oversee distribution of vaccines for public programmes. Provincial and territorial governments buy vaccines through federal government's Public Services and Procurement Canada, which has long-term contracts with manufacturers.	National public tenders used to buy vaccines.

Below is a more substantial discussion of Australia and England which are the two countries most cited as having better approaches than New Zealand's.

## Australia

The Pharmaceutical Benefits Advisory Committee is an independent expert body with statutory status that makes recommendations about which medicines should be covered under the Pharmaceutical Benefits Scheme. The scheme subsidises the cost of prescription medicines dispensed in community pharmacies and private hospitals, along with some medicines dispensed in public hospitals. The federal Department of Health manages the scheme and Services Australia administers it.

The federal Minister of Health is responsible for deciding which medicines should be covered by the scheme. However, Cabinet makes the decision if the net cost to the scheme of a medicine is more than \$A20 million a year. No medicine can be listed without a recommendation from the committee. Recommendations are based on an incremental cost-effectiveness ratio, defined by the added cost per quality-adjusted life year offered by a medicine. If the committee decides a proposed reimbursement price is too high, it can withhold a recommendation. It doesn't set an exact cost-effectiveness cut-off point because it factors in other criteria. However, medicines with a high cost per quality-adjusted life year are rarely covered by the scheme.

If the committee recommends a medicine, the Minister decides which of the scheme's two official lists a medicine will go on. The first is for single-source medicines that have no listed therapeutic equivalents. The second is for multiple-source medicines or single-source medicines that are therapeutically interchangeable with medicines already listed.

The scheme's schedule is equivalent to Pharmac's pharmaceutical schedule. It lists all medicines available for dispensing to patients at a government-subsidised price.

A combination of negotiation and statutory price disclosures and reductions controls the prices of subsidised medicines. To ensure the cost-effectiveness of medicines at list prices, PBAC employs risk-sharing agreements with manufacturers in which rebates are paid directly to the government. List One medicines are subject to a mandatory 5 per cent price cut after five years if competing medicines have not also been listed by then.

Manufacturers of medicines on the second list are legally required to tell the Department of Health the actual selling price of the medicines. They must also reveal information on rebates and incentives paid to wholesalers and pharmacies. If the difference between the scheme price and the disclosed selling price is more than 10 per cent, the scheme price drops to the disclosed price.

From the information reviewed to date, it is unclear if or how the Australian system considers equity within its decision-making and how it considers the needs of the Aboriginal and Torres Strait Island populations, including representation in the decision-making processes.

## England

Funding of medicines in the United Kingdom is complex. Each of the four countries in the union has its own “negative” list of licensed medicines that cannot be reimbursed through the National Health Service. Individual health authorities have their own official lists and oversee the purchasing of medicines and this can create disparities across the country (often referred to as a “postcode lottery”).

The National Institute for Health and Care Excellence (NICE) is responsible for assessing medicines, and its assessment process is well regarded (including by our submitters, one of whom expressed hope that we would review the institute’s latest five-year strategy as a model New Zealand could aspire to). It evaluates clinical benefits, cost-effectiveness, and social impact. The consumer voice is considered during the assessment process. Its recommendations are mainly for England, but it gives guidance to Scotland, Wales and Northern Ireland if required. Assessments use the incremental cost per quality-adjusted life year as a measure of a medicine’s cost-effectiveness. Costs of between £20,000 and £30,000 per QALY are considered an upper limit, with only exceptional cases accepted beyond this point.

In considering the NICE approach, the review asked about its approach to equity. Whilst the United Kingdom faces different types of equity issues, NICE noted it is considering this further, but it is challenging within the existing assessment systems.

Local health authorities select medicines for use in their area based on the institute’s assessments. Comparative cost-effectiveness is a key factor in deciding whether a medicine should go on the local list. Variations in decisions at this level are notorious.

In England and Wales, the National Health Service (NHS) oversees the Drug Tariff, which lists reimbursement prices for generic medicines paid to contracted dispensers. The NHS updates this document monthly for the Department of Health and Social Care.

Prices in England (and across the United Kingdom) are determined by a complex system of profit regulation, price rebate schemes and decisions by local health authorities about whether to include a drug on their lists.

The Pharmaceutical Price Regulation Scheme controls the list prices of brand-name medicines. This scheme is a voluntary, non-statutory arrangement negotiated every five years by the Department of Health and the Association of the British Pharmaceutical Industry. Companies that don’t participate in the scheme must follow statutory regulations. The scheme is complex. It contains stipulations aimed at setting a ceiling on profits earned from the sale of medicines to the NHS. However, it does allow for “flexible” pricing whereby companies can raise or lower an original list price.

For medicines not approved by NICE, patient-access schemes are available to lower prices to a point where they can be reimbursed under the National Health Service. This allows pharmaceutical companies to maintain high list prices, which other countries use for external reference pricing, while achieving the desired level of cost-effectiveness for the National Health Service based on individual patient needs.

For inpatient medicines, NHS Trusts run a separate tendering process with manufacturers to agree price and discounting arrangements.

## Review observations and next steps

In commissioning the international comparisons, the review observed that while there are different approaches to assessing pharmaceuticals for public funding, the themes are the same, with many countries struggling with measuring and attributing the costs and benefits of social outcomes and applying measures to counter inequity in the systems.

There is much to be learned from other countries and their approaches. The review is also mindful these comparisons have limitations and are not always the panacea that people believe them to be. For example, NICE in England is not involved in the negotiating and contracting of a medicine assessed as suitable for public funding. That decision sits with the National Health Service which makes decisions on what medicines it purchases. This means that not all medicines NICE approves are available in all parts of England.

The review plans to further consider the approaches of other countries and in particular:

- whether it is possible to have an assessment system that can measure the cost utility for the many and for the few
- how other countries consider matters of equity
- whether there are best practice examples for transparency, timeliness, and participation
- how other countries benchmark best practice.

## 9 Pharmac's place in the health system reform

Any review of Pharmac needs to be understood in the broader context of the health system. Medicines are an important intervention, but they must be viewed as part of an overall integrated health system along with preventive, primary and secondary care, collectively guided by the goal of achieving the best health outcomes for all New Zealanders.

In April the Government announced a major reform of the health system. A key objective of the reform is to ensure fairer access for all New Zealanders to primary and community healthcare by doing away with duplication and unnecessary bureaucracy between regions.

To support that objective the following structural changes have been announced:

- all district health boards will be replaced by one national organisation, Health New Zealand
- a new Māori Health Authority will have the power to commission health services, monitor the state of Māori health and develop policy
- a new public health agency
- strengthened stewardship in the Ministry of Health to monitor performance and advise Government.

Through Health NZ and the Maori Health Authority there is an opportunity to integrate medicines into care pathways to ensure optimal and equitable health outcomes and realise the substantial economic and societal benefits that innovative medicines deliver. (Industry submission)

Part of our role as a review is to consider whether Pharmac's 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 objectives should be changed.

Our review is happening at the same time as the structure and approach of the health and disability system are undergoing significant transformation. Much of this transformation is predicated on the need to do more to achieve equity and translate equity commitments into everyday action. The changes are also driven by persistent calls from Māori for greater control and influence within the health and disability system.

In making recommendations in our final report, we will be taking into account final policy decisions from Government, as we consider that Pharmac's success rests on it being an integrated part of a cohesive publicly funded health and disability system. As has been highlighted to the review, a key area of concern is that Pharmac may be operating too independently of the wider healthcare system and its decisions may not be adequately guided by overall system oversight and values. This is particularly true when it comes to achieving health equity, as health needs cannot be addressed through a single pharmaceutical intervention.

## 10 How to contact us

The review will continue its analysis, including drawing on the content from the submissions we received.

We welcome your thoughts on our interim report.

The Pharmac review and secretariat can be contacted by email at [pharmacreview@health.govt.nz](mailto:pharmacreview@health.govt.nz).

# Appendices

## Appendix A: Case studies to assess transparency and timeliness

### Empagliflozin

Empagliflozin is a drug for treating type 2 diabetes. Empagliflozin is a sodium glucose co-transporter 2 (SGLT2) inhibitor, and is indicated as a complement to diet and exercise for the improvement of glycaemic control in type 2 diabetes. SGLT2 is the main transporter that mediates reabsorption of glucose in the kidneys, from the glomerular filtrate back into the circulation. Empagliflozin improves glycaemic control by competitively inhibiting SGLT2, thereby reducing renal glucose reabsorption. Empagliflozin can be used as monotherapy or in combination with other glucose-lowering medicines. It is also indicated in patients with type 2 diabetes and established cardiovascular disease to reduce the risk of cardiovascular death.<sup>49</sup>

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<sup>49</sup> <https://www.medsafe.govt.nz/profs/PUArticles/December2020/Spotlight-on-empagliflozin.html>

**Table 9: Information disclosed in relation to the funding decision for empagliflozin**

Stage	Date (not a linear process)	Action
Application received	February 2015	The funding application is referred to one of Pharmac's Therapeutic Group Managers (TGMs), who reviews the application to ensure they have the relevant information to undertake a preliminary analysis.
Seeking clinical advice	October 2016	Pharmac identifies and gathers information required to get clinical advice.  Clinical advice received from Diabetes Subcommittee on 10 October 2016. The Subcommittee examined evidence for empagliflozin as part of a review of new antidiabetic agents. The Subcommittee did not make a recommendation about funding empagliflozin, instead recommending that "in light of the new evidence, PTAC consider the three classes of antidiabetic agents separately rather than as a group and consider applying separate Special Authority criteria to each one of the new classes of agents". See Diabetes Subcommittee minutes: <a href="https://pharmac.govt.nz/assets/ptac-diabetes-subcommittee-minutes-2016-10.pdf">https://pharmac.govt.nz/assets/ptac-diabetes-subcommittee-minutes-2016-10.pdf</a> .
	February 2017	Clinical advice received from pharmacology and therapeutics advisory committee (PTAC) at meeting Thursday 9 February 2017. The Committee reported that it would re-review empagliflozin and "noted that the Diabetes Subcommittee considered that these agents could potentially have additional renal and cardiovascular health benefits". PTAC noted that studies of the drug versus insulin would be most clinically relevant, and that comparisons to delaying commencement on insulin would be of value for its re-review of empagliflozin. See the PTAC minutes: <a href="https://pharmac.govt.nz/assets/ptac-minutes-2017-02.pdf">https://pharmac.govt.nz/assets/ptac-minutes-2017-02.pdf</a> .
	August 2017	Received additional information; clinical advice required.
	November 2017	Clinical advice received from PTAC at meeting on 9 November 2017. PTAC made two recommendations: (1) that empagliflozin for the treatment of patients with type 2 diabetes with established high cardiovascular risk be funded with a high priority, noting the importance of appropriately defining this population; and (2) that the application be referred to the Diabetes Subcommittee for advice regarding appropriate access criteria, including definition of a high cardiovascular risk population. See the PTAC minutes: <a href="https://pharmac.govt.nz/assets/ptac-minutes-2017-11.pdf">https://pharmac.govt.nz/assets/ptac-minutes-2017-11.pdf</a> .
	July 2018	Clinical advice required.

Stage	Date (not a linear process)	Action
Seeking clinical advice (continued)	February 2019	<p>Clinical advice received from PTAC at meeting 21 February 2019. PTAC noted the long-term trial evidence and outcome available reported that patients with type 2 diabetes at high risk for cardiovascular events had a lower rate of the primary composite cardiovascular outcome and of death from any cause when the study drug was added to standard care.</p> <p>PTAC also noted that the major adverse cardiovascular events (MACE) reductions demonstrated by empagliflozin were greater than those for dapagliflozin.</p> <p>Outcome: No formal recommendation. See the PTAC minutes: <a href="https://pharmac.govt.nz/assets/ptac-minutes-2019-02.pdf">https://pharmac.govt.nz/assets/ptac-minutes-2019-02.pdf</a>.</p>
	March 2019	<p>Clinical advice received from Diabetes Subcommittee at meeting Tuesday 19 March 2019. The Subcommittee noted the published evidence for cardiovascular outcome trials for empagliflozin<sup>50</sup> (see above).</p> <p>Outcome: No formal recommendation. See the Diabetes Subcommittee minutes here: <a href="https://pharmac.govt.nz/assets/ptac-diabetes-subcommittee-minutes-2019-03.pdf">https://pharmac.govt.nz/assets/ptac-diabetes-subcommittee-minutes-2019-03.pdf</a>.</p>
Under assessment	November 2017	<p>Working to compare options.</p> <p>Following clinical advice, Pharmac staff considered the advice, and the funding application underwent an assessment using the Factors for Consideration framework and additional information was sought as required.</p> <p>Research and economic analyses undertaken.</p>
	May 2019	Working to compare options.
Options compared	December 2018	The relative ranking of the pharmaceutical application completed.
	January 2020	The relative ranking of the pharmaceutical application completed.
Under consultation	September 2020	<p>Public consultation for this application is active. The funding application is consulted on as part of a broader proposal relating to medicines for type 2 diabetes, along with dulaglutide. The funding of both treatments would be restricted to people with type 2 diabetes who are at high risk of heart and kidney complications. Read the consultation process here: <a href="https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/proposal-to-fund-two-new-medicines-for-type-2-diabetes/">https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/proposal-to-fund-two-new-medicines-for-type-2-diabetes/</a>.</p>
Reviewing consultation feedback	October 2020	Public consultation for this application is closed. Pharmac reviews consultation feedback.

<sup>50</sup> Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes. New England Journal of Medicine. Zinman et al. 2015.

Stage	Date (not a linear process)	Action
Decision	December 2020	Empagliflozin and empagliflozin with metformin are funded from 1 February 2021 as the only SGLT-2 inhibitor for type 2 diabetes in New Zealand until at least 30 June 2024. Read the notification here: <a href="https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/decision-to-fund-two-new-medicines-for-type-2-diabetes/?type=Decision&amp;page=1&amp;status=closed">https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/decision-to-fund-two-new-medicines-for-type-2-diabetes/?type=Decision&amp;page=1&amp;status=closed</a> .

## Pembrolizumab

Pembrolizumab (Keytruda) is an immune checkpoint inhibitor used in the treatment of some advanced or metastatic cancers. Pembrolizumab (Keytruda) is a monoclonal antibody used in the treatment of some advanced or metastatic cancers. These currently include:

- melanoma
- non-small-cell lung carcinoma (NSCLC)
- classical Hodgkin Lymphoma (cHL)
- urothelial carcinoma.

Pembrolizumab is commonly known as an immune checkpoint inhibitor because it blocks the PD-1 pathway on immune dampening cells. This action helps the immune system to boost its response against cancer cells.<sup>51</sup>

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<sup>51</sup> <https://www.medsafe.govt.nz/profs/PUArticles/September%202018/SpotlightPembrolizumabKeytruda.htm>

**Table 10: Information disclosed in relation to the funding decision for pembrolizumab**

Stage	Date (not a linear process)	Action
Application received	May 2015	The new funding application is received and referred to one of Pharmac's Therapeutic Group Managers (TGMs), who reviews the application to ensure they have the relevant information to undertake a preliminary analysis.
Seeking clinical advice	September 2015	<p>Clinical advice required. Clinical advice received from Cancer Treatments Subcommittee (CaTSoP) at meeting Friday 18 September 2015.</p> <p>The Subcommittee recommended that pembrolizumab should be funded for the treatment of metastatic or unresectable melanoma stage III or IV with low priority. The Subcommittee noted that its low priority rating was influenced by the early evidence base, and consequent uncertainty about pembrolizumab's longer-term benefits and potential risks, as well as its very high cost. Read the minutes here: <a href="https://pharmac.govt.nz/assets/ptac-cancer-treatments-subcommittee-minutes-2015-09.pdf">https://pharmac.govt.nz/assets/ptac-cancer-treatments-subcommittee-minutes-2015-09.pdf</a>.</p>
	November 2015	<p>Clinical advice received from pharmacology and therapeutics advisory committee (PTAC) at meeting Thursday 5 November 2015. PTAC recommended that pembrolizumab be funded for the treatment of metastatic or unresectable melanoma stage III or IV with low priority. Read the minutes here: <a href="https://pharmac.govt.nz/assets/ptac-minutes-2015-11-pembrolizumab.pdf">https://pharmac.govt.nz/assets/ptac-minutes-2015-11-pembrolizumab.pdf</a>.</p>
	February 2016	<p>Clinical advice received from PTAC at meeting Thursday 11 February 2016. The Committee recommended that pembrolizumab as monotherapy be funded with low priority for the second- or third-line treatment of locally advanced, or metastatic, unresectable NSCLC expressing PD-L1 at a level of equal or greater than 1%. The Committee also recommended that the application be referred to the Cancer Treatments Subcommittee for advice regarding the appropriate duration of treatment, utility of PD-L1 as a biomarker, and development of Special Authority criteria. Read the minutes here: <a href="https://pharmac.govt.nz/assets/ptac-minutes-2016-02-update-2.pdf">https://pharmac.govt.nz/assets/ptac-minutes-2016-02-update-2.pdf</a>.</p>
	April 2016	<p>Clinical advice received from CaTSoP at meeting Friday 22 April 2016. The Subcommittee noted that based on the currently available evidence, noting the difference in trial design and absence of head-to-head comparative data, pembrolizumab and nivolumab appeared to be mechanistically similar and the Subcommittee considered that the two treatments would provide the same or similar therapeutic effect in the treatment of advanced melanoma to the extent that it would be reasonable to run a competitive process that would result in only one PD-1 inhibitor being funded. Read the minutes here: <a href="https://pharmac.govt.nz/assets/ptac-cancer-treatments-subcommittee-minutes-2016-04.pdf">https://pharmac.govt.nz/assets/ptac-cancer-treatments-subcommittee-minutes-2016-04.pdf</a>.</p>

Stage	Date (not a linear process)	Action
Under assessment	April 2016	Following the clinical advice, Pharmac staff consider the advice, and the funding application undergoes an assessment using the Factors for Consideration framework. Research and economic analyses are undertaken.
Options compared	December 2015	Relative ranking of the pharmaceutical application completed.
	June 2016	Relative ranking of the pharmaceutical application completed.
Under consultation	June 2016	Public consultation for this application is active.
Reviewing consultation feedback	July 2016	The consultation period closes. Following the consultation process, Pharmac staff consider the feedback and identify any additional information required as part of a gap analysis.
Decision	July 2016	Pembrolizumab is funded from 1 September 2016 for the treatment of patients with unresectable or metastatic (advanced) melanoma, subject to the same clinical criteria as nivolumab. Read the decision here: <a href="https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/decision-regarding-funding-of-pembrolizumab-keytruda-nivolumab-opdivo-posaconazole-noxafil-and-raltegravir-isentress/">https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/decision-regarding-funding-of-pembrolizumab-keytruda-nivolumab-opdivo-posaconazole-noxafil-and-raltegravir-isentress/</a> .