The future of Aotearoa's Medicines access – fixing the funding model

A Shawview report

Ko te pae tawhiti, whaia kia tata
Ko te pae tata, whakamaua kia tina

Secure the distant horizons so that they become closer
Secure the close horizons so that they become a reality.

SHAWVIEW CONSULTING

Ki mai ki ahau, he aha te mea nui o te ao?
Māku e ki atu, he tāngata, he tāngata.

If you care to ask me
What is the most important in the world?
I would reply, it is people, it is people.

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Executive Summary

Modern medicines can provide quick, efficient and scalable medical treatment, alleviation of illness symptoms, as well as pain and side effect management. Innovation in modern medicine options can also improve health faster, ensure a higher quality of life and productivity and reduce health system costs, such as reducing hospitalisations.

Many new innovative medicines are also demonstrating greater efficacy in addressing unmet medical need, especially for populations where patients have either exhausted current treatment options or there are none yet available - some new medicines represent a potential for incremental step-changes, some transformational changes, and some are even potentially curative changes for patients.

- For New Zealand patients with significant unmet medical needs, where treatments address serious or life-threatening conditions and/or major public health needs, the regulatory authority Medsafe provides expedited assessments and access. Pharmac, New Zealand's pricing and reimbursement decision maker, needs to similarly recognise unmet medical needs in the community.
- New Zealand has fallen behind similar high-income OECD countries in providing access to new medicines and treatments for its population. New Zealanders do not get access to the same range of innovative new medicines to treat diseases that people in other similar countries enjoy. While the problem has existed for many years, growing community concern and a worsening access problem has led to this point today where reform is urgently needed.
- For New Zealand health care teams, individuals, whānau, families and communities experiencing significant delays in trying to access modern medicines creates an ethical dilemma for New Zealand's health care teams treating patients
- International experience from several other countries with similar economic circumstances to New Zealand demonstrates the types of reforms and policy innovations that can be introduced to improve New Zealanders' access to new medicines. Medicines funding reforms in countries such as Germany, Italy, Japan, and the United Kingdom can be used to identify what New Zealand could do to redress its access gap.
- The government needs to reconsider what it is asking Pharmac to do for New Zealanders. Strong policy direction from government is needed to mandate Pharmac to improve health outcomes by enabling timely access to innovative new therapeutics and consider the broader societal benefits of medicines in its health technology assessment and decision making.
- To avoid any conflicts of interest with Pharmac's revised mandate, the government should consider requiring Te Whatu Ora/Health New Zealand and/or the Cabinet process to manage the funding decision for new medicines, based on Pharmac health technology assessment, rather than Pharmac itself. A government- or Cabinet-led decision-making process could

help improve transparency and integrity in the process and help deliver good value for money for New Zealand taxpayers.

- Pharmac's statutory objective for three decades has been "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" (emphasis added). The organisation has managed its financial objective very well, but this has been at the expense of timely access to modern medicines and health outcomes foregone for New Zealanders.
- Operating under a capped budget, the Pharmac model relies heavily on generating savings from old medicines to fund new advances in medicines, with limited year on year budget increases. This has ultimately caused delayed access to medicines, increased inequity and likely increased costs in other parts of the health system, the government and the economy.
- New Zealand needs to focus on the 4 Ps of access to medicines - Policy, Process, Prioritisation and Payments to help alleviate the current 'lag' in access to medicines in New Zealand. This requires both short-term interventions to fix the current gap in medicine access in New Zealand, as well as longer-term initiatives to reform the medicines evaluation and funding system.
- New Zealand has fallen behind its peers in terms of investment in therapeutic innovation. The country needs to invest in therapeutic innovation to improve health outcomes and close the gap between Māori and non-Māori populations. This investment should be in the form of additional funding for health interventions that are assessed for their relative incremental clinical benefits (clinical effectiveness approach) when valuing a new health technology (eg. Germany), or through a clinical plus cost-effectiveness approach, utilising an incremental cost-effectiveness ratio (ICER) (eg. the UK).
- Pharmac's evaluation of medicines should also include a broader societal consideration and valuation of the benefits of treatment, such as the burden for carers, the social and economic productivity benefits of treatment and longer-term dynamic efficiency in New Zealand's health system.
- There is currently a backlog of more than 109 promising new technologies that have been evaluated for cost effectiveness but are awaiting funding on Pharmac's "Options for Investment' list. There is an urgent need for near term investment in these new medicines that address a range of diseases, rare disorders and paediatric conditions.
- New Zealand needs to find new innovative ways to accommodate changing technology paradigms and harness the full potential of emerging therapeutic innovations to improve health outcomes of its population.
- To do so, New Zealand will need to constantly evolve its health technology assessment framework, manage inherent uncertainties, assess overall economic impact and understand how these interventions might better value aspects of relevance to patients and society.
- International experience demonstrates there are a range of reforms that New Zealand should consider such as improve the way it evaluates and funds innovative new medicines for the community

Proposed reforms

Short-term

- In the immediate short-term, first and foremost there is an urgent need to **fund the backlog** of innovative medicines on the Options for Investment **list that Pharmac has already deemed to be cost-effective and of benefit** to the New Zealand community but have not been funded due to a constrained budget.

Longer-term

- **The New Zealand Government should develop a forecast and a plan to increase the medicines budget** year on year to get closer to the OECD average and avoid under investment in cost effective medicines that have potential to improve the productivity of its healthcare system.
- To ensure good value for money and sustainability of the medicines budget, New Zealand can look to **innovative individual financing mechanisms** such as managed entry agreements that are being used in Europe to improve access to new technologies. See section III.
- New Zealand can **apply learnings and experiences of comparable countries** in Europe to make progress on access to medicines and use more progressive and pragmatic approaches to price medicines. See section III.
- **Create a well-crafted "innovation fund"** to demonstrate the political will to transform medicines access to not only addresses the immediate crisis but also set the course for future access for New Zealanders. This dedicated fund will help expedite the listing and funding of new treatments for a range of diseases, rare disorders, paediatric indications and other priority diseases over the long-term.
- **Apply a societal perspective approach to valuation in Pharmac's health technology assessments** consistent with New Zealand's economic policy approach that takes into account the broader social and economic benefits of government spending in services, consistent with New Zealand's broader economic and fiscal policy agenda.
- **New Zealand needs an updated medicines strategy** that acts as guiding principle for the future and when in doubt, could be relied upon to show the path forward regardless of political affiliation. This strategy should prioritise equity, fairness, early access to the latest treatments for New Zealanders, include horizon scanning and promote evaluations that consider other value aspects of relevance to patients and society and not cost and benefits in the current sense.

Introduction

Modern medicines can provide quick, efficient and scalable medical treatment, alleviation of illness symptoms, pain and side effect management and flexibility in treatment options. This leads to improved health, a better quality of life, higher productivity and reduced health system costs such as reduced hospitalisations.

Many new innovative medicines are demonstrating greater efficacy in addressing unmet medical need, especially in populations where patients have either exhausted current treatment options or where none is yet available. Some new medicines represent an opportunity for incremental step-changes, some are transformational changes, and some are even potentially curative change for the patient. Both regulatory authorities and funding authorities need to provide expedited assessments and funded access where treatments address serious or life-threatening conditions and/or major public health needs.

There is growing concern within the New Zealand population, who have placed their trust in government agencies like Pharmac, about the country's ability to assess and fund medicines in a timely and equitable manner. This report examines current access to medicines in New Zealand, reviews examples of international best practices from other countries, and identifies ways to reform the system of assessing, funding and providing medicines for the New Zealand community.

The New Zealand government and its Crown entities such as Health New Zealand and Pharmac should work to reinvigorate New Zealanders' access to medicines by exploring new ways to address the four 'P's *(Policy, Processes, Prioritisation and Payment)* that strengthen the government's ability to achieve better health outcomes for New Zealanders. Multiple international examples point to innovative ways where other comparable countries are addressing the dual challenge of improving population wide publicly funded access to promising therapeutic innovation while ensuring long-term fiscal sustainability is maintained in the long run.

This report is divided into four parts. Part I summarises the current state of access to medicines in New Zealand looking at the issues around oncology medicines as an example. This includes noting some learnings from the 2022 Pharmac review of that agency's current practices and issues. Part II looks at defining the 'problem to solve' from a policy, process, prioritisation and payment (funding) perspective to improve timely and equitable access to medicines in New Zealand. This includes redefining organisational roles and responsibilities to improve transparency, introducing better governance and promoting increased accountability.

Part III outlines international examples of how other countries achieve better access to medicines for their populations while balancing their fiscal priorities. This section includes discussion on how such examples could be emulated in New Zealand. Part IV sets out a roadmap for New Zealand, including some "quick wins" that can positively improve New Zealanders' access to medicines in the short-term.

Part I:
Current state of access to medicines in New Zealand – the example of oncology medicines

Access to medicines in general

Delayed access to medicines in New Zealand is nothing new. In the most recent report on the New Zealand medicines waiting list, it was noted that, on average, it took an average 7.7 years to achieve a funding decision for medicines. This delay is partially attributable to the assessment and prioritisation process which is outdated and needs an overhaul. Additional delay is caused by the lack of funds available in what is a fixed medicine budget that has not kept pace with rising demand or the pace of innovation. Delay in access to cost-effective medicines means that less cost-effective medicines continue to be used in New Zealand clinical practice. This adds to overall disease burden and reduces the efficiencies of the country's healthcare system.

New Zealand's current medicine procurement model administered by its Crown entity, Pharmac, has for decades prioritised managing a limited budget with no little or no growth in expenditure, at the expense of improving health outcomes.

However, as science progresses and as clinical practice evolves to become more personalised, the cost of developing and bringing new medicines to market has increased. In this context, Pharmac's practice of "bargain hunting" by prioritising managing a fixed budget is increasingly becoming an impediment to New Zealanders' access to medicines, leading to unnecessary delays and pushing New Zealand to the back of the 'queue' in securing new medicines. New Zealand is an example of a healthcare system with an outdated medicines procurement model that other countries have chosen to avoid, rather than emulate, when seeking to improve population health outcomes. Even Australia, New Zealand's closest neighbour with strong cultural ties, while having issues in its own medicines funding system, has avoided the Pharmac procurement model.

In the past there has been commentary about New Zealand's success in managing its medicines budget – by definition a fixed budget tends to do that. However, this view tends to prioritise the cost implications and ignores the health outcomes foregone and years of life lost because of delayed access. It also disregards the hardship that patients have to endure, the loss of loved ones prematurely from an illness which could be managed with a new therapeutic option and the adverse impact on communities, society and the economy. Similarly, access delays are also impacting people living with debilitating chronic conditions who could live more productive lives if they could access additional therapeutic options to manage their conditions much like their peers in other comparable countries in a consistent and timely manner.

New Zealand's access to new medicines has substantially fallen behind comparable countries with similar economic circumstances such that today Kiwis wait longer for new medicines than people in comparable countries such as Australia. Alarmingly, this gap is widening. For example, according to a recent Access to Medicines Report (2021), median wait time for new medicines in New Zealand was 1014 days in 2020, compared to 422 days in Australia. This compares with median wait times in 2013 when patients in Australia and New Zealand waited for roughly the same number of days (398 days vs. 402 days respectively)[1].

Alarmingly, by 2023 these delays have almost doubled. According to the most recent report "Pharmac's Medicines Waiting Lists: Impacts on Patients in Aotearoa New Zealand", (April 2023), applications that achieved a funding decision did so on average 7.7 years following their submission to Pharmac[2].

[1] IQVIA, Medicines New Zealand – Access to Medicines (AtoM 3) Report (November 2021), Pg 5, available at https://www.medicinesnz.co.nz/resources/publications

[2] HealthiNZ. 2023. Pharmac's Medicines Waiting Lists: Impacts on Patients in Aotearoa New Zealand, April, Report commissioned by Medicines New Zealand, p. 3, https://www.medicinesnz.co.nz/fileadmin/user_upload/Publications/Pharmac_s_Medicines_Waiting_Lists_-_Impacts_on_Patients_in__Aotearoa_New_Zealand.pdf, accessed 14/7/2023.

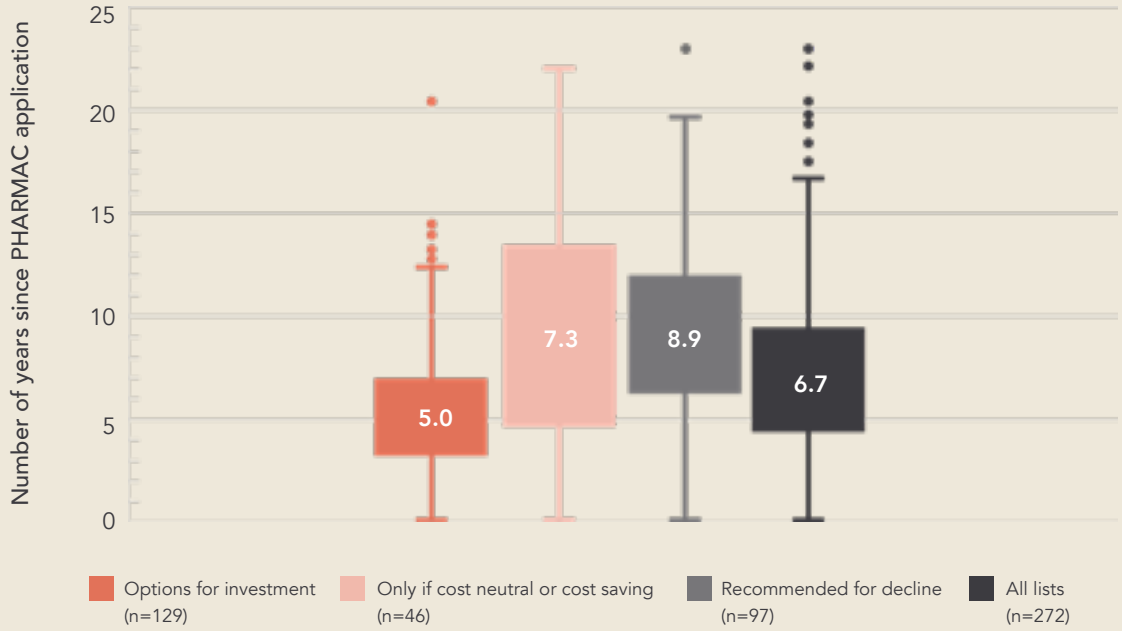

Figure 1: Median number of years since application by PHARMAC list

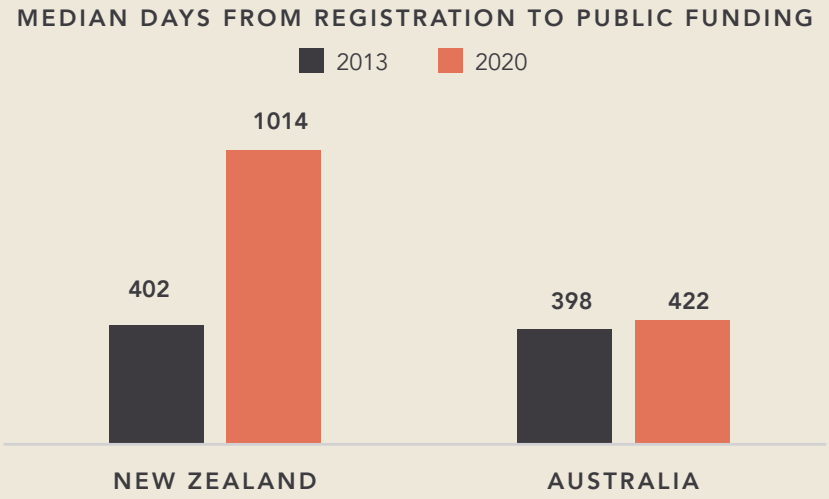

Figure 2: Median wait time for new medicines funding (in days)
Source: IQVIA, Medicines New Zealand – Access to Medicines (AtoM 3) Report (November 2021), Pg 5, available at https://www.medicinesnz.co.nz/resources/publications

Access to cancer medicines

Access to medicines in New Zealand has been hotly debated for many years. Oncology medicines are particularly worthy of mention in this context as cancer is the leading cause of death in New Zealand, for both Māori and non Māori[5]. According to Te Aho o Te Kahu - New Zealand Cancer Control Agency, nearly 25,000 people are diagnosed with cancer each year New Zealand[3] and these numbers are likely to increase year on year to reach 52,000 in 2040[4]. This increase can be partially attributed to better and earlier diagnosis of cancer. Death rates from cancers, however, remain a cause for concern with 66 people in New Zealand being diagnosed with cancer every day and 9,000 people dying of cancer each year in New Zealand[5].

According to the Ministry of Health in New Zealand, the leading causes of death in 2020 were cancer, ischaemic heart diseases and cerebrovascular diseases (with 109.9, 41.9 and 18.9 deaths per 100,000 population respectively). For Māori, the leading causes of death in 2020 were cancer, ischaemic heart diseases and chronic lower respiratory diseases (with 163.8, 72.2 and 37.9 deaths per 100,000 Māori population respectively)[6].

These statistics make sobering reading and are a grim reminder that diseases like cancer still top the list when it comes to premature deaths, particularly in the indigenous Māori population. According to

Te Aho o Te Kahu - New Zealand's Cancer Control Agency.

"Cancer medicines – whether curative or life prolonging – are a critical part of cancer care. Better cancer outcomes are more likely to be achieved when there is equitable access to effective medicines. People living with cancer and their whānau often rely on cancer medicines and, understandably, expect that when they need a cancer medicine, it will be available".[7]

Notwithstanding the delayed access, there is also a smaller number of new medicines available to New Zealanders and their clinicians. According to the report published by the Te Aho o Te Kahu - Cancer Control Agency of New Zealand which cited multiple sources,

"It is well established that there are fewer cancer medicines available in Aotearoa compared with other high-income countries, such as Australia, the United Kingdom (UK), the United States of America (USA) and Canada."[8]

According to the Access to Medicines Report 2021, in the period from 2011 to 2020, Australia funded almost three times more medicines than New Zealand (143 medicines in Australia vs. 51 in New Zealand)[9]. This difference in access was also noted by the Te Aho o Te Kahu - Cancer Control Agency of New Zealand in their own analysis which identified 20 different medicine-indication pair gaps, across nine different solid-tumour cancer types, where the medicines were publicly funded in Australia and not in New Zealand, and where the ESMO-MCBS score indicated that the medicine would offer substantial clinical benefit.[11]

There is a real risk that delayed and inequitable access to medicines in New Zealand is leading to a "two-tiered" healthcare system. This occurs as people with the financial means pay for new medicines to get earlier access through the New Zealand private market, or travelling to countries like Australia for treatment, while their less well-off Kiwi counterparts miss out or face an agonising wait for years. As noted by Te Aho O te Kahu, the Cancer Control Agency of New Zealand, in its 2022 recent report,

"delays in availability of new effective cancer medicines in Aotearoa (New Zealand) exacerbate inequities in outcomes as only those who can afford to pay out-of-pocket for new, non-funded medicines (or have private insurance) may be able to receive them."[12]

Cancer is New Zealand's leading cause of death. In the next 20 years the number of people diagnosed each year with cancer is forecast to increase by 40 percent[13]. For the Māori population, cancer is the cause of more than a quarter of all deaths and they are twice as likely to die from cancer than the non-Māori population in New Zealand.

However, notwithstanding the burden of cancer in New Zealand, the country lags other nations in providing cancer medicines to its population: a fact acknowledged in the Pharmac review final report published in 2022 and highlighted by Te Aho o Te Kahu - Cancer Control Agency in their report the same year[14]. The final report of the Pharmac review noted that this gap is widening, particularly between Australia and New Zealand:

"There is no doubt New Zealand lags behind other countries in the provision of cancer medicines. Recent research shows the gap is widening, particularly between Australia and New Zealand."[15]

Similarly, an earlier report in 2021 published by the Swedish Institute of Health Economics showed that

New Zealand ranks relatively low compared to other high-income countries in the Asia-Pacific region. This report further noted that of 38 new cancer medicine indications approved by the United States Food and Drug Administration between 1998 and 2020, New Zealand only reimbursed 29%, the lowest amongst the high-income countries.[16]

This lack of availability of new cancer medicines is matched by a lack of investment in medicines spending. Cancer medicine expenditure per capita and cancer medicine expenditure per cancer case in New Zealand in 2019 were both much lower than other high-income Asia-Pacific countries. This points to the need for improving the quantum of investment, which is an important part of cancer care in New Zealand according to the Te Aho o Te Kahu - Cancer Control Agency of New Zealand.

Analysis conducted by Te Aho o Te Kahu - Cancer Control Agency[17] compared New Zealand to Australia found that 72 cancer medicines funded in Australia were either not funded at all in New Zealand, or not funded for the same specific cancer types. Furthermore, in contrast to previous assessments, the Te Aho o Te Kahu – Cancer Control Agency analysis identified 19 specific gaps for cancer medicines to treat solid tumours that could deliver substantial clinical benefits to New Zealanders living with cancer and noted that there could be additional gaps for haematological cancers that required further analysis.

Comparing and combining all previous assessments of the reported lag and unavailability of promising therapeutic interventions in New Zealand paints a grim picture of the changing state of cancer medicines over time in New Zealand. It is certainly encouraging to see that New Zealand's Cancer Action Plan 2019 – 2029 recognises the importance of early access to safe and effective cancer medicines as one of many interventions within a 'whole of health system' approach. This is important as the management of cancer in moving rapidly towards earlier detection and more personalised treatment as a result technological developments in areas like genomics and targeted personalised treatment.

[3] Te Aho o Te Kahu. 2022. Mārama ana ki te Āputa: he tātari i te wāteatanga o ngā rongoā mate pukupuku i Aotearoa | Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa. Wellington: Te Aho o Te Kahu, 2022 Available at https://teaho.govt.nz/publications/cancer-medicines

[4] Ministry of Health. 2019. New Zealand Cancer Action Plan 2019–2029 – Te Mahere mō te Mate Pukupuku o Aotearoa 2019–2029. Revised January 2020 Wellington: Ministry of Health (Pg. 4) last accessed on 14 February 2023

[5] Ministry of Health. 2022. Health and Independence Report 2021: The Director-General of Health's Annual Report on the State of Public Health. Wellington: Ministry of Health (Pg 39). last accessed on 14 February 2023

[6] Mortality web tool, Health New Zealand, available at https://www.tewhatuora.govt.nz/our-health-system/data-and-statistics/mortality-web-tool, last accessed on 14 February 2023

[7] Te Aho o Te Kahu. 2022. Mārama ana ki te Āputa: he tātari i te wāteatanga o ngā rongoā mate pukupuku i Aotearoal Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa. Wellington: Te Aho o Te Kahu, 2022 Pg iii Available at https://teaho.govt.nz/publications/cancer-medicines [8]

[8] Te Aho o Te Kahu. 2022. Mārama ana ki te Āputa: he tātari i te wāteatanga o ngā rongoā mate pukupuku i Aotearoa | Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa. Wellington: Te Aho o Te Kahu, 2022 Pg 5, Available at https://teaho.govt.nz/publications/cancer-medicines

[9] IQVIA, Medicines New Zealand - AtoM 3 Report (November 2021), Pg 5, available at https://www.medicinesnz.co.nz/resources/publications

[10] ESMO-MCBS assesses the magnitude of clinical benefit of cancer medicines to inform decisions about cancer medicines at a policy and population level.

[11] Te Aho o Te Kahu. 2022. Mārama ana ki te Āputa: he tātari i te wāteatanga o ngā rongoā mate pukupuku i Aotearoa | Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa. Wellington: Te Aho o Te Kahu, 2022 Pg 2, Available at https://teaho.govt.nz/publications/cancer-medicines

[12] Ibid. Pg 40.

[13] Te Aho o Te Kahu. 2022. Mārama ana ki te Āputa: he tātari i te wāteatanga o ngā rongoā mate pukupuku i Aotearoa | Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa. Wellington: Te Aho o Te Kahu, 2022 Pg iii Available at https://teaho.govt.nz/publications/cancer-medicines

[14] Ibid. Pg 5

[15] Pharmac Review Panel. 2022. Pharmac Review: Final report. Pg 66 Wellington: Ministry of Health, https://www.health.govt.nz/publication/pharmac-review-final-report

[16] Hofmarcher T, Keel G, Lindgren P. Patient Access to Innovative Cancer Drugs in Asia-Pacific. IHE Report 2021:3e.IHE: Lund, Sweden, https://ihe.se/en/publicering/access-to-cancer-drugs-in-asia-pacific/

[17] Te Aho o Te Kahu. 2022. Mārama ana ki te Āputa: he tātari i te wāteatanga o ngā rongoā mate pukupuku i Aotearoa | Understanding the Gap: an analysis of the availability of cancer

Part II:
Issues in New Zealand's medicines funding system

(a) Time delays in the assessment and funding of medicines

It is critical that assessment and funding decisions about new medicines for New Zealanders are made within reasonable timeframes. Currently, there are no timeframes or targets in place to benchmark the time it takes to have medicines funded in New Zealand. The April 2023 report by HealthiNZ, *Pharmac's Medicines Waiting Lists: Impacts on Patients in Aotearoa New Zealand*, noted that for the 29 applications that achieved a funding decision did so on average 7.7 years (or median 6.5 years) following their submission to Pharmac[18]. It is important to note that these are average figures and that some medicines took even longer than this to get funded[19]. Compared to many other OECD countries, New Zealand falls short in numbers of medicines (new molecular entities) with regulatory registrations, launched on the market by companies, and reimbursed by funding agencies (Figure 3).

By contrast, in Germany, medicines are reimbursed within days of receiving initial regulatory approval and companies supplying medicines in that country are allowed to immediately provide medicines to patients through funding schemes at their own prices for the first six months on the market (previously 12 months) while value assessment and price negotiations are undertaken. This allows patients early subsidised access to new medicines as soon as regulators have approved with minimal delay. Similarly, in Japan, the time to secure health system funding for a new medicine is typically within 90 days after regulatory approval by the country's regulator (PMDA). These timeframes are strictly observed in Japan and facilitated by a well-established medicine pricing formula that consistently and transparently calculates the base price for a new medicine and also adds any applicable premiums based on medicine's innovativeness or usefulness so as to encourage therapeutic innovation. Finally, adjustments are made to the price of a medicine based on the prices paid in comparable countries (USA, Germany, France and UK). This helps to ensure prices paid in Japan are consistent with similar countries and appropriately maintain spending levels while securing early access to medicines for people in Japan and encouraging innovation.

Assessing health technology for clinical and cost effectiveness in a timely manner is an important step to establish value of an intervention in the local context. But timely access to that intervention also requires the allocation of sufficient funds to ensure that medicines are made available promptly without unnecessary delays once a technology has been deemed to provide sufficient "value for money". For example, in the United Kingdom, once the HTA evaluation body, the National Institute for Health and Care Excellence (NICE), makes a positive recommendation that a health technology is good value for money, there is a legal directive which requires NHS England to implement NICE recommendations and provide funding within 90 days or sooner. This ensures that patients across England and Wales have access to these promising new health technology within strict timeframes. Therefore, streamlining the value assessment process and improving assessment timeframes in New Zealand would be a welcome step, but this needs to be supported with timely allocation of funding to adopt promising new health technologies.

For instance, the processing of funding applications of new cancer medicines by Pharmac in parallel with MedSafe safety assessment process was introduced in 2020[20]. This is a positive step in the right direction and should be extended to other therapy areas. However, parallel processing serves only to speed up the assessment process and does not necessarily translate into faster access to cancer medicine in New Zealand when a lack of sufficient funding remains the critical limitation. Much like other countries, New Zealand needs to set a timeframe for Pharmac to assess and fund medicines that are deemed good value for New Zealand healthcare dollars without unnecessary delays.

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[18] HealthiNZ. 2023. Pharmac's Medicines Waiting Lists: Impacts on Patients in Aotearoa New Zealand, April, Report commissioned by Medicines New Zealand, p. 3, https://www.medicinesnz.co.nz/fileadmin/user_upload/Publications/Pharmac_s_Medicines_Waiting_Lists_-_Impacts_on_Patients_in__Aotearoa_New_Zealand.pdf, accessed 14/7/2023.

[19] Pharmac. 2023. "Priority lists for funding application", April, https://connect.pharmac.govt.nz/apptracker/s/ranking-lists-for-funding-applications?reportType=OFI, accessed 14/7/2023.

[20] Cancer medicine funding: Parallel assessment (https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/from-application-to-funded-medicine-how-we-fund-a-medicine/cancer-medicine-funding-parallel-assessment/)

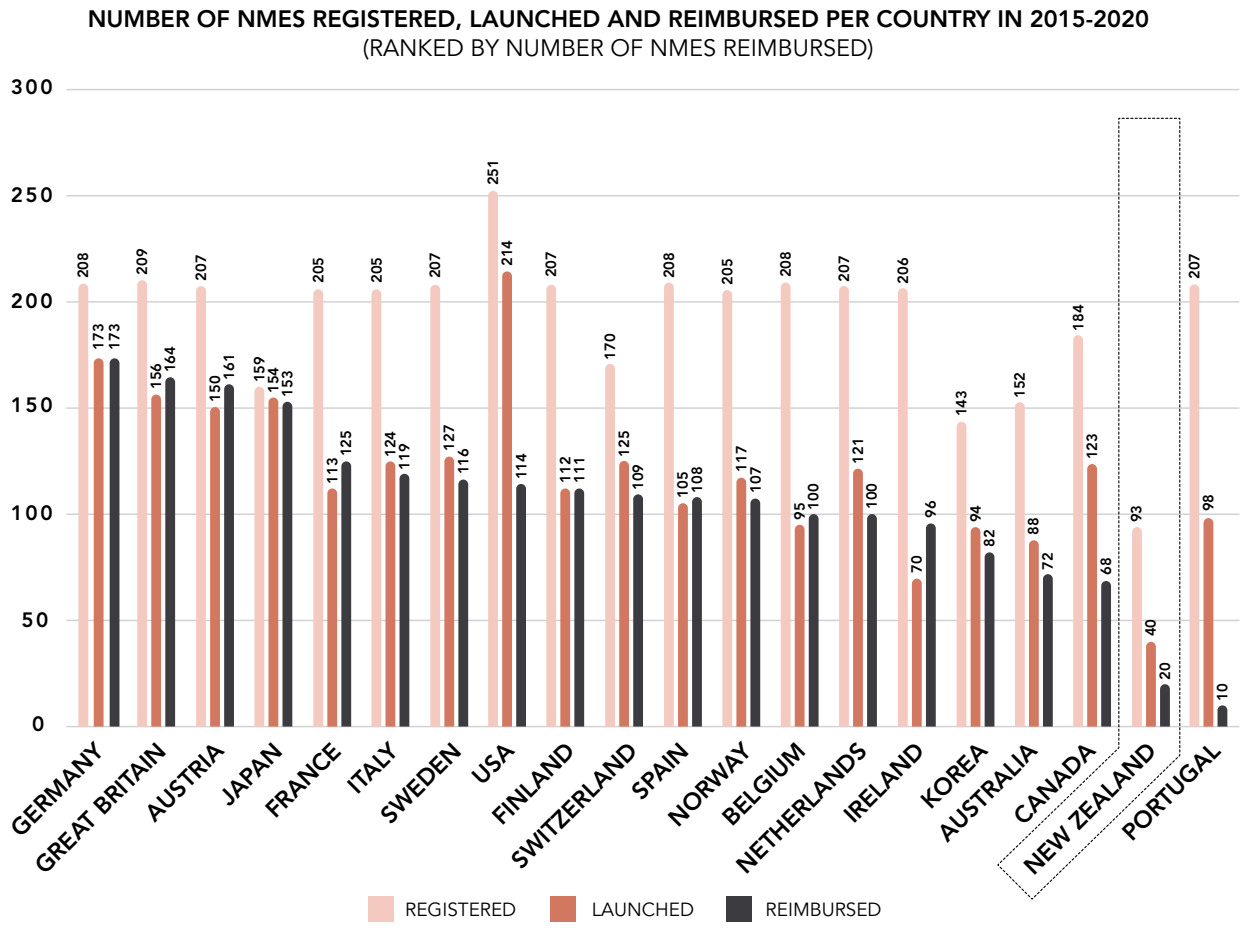

Figure 3: Number of NMEs registered, launched and reimbursed per country in 2015-2020
Source: Medicines Australia. 2022. Medicines Matter: Australia's Access to Medicines 2015-2020, p. 6, https://www.medicinesaustralia.com.au/wp-content/uploads/sites/65/2022/11/Medicines-Matter-Australias-access-to-medicines-2015-2020.pdf

(b) Chronic underinvestment in medicines

There is a chronic under investment on medicines in New Zealand that is at the heart of the issue and is a major reason for the observed delays in access to medicines that New Zealanders regularly experience. The ongoing underfunding of Pharmac is reflected in the backlog of innovative new medicines that are not available to most New Zealanders. Based on the Pharmac website, there are 109 applications in its Options for Investment List, as at 6 April 2023[21], including at least 44 oncology applications as at May 2023. Note that these medicines have already been deemed cost effective by Pharmac, having already undergone clinical assessment and negotiations with manufacturers, yet have not been funded for some time.

There is one view that has been put forward that New Zealand spends its money wisely and therefore numerical comparisons of the country's health spending levels with other countries are not appropriate[22]. This argument is misplaced and, again, reflects the focus placed on managing a budget at the expense of securing better health outcomes for the people of New Zealand. These medicines are likely to provide substantial clinical benefits to patients in New Zealand[23].

[21] Pharmac. 2023. "Priority lists for funding applications", last updated 16 May 2023, https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/priority-lists/, accessed 8/7/2023.

[22] Evans.J et al, Mind the gap: An analysis of foregone health gains from unfunded cancer medicines in New Zealand, 2016, https://www.sciencedirect.com/science/article/pii/S0093775416300586

[23] Te Aho o Te Kahu. 2022. Mārama ana ki te Āputa: he tātari i te wāteatanga o ngā rongoā mate pukupuku i Aotearoa | Understanding the Gap: an analysis of the availability of cancer medicines in Aotearoa. Wellington: Te Aho o Te Kahu, 2022 Pg 37 Available at https://teaho.govt.nz/publications/cancer-medicines

Therefore, making a numerical comparison is appropriate if it is done objectively to ensure that New Zealanders have comparable access to therapeutic options that are likely to improve their health outcomes.

Earlier studies have shown that this shortfall and ongoing delay in funding new medicines is not a new phenomenon but a continuing trend. Several studies over the years have noted this worsening access to new innovation in New Zealand. For instance, Wonder and Milne (2011) noted that access to new medicines in New Zealand was limited and delayed when compared to Australia[24]. Cheema et al (2012) concluded that New Zealand was one of the few countries in his analysis with the lowest access to medicines and, to an extent, attributed this to the fixed budgets for medication[25]. Evans et al 2016 conceded that New Zealand funded fewer cancer medicines than Australia and that Pharmac has no definitive timeframe for when its funding decisions must be made, highlighting the limitation of fixed budget and lack of funding[26]. Wonder and Fisher (2016)[27] were scathing of the chronic lack of funding for innovative new medicines in the context of unfunded melanoma drugs in New Zealand. They concluded "New Zealand should not be in the unenviable position whereby it has the highest incidence of a fatal disease yet is the last country in the Western world to fund effective treatments for it. We offer recommendations to all stakeholders to break the current access impasse." Babar et al (2019)[28], while highlighting the differences in medicines policy between Australia and New Zealand, noted that Australia covered and reimbursed a greater number of medicines compared to New Zealand policy that prioritised achieving lower prices rather than broader access.

Similarly, a recent analysis by the New Zealand Institute of Economic Research (NZIER)[29], showed that the level of investment on community medicines dispensed in pharmacies in New Zealand has been in decline for some time. This report further identified a $332 million investment gap in medicines funded on the Combined Pharmaceutical Budget (CPB). Yet the $14.9 billion boost to health care over 4 years in 2022 Budget included only a modest boost of $191 million over two years for medicines. In November 2022, a one-off, out of budget cycle increase of $66m was approved by the Cabinet to support a discreet set of confidential medicines[30]. This under-investment is continuing despite the Pharmac Review final report noting that an estimated annual investment of around $400 million would be needed to fund medicines on the agency's Options for Investment list. This ongoing under-investment in medicines has resulted in New Zealanders missing out on innovative new treatments for disease.

Despite Pharmac's protestations to the contrary, ultimately the cause of these backlogs and delays is the restrictive budget constraints applied to New Zealand's medicines budget. Poor access to medicines is the policy outcome of a restrictive, capped budget. New Zealand is spending less on medicines than its peers and the delayed access to cost effective medicines in on public record.

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[24] Wonder, M. & Milne, R. 2011. "Access to new medicines in New Zealand compared to Australia", New Zealand Medical Journal, Vol 124 No 1346: 25 November, https://journal.nzma.org.nz/journal-articles/access-to-new-medicines-in-new-zealand-compared-to-australia

[25] Cheema, P. et al. 2012. "International variability in the reimbursement of cancer drugs by publicly funded drug programs", Current Oncology, Jun; 19(3): e165–e176, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3364777/

[26] Evans, J. et al. "Mind the gap: An analysis of foregone health gains from unfunded cancer medicines in New Zealand". Seminars in Oncology. 2016;43(6): 625-637, https://www.sciencedirect.com/science/article/pii/S0093775416300586

[27] Wonder, M. & Fisher, R. 2016. "Subsidised access to new melanoma drugs: in need of further innovation?", New Zealand Journal of Medicine, August, 129(1440):37-54, https://pubmed.ncbi.nlm.nih.gov/27538038/

[28] Babar, Z. et al. 2018. "Patient access to medicines in two countries with similar health systems and differing medicines policies: Implications from a comprehensive literature review", Research in Social and Administrative Pharmacy, March;15(3):231-243, https://pubmed.ncbi.nlm.nih.gov/29678413/

[29] New Zealand Institute for Economic Research. 2018. Community pharmaceuticals: Expenditure trends, Report to Medicines New Zealand, December, https://www.medicinesnz.co.nz/fileadmin/user_upload/Information_Leaflets/community_pharmaceutical_expenditure_nzier_to_medicines_nz_december_2018_update_final.pdf

[30] Office of the Minister for Health. 2022. "Investment to increase access to medicines", Social Wellbeing Committee, 22 November, https://www.health.govt.nz/system/files/documents/information-release/investment_to_increase_access_to_medicines.pdf

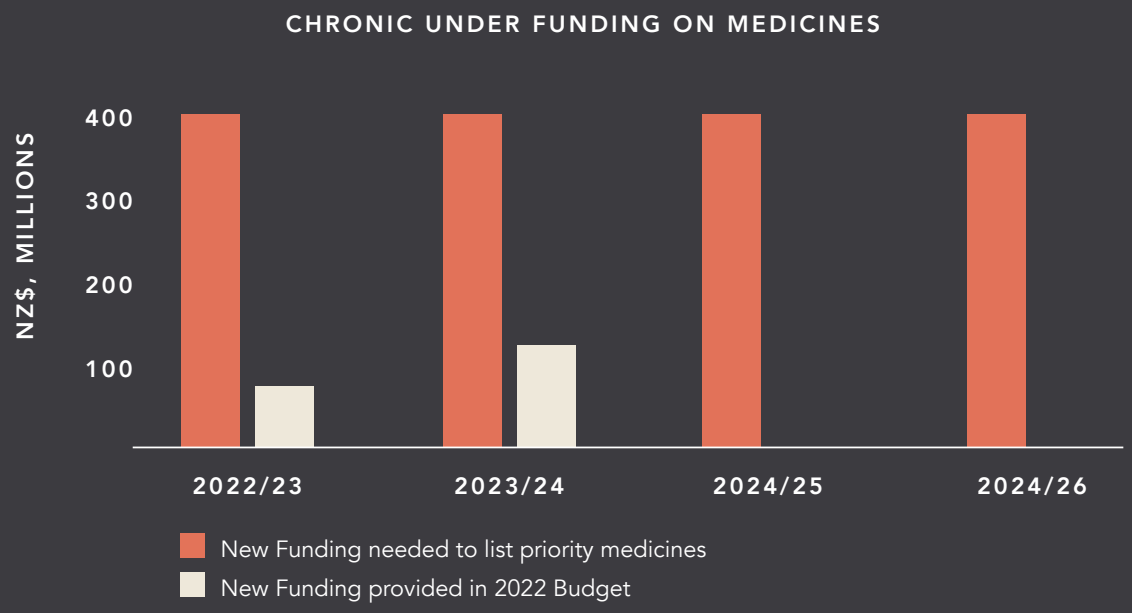

Figure 4: Discrepancy in New Funding for Medicines in New Zealand

The lack of publicly funded access to innovative new medicines is a sad reality for many New Zealanders, necessitating the need to break into their retirement funds or fund raise money to pay for treatments[32]. Those who have not been able to afford securing medicines on the private market have had to make do with the restricted options available to them under New Zealand's health system. This presents obvious equity problems in New Zealand, particularly for the country's Māori population and other parts of the community who suffer worse health outcomes. Overseas observers find it difficult to understand how a high-income country like New Zealand – a country that is in terms of GDP per capita[33] almost on par with leading European economies and better than the United Kingdom and Japan – could be in this situation. This current lag and access to medicines crisis could have been avoided had the investments in health technologies kept pace with current unmet need, the growing burden of illness, the ageing population, and increasing healthcare demands in New Zealand.

The ongoing policy focus on maximising savings rather than health outcomes and operating within fixed drug budgets year-on-year needs to be re-examined urgently. There is need to introduce an ongoing consistent increase in investment to fund promising health technologies that are deemed cost effective by Pharmac. In the long run, more cost-effective technologies are likely to improve overall productivity of New Zealand healthcare system[34,35].

However, by curtailing access and delaying use of new therapeutic innovation in clinical practice, as has been the case for years, patient treatment is based on older medicines that can lead to higher costs in other parts of the country's healthcare and welfare system. New Zealand needs to look for opportunities to take a holistic approach to medicine investment rather than jeopardise future health outcomes of the population and decrease overall productivity of its healthcare system.

[32] https://www.rnz.co.nz/news/national/466102/people-are-having-to-beg-for-money-cancer-patients-struggle-to-self-fund-treatments

[33] GDP per Capita (in current US$), 2021, based on World Bank data - https://data.worldbank.org/

[34] Claxton K, Longo R, Longworth L, McCabe C, Wailoo A. The Value of Innovation [Internet]. London: National Institute for Health and Care Excellence (NICE); 2009 May 22. PMID: 28481490.

[35] Santiago G. Moreno & Joshua A. Ray (2016) The value of innovation under value-based pricing, Journal of Market Access & Health Policy, 4:1, DOI: 10.3402/jmahp.v4.30754

(c) Opaque value assessment process

The recent review into Pharmac noted that the agency has limited transparency or accountability for its actions[36]. There have been past efforts to defend Pharmac's non-transparent and arbitrary decision-making processes which, in the process, have documented some of the untoward administrative practices that Pharmac has engaged in to first and foremost prioritise its budget management function[37].

However, on the back of growing community anger at Pharmac's approach to healthcare and a series of increasingly serious incidents[38] where patient welfare was put at risk, Pharmac's processes were reviewed by an independent committee. The final report of 2022 Pharmac review was scathing of the agency's heavy-handed approach to medicines access[39]. The review found that Pharmac decision making process did not always follow its own internal guidance, its documentation processes were fragmented, and the agency lacked strong oversight. The final report also notes that Pharmac often fails to consider the suitability of the information it uses in its analysis. The review found multiple examples within Pharmac assessments and decision-making documents where information was used without consideration of its pertinence to New Zealand or its relevance in the context of the country's healthcare system.

Notwithstanding the above, report also worryingly noted that:

"Pharmac appears to omit potentially significant effects that may cause bias in its assessment and decision-making"[40].

When assessing medicines for funding, Pharmac omits potentially important effects that could understate or overstate the benefits of funding certain medicines. This potentially results in biased decisions. The report found that Pharmac sometimes acknowledges these effects qualitatively but does not actively consider the consequences of excluding such effects from the evaluation in its value assessments.

There is also an excessive level of secrecy that covers the operations of Pharmac. The interim report published in late 2021 noted that assessing the performance of Pharmac against its stated objectives was extraordinarily difficult. Reflecting on their own experience during the review, the interim report authors noted that:

"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."[42]

The review also explored whether Pharmac saves as much as it claims and concluded that it did not. The report noted that despite the rhetoric, "Pharmac statements on savings are overly optimistic" . The report even questions where Pharmac adds value given the bulk of its savings come from genericised medicines.

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[36] Pharmac Review Panel. 2022. Pharmac Review: Final report. Wellington: Ministry of Health, https://www.health.govt.nz/publication/pharmac-review-final-report

[37] Gleeson, Deborah & Lopert, Ruth & Reid, Papaarangi. (2013). "How the Trans Pacific Partnership Agreement could undermine PHARMAC and threaten access to affordable medicines and health equity in New Zealand", Health Policy (Amsterdam, Netherlands). 12(3), October, https://www.sciencedirect.com/science/article/pii/S0168851013002108

[38] https://www.stuff.co.nz/national/health/300236376/epilepsy-drug-deaths-medsafe-told-pharmac-it-was-not-desirable-to-switch-brands

[39] Pharmac Review Panel. 2022. Pharmac Review: Final report. Pg 53 Wellington: Ministry of Health, https://www.health.govt.n¬-z/publication/pharmac-review-final-report

[40] Ibid Pg55

[41] Pharmac Review Panel. 2021. Pharmac Review: Interim report. Wellington: Ministry of Health https://www.health.govt.nz/publication/pharmac-review-interim-report

[42] Pharmac Review Panel. 2021.Pg 19, Pharmac Review: Interim report. Wellington: Ministry of Health, https://www.health.govt.nz/publication/pharmac-review-interim-report

[43] Pharmac Review Panel. 2022 Pg 24. Pharmac Review: Final report: Executive summary. Wellington: Ministry of Health

(d) Poor decision-making and prioritisation processes

To some extent, the various problems in Pharmac's administration can be explained in part by the budgetary constraints the organisation is forced to work under. Decision-making and prioritising which medicines to fund is more problematic under circumstances where the health system operates under a fixed budget approach to medicines funding. The 2021 review found that the prioritisation process used by Pharmac was protracted and could take an average of 14 months to rank and prioritise medicines for use in New Zealand. Within this context it further noted that:

"Staff appear to have the most say in what is assessed and prioritised. The prioritisation and ranking of medicines lack governance oversight. The Board sees the options for investment list and movement within it through the business reporting process. The Board typically appears to see summary information and does not have sight of the detailed analysis that lies behind it."[44]

"The review notes deficiencies in the nature of the decision-making process (from the Board down) and the quality of the decisions that came out of it. The result has been inequitable outcomes for Māori, Pasifika, disabled people and other priority populations. Essentially our recommendations call for better oversight, better processes and more voices to be heard in deciding which medicines will be funded and for whom".[45]

It went on to note that *"the prioritisation and ranking of medicines seem to happen within a small group, to which other staff are occasionally invited."* It also appears that broader stakeholder contribution to this internal prioritisation process is limited and lacks sufficiently broad expertise. The review found that stakeholders not included in the process include members of PTAC, specialist advisory committees, the Consumer Advisory Committee (statutory committees), or people with direct personal experience of conditions or disorders.[46] The review also reported a lack of governance and oversight in Pharmac's decisions:

"The review's principal concern in this area [delegated authority], is not about the level of financial delegation per se, but rather how funding decisions are overseen by the Board. In the 12 months to 30 June 2021, Pharmac made 32 funding decisions – 13 to fund new medicines and 19 to widen the use of existing medicines. Of these, the chief executive or one of her delegates made 29 decisions, and the Board made three. In the same 12 month period, Pharmac made decisions to switch the brands of 26 medicines. The chief executive or one of her delegates made all 26 decisions."[47]

The Final report noted that errors and omissions in Pharmac's decision making could be accentuating existing inequities[48]. The current prioritisation mechanism lacks rigour, objectivity, empathy for patients, is silent on equity and does not meet best practice standards of public administration. Instead, the prioritisation of medicine funding in New Zealand should be evidence based, rigorous, collaborative, focussed on current and future disease burden and aligned with principle of social justice and equity. The prioritisation must also be strictly time bound with appropriate oversight and quality assurance, responsiveness and accountability. Not doing so risks inefficient use of health resources, and inequitable access to treatments for New Zealanders.

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[44] Ibid p.58

[45] Ibid, p. 1.

[46] Pharmac Review Panel. 2021, Pharmac Review: Interim report. Wellington: Ministry of Health, https://www.health.govt.nz/publication/pharmac-review-interim-report

[47] Pharmac Review Panel. 2022. Pharmac Review: Final report. Pg 32, Wellington: Ministry of Health, https://www.health.govt.nz/publication/pharmac-review-final-report

[48] Pharmac Review Panel. 2022 Pg 55. Pharmac Review: Final report: Executive summary. Wellington: Ministry of Health, https://www.health.govt.nz/system/files/documents/publications/pharmac-review-executive-summary.pdf

(e) Processes need to evolve with changing treatment and economic paradigms

New Zealand's medicines policy system needs to evolve with technological development and changing treatment paradigms. For example, the management of cancer is shifting towards early diagnosis and personalised treatment. The science and our understanding of cancers has evolved markedly in recent decades, which is leading to more targeted and effective treatments for people living with cancers. This combination of early detection and therapeutic innovation is positively impacting clinical outcomes. The current treatment paradigm that relies on achieving remission and moving to next line of therapy on relapse is rapidly becoming outdated medical practice. Scientific advances which are making it possible to detect cancers much earlier and able to assess the type of tumour will increasingly make this approach redundant and bring in new way of treating disease early with targeted therapies. This will require a change in the current approach to how cancer therapies are assessed and valued in New Zealand.

The example of issues in assessing cancer medicines highlights broader issues that all innovative medicines face in securing timely funding in New Zealand. The 2021 Pharmac review concluded that oncology therapies should be assessed in the same way as other medicines. Newer therapeutic innovations face a range of hurdles in funding as they often target smaller populations, the sizes of their clinical trials are often smaller, treatment follow-ups are of shorter duration and clinical trial recruitment costs are higher. Health technology assessment methodologies are being challenged by the changing science and economics of emerging health technologies.

New Zealand needs to ensure its evaluation processes evolve as the science, evidence and opportunities for health care evolve. For example, with the progression of technological development in areas like genomics, artificial intelligence, data analytics and diagnostics, it is becoming increasingly possible to detect cancers in early stages allowing targeted treatment with therapeutic interventions earlier to improve clinical outcomes. This will require among other things, redefining how New Zealand values oncology medicines in terms of clinical and other value components such as value to patients along with broader economic and societal benefits.

At a broader macroeconomic level, an increasing number of OECD countries are also adopting broader, holistic reporting and assessments of the value of government expenditure. Along with Australia, Canada, Scotland and the OECD, New Zealand is one of the countries increasingly recognising the importance of measuring and considering the value of government expenditure to society as well as its cost. The New Zealand Treasury's *Living Standards Framework*[49], highlights the importance of adopting a holistic approach to government expenditure to ensure it is sufficiently valued and that the broader social and economic benefits of such expenditure are recognised and considered when new spending decisions are being made.

All sides of politics in New Zealand have recognised the importance in accounting for the benefits of government spending, whether that is building a wellbeing framework, doing more to recognise the value of social investment in government programs, or seeking better measurement of the broader social and economic returns on investment from government expenditure. It is important that these broader social and economic objectives of government policy are reflected in the assumptions, processes and evaluations of Pharmac in the future.

[49] New Zealand Treasury. 2021. The Living Standards Framework 2021, 28 October, https://www.treasury.govt.nz/sites/default/files/2021-10/tp-living-standards-framework-2021.pdf, accessed 5/2/2023.

Part III:
International best practices

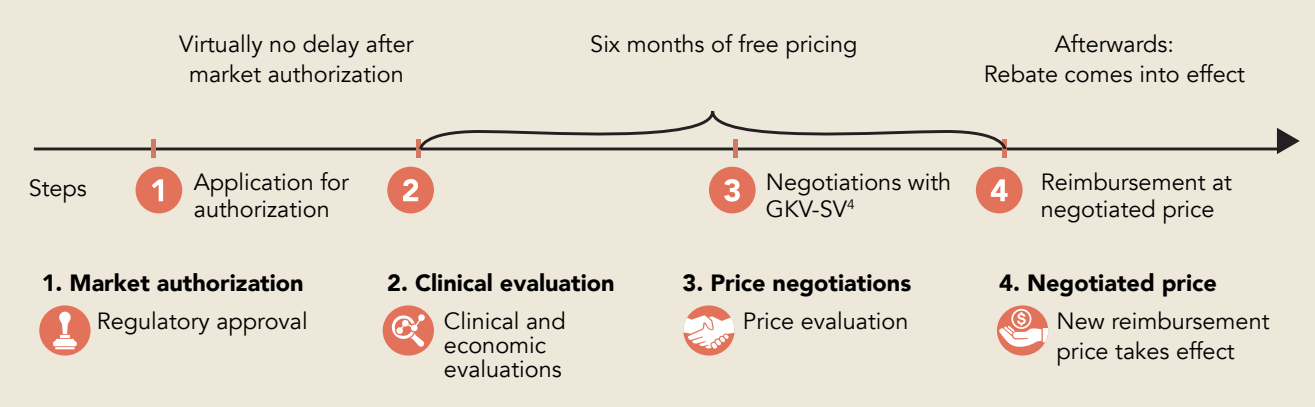

Figure 5: Timely access to medicines in Germany – Process timelines are predictable

(a) Timely access to medicines

There are international best practice examples of access to medicines mechanisms from other countries that New Zealand could look to emulate or identify as options for reform. While some aspects of these different countries' systems will suit New Zealand more than others, looking at examples of how other countries seek to manage and improve patient access to medicines can steer how New Zealand can reform its medicines policy and funding systems.

Germany, for example, has a system where there is no value assessment required prior to launching a new medicine. Under the German system, all prescription medicines are reimbursed by the country's funding system within days of approval by the regulator, the European Medicines Agency (EMA)[50]. This speed and extent of innovative drug access enjoyed by German patients could be a benchmark even for many countries in Europe and globally. In a recent report on oncology medicines, the OECD highlighted unequal access to medicines but noted that Germany was second only to USA in terms of product/indication pairs covered.[51] The value assessment undertaken by funding agencies in Germany occurs in parallel within the first six months after the launch of medicines. In contrast to other countries, the German system, with its post-launch value assessment process, enables faster access to medicines for patients. This is particularly helpful for both single and multi-indication medicines in areas like oncology where there is huge unmet need. Although Germany has recently reduced the time allowed for value assessment after launch from 12 months to six months[52], it will continue to allow new medicines to be launched soon after regulatory approval.

In addition, Germany uses comparative effectiveness as the basis for assessing a medicine's added benefit over its most appropriate comparator.[53] By considering statistical significance, clinical relevance and the severity of the disease, the process determines the level of additional benefit, which then becomes the basis for the price negotiations between the manufacturer and the peak body of Statutory Health Insurances in Germany (GKV-SV). In comparison with New Zealand, Germany achieves better timeliness in access to medicines with less delays, safeguards equity and choice while ensuring innovation is rewarded and patient relevant outcomes are measured consistently. It is a strict system with price negotiations that help ensure spending remains sustainable, but achieves quicker access to medicines than New Zealand.

[50] Lawlor. R et al. 2021, "Accelerating patient access to oncology medicines with multiple indications in Europe", Journal of Health Policy and Market Access, 2021, v. 9, https://pubmed.ncbi.nlm.nih.gov/34436506/

[51] OECD 2020, Addressing Challenges in Access to Oncology Medicines, available at https://www.oecd.org/health/health-systems/addressing-challenges-in-access-to-oncology-medicines.htm

[52] https://www.eversana.com/2022/08/04/global-pricing-news-alert-german-cabinet-passes-financial-stabilisation-of-the-statutory-health-insurance-system-bill/

[53] OECD 2018, Pharmaceutical Reimbursement and Pricing in Germany, available at https://www.oecd.org/els/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf

		Implications on price negotiation
1	**Major** *(„erheblich")* ! To qualify for negotiating a price premium vs. the clinical comparator, an additional benefit in at least one patient subgroup is required.	• Price/rebate negotiation: New reimbursed price will be negotiated (ex-manu. price lowered accordingly) • Reimbursement price may be higher than the reimbursement price of the clinical comparator • No strict rule on how the level of benefit translates into a new reimbursement price in the price negotiations • Other factors considered: Price of other comparable therapies, price in other EU countries
2	**Considerable** *(„beträchtlich")*	
3	**Minor** *(„gering")*	
4	**Non-quantifiable**	
No additional or lower benefit: 5 to 6		
5	**No additional benefit** ϟ The cost to sick funds must be not higher than the cost of the appropriate comparator therapy^	• Assignments to FRP group if possible, reimbursement price = FRP, otherwise price negotiation • Reimbursement price ≤ reimbursement price of comparator treatment
6	**Lower benefit than ACT2** ϟ Therapy is not appropriate, i.e. sick funds can initiate penalties (regress) to physicians if prescibed in the respective subgroup	

Figure 6: Comparative effectiveness – "Added Benefit" basis for price negotiations

Japan is another example of a country that delivers relatively better timeliness and predictability in access to new medicines than New Zealand. In Japan, the National Health Insurance price is decided by the government, yet this is done in a timely manner and new medicines are listed within 90 days following marketing authorisation or regulatory approval. According to Takayama and Narikawa (2016), the average time between marketing authorization and the initiation of reimbursement was 66 days[54]. The presence of clearly defined national timelines for decision-making creates predictability for patients, and incentives for manufacturers and the government to work together to achieve access within strict timeframes. This stands in stark contrast to the unpredictable, limited and opaque approach of Pharmac in New Zealand.

[54] Takayama A and Narukawa M, 2016, Pharmaceutical Pricing and Reimbursement in Japan: For Faster, More Complete Access to New Drugs, Therapeutic Innovation & Regulatory Science 2016, Vol. 50(3) 361-367

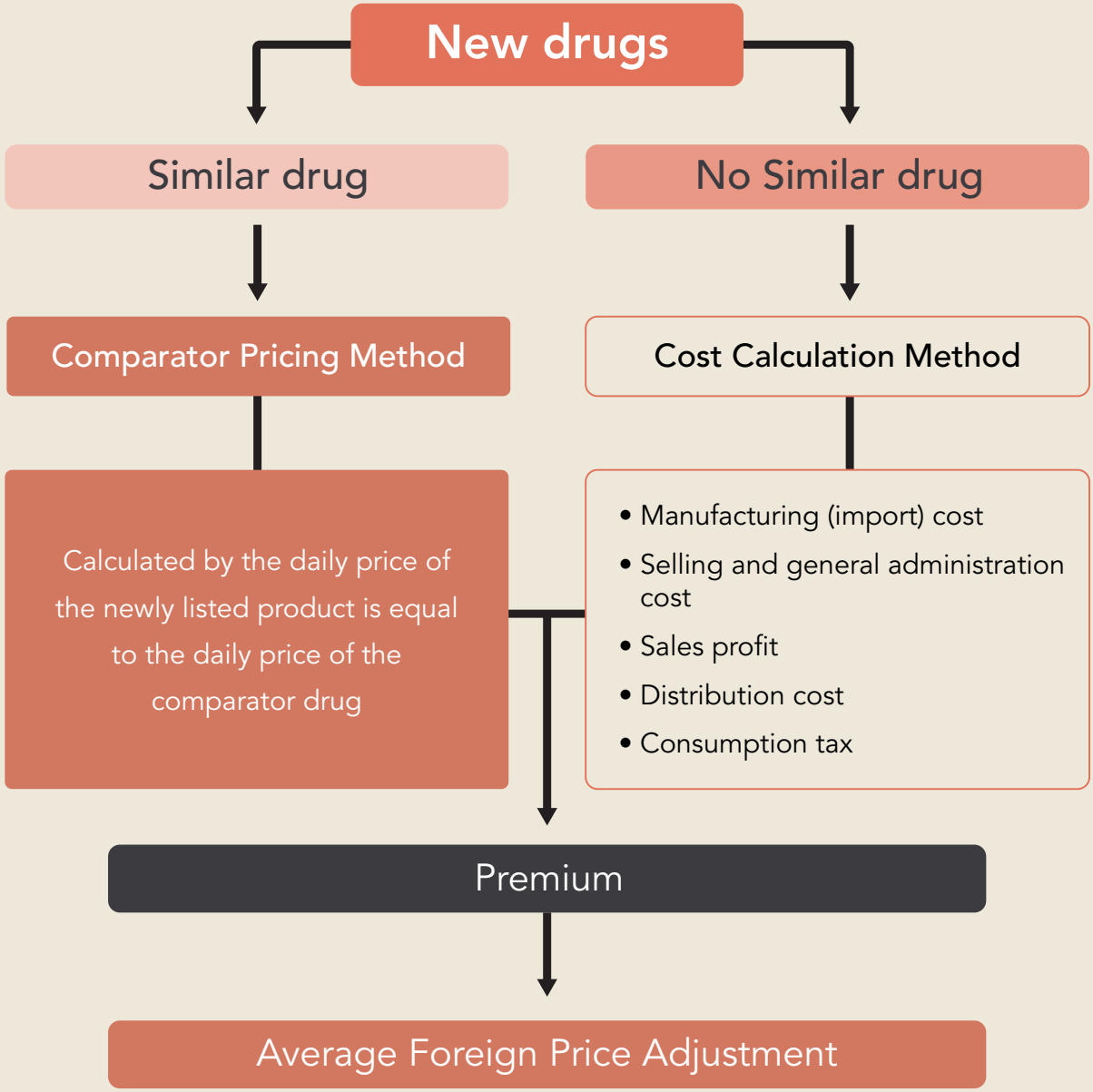

Figure 7: Predictable, transparent pricing mechanism in Japan

Much like Germany, Japan uses comparative effectiveness to establish the additional benefits of a medicine versus its comparator medicines. Its pricing mechanism is predictable and ensures premiums and price maintenance rewards innovation and medicines targeting areas of unmet need, such as orphan and paediatric indications.

[55] https://www.ispor.org/docs/default-source/conference-ap-2018/ispor_ap-ip1-20180909-fukuda.pdf?sfvrsn=84310438_0

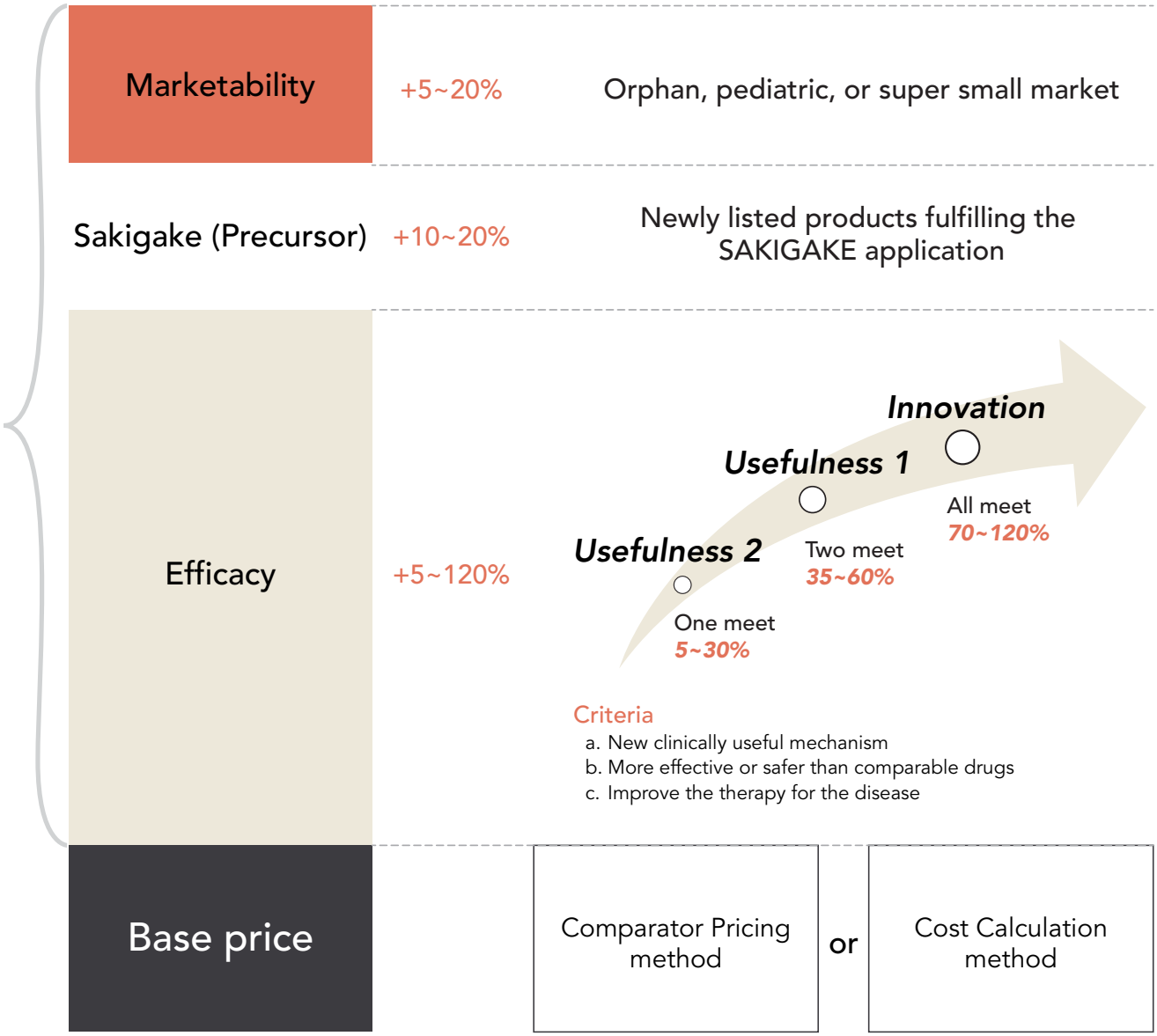

Figure 8: List of Premiums for New Drug in Japanese Pricing System[56]

Although Japan has recently introduced a system of health technology assessment (HTA), it has deliberately confined the use of HTA to adjusting the 'premium' portion of the price for certain drugs with high budget impact, rather than making it mandatory for every new medicine or even a condition of listing for funding. This avoids delays to patients obtaining subsidised access to new medicines, while achieving balance in terms of healthcare system sustainability through the country's pricing mechanisms. Again, Japan outperforms New Zealand here.

[56] ibid

In the **United Kingdom** since 2016 the government's evaluator, National Institute for Health and Care Excellence (NICE), appraises all cancer drugs on an accelerated appraisal timetable and publishes its final guidance within 90 days of a drug indication receiving its marketing authorisation. This has been done to improve timely patient access to oncology medicines through the country's Cancer Drugs Fund.[57]

Similarly, the United Kingdom's Early Access to Medicines Scheme (EAMS)[58] helps to give people with life threatening or seriously debilitating conditions early access to new medicines that do not yet have a marketing authorisation but where there is a clear unmet medical need. EAMS is a key part of UK's commitment to accelerate patient access to innovative, life changing treatments, and support its position as a global leader in life sciences. Since the scheme launched in 2014, over 1,200 people with conditions ranging from cancer to Duchenne Muscular Dystrophy from across the UK have benefited from early access to new treatments through EAMS. Aside from the obvious advantage for patients, participating in EAMS also ensures shorter timeframes to baseline NHS funding if the medicine receives a positive NICE recommendation in the future (30 days vs. 90 days).

In **France**, the Early Access Program and Compassionate Access Program facilitates relatively early access to drugs for patients under special conditions. These procedures are applied for new and promising drugs under development. They aim to facilitate quick access to medicines for patients with severe conditions or cases where there is no licensed alternative (off-label use). The scheme has so far allowed for rapid access to targeted therapies, immunotherapy, and cell and gene therapies, which have prolonged patient survival or offered a cure for certain serious illness such as leukemia and lymphoma.[59]

[57] https://www.england.nhs.uk/cancer/cdf/

[58] https://www.gov.uk/guidance/apply-for-the-early-access-to-medicines-scheme-eams

[59] https://www.eversana.com/2021/06/28/frances-atu-scheme-reform-to-come-into-force-from-july/

ATU and RTU program previously divided into six systems has now been grouped into two:

Compassionate access program (CAP)

- Medicines not intended to be marketed in the relevant indication
- No ongoing/planned development
- No approach to marketing authorization

Early access program (EAP)

- Medicines intended to be marketed in the concerned indication
- Allegedly innovative medical products
- Clinical data available or being collected

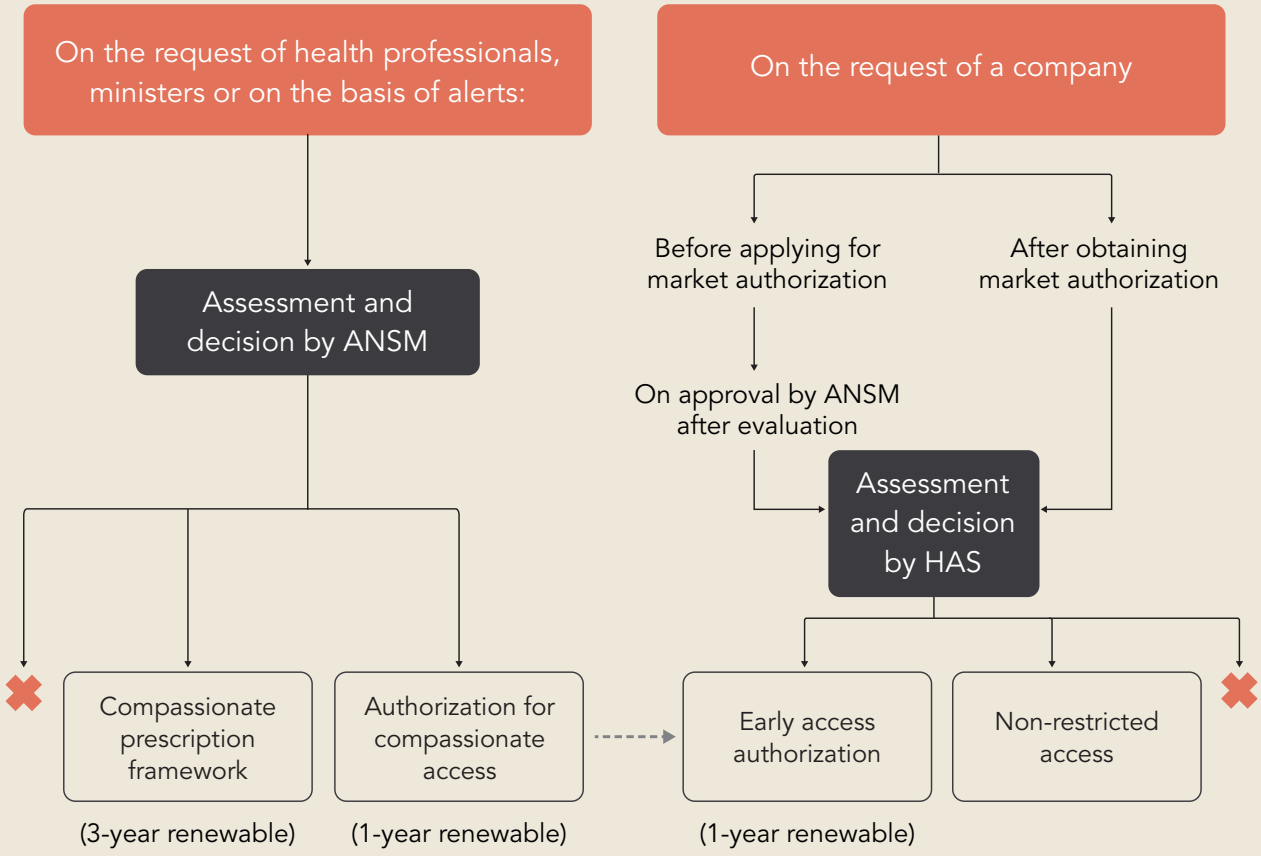

Figure 9: Early access to medicines for patients with severe conditions in France

(b) Dealing with evidence uncertainties

Clinical uncertainties related to the immaturity of clinical trial data is often cited as an issue which makes it difficult for Pharmac in New Zealand to fund a new medicine or a new indication of an existing medicines using its standard process. However, there are examples of how other countries have dealt with this issue in a better way than New Zealand.

For example, the New Cancer Drug Fund (new CDF)[50] in the United Kingdom provides 'ring fenced' funding for promising oncology medicines that have higher uncertainty surrounding their clinical data and cost effectiveness estimates at the time of application for funding. All new oncology indications are appraised by NICE for use on that country's National Health Service (NHS). NICE is required to make one of three recommendations within 90 days of a drug indication receiving its marketing authorisation from the regulator: (1) recommended for routine use in the NHS; (2) not recommended for use, or (3) recommended for use within the CDF.

In making its determination for an oncology medicine to be used in the CDF, NICE uses multiple criteria such as whether the drug has plausible potential to be cost-effective at the current price, whether the clinical uncertainty can be reduced with additional data collection and whether it is feasible to collect such data to reduce the uncertainty. A Managed Access Agreement is then signed between the manufacturer and the NHS which stipulates the data collection arrangements and outcomes that need to be in place to address key areas of clinical uncertainty. Typically, these Agreements run for a two-year period and involve a commercial agreement that determines the cost paid by NHS during the managed access period. The objective of CDF therefore is to enable rapid access to promising new oncology medicines in the UK and manage the uncertainty.[51]

Italy also has provisions in place for manufacturers to enter a Managed Entry Agreement (MEA, see Figure 10) when the clinical outcomes are uncertain at the

Type of Outcome-based agreements according to AIFA definition

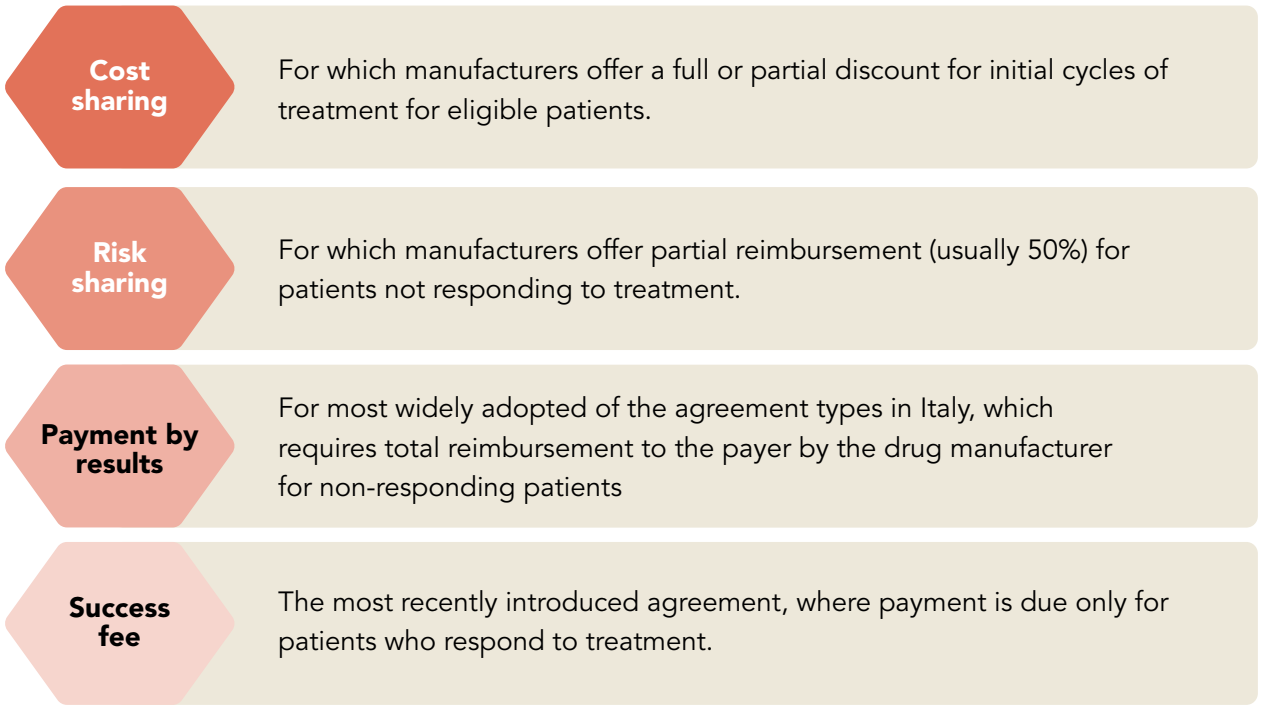

Figure 10: Outcome based agreements in Italy

time of application for funding. These MEAs usually last for two years and are renewed unless either party decides to re-negotiate the terms. The three types of MEAs that are available for use are (1) risk sharing agreements to either share cost in a finance-based MEA, (2) payment-by-results in a performance-based MEA whereby the company pays back refunds to the funder depending on the results of the treatment per patient, or (3) a fee-for-efficacy MEA where the manufacturer receives payment when and if the treatment is deemed effective. Although the fee-for-efficacy MEA is rarely used in practice, the other two types of MEAs are more commonly used.

In addition, Italy has national treatment registries in place to track the performance of various products in real world clinical settings. The availability of this infrastructure enables implementation of managed entry agreements in Italy. Manufacturers are reimbursed based on the net price for each indication linked to volume of usage. However, the claw back or pay back of funds is based on performance that is tracked through these treatment registries. Although the financial details of the agreements are confidential, over half of all managed entry agreements in Italy are performance based. In the case of CAR-T therapies, for example, Italy has established a new registry to support a staged payment scheme whereby payments will be made in instalments if agreed outcomes are achieved and sustained.[52]

[50] https://www.england.nhs.uk/cancer/cdf/

[51] ibid

[52] Lawlor. R et al. 2021, "Accelerating patient access to oncology medicines with multiple indications in Europe", Journal of Health Policy and Market Access, 2021, v. 9, https://pubmed.ncbi.nlm.nih.gov/34436506/

Type of financial agreements according to AIFA definition

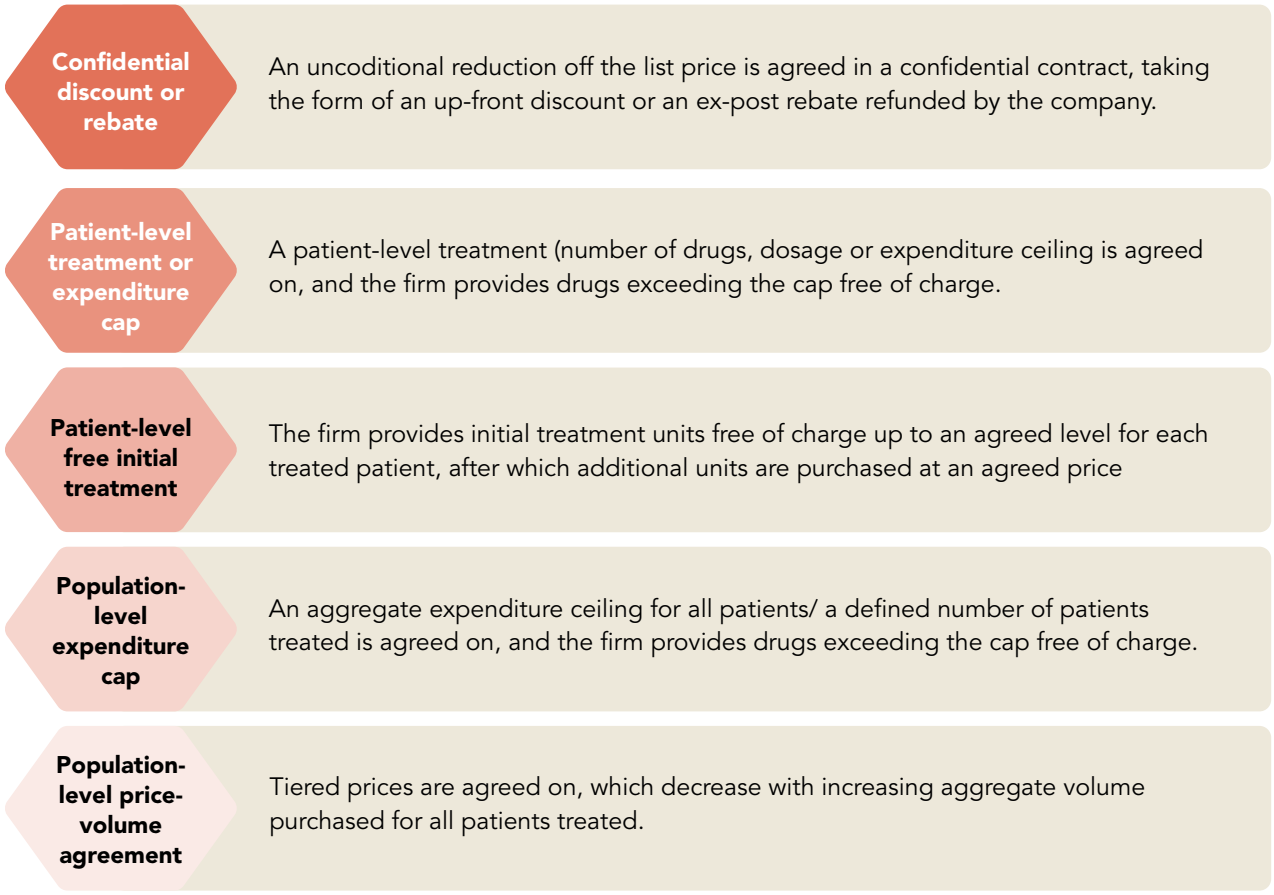

Figure 11: Dealing with financial uncertainties – types of financial agreements used in Europe

To deal with challenges associated with multiple indications and reduce the number of assessments for each indication, the bundled assessments approach used in Germany since 2017 is another example of how to deal with successive indications[53]. Drugs with successive indications that are expected to receive approval within six months of each other can undergo a joint single procedure in Germany also known as the bundling procedure. This helps streamline the assessment workload and ensure rapid access to successive indication for patients. The price is still based on the value of the drug across all indications and a single 'blended' price is maintained which is based on volume weighted average price per indication. To deal with financial uncertainties, a number of different mechanisms exist and are actively used by number of jurisdictions across Europe to manage risks to their budget (see Figure 11).

Whereas historically Pharmac in New Zealand has cited clinical and budgetary uncertainty to explain delayed access to promising new medicines for New Zealand patients, other countries have invested in funding, developed innovative funding mechanisms and evolved their methodologies to allow their populations to have earlier subsidised access to innovative medicines. There is a real opportunity for Pharmac and New Zealand to address this issue with novel and pragmatic solutions. New Zealand is not unique in facing these issues, as many countries face similar challenge. However, other countries have developed novel mechanisms and strategies to address these issues head-on rather than avoid change and reform.

[53] ibid

(c) Dedicated funds for innovative medicines

Various countries have also developed funding structures to expedite the availability of new medicines for their populations. The fiscal commitment that some European countries have demonstrated to ensure their populations have timely and equitable access to new therapeutic innovation demonstrates a degree of political, policy and administrative will that New Zealand could look to emulate.

For example, the new Cancer Drugs Fund (CDF) in the United Kingdom covers promising new oncology medicines where the cost effectiveness of a medicine is initially uncertain. The current CDF, which builds and improves on its earlier predecessor, covers new oncology medicines and allows the opportunity to resolve that uncertainty while the medicine is already available to British patients. Once recommended by NICE, funding on the CDF requires a Managed Access Agreement which contains a data collection arrangement and a CDF Commercial Agreement. An expenditure control mechanism is built in the managed access agreement to ensure cost blowouts are avoided. An annual budget of GBP 340 million is proposed for the new CDF scheme and comes with a rider that ensures that if the proposed budget is exceeded, all companies with medicines funded through the CDF will pay rebates in proportion to their own sales.

More recently, the UK introduced an additional Innovative Medicines Fund for innovative non-cancer medicines that operates with similar structures, condition and budget to the CDF . This is a GBP 340 million fund that is designed to provide opportunities for faster access to new medicines for patients in the UK while further data is collected on clinical and cost-effectiveness . The intention is to ensure that treatment using new medicines can begin for UK patients without delay and that NHS clinicians at the same time can build the evidence-base for such new treatments.[55]

Similarly in **Italy**, an annual fund of EUR 500 million has been in place to fund new innovative oncology medicines since 2017.[56] This fund is renewed every three years. Based on its success, the fund now covers innovative oncology and non-oncology medicines with a combined budget of EUR 1 billion from January 2022 with increased allocations of EUR 100 million for 2022, EUR 200 million for 2023, and EUR 300 million for 2024. A new algorithm was developed to assess the degree of innovation in a new medicine. Among the criteria for the algorithm, unmet therapeutic needs, added therapeutic value and quality of evidence from clinical trials was included to help the Italian Medicines Agency, AIFA, score the products and assign them to one of the three categories: innovative, not innovative, or conditionally innovative. Products that achieve the 'innovative' designation can draw funding from the innovative drugs fund and are also included in regional formularies immediately to enable rapid patient access.

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[54] See for example Angelis, A., Aggarwal, A. & Briggs, A. 2023. "The success of NHS England's Innovative Medicines Fund will depend on its operational details", Nature Medicine, 29, pp. 289–291, https://www.nature.com/articles/s41591-023-02206-w, accessed 8/7/2023; NHS. "Innovative Medicines Fund", website, UK Government, https://www.england.nhs.uk/medicines-2/innovative-medicines-fund/, accessed 8/7/2023; Association of the British Pharmaceutical Industry. 2022. "Briefing on the Innovative Medicines Fund", https://www.abpi.org.uk/publications/briefing-on-the-innovative-medicines-fund/, accessed 8/7/2023.

[55] NHS. "Innovative Medicines Fund", website, UK Government, https://www.england.nhs.uk/medicines-2/innovative-medicines-fund/, accessed 8/7/2023.

[56] OECD 2020, Addressing Challenges in Access to Oncology Medicines, available at https://www.oecd.org/health/health-systems/addressing-challenges-in-access-to-oncology-medicines.htm

Part IV:
Roadmap to timely access

There is a clear need for New Zealand to reduce the current delays in access to innovative medicines in areas such as oncology and improve investment in decision-making processes. The chronic under investment in medicines that has occurred needs to be addressed as a matter of high priority. The argument that New Zealand spends its money wisely and that international comparisons with other countries are not valid does not stand up to scrutiny. New Zealand is spending less on medicines than it did in the past, while the numbers of cost-effective medicines delayed and the time delay to funding are increasing. In addition, there is growing community awareness and concern over the underlying problems that have plagued the Pharmac system for years. The agency's evaluation methodologies, decision-making processes, transparency and engagement with patients do not meet community standards.

In terms of how to go forward and improve the access to medicines situation in New Zealand, there is the need for an early immediate or short-term remedy to address the current list of unfunded medicines, and a longer-term strategy to evolve the system to meet the needs of the community in the 21st century.

Short-term

In the immediate short-term, first and foremost there is a pressing policy need to fund the backlog of innovative medicines that Pharmac has already deemed to be cost-effective and of benefit to the New Zealand community, but that have not been funded due to a constrained budget.
New Zealand has the fiscal means and public mandate to make a 'catch-up' financial commitment to clear the current backlog of medicines and increase the current budget allocation, whether as part of general total budget or sequestered funding for innovative new medicines for a fixed duration. The current New Zealand Government has shown some commitment by investing $71 million investment in 2022 and another $120 million increase for next year. This initial investment was welcome news for many patients who have missed out basic interventions such as life-saving adrenalin autoinjectors for people at risk of anaphylaxis, and patients living with spinal muscular atrophy.

The New Zealand government has made some welcome additional funding commitments in the wake of the Pharmac review, with Pharmac receiving $1.2 billion of Government funding in 2022-23 and an additional $191 million over 2022-23 and 2023-24[57]. However, this funding is not going to be sufficient to fund every promising and cost-effective medicine that is currently sitting on Pharmac's Options for Investment list. – recalling that these medicines have all been reviewed, deemed cost-effective and are now waiting for funding.

Further immediate funding should be considered to ensure that all medicines that have already been deemed cost-effective by Pharmac can be funded and made available to New Zealanders as soon as possible. From a financial standpoint, the New Zealand government would appear to have the fiscal headroom to consider such a move. The total Crown operating balance is steadily improving and likely to go into a surplus in 2024, with the government having surplus funds in reserve that could be directed to redress the Pharmac funding gap.

[57] Pharmac. 2022. "Pharmac will use biggest budget increase ever to fund more medicines for more New Zealanders", 19 May, Press Release, https://pharmac.govt.nz/news-and-resources/news/2022-05-19-media-release-pharmac-will-use-biggest-budget-increase-ever-to-fund-more-medicines-for-more-new-zealanders/, accessed 26/7/2023.

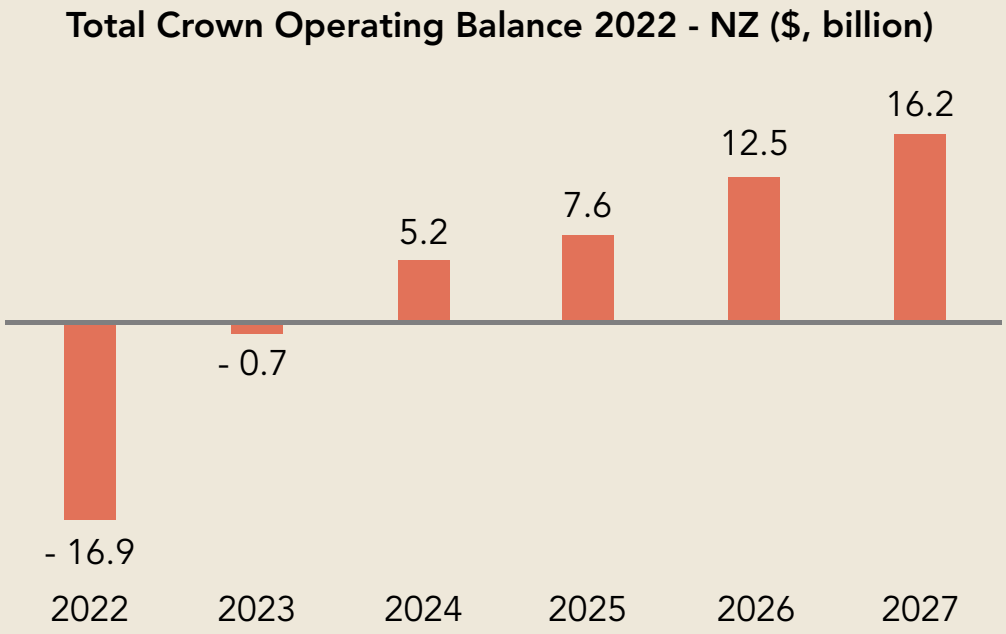

Figure 12: Total Crown Operating Balance 2022 - New Zealand ($ billion)
Source: Half Year Economic and Fiscal Update (Oct 2022)

Longer-term

While a short-term catch-up financial injection will help address the immediate long-running backlog of new (or not-so-new) medicines that have yet to be funded, consideration should be given to initiatives for the longer-term goal of reforming and developing New Zealand's medicines funding system for the future. Several options are available for consideration.

- **Long-term strategy to increase funding**

  The New Zealand government should develop a plan to increase the medicines budget year on year to get closer to the OECD average level of funding and avoid under investment in cost effective medicines that have the potential to improve the productivity of the country's healthcare system. It is important that the government, irrespective of political leanings, allocates funds for innovative medicines that are deemed cost effective. Given New Zealand's long history of under-funding access to medicines and adopting a capped budget approach, the time has come when the country should develop a financial plan to lift investment in new medicines and treatments.

- **Develop innovative medicine financing mechanisms**

  To ensure good value for money and sustainability of the medicines budget, New Zealand can look to innovative financing mechanisms/agreements that are being used in other countries to improve access to new technologies. These could be used for medicines and treatments that show promise but do not yet have sufficient long-term effectiveness data. Instead of running away from new medicines due to uncertainty, New Zealand could explore new ways to embrace innovation, while quantifying and managing the uncertainty to reap the benefits while maintaining fiscal discipline. New Zealand can apply learnings and experiences of comparable countries to progress access to medicines and use more progressive and pragmatic approaches for pricing. This will assist in keeping costs under control to guard

against any risk of budget blow outs. Creating a well-crafted agreement would demonstrate the political will to transform medicines access not only to address the immediate crisis, but also set the course for future access for New Zealanders.

- **Introduce a dedicated fund to finance innovative medicines**

  Like the Cancer Drugs Fund and Innovative Medicines Fund in the United Kingdom, New Zealand could look to establish a dedicated fund to expedite the listing and funding of new treatments over the long-term. Typically, these funds have been created where the normal evaluation processes used in a country have been too slow or too restrictive to allow patients access to innovative new medicines. They often provide initial early funding for medicines while the evaluation process is undertaken to resolve longer-term funding. The New Zealand Government could establish a dedicated fund with an earmarked financial resource provided towards new medicines before their inclusion into regular health care budgets, along the lines of the Cancer Drugs Fund in UK or the Innovations Fund in Italy. Health New Zealand would be best placed to manage a 'New Zealand Innovation Fund' with additional legislated powers to make the investment decisions. This could free up Pharmac to focus on reform of the assessment and prioritisation process for new medical technologies and allow Te Whatu Ora, Health New Zealand to take responsibility for funding and budget decisions.

- **Ensure medicines assessment processes reflect government policy priorities**

  While New Zealand economic policy has evolved to take greater account of the social and economic benefits of government spending in services, this more holistic valuation has not been reflected in Pharmac's decision making policies and processes. All sides of politics in New Zealand have expressed greater support for a broader view of the value of government expenditure, be it through wellbeing budgeting or views on social investment and positive returns on government expenditure. Pharmac's valuation of new medicines should reflect this greater appreciation of these government policy goals by widening its lens to look beyond the direct costs of medicines. In its evaluations, the agency should consider broader societal benefits and costs of the treatments it evaluates, such as the socio-economic impact of treatment for people living with diseases, the social and productivity benefits for their carers, the downstream expenses that are avoided due to use of effective treatments early on in the disease progression, and the broader economic value and productivity benefits of investing in new medicines.

- **Develop a national medicine policy**

  New Zealand needs an updated medicines strategy that acts as guiding principle for the future and provides strategic direction for medicines policy regardless of day-to-day issues. This strategy should prioritise equity, fairness, early access to the latest treatments for New Zealanders, and promote evaluations of medicines that consider other value aspects of relevance to patients and society, and not just cost and benefits in the more traditional sense. A national medicines policy should provide strategic direction to Pharmac and the broader New Zealand health system about the importance society places on New Zealand being at the front of the queue in obtaining and funding new medicines.

- **Reform the medicines evaluation and decision-making process**

  There are a variety of policy and administrative reforms that are needed in the way the New Zealand government evaluates and funds new medicines, several of which were identified in the most recent 2022 review of Pharmac.

1. Pharmac should place much greater emphasis on patient views in its assessment and decision making and involve patients early on in ongoing review and coverage decisions.
2. More predictability and transparency in Pharmac's decision making is urgently required to improve the accuracy and fairness of decisions.
3. To manage clinical uncertainty, New Zealand could establish conditional approvals/funding alongside setting up of disease registries to collect real world effectiveness data to address clinical uncertainty.
4. For medicines that have multiple indications in different disease areas like oncology, it will be worthwhile for New Zealand to consider multi-year contracts and innovative funding and payment terms to ensure budget sustainability.
5. Harnessing the potential of data technology is another good strategy to explore to track medicine usage and health outcomes in clinical practice. The United Kingdom's Blueteq and SACT datasets are examples that could be emulated in New Zealand or extend the use and applicability of the Statistic New Zealand Integrated Data Infrastructure (IDI)
6. Consider the use of time-bound deadlines for medicines reimbursement for Pharmac once the medicine has received a PTAC recommendation.
7. Consider the separation of the evaluation function for a medicine from the funding decision. Given the sometimes-conflicting policy objectives and potential for goal displacement in the funding decision, consideration should be given to giving Pharmac the responsibility for evaluation and recommendation, and te Whatu Ora/ Health New Zealand or Government Cabinet the separate responsibility for the final funding decision for a new medicine. This would improve transparency and accountability in decision making.

Conclusion

The New Zealand government needs to provide the necessary national leadership and inject a dose of pragmatism in dealing with the complexities of medicines access without shying away from taking decisions to fund innovation in a timely manner. Access to medicines needs to be seen with through appropriate lens that reflects community standards and expectations: not seeing medicines first and foremost as a cost but recognising them as an investment. For decades many of the problems in New Zealand's access to medicines have stemmed from not getting the balance right between fiscal responsibility, early patient access to new treatments, fair and equitable administration, and the value of investing in the welfare of the New Zealand people. For too long, budget management and cost containment have been a major objective of Pharmac ahead of many other important social and economic policy goals.

New Zealand's medicines policy should be built to achieve superior patient outcomes and encourage further innovation and introduction of new technologies that add further value to the provision of healthcare in New Zealand. This policy approach should create both urgent additional focus on improving the health outcomes of the Māori population while improving health outcomes of the general population more generally, as well as the growing migrant communities which may all have different healthcare needs. Healthcare financing decisions should consider the broader economic benefits of healthcare provision. It should also support a thriving healthcare industry in New Zealand, create high paying jobs, encourage in cutting-edge science, and streamline Pharmac's value assessment processes and reduce uncertainties. Value assessment processes should be efficient, transparent, predictable and time bound.

International experience shows that there are policy options and strategies that New Zealand could adopt to improve the way it evaluates and funds innovative medicines. With growing community recognition of the value of investing in medicines and vaccines, particularly in the aftermath of the Covid-19 pandemic, the time has come for New Zealand's system to change for the better. There is a lot to do, but the important thing is to make a start.

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