# Pharmac's Medicines Waiting Lists: Impacts on Patients in Aotearoa New Zealand

**April 2023**

HealthiNZ

Advancing life-changing solutions

This white paper report was written by HealthiNZ

## Acknowledgements

This report was commissioned by Medicines New Zealand

## About HealthiNZ

Andrew Cameron is the Principal Consultant at HealthiNZ, which provides a range of strategic advisory healthcare services in NZ and overseas. Andrew has over 20 years' commercial healthcare experience, including as health economist, with a passion for healthcare innovation and new technologies that deliver patient outcome-led advances in healthcare and wellbeing. In 2020 and again in 2022 he authored the Voice of Rare Disorders White Papers to understand the impact that living with a rare disorder has on people, family, whānau and wider society. Further information can be found at www.healthinz.co.nz.

# Executive summary

Access to modern medicines in Aotearoa New Zealand remains challenging for people, families and whānau who need them. A number of reports have previously highlighted differences compared with other OECD countries, both on the number of medicines funded and the time taken to achieve funding following application to international public reimbursement agencies equivalent to New Zealand's Pharmaceutical Management Agency (Pharmac).

In response to calls to increase transparency of their decision-making processes Pharmac has made available three lists to view all the proposals currently ranked for funding. These are the *Options for Investment*, *Cost Neutral/Cost Saving*, and *Recommended for Decline* lists, each with a different purpose and intent to fund.

Analysis of these lists and use of Official Information Act (OIA) requests has revealed the following key findings.

**There is an average waiting time of 7.7 years and counting for applications across all Pharmac lists.**

This waiting time is only expected to increase while funding decisions are still to be achieved. This was reflected across all Pharmac lists, with a median 6.7 years since applications were submitted to Pharmac.

**Many medicines on these lists are already funded and have become a standard of care in other countries.**

Overall, there are 73 different countries where medicines on Pharmac lists are already known to be publicly funded, with the most prevalent being for Australia, EU and UK. 36 (61%) medicines were known to be publicly funded in at least 5 other countries. In addition, 83 applications were also considered a standard of care in other countries, the majority of these (n=59) being on the *Options for Investment* waiting list.

**It has been an average of 5.9 years and counting for applications currently on the *Options for Investment* waiting list.**

This list represents those applications that Pharmac indicated they would like to fund, subject to budget with an average 5.9 years (median 5.0 years). This waiting time is only expected to increase while funding decisions are still to be achieved.

**1,466,960 New Zealanders would benefit if the *Options for Investment* waiting list was funded today.**

Or put another way, this is the number of people affected by a delay in funding medicines. Even excluding vaccines, an additional 171,937 people would benefit in the 1$^{st}$ year following funding. This would increase to 269,238 people after 5 years if the waiting list was funded today.

**A high percentage of medicines addressing severe health needs are still without a funding decision.**

Severe, very severe, or extreme health needs were listed for 89 (72%) of funding applications on the *Options for Investment* waiting list. However, the need level did not appear to correlate with the likelihood of achieving a funding decision unless it was extreme. Overall, there was an opportunity to benefit another 43,395 people by funding medicines where their health needs were assessed as being severe or very severe.

**Even if a Māori health need has been identified there is no increased likelihood of being funded.**

Māori health need was identified for 63 applications on the *Options for Investment* waiting list, with 12 (19%) of these achieving a funding decision. However, this was a similar funding decision percentage to that achieved across the total *Options for Investment* waiting list (19%) over the same period. Furthermore, while specified Māori health areas of focus were associated with 16 applications, only 1 of these achieved a funding decision over the reporting period. This appears to support inconsistent application of Pharmac's own factors for consideration, further confirming the recent Pharmac review findings.

**Cancer is a government priority condition yet remains under-represented in funding decisions.**

Cancer is a government priority condition, and this is reflected in the proportion of applications being identified as Oncology Agents and Immunosuppressants on the *Options for Investment* waiting list. However, these are then under-represented in funding decisions, being reached. Despite a number of funding decisions being reached that identified with this therapeutic group, this still represented only 10% of all relevant applications on the waiting list.

**The time taken to achieve funding decisions remains too long.**

29 applications that achieved a funding decision did so on average 7.7 years (or median 6.5 years) following their submission to Pharmac. This was almost double the length of time for funding decisions achieved in the 2020/21 period. Almost 70% came from 3 therapeutic groups: Alimentary Tract and Metabolism (ustekinumab, vedolizumab, liraglutide, selenium and copper chloride), Oncology Agents and Immunosuppressants (brentuximab vedotin, ibrutinib, obinutuzumab, vinorelbine) and Hormone Preparations (cinacalcet HCl, progesterone).

**The time taken to achieved funding decisions has increased in the last 2 years.**

Only 1 (3%) application that achieved a funding decision did so within 20 months, while in 2020/21 this same result was achieved for 16 (39%) applications. This further reinforces the finding that the time taken to achieve funding decisions has only increased over the last two years.

**Summary of recommendations for Pharmac.**

In light of the finding of this report it is recommended that Pharmac do the following:

- Maintain an increased rate of funding decisions.
- Establish a reasonable performance benchmark for the time taken to achieve funding decisions, taking into account the experiences and timeframes from other countries.
- Continue to review, optimise, and demonstrate more rapid turnaround in receiving further information or clinical advice throughout the medicines funding process.
- Make the following information publicly available on Pharmac website for each application and in summary reporting: Numbers of benefiting patients, alignment with factors for consideration, assessment by therapeutic group and time since submission.

By increasing the transparency of decision making by Pharmac is likely to lead to more meaningful and well-informed dialogue with a wider range of health stakeholders, ensuring medicines funding can achieve the greatest possible benefit for all people in Aotearoa New Zealand.

# Contents


Modern medicine access and impact on patients in Aotearoa New Zealand ..... 1

April 2023 ..... 1

Executive summary ..... 3

Background and Context ..... 6

*Medicines Funding in Aotearoa New Zealand* ..... 6

*Pharmac Lists and Prioritisation* ..... 7

*Health Need* ..... 9

*Medicine Access* ..... 10

Methods ..... 11

*Data Collection* ..... 11

*Data Preparation* ..... 11

Results ..... 12

*Time since Pharmac application* ..... 12

*Countries already funding medicines on Pharmac lists* ..... 14

*Number of patients benefiting if the waiting list was funded* ..... 15

*Health need* ..... 16

*Māori health need* ..... 17

*Oncology therapeutic group funding decisions* ..... 18

*Number of funding decisions* ..... 19

*Time since Pharmac application to reach funding decision* ..... 22

*Time to achieve funding decision - comparison with previously reported data* ..... 23

Conclusions ..... 24

*Medicines still waiting on the Options for Investment list after almost 6 years* ..... 24

*Aotearoa lags behind rest of world in access to standard of care medicines* ..... 24

*Over 1 million patients would benefit from immediately funding waiting list* ..... 24

*Focus on those patients with highest unmet health needs* ..... 25

*Unclear how Māori health need is being considered by Pharmac* ..... 25

*Time taken to achieve funding decision remains too long* ..... 25

*Time taken to reach funding decision is increasing over the last 2 years* ..... 26

*Final reflections* ..... 26

References ..... 28

# Background and Context

## Medicines Funding in Aotearoa New Zealand [1,2]

The role of the Pharmaceutical Management Agency (Pharmac) as a government agency is set out in the Pae Ora (Healthy Futures) Act 2022. Pharmac is responsible for procuring medicines at a subsidised rate for Kiwis, using the fixed annual Combined Pharmaceutical Budget (CPB) set by the Minister of Finance. It decides what medicines to fund and manages a fixed budget for those medicines.

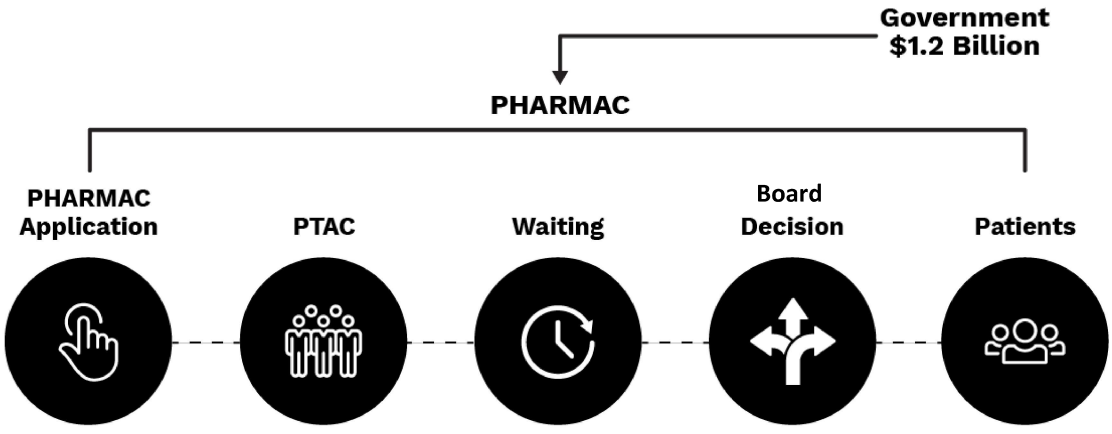
While there is always a focus on improving access to new medicines, it is also acknowledged that many New Zealanders are not getting the funded medicines they need to live their healthiest lives. People affected by inequity include Māori, Pacific Peoples and people who live rurally. Pharmac want to improve access to the medicines they already fund, believing this will have the greatest benefit to Aotearoa New Zealand.

An application to Pharmac is the first step in the medicines funding process and this can be made by the sponsor company, clinician, consumer or even initiated by Pharmac or a recommendation from one of its various committees.

To assist Pharmac in decision-making about what to fund, all applications are also reviewed by Pharmac's committee of clinical experts – the Pharmacology and Therapeutics Advisory Committee (PTAC). The role of PTAC is to advise Pharmac on each application and make a funding recommendation to Pharmac based on an objective clinical assessment of the medicine concerned. Pharmac has a fixed budget and their ability to fund medicines that are safe and clinically beneficial is limited. It is noted that a positive recommendation from PTAC is not a guarantee that Pharmac will fund the medicine.

Until a funding decision is made by Pharmac they remain on one of three distinct lists, which in Figure 1 has been designated as the **Waiting** stage. Analysis of insights and trends from these three Pharmac lists is the focus of this report.

### Figure 1 The Medicines Funding Process in Aotearoa New Zealand [1]



## Pharmac Lists and Prioritisation

Medicine funding applications are assigned to one of three lists by Pharmac based on their priority for funding. These were first publicly released in July 2021 in order to increase the transparency of Pharmac's decision-making processes and continue to be updated over time.[3, 4]

This enabled people to view all the proposals currently ranked for funding, the list they are sitting on (*Options for Investment*, *Cost Neutral/Cost Saving*, or *Recommended for Decline*) sorted in alphabetical order by medicine/proposal name, and details of the indication and therapeutic grouping for each proposal.

Each of these lists has a specific purpose, focus and priority to fund for those included applications, which have been described in Table 1.

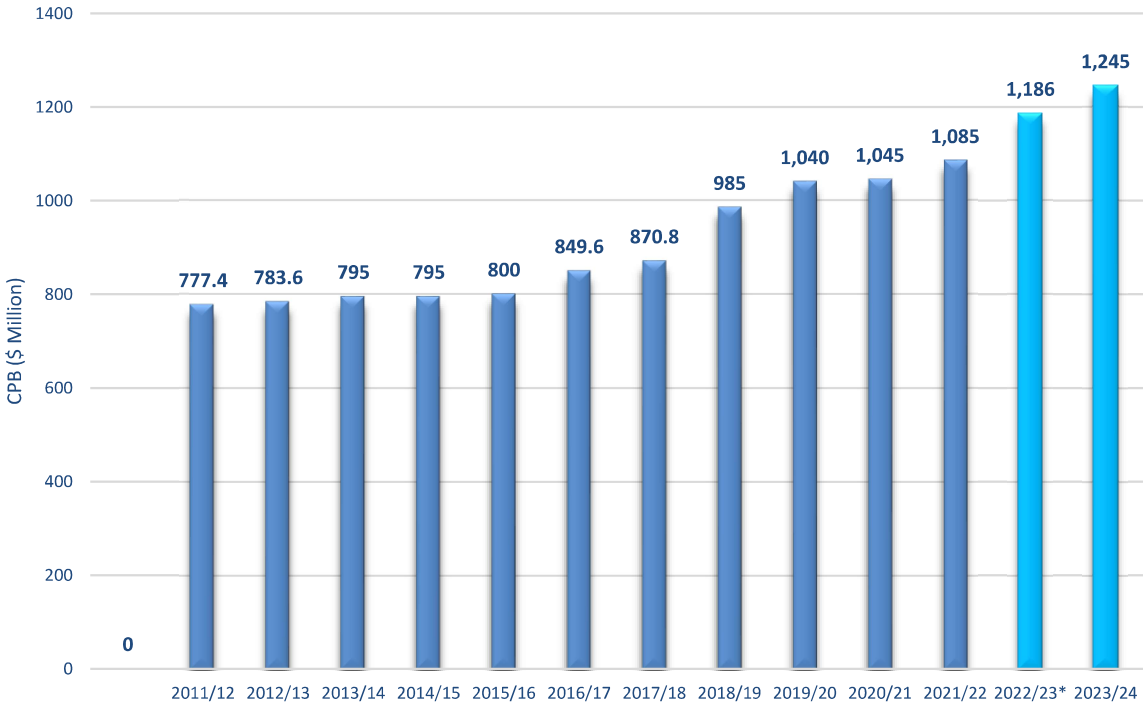
### Table 1 Pharmac list description [4]

| List name | Description | Prioritisation |
|---|---|---|
| *Options for Investment* list | **Includes all the applications that would be funded if Pharmac had the budget for them.**<br><br>Some are for new medicines, and some are for medicines already funded that Pharmac would like to fund for wider use for more patients. The preferential ranking for applications is determined using Pharmac's decision-making framework, the Factors for Consideration. However, the application's preferential ranking remains confidential, helping Pharmac negotiate the best prices for medicines. | **Effective waiting list** |
| *Only if cost neutral or cost saving* list | **Includes applications that may get funded if Pharmac can negotiate a deal that saves money, or at least doesn't cost more.**<br><br>These applications would not deliver better health outcomes than those already available, so Pharmac will only consider negotiations with any supplier who offers cost neutral or cost saving pricing. | **Not a Pharmac priority unless supplier offers cost neutral or cost neutral pricing** |
| *Recommended for Decline* list | **Includes applications that Pharmac's expert clinical advisors have suggested Pharmac turns down.**<br><br>Often this is because these medicines would add no value or are harmful. Pharmac does not actively work on these applications. | **Not prioritised by Pharmac** |

It is important to note that a ranked list of prioritised funding applications for the *Options for Investment* waiting list is required due to limitations on available budget at any one time for Pharmac to progress. For example, there were at least 100 applications on this list throughout the reporting period and it is expected the cost for funding all of these applications would be considerable.

Given the inextricable link of available budget for funding applications from the *Options for Investment* waiting list, it is important to understand how the CPB has changed over time. Trends in the CPB since 2011/12 are shown in Figure 2.

## Figure 2 Combined Pharmaceutical Budget (CPB) trends and budget announcements since 2011/12[5,6]




*Current financial year

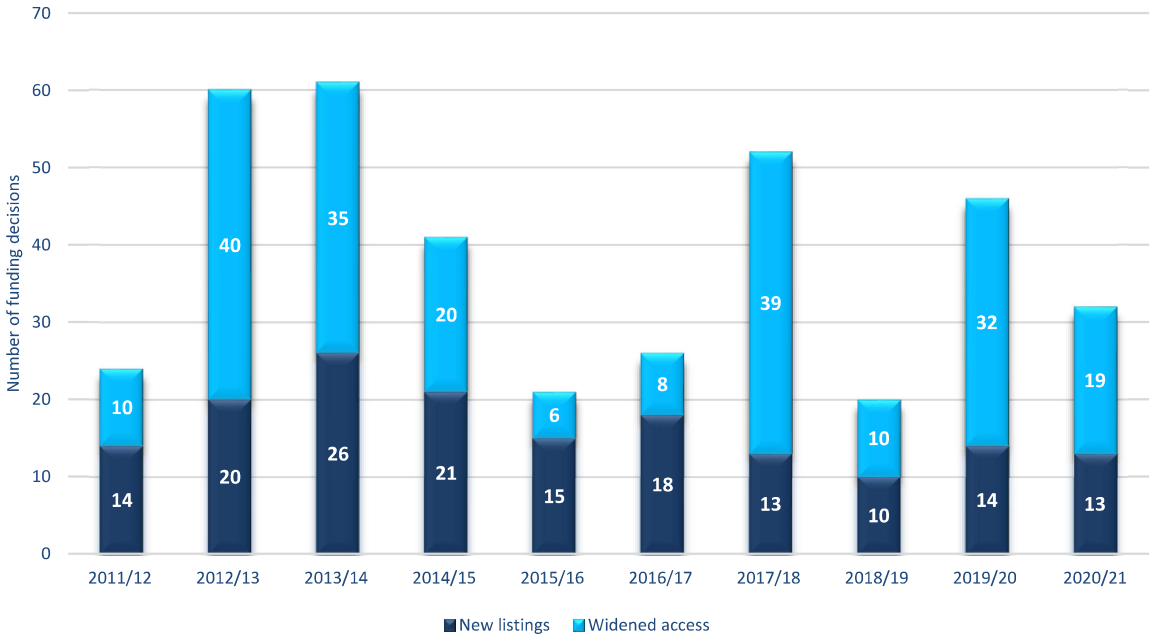
These trends show that the CPB has been increasing by approximately $40 million annually over this period. This also takes into account appropriations for 2022-23 of $1,186 million[i] to support the implementation of the health and disability system reform together with the 2023-24 budget estimate, representing increases of $71 million and $120 million, respectively vs prior years.[6]

While this indicates growing capacity to fund medicines on priority lists, it should be noted that this does not guarantee new medicines will be funded. This is given the cost of funding all currently funded medicines also increases over time. In fact, just as important as CPB increases is Pharmac's success in driving down the cost of already funded medicines to ensure budget then available to support funding decisions for new medicines or widening use of existing medicines.[2]

Overall trends in funding decisions by Pharmac in terms of new listings and widened access over the last 10 years up to 2020/21 is given in Figure 3.

[i] Includes $1,115 million for a baseline transfer from the previous appropriation structure to reflect the new structure of the Vote Health appropriations to support the health reform, and $71 million for the Budget 2022 initiative Increase in the Combined Pharmaceutical Budget

## Figure 3 Number of medicines Pharmac has funded over the last 10 years[3]




Given these trends, we would expect the average number of funding decisions to be 38 for any one year. This would be made up of 16 new listings and 22 widened access decisions. By taking this same approach for the 4-month period of this report we would expect approximately 13 funding decisions to be made, comprised of 6 new listings and 7 widened access decisions.

## Health Need

When proposals are ranked on the *Options for Investment* waiting list (in particular) they should consider all key documentation relating to the Pharmac **Factors for Consideration**, **Government Health Priorities** and **Māori Health Areas of Focus**. Specific details for each of these are included in Table 2.

### Table 2 Key considerations for proposal inclusion and ranking on the Pharmac lists

| | Factor | Description |
|---|---|---|
| **Factors for Consideration** | Need | • Health need of the person<br>• Availability and suitability of existing medicines, medical devices & treatments<br>• Health need of family, whānau, and wider society<br>• *Impact on the Māori health areas of focus & Māori health outcomes*<br>• Impact on the health outcomes of population groups experiencing health disparities<br>• Government Health Condition Priorities<br>• *Impact on government health priorities* |
| | Health benefits | • Health benefit to the person<br>• Health benefit to family, whānau and wider society<br>• *Consequences for the health system* |
| | Suitability | • Features of the medicine or medical device that impact on use by the person<br>• Features of the medicine or medical device that impact on use by family, whānau and wider society<br>• Features of the medicine or medical device that impact on use by the health workforce |
| | Costs and Savings | • Health-related costs and savings to the person<br>• Health-related costs and savings to the family, whānau and wider society |

| | | |
|---|---|---|
| | | • Costs and savings to pharmaceutical expenditure<br>• Costs and savings to the rest of the health system |
| **Government Health Priorities** | Specific priority health condition | • Relates to the Factor *'Impact on Government health priorities'*<br>• The following are priority health conditions: **Rare Diseases**[ii], **Cancer**, **Long Term Conditions**[iii] and **Infectious Diseases** |
| | Overarching priorities for the health system | • Relates to two Factors: *'The impact on Government health priorities*', and *'Consequences for the health system'*.<br>• Includes **Child wellbeing**, **Mental wellbeing** (including alcohol and drug addiction), **Prevention** (including smoking cessation, infectious diseases / immunisation, antimicrobial stewardship, and sexual health, **Health equity**[iv] (focused on achieving equity in health outcomes and enhancing equitable access to medicines) and **Primary health care** (making medicines available and accessible in primary care settings) |
| **Section 3: Māori Health Areas of Focus** | Identified by Māori as being of importance | • Relates to Factor of '*Impact on the Māori health areas of focus'*<br>• **Mental health** (Hauora hinengaro), **Diabetes** (Matehuka), **Heart health** – high blood pressure and stroke (Manawa Ora), **Respiratory health** (Romaha Ora), **Cancer** – lung and breast (Mate Pukupuku) |

The Pharmac Factors for Consideration were developed in response to criticism Pharmac was failing to adequately consider fairness, equity, and community values. However, the recently completed Pharmac review noted that these factors were wide-ranging, and their application and consistency in use was not being formally evaluated.[7] This was considered likely to have a compounding effect on the health of Māori, Pasifika, and disabled people in particular, adding to the already well-documented inequities they face.

## Medicine Access

Pharmac reported on the average time to a funding decision for the first time in 2020/21, which is the time taken to fund an application from the date an application was first submitted until the day a funding decision is made.[3]

Many factors affect how long an application takes to be funded, which may include waiting for extra information about a medicine and the right expert advice from the network of clinicians before Pharmac can prioritise an application. Even once prioritised, enough money is needed in the budget to fund the medicine in current and future years, and this can affect time to funding decision.

In 2020/21 Pharmac funded 41 applications, which took on average 3.4 years (41 months) for a funding decision. About 40% of applications were approved in 20 months or less.[3] Importantly this result coincided with the first full year period impacted by the COVID pandemic.

Focusing on average time to a funding decision is important given that unnecessary delays provide significant setbacks for the health system and patients who could benefit from the medicine being funded. Comparable countries have access to breakthrough world-class medicines and treatments, which often become established as standard of care.

Given all this, there are three key areas this report will focus on for modern medicines access in Aotearoa New Zealand:

- Overall trends in the Pharmac lists
- Health need and impact on person, family, whānau and wider society
- Time taken to achieve funding decisions

[ii] Covers conditions that meet Pharmac's definition of a rare disease (1:50,000 population)
[iii] Includes diabetes, cardiovascular disease, chronic respiratory disease, and neurological diseases such as dementia.
[iv] Specific focus on achieving pae ora (healthy futures) for Māori as Te Tiriti partners. Priority populations identified by Pharmac to support equity are: Māori, Pacific people, low socio-economic status, refugees, rural populations; priority health conditions identified by Pharmac to support equity are: cardiovascular disease, diabetes, asthma, COPD, gout.

# Methods

## Data Collection

The three lists, the *Options for Investment* waiting list, the *Only if Cost Neutral or Cost Saving* list and the *Recommended for Decline* lists include all applications in Pharmac's system awaiting a decision and are available on the Pharmac website. These lists were accessed and downloaded from the Pharmac website on 7th November 2022 and were used to establish a baseline for analysis. Updated lists were downloaded on 16th December 2022 to account for changes (new additions, consultations, funding decisions and funding). Both date versions of each of these lists have been referenced in this report.

Requests were made to sponsor companies for a range of information relating to medicine applications on all three Pharmac lists. This included (1) providing information and supporting references if the medicine was considered a standard of care in other countries (2) the total number of patients that would be impacted by the application and (3) a listing of the countries where the medicine was already funded.

To understand the level of unmet need and patient impact addressed with each application an Official Information Act (OIA) request was made for all applications on the *Options for Investment* list. The response has been used to inform more detailed analysis.

## Data Preparation

Standard statistical techniques were used to perform analysis of the Pharmac lists. One if the main ways that applications have been described is in terms of their status at the conclusion of the analysis period (16th December 2022) which has been detailed further in Table 3.

### Table 3 Description of status of medicine applications on each Pharmac list

| Status | Description |
|---|---|
| **New** | New application on list at end of analysis period |
| **No Change** | No changes in status of application during analysis period, remaining on list |
| **Consultation** | Medicine is under Consultation, and this has been announced on the Pharmac website |
| **Removed from Priority List** | The medicine application is no longer on the list at the end of the analysis period. This may happen after conclusion of formal Consultation process |
| **Decision to Fund** | A funding decision has been made and announced on the Pharmac website |
| **Funded** | The medicine has been funded |

In some cases, we have used the terms funding decision to describe those medicine applications with a status of **Decision to Fund** or **Funded** through the analysis period.

In some cases, more than one medicine application on the *Options for Investment* list was referenced for the same indication completely, or potentially as a subgroup of an indication. To avoid double counting these were considered duplicates for analysis of patient numbers, health need, other health costs etc. In these instances, the largest estimated number of patients for duplicate or overlapping indications was used. These data were generally not available for reporting on other Pharmac lists, having not been expressly requested for in the OIA.

Where provided we have reported on the extent that funding decisions aligned with the **Factors for Consideration**, **Government Health Priorities** and **Māori Health Areas of Focus**.

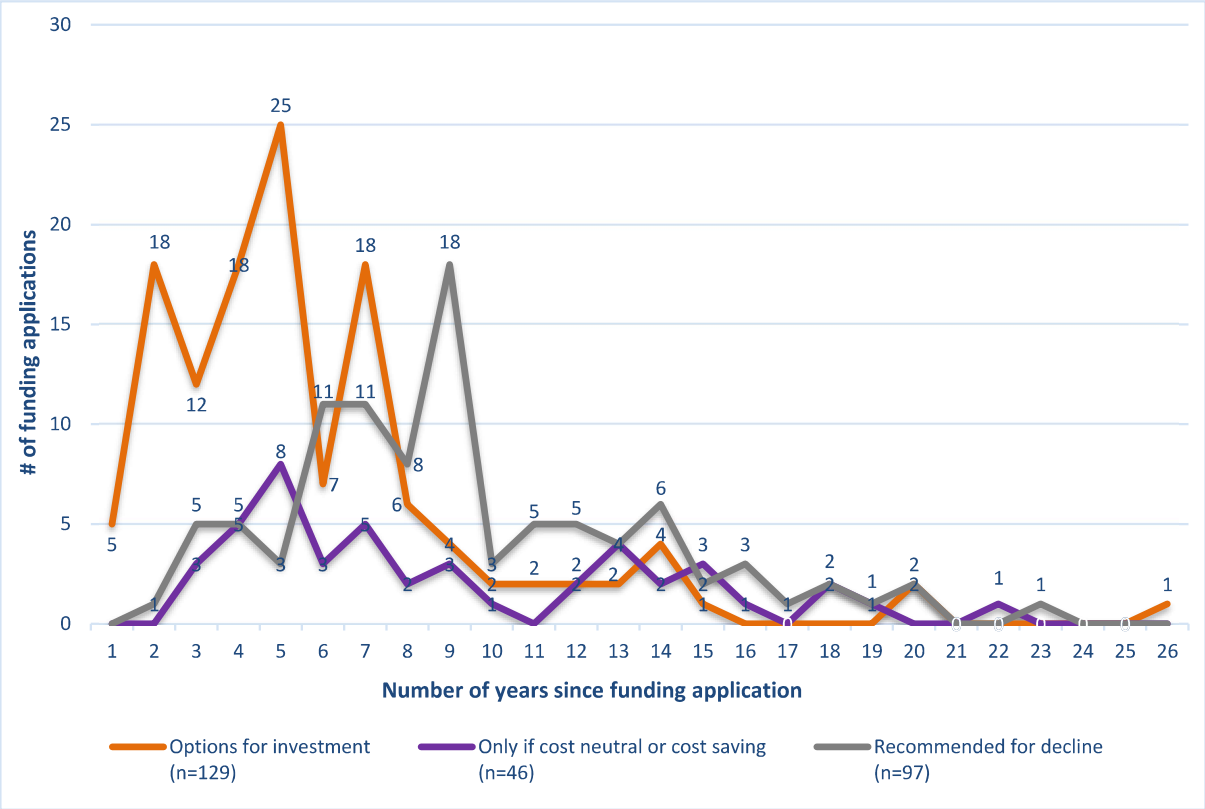
# Results

This section presents the results of analysis of the three Pharmac lists. Where appropriate these have been either combined or presented alongside one another, to compare and contrast the results.

## Time since Pharmac application

The distribution of years since Pharmac application for each of the lists is shown in Figure 4.

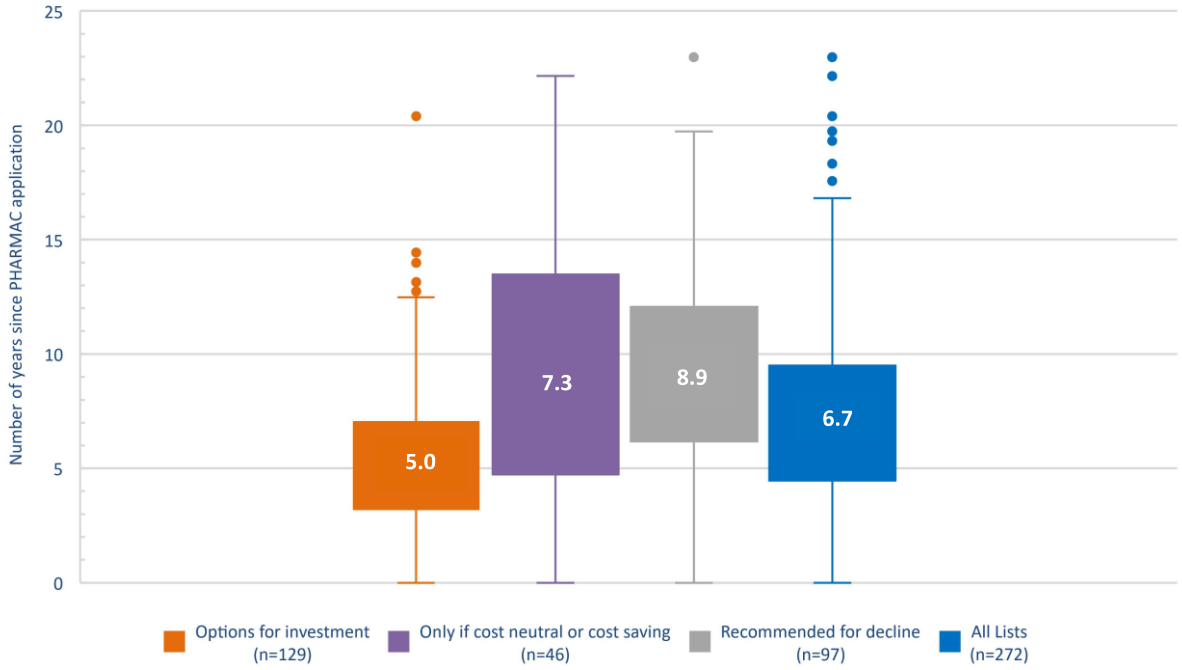
### Figure 4 Distribution of years since application by Pharmac list




The mean number of years since funding application was 5.9 years for the *Options for Investment* list, 9.2 years for the *Only if cost neutral or cost saving* list, and 9.5 years for the *Recommended for Decline* list. Across all Pharmac lists this was 7.7 years.

The distribution of years showed a wide range, with all lists including applications that had been submitted at least 20 years ago. Given this skew in the distribution shape, comparative analysis has also been performed using the median and range of data sets for each list. This will limit the impact of any outlying applications, and is a more conservative treatment. The median number of years since Pharmac application is shown in Figure 5.

## Figure 5 Median number of years since application by Pharmac list

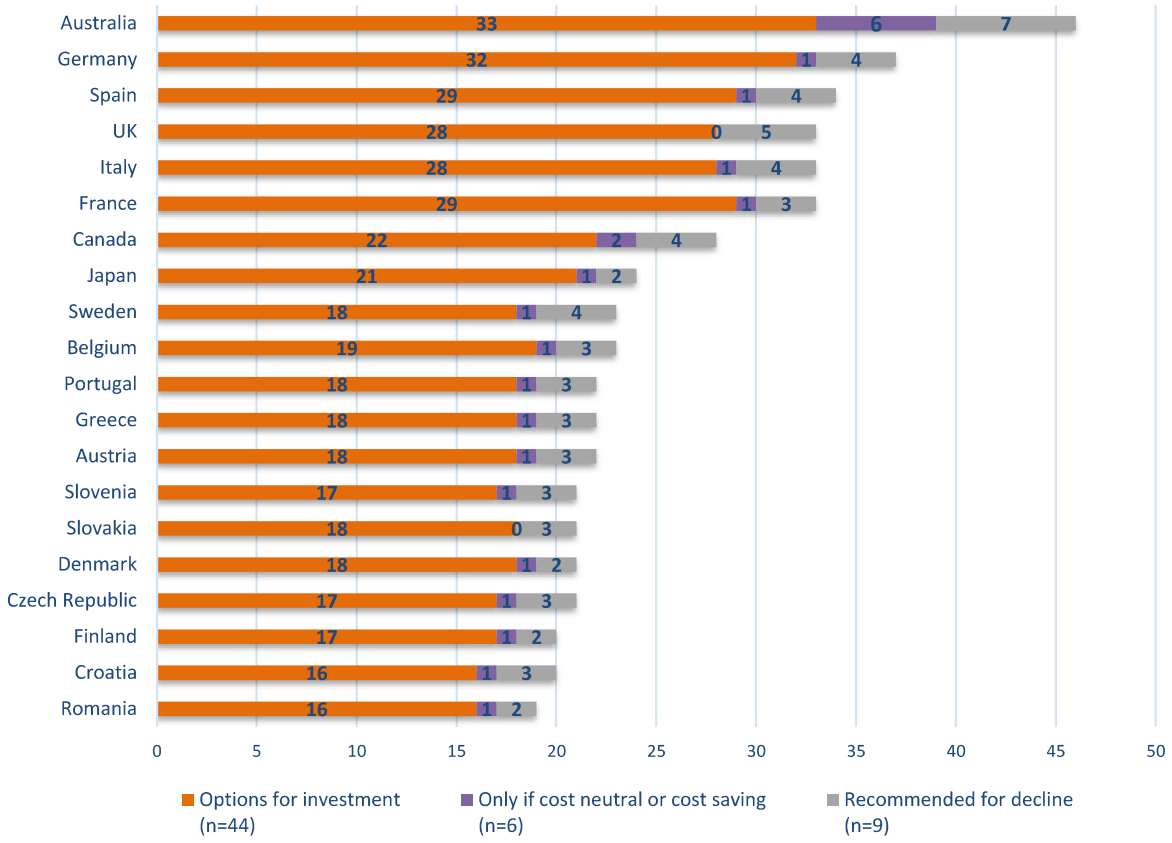



It was a median of 6.7 years since the application to Pharmac had been made for medicines across all lists, although this was variable. The time since application was lowest at 5.0 years for the *Options for Investment* list and highest for the *Recommended for Decline* list at 8.9 years.

## Countries already funding medicines on Pharmac lists

A list of those countries where medicines on Pharmac lists are already known to be publicly funded was provided, with responses for 59 applications. The majority of these were currently on the *Options for Investment* waiting list. This is shown in Figure 6, which gives the overall distribution of the top 20 countries where medicines are currently publicly funded.

### Figure 6 Top 20 countries where medicines are currently publicly funded.




The most prevalent countries where Pharmac list medicines are currently publicly funded were from Australia, EU, and UK. There were 36 (61%) medicines known to be publicly funded in at least 5 other countries. Overall, there were 73 different countries where list medicines were currently publicly funded. In addition, almost all medicines on the *Options for Investment* waiting list, where reported, were publicly funded in at least one other country[v].

### *Standard of care medicine applications*

Where available, sponsor companies reported on whether applications were seen as a recognised standard of care in other countries. In many instances a specific reference was provided to support this information.

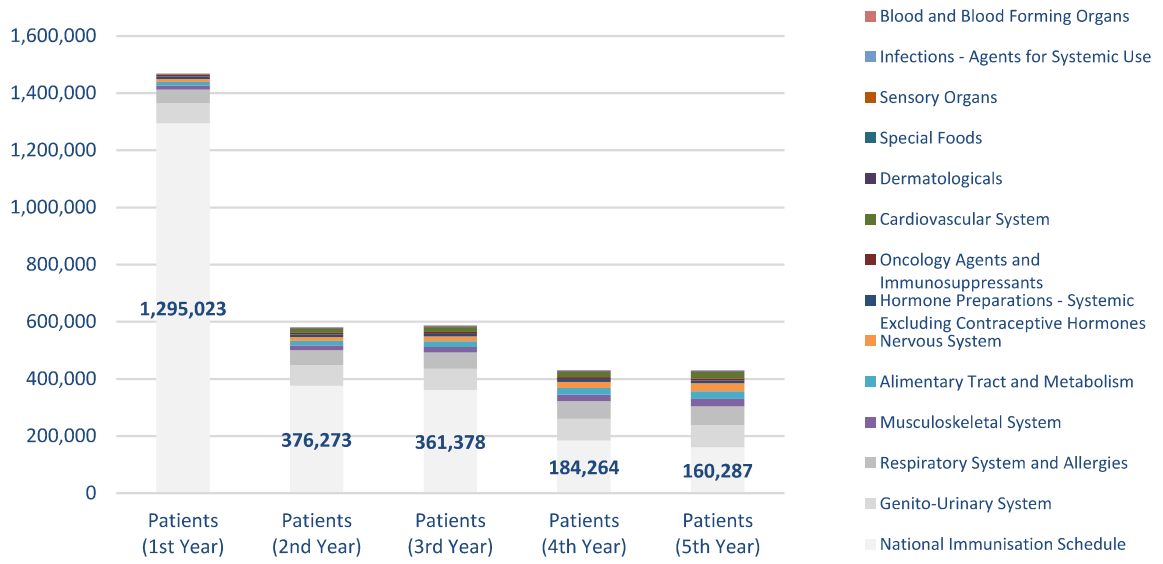
Overall, 83 applications were associated with being a standard of care in other countries, the majority of these (59) on the *Options for Investment* waiting list. Of the total applications, 49 provided a specific reference to the standard of care for the medicine. By contrast where reported on, 5 applications were not considered to be a recognised standard of care, almost all were on the *Recommended for Decline* priority list.

[v] Exception was ustekinumab for Crohn's disease, severe, 3rd line after infliximab and adalimumab.

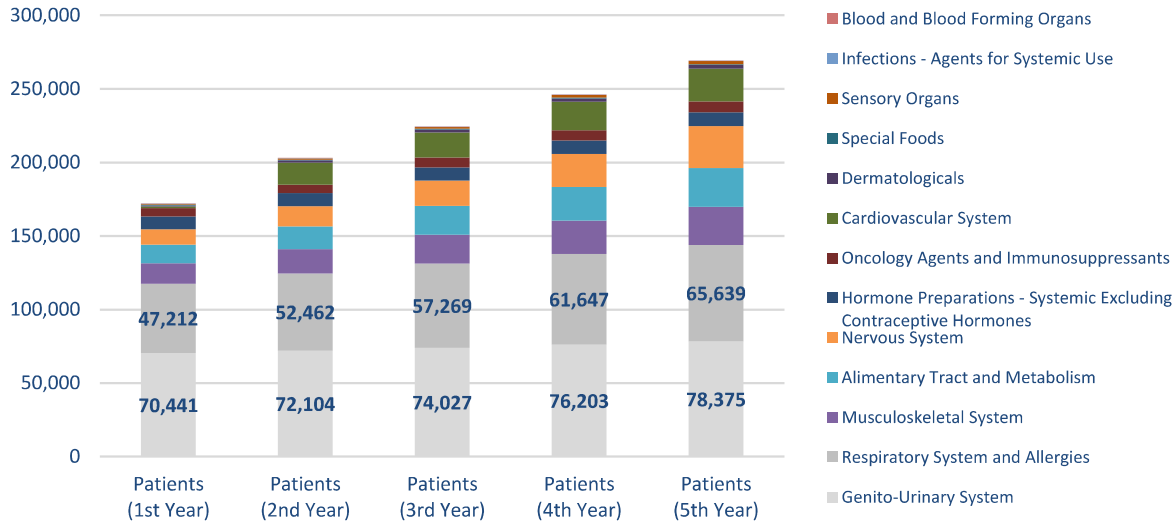
## Number of patients benefiting if the waiting list was funded.

An assessment of the total number of patients that would benefit from the funding of all medicines on the *Options for Investment* waiting list are provided in Figure 7 and Figure 8. In addition, given the impact of the National Immunisation Schedule on the total number of patients, the analysis was performed both with and excluding vaccines.

### Figure 7 Number of patients that could benefit from funding of medicines - first 5 years




### Figure 8 Patients benefiting from funding - first 5 years (excluding vaccines)




Overall, 1,466,960 patients would benefit from funding decisions in the 1st year, or 171,937 people excluding the immunisation schedule. This increases to 202,992, 224,404, 246,076 and 269,238 people that would benefit from funding in the 2nd, 3rd, 4th, and 5th year, respectively.

While this same data was not provided for the other priority lists, sponsor provided data from a further 15 *Recommended for Decline* applications and 12 *Only if cost neutral or cost saving* applications indicated a further 347,048 people would benefit from funding of medicines other lists. However due to paucity of data these are likely to be very conservative estimates.

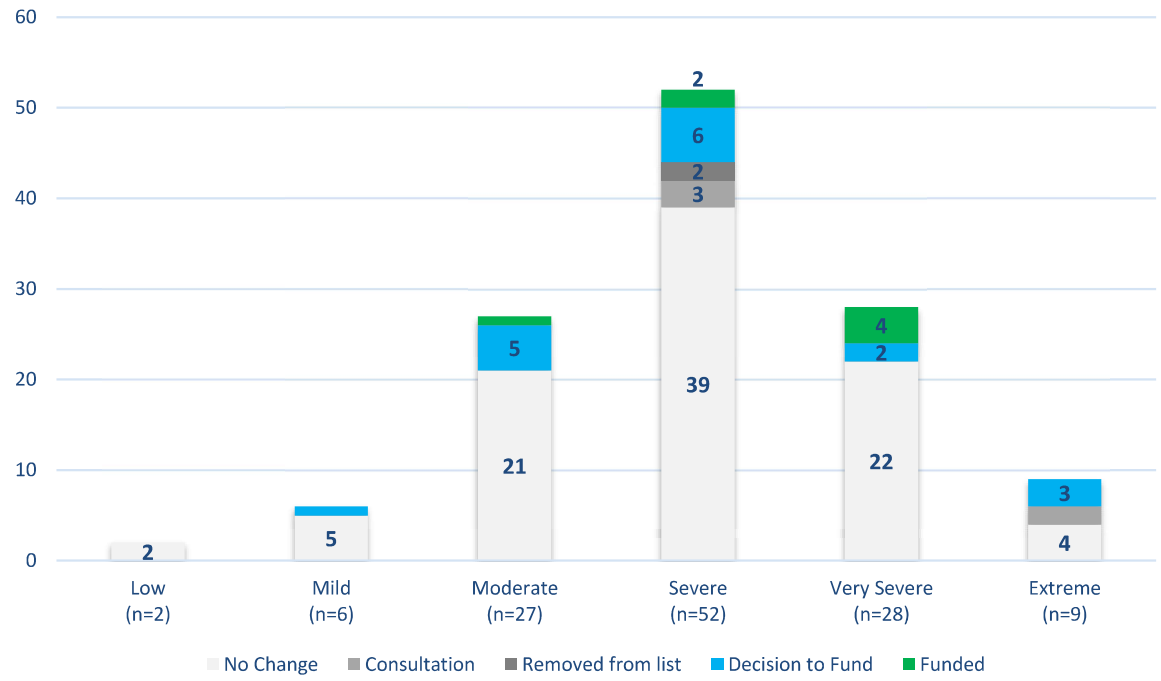
## Health need

To understand the impact of funding we evaluated those funding applications that described the health need of the condition. This is an important factor for consideration Pharmac have when ranking funding proposals.

For this section data has only been obtained following an OIA request from the applications on the *Options for Investment* waiting list. Results should be interpreted with caution if trying to apply findings to other lists.

Those funding applications that included an assessment of health need are given in Figure 9. These are shown by their current status.

### Figure 9 Health need assessment for applications on *Options for Investment* waiting list




89 (72%) of funding applications on the *Options for Investment* waiting list had their health need listed as severe, very severe, or extreme.

There did not appear to be a strong overall correlation between health need severity and likelihood of achieving a funding decision, which averaged around 19% across all health need levels. However, for those where the health need was considered to be extreme, a Decision to Fund had been made for 3 (33%) applications, with a further 2 (22%) currently out for Consultation at the time of writing this report.

There remained a further 65 applications where the health need was considered to be severe and extreme that had not reached a funding decision at the time of writing this report. The cumulative impact of funding all these medicines would be 43,395 people[vi].

[vi] Excluding overlapping conditions and indications

## Māori health need

Funding applications that identified with Māori health need, or those for a Māori health area of focus were evaluated. These are all important factors for consideration Pharmac have when ranking funding proposals.

In this case data was obtained following an OIA request from the applications on the *Options for Investment* waiting list. Results should be interpreted with caution if trying to apply findings to other lists.

The funding applications that identified with Māori health need are given in Table 4. These are shown by the current status of the application.

### Table 4 Applications that identified with Māori health need by status

| Current application status | Yes (n=62) | No (n=19) | No difference (n=4) | Grand Total (n=85) |
|---|---|---|---|---|
| **No Change** | 73% | 53% | 50% | 71% |
| **Consultation** | 8% | 0% | 0% | 5% |
| **Removed from list** | 0% | 11% | 0% | 2% |
| **Decision to Fund** | 13% | 32% | 50% | 17% |
| **Funded** | 6% | 5% | 0% | 5% |

Overall, 62 applications identified with a Māori health need. 73% of these maintained their status on the Pharmac list over the analysis period. In total 12 (19%) of those funding applications with a Māori health need achieved a funding decision (either a Decision to Fund, or were Funded). This was a similar percentage to the total *Options for Investment* waiting list over the same period (20%).

Māori health areas of focus are those that have been identified by Māori as being of importance. There were 16 applications that identified with at least one Māori health area of focus, with only 1 of these achieving a funding decision. This included cancer (9), diabetes (2), heart health (1), mental health (1) and respiratory (4). By contrast there were 78 applications that stated “none identified” in terms of a Māori health area of focus. Of these, 20 applications achieved a funding decision. However, these findings should be interpreted with caution due to small numbers.

## Oncology therapeutic group funding decisions

At 92, the largest number of funding applications on any Pharmac list was for the **Oncology Agents & Immunosuppressants** therapeutic group. This was also the specific case for the *Options for Investment* (n=58) and *Recommended for Decline* lists (n=25).

The median time taken since application varied by Pharmac list. For those applications on the *Options for Investment* waiting list the median time was 5.3 years. Overall lists the time since application was 5.8 years.

Cancer is identified as a Government priority condition. Given this, the distribution and status of these applications listing cancer were reviewed and compared to applications associated with any Government priority condition. This is provided in Table 5.

### Table 5 Applications associated with Government priority condition by status

| Current application status | Cancer (n=52) | Grand Total (n=115) |
|---|---|---|
| **No Change** | 85% | 75% |
| **Consultation** | 6% | 4% |
| **Removed from list** | 0% | 2% |
| **Decision to Fund** | 8% | 14% |
| **Funded** | 2% | 6% |

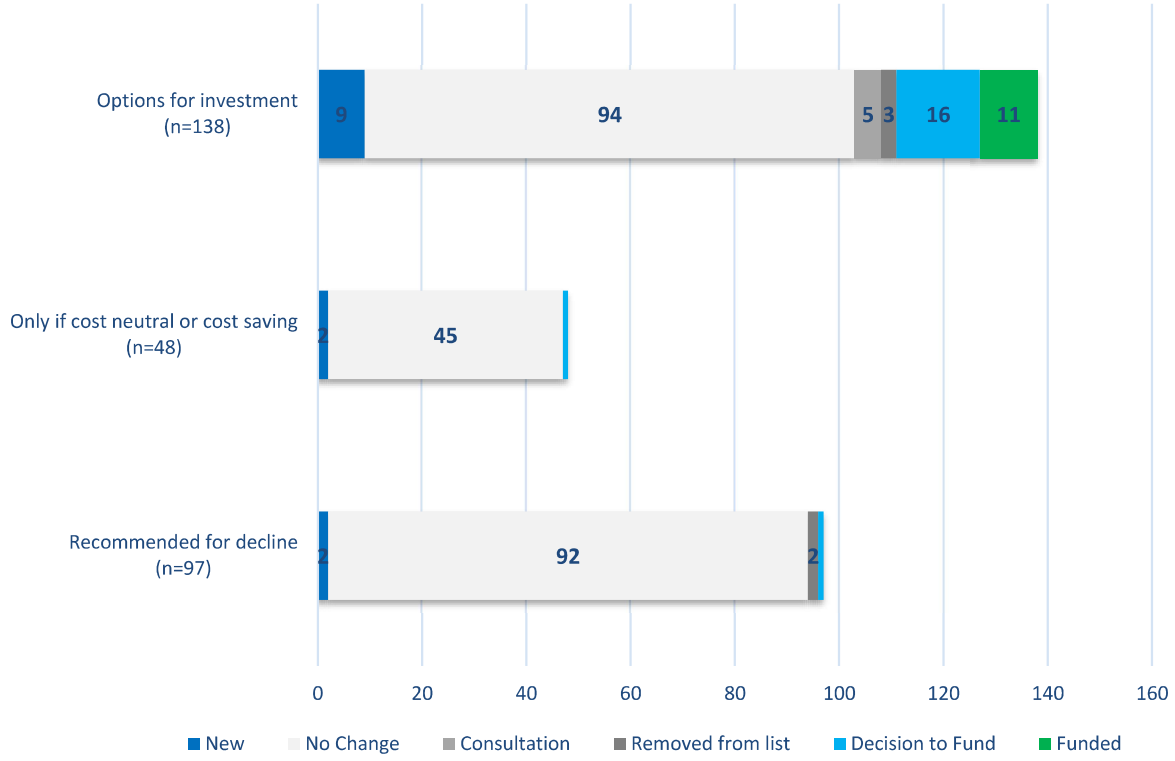
52 applications identified with cancer as a Government priority condition, compared with 115 overall. As a proportion of each condition, the likelihood of a funding decision (either a Decision to Fund, or were Funded). was lower for Cancer (10%) then for other priority conditions (20%).

There were 6 Oncology Agents and Immunosuppressant applications for 3 different medicines (brentuximab vedotin, ibrutininb, obinutuzumab,) on the *Options for Investment* waiting list that achieved a funding decision. This also equated to 10% (6/58) of all relevant applications achieving a funding decision, which was lower than 19% reported for the total list. In addition, despite being 24% of all funding decisions achieved, these medicines cumulatively benefit 52 people in year 1. The number of benefiting patients will decrease to 42 people after 5 years.

## Number of funding decisions

During the period of September-December 2022 There were 29 funding decisions, shown through the changes in status of applications in Figure 10. This result was over double the calculated average rate of funding decisions using historical data, which predicted 13 funding decisions would be achieved over the same period.

### Figure 10 Status of applications for each Pharmac list by December 2022




The most significant were funding decisions from the *Options for Investment* waiting list with a **Decision to Fund** or **Funded** status achieved for 27 (20%) of applications on the list. By contrast for the *Only if Cost Neutral or Cost Saving* list and the *Recommended for Decline* list only one application for each achieved a funding decision through this period, for specific reasons. Decisions to fund Vinorelbine (oral) came through Pharmac's annual tender process, and for liraglutide (Victoza) in response to a dulaglutide supply issue.

Almost 70% funding applications that achieved a funding decision were from 3 therapeutic groups: **Alimentary Tract and Metabolism**, **Oncology Agents and Immunosuppressants** and **Hormone Preparations**. This is not surprising, especially given the first two therapeutic groups have the first and second highest associated number of funding applications. This is both on the *Options for Investment* waiting list and across all lists combined.

The 29 funding decisions that were achieved have been detailed in Table 6. This table includes information on the length of time from submission to Pharmac's decision to fund, as well as the number of patients expected to benefit from these decisions after 5 years.

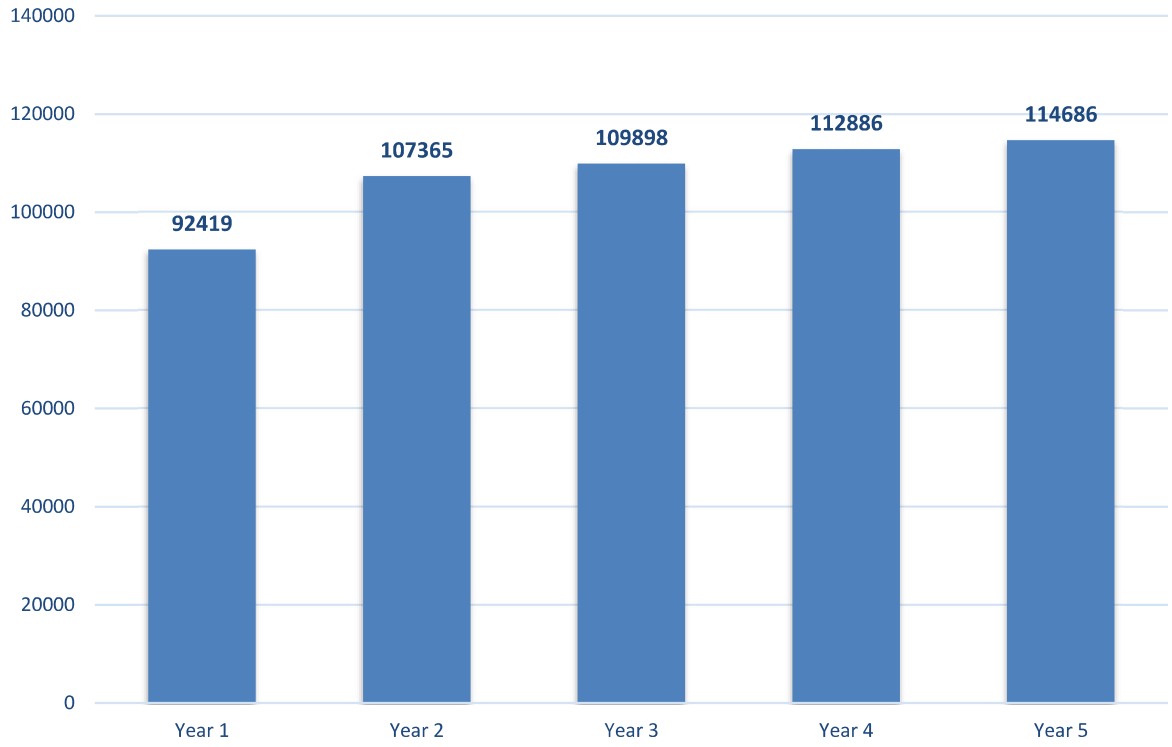
## Table 6 Detail of all funding decisions between September and December 2022[vii]

| Pharmaceutical name | Condition | Therapeutic group | List | Years since application | Patients (5 years) |
|---|---|---|---|---|---|
| **Adrenaline auto-injector** | Treatment of anaphylaxis; have had an anaphylactic reaction or are at High risk of reaction | Cardiovascular System | OFI | 25.68 | 17000 |
| **Brentuximab vedotin** | Relapsed or refractory Hodgkin's lymphoma, ASCT ineligible patients | Oncology Agents and Immunosuppressants | OFI | 6.84 | 4 |
| **Brentuximab vedotin** | Relapsed or refractory Hodgkin's lymphoma and anaplastic large cell lymphoma | Oncology Agents and Immunosuppressants | OFI | 6.84 | 21 |
| **Brentuximab vedotin** | CD30-positive systemic anaplastic large-cell lymphoma | Oncology Agents and Immunosuppressants | OFI | 6.84 | 7 |
| **Brentuximab vedotin** | Relapsed or refractory Hodgkin's lymphoma after auto transplantation | Oncology Agents and Immunosuppressants | OFI | 6.84 | 10 |
| **Cinacalcet HCl** | Primary hyperparathyroidism | Hormone Preparations - Systemic Excluding Contraceptive Hormones | OFI | 14.43 | 224 |
| **Cinacalcet HCl** | Tertiary hyperparathyroidism | Hormone Preparations - Systemic Excluding Contraceptive Hormones | OFI | 14.43 | 114 |
| **Cinacalcet HCl** | Secondary hyperparathyroidism | Hormone Preparations - Systemic Excluding Contraceptive Hormones | OFI | 14.43 | 526 |
| ***Ibrutinib*** | *Chronic lymphocytic leukaemia, who progress during or relapse after venetoclax treatment or are intolerant of venetoclax* | *Oncology Agents and Immunosuppressants* | *OFI* | *7.17* | *66* |
| ***Meningococcal group B vaccine - Invasive meningococcal disease*** | *Entrants to close living situations (13 to 25 years) - no catchup* | *National Immunisation Schedule* | *OFI* | *4.83* | *6000* |
| **Meningococcal group B vaccine - Invasive meningococcal disease** | Entrants to close living situations and one-year catch-up (13 to 25 years) | National Immunisation Schedule | OFI | 4.83 | 6100 |
| **Meningococcal group B vaccine - Invasive meningococcal disease: Infant (2+1)** | Infant Schedule (2+1 dosing) | National Immunisation Schedule | OFI | 4.83 | 54000 |
| ***Nusinersen*** | *Spinal muscular atrophy Type I, II and III* | *Nervous System* | *OFI* | *4.34* | *62* |
| **Nusinersen** | *Pre symptomatic individuals with spinal muscular atrophy* | *Nervous System* | *OFI* | 3.34 | 17 |
| **Obinutuzumab** | Indolent Non-Hodgkin's lymphoma (relapsed after or refractory to rituximab) | Oncology Agents and Immunosuppressants | OFI | 4.58 | |
| **Paliperidone 3 monthly depot injection** | Schizophrenia | Nervous System | OFI | 6.51 | 3500 |
| ***Progesterone*** | *Recurring early pregnancy loss (3 or more) with pre-vaginal bleeding* | *Hormone Preparations - Systemic Excluding Contraceptive Hormones* | *OFI* | *2.08* | |
| **Progesterone** | Menopause | Hormone Preparations - Systemic Excluding Contraceptive Hormones | OFI | 10.34 | |
| **Progesterone** | Open-listing | Hormone Preparations - Systemic Excluding Contraceptive Hormones | OFI | 10.34 | 28,000[8] |
| **Selenium and copper chloride** | Patient is admitted to hospital with burns. | Alimentary Tract and Metabolism | OFI | 2.75 | 195 |
| **Tolvaptan** | Polycystic chronic kidney disease | Cardiovascular System | OFI | 6.75 | 408 |
| ***Ustekinumab*** | Crohn's disease, severe, 2nd line after infliximab and/or adalimumab | *Alimentary Tract and Metabolism* | OFI | *5.59* | *602* |
| ***Ustekinumab*** | Ulcerative colitis, moderate to severe, 2nd line after infliximab | *Alimentary Tract and Metabolism* | OFI | *2.83* | *310* |
| **Ustekinumab** | Crohn's disease, severe, 3rd line after infliximab and adalimumab | Alimentary Tract and Metabolism | OFI | 5.59 | 369 |
| **Vedolizumab** | Ulcerative colitis, moderate to severe, 2nd line after infliximab | Alimentary Tract and Metabolism | OFI | 6.51 | 355 |
| **Vedolizumab** | Crohn's disease, severe, 2nd line after infliximab and/or adalimumab | Alimentary Tract and Metabolism | OFI | 6.51 | 936 |
| **Zoledronic acid** | Open-listing | Musculoskeletal System | OFI | 1.67 | 2900 |
| **Vinorelbine (oral)** | Non-small cell lung cancer | Oncology Agents and Immunosuppressants | CN/CS | 15.01 | |
| **Liraglutide** | Diabetes - type 2 | Alimentary Tract and Metabolism | RFD | 10.84 | |

[vii] Those applications in italics are considered secondary and have been excluded when counting unique additional patient numbers from funding decisions due to presence of an overlapping treatment or indication.

The total number of patients expected to benefit from these funding decisions after 5 years are shown in Figure 11.

## Figure 11 Patient numbers that will benefit from recent funding decisions [viii]




As well, the recent funding decisions were for medicines that, where reported on, were already available in many other countries and referenced as a standard of care. There were 8 reports of funded medicines being available in an average of 39 other countries. In addition, there were 9 reports where the medicine could be referenced as a standard of care elsewhere in the world.

[viii] In addition to patient numbers from OIA response this includes reported numbers for the open listing for progesterone, which is estimated to benefit over 7,000 people in the first year, increasing to over 28,000 people per year in the next five years.

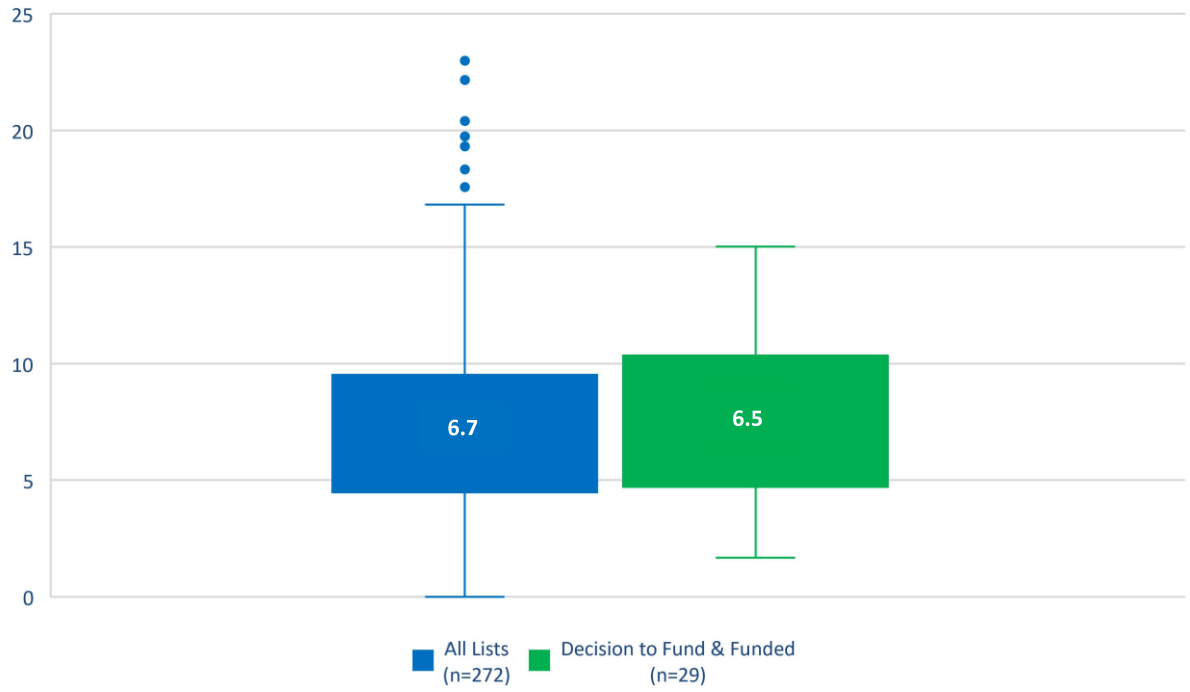
## Time since Pharmac application to reach funding decision

Those Pharmac applications where a funding decision was achieved has been assessed in terms of the time taken. Data has been presented both as mean and median values.

The mean number of years to reach a funding decision for the 29 applications was 7.7 years, which was the same as the time for all applications on lists, regardless of their funding status.

The median distribution of these times is presented in Figure 12.

### Figure 12 Median number of years since Pharmac application by funding decision



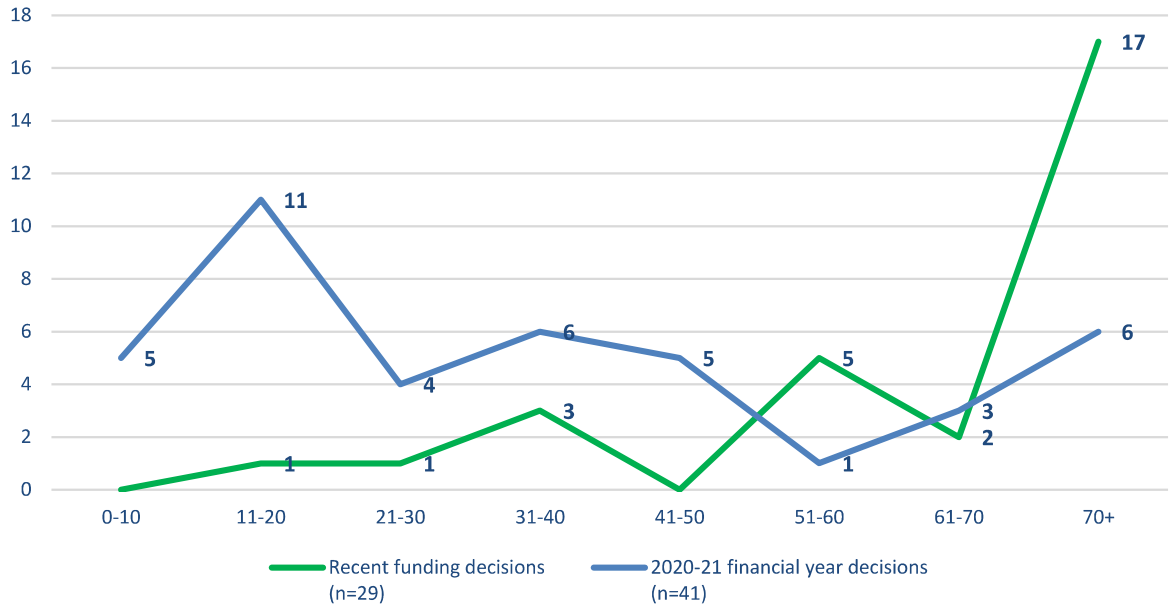

For those 29 applications it took a median of 6.5 years to reach a funding decision, generally between 4-10 years. This length of time was similar to the current distribution for all applications on lists regardless of their funding status.

These times are almost double those of previously published data for funding decisions. For example in 2020/21 it took on average 3.4 years to go from applications received to being funded.[3] This evidence suggests that the time to achieve funding decisions has increased dramatically over the last two years.

## Time to achieve funding decision - comparison with previously reported data

The distribution of time from Pharmac application to achieving a funding decision could be compared with the 2020/21 annual report data. In this case this was by looking at the number of months since application, grouped in 10-month increments. This is shown in Figure 13.

### Figure 13 Comparison of time since Pharmac application for recent funding decisions compared with the 2020/21 financial year (in months)




There was an appreciable increase in the time since Pharmac application for recent funding decisions compared with previously reported data. Over 50% (17/29) of recent funding decisions took at least 70 months to achieve, whereas in 2020/21 the median time was between 31-40 months. Importantly in 2020/21 16 (39%) applications had their funding decision achieved within 20 months compared with only 1 (3%) for recent funding decisions.

The reasons for these differences are unclear, although it should be noted that small numbers and different time periods limit more detailed comparisons.

# Conclusions

The results have provided a number of important findings which can be seen in the context of other available data and insights. As well this provides evidence for recommendations to Pharmac in order to further improve the medicines funding process, including decision making for each of the three lists.

## Medicines still waiting on the *Options for Investment* list after almost 6 years

It was an average of 5.9 years (median 5.0 years) since submission for applications currently waiting on the *Options for Investment* list and 7.7 years across all lists. This will continue to increase while funding decisions are not made. It is unlikely to compare favourably with other similar countries, given that in one report from 2011 to 2020 Australia already made funding decisions almost a year faster than Aotearoa New Zealand.[9]

Importantly though, there have been recent increases in the CPB through 2022/23 ($71 million) and 2023/24 ($120 million). It could be reasonably expected then that some of this additional budget could be used to accelerate funding decisions moving forward. This is especially for medicines waiting on the *Options for Investment* list that could benefit patients sooner.

## Aotearoa lags behind rest of world in access to standard of care medicines

Medicines on the *Options for Investment* waiting list in particular, are already known to be publicly funded in many other countries with the most prevalent being Australia, EU, and UK. In addition, many were also referenced as standard of care in other countries. The results presented in this report need to be seen in the context of the continuing challenge in timely access of modern medicines in Aotearoa New Zealand, compared with the rest of the world. For example, one report showed that from 2011 to 2020 Australia made funding decisions almost a year faster than Aotearoa New Zealand.[9] This is especially important given that many of these modern medicines soon became the standard of care once they are publicly funded for a given country.

Moving forward, it will be important to establish a reasonable benchmark for the time taken to achieve funding decisions and this should be reported on regularly at an individual and aggregate level. This should take into account the experiences and timeframes from other countries, given a number of reports have previously highlighted differences to other OECD countries on the number of medicines funded.

## 1 million+ patients to benefit from immediate funding of the OFI waiting list

The effects of delays in time to funding decision is exacerbated when looking at the number of people expected to benefit from day 1 following funding, and subsequently over the next 5 years. For the *Options for Investment* waiting list, for example, there would be 1,466,960 patients benefiting from funding the list in the 1st year alone. Even excluding vaccines shows an additional 171,937 people would benefit from funding this waiting list in the 1st year. This only increases in the five years following funding to benefit 202,992, 224,404, 246,076 and 269,238 people respectively.

These numbers should be considered together with the cumulative level of unmet health need while the medicine remains unfunded to give the true opportunity cost of delayed funding decisions. Or put into context, approximately 29% of the current Aotearoa New Zealand population would benefit if all applications on the *Options for Investment* waiting list were funded immediately. Even funding all medicines other than vaccines would benefit 3.5% of the country's population straight away.

## Focus on those patients with highest unmet health needs

The health need of the condition is an important factor for consideration Pharmac have when ranking funding proposals on lists. However, in many instances the correlation of these factors with the likelihood of a funding decision then being achieved for an application were unclear.

Looking at health need specifically, there were 65 unfunded applications where the heath need was considered to be severe or extreme and had the potential to benefit 43,395 people. The recommendation is that the same focused approach for applications associated with extreme health need is extended to those applications associated with severe health needs.

## Unclear how Māori health need is being considered by Pharmac

It was unclear how one factor for consideration, that of being identified with a Māori health need, was being applied by Pharmac given recent funding decisions. A focus on Māori health priorities was not particularly well correlated with the likelihood of achieving a funding decision. Of those applications that identified with a **Māori health need**, 12 (19%) achieved a funding decision, which was a similar percentage to all funding decisions achieved across the total *Options for Investment* waiting list. Furthermore, only 1 application that achieved a funding decision specified a Māori health area of focus.

One explanation for unclear application of Pharmac's factors for consideration in action may have been due to gaps in data provision and reporting for these key factors which is a limitation of this research as we were only able to analyse factors provided through the OIA. This suggests there would be a benefit in making this identification publicly available for each relevant application, so it can be assessed whether and how consistently the factors have been applied.

## Time taken to achieve funding decision remains too long

It took an average of 7.7 years (median 6.5 years) from submission to Pharmac to achieve a funding decision. This is a length of time similar to all remaining applications on Pharmac lists, suggesting that even increasing the rate of funding from this point will not materially reduce this number. These times are almost double those of published data in 2020/21 demonstrating that the time to achieve funding decisions has only increased over the last two years. While it could be anticipated that some of this is due to the impact of the COVID pandemic on usual business process, this increasing length of time will now be 'baked in' for existing Pharmac list applications.

How long a medicine takes to be funded is considered a function of (1) the time taken for Pharmac to prioritise an application together with (2) time taken to achieve funding decision from each list. Delays may be caused by waiting for extra information or the right expert advice, through to having enough money in the budget to fund the medicine in current and future years.[2]

There still remains the opportunity to reduce time to funding decisions through a more rapid turnaround in receiving further information or further clinical advice throughout the process. One observation in this report is the proportion of non-sponsor initiated submissions, with little insight as to how involved the sponsor is with these applications throughout the funding process. It is recommended that Pharmac continue to review and optimise this part of the process to reduce time taken.

## Time taken to reach funding decision is increasing over the last 2 years

Looking at the distribution of time taken to reach a funding decision, some applications are able achieve a funding decision much faster than others. In 2020/21, about 40% of Pharmac funded applications were approved in 20 months or less whereas this had fallen to 3% through this reporting period. Understanding the underlying causes of this reduction in rapidly achieved funding decisions will be important, given the number of patients unable to benefit sooner.

Moving forward, it will be important for Pharmac to build on the recent increased rate of funding decisions. If maintained, this should in turn eventually lead to reductions in the time to funding decision being reached. It will also allow for continued renewal of the priority list with new funding applications for modern medicines that address other unmet health needs. However, given this increased rate is commensurate with CPB changes it signals the importance of appropriate medicines funding in future years.

## Final reflections

The publishing and maintenance of lists by Pharmac is an important step in increasing transparency for applicants and the benefitting patients as to the stage of a given application in the funding process. However, it has become clear through the development of this report that there is a wide range of additional information not currently publicly available that can aid reporting, help generate insights and support further improvements in the medicines funding process. This includes a number of benefiting patients, provision of factors for consideration, assessment by therapeutic group and ability to review aggregated time since submission data across a wider range of applications. In these cases, these were only provided under an Official Information Act request. Our view is that such data as these should be transparently available for the public to see on the application on the list.

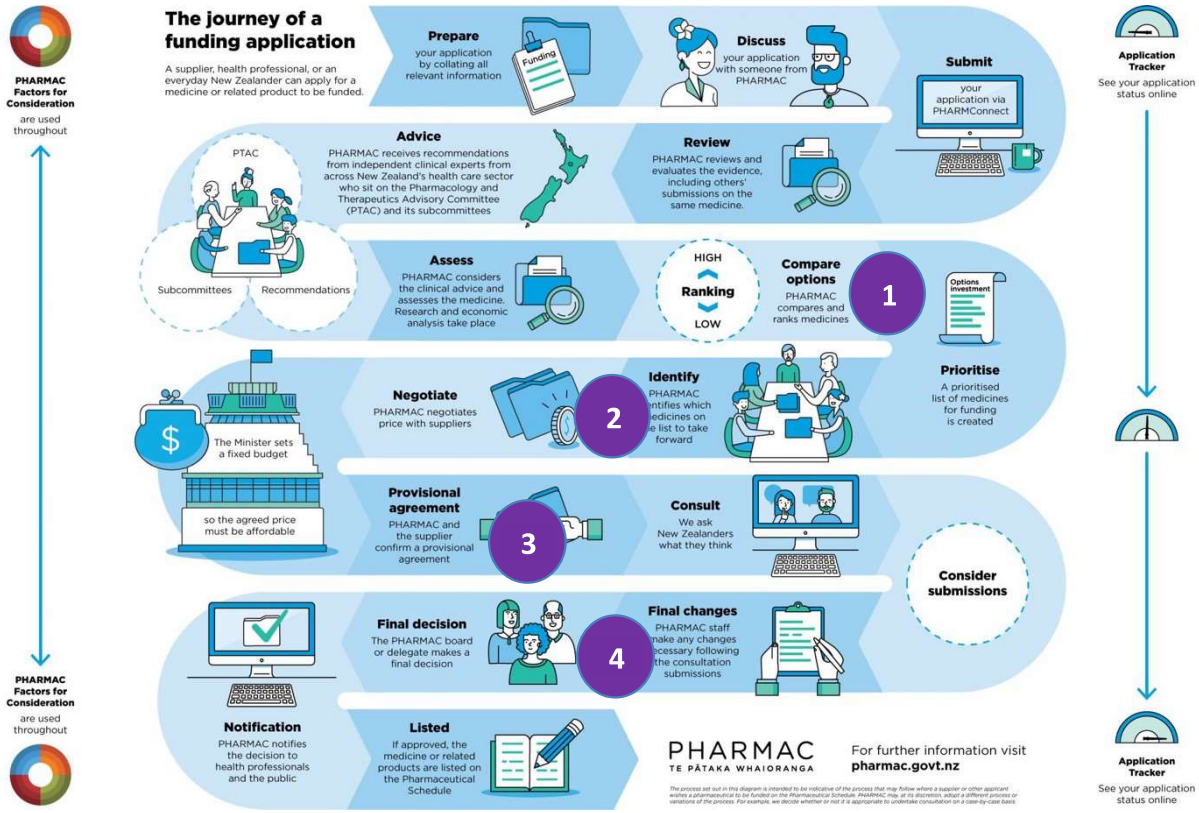
While the reporting of benefiting patients associated with each application would be welcome, there is a risk that funding decisions from the National Immunisation Schedule has the potential to dominate and distort understanding and insight. This is especially the case for conditions where the assessed need is high but will benefit a much smaller number of patients. Given this, it is recommended that key reporting on patients benefiting both includes and excludes the impact of vaccines or includes them as a sub-group. This also mitigates the potential for applications associated with priority Government conditions such as cancer and rare diseases to be marginalised.

Moving forward it is recommended that Pharmac look at the opportunity to explicitly make the factors for consideration associated with each funding application publicly available, so it can be better understood whether and how consistently these factors are being applied. These are important criteria used to support Pharmac's decision making process and address fairness, equity, and community values. They would allow Pharmac to demonstrate that their decisions align with these factors on the basis of health need of the condition, Māori health need or Government health priority.

Furthermore, increasing the transparency of decision making by Pharmac is likely to help increase understanding of how the medicines funding process works for given situations. This is likely to lead to more meaningful and well-informed dialogue with a wider range of health stakeholders to ensure medicines funding can achieve the greatest possible benefit for all people in Aotearoa New Zealand.

## Appendix 1: The journey of a Pharmac funding application [2]

The journey of a funding application with the key steps in prioritising and funding decisions across the process that have been referenced throughout this report.




1. **Prioritise:** Prioritised lists of medicines for funding is created. For the purposes of this report the first stage for analysis of medicine applications is once they have been placed on one of the three Pharmac lists (**New**). Maintenance on the list over time is indicated as **No Change**.

2. **Consult:** Asking New Zealanders what they think for medicine applications being taken forward is through a defined period of **Consultation.**

3. **Final decision:** the Pharmac Board or delegate makes a final decision. For the purposes of this report the stage is equivalent to **Decision to Fund** where it has been indicated and announced on the website.

4. **Listed:** The medicine is listed on the Pharmaceutical Schedule. For the purposes of this report, the stage is equivalent to being **Funded.**

# References


[1] https://www.fairnessinfocus.co.nz/about-medicines-funding-in-nz

[2] www.pharmac.govt.nz

[3] PHARMAC 2020-21 annual report (2021), Wellington, New Zealand. *Available from:* https://pharmac.govt.nz/assets/Annual-Report-2020-2021.pdf

[4] https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/priority-lists/

[5] https://pharmac.govt.nz/news-and-resources/official-information-act/official-information-act-responses/combined-pharmaceutical-budget-cpb-and-covid-19-allocations-and-appropriations-over-past-10-years-since-201112/#_ftnref1

[6] https://www.treasury.govt.nz/sites/default/files/2022-06/est22-v5-health.pdf

[7] https://www.health.govt.nz/system/files/documents/publications/pharmac-review-final-report.pdf

[8] https://pharmac.govt.nz/news-and-resources/consultations-and-decisions/2022-05-19-proposals-to-widen-access-to-progesterone-antiretrovirals-and-nitrofurantoin/

[9] IQVIA. (2021). Access to Medicines (AtoM 3): 2011- 2020. Available from*:* *https://www.medicinesnz.co.nz/fileadmin/user_upload/IQVIA_Access_to_Medicines_3__AtoM_3__Report.pdf*