PHARMAC REVIEW
Te Arotake i Te Pātaka Whaioranga

New Zealand Government

Submission form

To help us to consider your submission we are asking that you focus on the following questions. There is the opportunity to provide additional feedback at the end. We expect to get a high response and ask that, where you can, you are concise. Once you have completed your submission please send it to: pharmacreview@health.govt.nz

Note that submissions are subject to the Official Information Act and may, therefore, be released in part or full.

If your submission contains any confidential information please state this within submission, and set out clearly which parts you consider should be withheld and the grounds under the Official Information Act 1982 that you believe apply. We will consult with submitters when responding to requests under the Official Information Act.

Submission questions

Tell us about your current experience with PHARMAC and how it functions

1. What is your understanding of what PHARMAC does?

PHARMAC is a governmental agency legislated to fund medicines and medical devices within an allocated budget. The Cancer Society understands PHARMAC's functions to be as described in its legislation, on PHARMAC's website and in other publicly available documentation.

Regarding cancer medicines, PHARMAC purchases all cancer medicines on the pharmaceutical schedule on behalf of DHBs. Access to high cost cancer medicines is restricted via special authority criteria. Access to lower cost generic cancer medicines is largely unrestricted. PHARMAC does not have a role in determining best selection of cancer treatments and does not have a role in regulating bone marrow transplantation access or radiotherapy schedules.

2. What has been your experience of working with PHARMAC?

Cancer Society New Zealand's usual engagement with PHARMAC is through PHARMAC consultation processes. However, our feedback here is also informed by the voices and stories we hear from people going through cancer treatment and who we support.

In addition, we have volunteers and Board members who have direct experiences of working with PHARMAC. These experiences include engagements on behalf of patients and also performing clinical roles for PHARMAC (e.g. they have been members of the

Pharmacology and Therapeutics Advisory Committee (PTAC) and its Cancer Treatments Subcommitee (CaTSoP)).

We do not currently have representation on PHARMAC's Consumer Advisory Committee, but we are not sure this committee is an integral part of decision-making at PHARMAC in practice.

We have commented extensively on some of PHARMAC's decisions and processes, and have called for a review of PHARMAC based on response to concerns about access to cancer medicines from the community affected by cancer. We have found PHARMAC to act with professionalism and integrity but have found them unresponsive to feedback and constructive criticism. We have seen little evidence of change in processes or procedures that have changed engagement or outcomes in the past decade.

3. What are the challenges with PHARMAC's functions for funding medicines and devices?

There are significant challenges with PHARMAC's functions. For example, it is challenging to come up with a process to compare vastly different medicines.

PHARMAC's core statutory functions refer to "best health outcomes" but this is being construed far too narrowly by PHARMAC. Pharmaceuticals and devices are provided within the broader health system (which is going through significant change). There needs to be more consultation with, and consideration of, which medicines and devices will provide the best health outcomes within a New Zealand context. Cancer Society of New Zealand's Chief Executive, Lucy Elwood, provided some practical examples of changes that are required at hui with the PHARMAC review panel members in July 2021. It is important that after this review PHARMAC consider funding decisions within the context of models of care, the broader health system and the current health inequities in New Zealand.

The Cancer Society would also like to endorse comments made at these hui, and in other submissions to the review, regarding current challenges such as the lack of accessibility, the lack of transparency, and the lack of timeliness of PHARMAC decisions.

Some practical examples of challenges:

- PHARMAC's clinical advisory committee Pharmacology and Therapeutic Advisory Committee (PTAC) and its cancer subcommittee (CaTSoP) provide recommendations that are advisory only in the PHARMAC decision (1). We believe that expert advice should be focused strictly on clinical advice and that PTAC/CaTSoP should not also be considering budget constraints. In other words, there needs to be separate assessment of therapeutic assessment and affordability - as is the case in other jurisdictions.
- PHARMAC does not have a surveillance mechanism that easily allows it to reconsider a funding decision in light of new evidence or costings. For instance, we are aware of a cancer drug which was rejected for funding and is now at half of its original cost and there is even more evidence of its effectiveness (dabrafenib and trametinib in melanoma). However, to re-consider this medicine for funding the application would need to be resubmitted to PHARMAC to start the process all over again. As the

supplier no longer has a domestic presence this seems unlikely. Due to the lack of success of funding submissions previously few clinicians see high value in submitting applications.

- There have been instances of disagreement regarding advice and recommendations between PTAC and the Cancer Treatment Subcommittee (CaTSoP) on various cancer medicines. It is unclear how the PTAC and CaTSoP recommendations are weighed when they are in conflict, or which committee, PTAC or CaTSoP, receives a cancer related application first.
- Cost appears to be the over-riding criteria for PHARMAC prioritisation. Technically PHARMAC's published criteria for prioritisation include other Factors for Consideration, but it is completely unclear how these factors are weighted.
- PHARMAC consults on its decisions only after the 'decision to fund' has been made, and the consultation then relates only to the special authority criteria. This means the wider community is not informed of, or consulted on, decisions 'not to fund' or where recommendations to fund with a low priority are made. There is no formal mechanism to provide feedback to CaTSoP or PTAC about any decision or elements of process other than on positive recommendations to fund.
- There is limited information on the criteria under which PTAC considers applications, the extent to which PHARMAC undertakes horizon scanning, and how PHARMAC identifies the unmet needs or priorities for communities. These are critical decisions.
- It takes too long for PHARMAC to make funding decisions for most cancer therapeutics compared to other jurisdictions. We note that there are occasions where funding can be forthcoming quickly in certain circumstances, but these instances are rare and infrequent. It is much more common for PHARMAC decisions to lag significantly behind comparator countries such as UK, Canada and Australia even after PTAC assessment suggests funding is a high priority. We have particular concerns that we have no funding for newer more effective medicines for lung or liver cancers, which are high priority cancers for Māori. We strongly believe that the average of 512 days (3) it takes PHARMAC to approve funding for lifesaving drugs is too long.
- PHARMAC's current processes for considering funding will break further as more personalised medicines become available.

References

1 PHARMAC. (2021). Pharmacology and Therapeutics Advisory Committee (PTAC). https://pharmac.govt.nz/about/expert-advice/pharmacology-and-therapeutics-advisory-committee-ptac/

2 PHARMAC. (2019). OIA Response: Pembrolizumab criteria. https://pharmac.govt.nz/about/what-we-do/accountability-information/official-information-act/2019-oia-responses/oia-response-pembrolizumab-criteria/

3 IQVIA. (2019). INTERNATIONAL COMPARISONS OF MODERN MEDICINES (ICOMM). https://www.medicinesnz.co.nz/fileadmin/user_upload/IQVIA_ICOMM_Report__August_2019___1_.pdf

What do you know about PHARMAC's processes and how they work?

4. What do you think works well with the processes PHARMAC uses to assess the funding of medicines and medical devices?

Some of PHARMAC's processes appear to help to ensure that pharmaceutical funding decisions are apolitical.

There is some evidence that some elements of current regulatory mechanisms (budgeting, reference pricing, and tendering) meets the PHARMAC goal to save taxpayers money and provide universal coverage for highly used medications (1). However, this model does not allow for the timely introduction of new medicines in high-speed evolving areas such as cancer therapy and prevents development of precision medicine in New Zealand. Plus the lack of horizon scanning and lack of comparison against relevant international benchmarks means that the budget in New Zealand is now far below what is needed.

The Named Patient Pharmaceutical Assessment pathway (NPPA) has met the needs of some unique individual patients. However, this is far from universal and significant improvements are needed.

References

1 Kelley, L. T., Tenbensel, T., & Johnson, A. (2018). Ontario and New Zealand pharmaceuticals: Cost and coverage. Healthcare Policy, 13(4). https://doi.org/10.12927/hcpol.2018.25496

5. What do you think are the barriers to accessing medicines and devices?

As discussed with Review Panel members at the hui, there are significant issues.

A main barrier for patients is the current rigid and bureaucratic process that lacks the flexibility required in a dynamic evolving cancer treatment space. There are several examples demonstrating limited access, lack of transparency and lack of accountability at different levels of current system.

- Cost is a major barrier. Cancer Society staff have seen numerous clients who are aware of treatments which are not funded by PHARMAC, yet these treatments have been approved for use in other developed countries such as Australia, Canada, and the USA. This situation leads to enormous emotional and financial impact on cancer patients and their whānau, especially those who are unable to access or raise funds to access these potential lifesaving / extending treatments.
- It is hard for people to access information about drugs funded for their conditions and about treatment options available for them. This is because PHARMAC publishes information by drug name, but not by disease and one must check each single drug to understand if it can be used for their condition.
- There is mis-information provided in regard to applying for NPPA. We are aware of occasions where it has been suggested that a cancer patient that can't afford an unfunded drug should apply under the NPPA. This is despite the fact that the drug has already been declined under a scheduled application that precludes it from

being considered under NPPA. This circular process frustrates both clients and clinicians, and often gives a patient false hope.

- Absence of an objective appeal process is a barrier for people to access cancer medicines. We have been involved in a case when a patient wanted to access Tomudex® under NPPA, but PHARMAC decided that the decision would set a precedent for a large number of patients affected and therefore declined. Our assessment on the number of potential patients differed from PHARMAC's by a very wide margin, however there is no process in place to dispute the estimate and then resolve the difference.

6. Is there any other country that does it better? What is it that it does better and would any of those systems apply here?

In a recent report, New Zealand received the lowest rank among 20 OECD countries in terms of numbers of modern medicines publicly funded during 2011- 2017, including cancer drugs (1).

The systems in Canada and Australia result in faster and generally broader access to cancer medicines and therefore deserve consideration. They also have broader frameworks for consultation, more detailed technology appraisal decisions, and greater consumer engagement. All of these process elements could be added and warrant consideration.

In the UK, NICE is the technology assessment body that informs and influences on decisions about the right criteria, right treatment, and right time for the specific condition. This model should also be considered, including the split of functions between NICE and NHS. For example, consider the scheme of cancer drugs appraisal and funding introduced by the NHS England in 2016 as way to allow a faster access to modern cancer medicines while considering value for money. The scheme provides an opportunity for interim funding and setting a specific timeframe (2).

References

1 IQVIA. (2019). INTERNATIONAL COMPARISONS OF MODERN MEDICINES (ICOMM). https://www.medicinesnz.co.nz/fileadmin/user_upload/IQVIA_ICOMM_Report__August_2019___1_.pdf

2 NHS England Cancer Drugs Fund Team. (2016). Appraisal and Funding of Cancer Drugs from July 2016 (including the new Cancer Drugs Fund) - A new deal for patients, taxpayers and industry. https://www.england.nhs.uk/wp-content/uploads/2013/04/cdf-sop.pdf

What should PHARMAC's role include in the future?

7. How might PHARMAC look in the future? And what needs to change for this to happen?

PHARMAC must be flexible and responsive to quickly evolving medicines and treatments developments. For example:

- We would like to see a streamlined decision-making process.

- We would like to see greater consideration of the specificity of cancer space and greater involvement of stakeholders and clinicians in decision-making process (1,2).
- The decision- making process must consider objective criteria and public health benefit which are available publicly. It must also consider models of care, international best practice and how to reduce inequities of health outcomes in New Zealand. Greater transparency on reporting against objective criteria will enhance the quality of the process.
- We prefer that clinical committees such as PTAC and CaTSoP are limited in their scope to evaluate clinical benefit and scientific quality, without considering cost. The health gains evaluated then inform a separate pharmacoeconomic evaluation process where cost utility is assessed. The PHARMAC Board would then be responsible for considering cost utility and overall prioritisation to achieve best health outcomes, after considering interests across the overall system. This separation of roles would avoid the present conflation of cost with rigour of evidence. PHARMAC consultation process and community engagement must be improved. This, in turn, will enhance the quality of the decisions made and confidence in them.
- We would like to see extensive horizon scanning, and the provision of transparent advice to the Government on how New Zealand's budget for pharmaceuticals and devices compares to relevant OECD jurisdictions. New Zealand is slipping further and further behind. None of these changes would necessarily result in extra spending, but would result in more transparency.

References

1 European Federation of Pharmaceutical Industries and Associations. (2021). HTA & Relative Efficacy Assessment Assessing the added value of medicines to support access: the benefits of European cooperation. *https://www.efpia.eu/about-medicines/use-of-medicines/hta-relative-efficacy-assessment/*

2 The International Decision Support Initiative (iDSI). (2018). HTA Toolkit v1. *https://www.idsihealth.org/HTATOOLKIT/*

Are there additional or different things that PHARMAC should be doing?

- PHARMAC should have better engagement with technology assessment agencies and expert knowledge agencies such as Te Aho o Te Kahu (Cancer Control Agency).
- There should be a transparent process and consultation by PHARMAC on the broader implications of its decisions on the health system (e.g. availability of the workforce to administer pharmaceuticals, availability of other relative treatments and services), in addition to consultation on pharmaceutical expenditure. Changes are needed to address inequities in health outcomes.
- PHARMAC should use an evidence-based framework that clearly identifies medicines or devices that have best clinical benefit for patients to guide the decision-making. An example of such framework is one developed by European Society of Medical oncology (1).
- In 2016 the Cancer Society outlined in its position statement that PHARMAC should have an additional function as a managing agency for an early access to medicine scheme with a separate budget (2).

References

1 European Society of Medical Oncology. (2021). ESMO-MAGNITUDE OF CLINICAL BENEFIT SCALE (V1.1). https://www.esmo.org/content/download/288505/5736229/1/ESMO-MCBS-Factsheet.pdf

2 Cancer Society of New Zealand. (2016). Breakthrough therapies and the introduction of a New Zealand Early Access to Medicines Scheme (EAMS). https://www.cancer.org.nz/cancer/our-advocacy-work/position-statements/breakthrough-therapies-and-the-new-zealand-early-access-to-medicines-scheme/

8. What do the wider changes to the Health and Disability system mean for PHARMAC?

Health NZ, on behalf of DHBs, will lead the national specialised services planning under the health system reforms. Also, there is a consideration to separate funding for high-need and high-cost patients (1). Therefore, we would assume that within this new funding environment PHARMAC will be required to become more responsive to requests and reconsider its criteria and approach to consultation to ensure best health outcomes.

References

1 HEALTH AND DISABILITY SYSTEM REVIEW | AROTAKE PŪNAHA HAUORA, WHAIKAHA HOKI. (2020). https://systemreview.health.govt.nz/assets/Uploads/hdsr/health-disability-system-review-final-report.pdf

How should PHARMAC address the need for greater equity in the decisions it takes, in particular for Māori, Pacific and disabled people?

9. How well does PHARMAC reflect the principles of Te Tiriti o Waitangi?

PHARMAC has a set up Te Whaioranga (PHARMAC's Māori Responsiveness Strategy), but we would like to see more evidence and reporting from PHARMAC on how their decisions have impacted Māori health in respect to cancer.

Māori are twice as likely to die from cancer than non-Māori. Māori are disproportionally affected by the top 10 most common cancers compared to non-Māori (1). Yet it is unclear how this is factored into PHARMAC decisions.

We remain to be convinced that Māori cancer needs have been prioritised in any funding decisions by PHARMAC. There is presently little to no evidence that PHARMAC preferentially fund medicines of benefit to Māori and as a priority population this needs to be an area of specific and increased focus.

References

1 Gurney, J. K., Robson, B., Koea, J., Scott, N., Stanley, J., & Sarfati, D. (2020). The most commonly diagnosed and most common causes of cancer death for Māori New Zealanders. New Zealand Medical Journal, 133(1521). https://assets-global.website-files.com/5e332a62c703f653182faf47/5f5008ea9a62497fd5783f0e_Gurney FINAL.pdf

10. How can PHARMAC achieve more equitable outcomes? We believe that PHARMAC can achieve more equitable outcomes by focusing not on the cost of the medicine or device, but on the impact it would bring to Māori patients an their whānau.

Additional feedback

Is there anything else that you think the Review Panel should consider? Most people wrongly assume that PHARMAC controls access to all cancer treatments. However, PHARMAC does not control the conditions under which many people access chemotherapy because most chemotherapy drugs are generic and hence low cost. PHARMAC does control access to high-cost special authority medicines, but does not sufficiently factor into its decision-making processes in relation to these medicines consideration of the clinical staff and technology required to administer these medicines, and which medicines will achieve better outcomes for patients (e.g. such as the travel arrangements needed to access treatment). Better engagement with clinicians and community is required to fully inform these funding decisions. Although budget is outside the scope of this review, it should be within the scope of PHARMAC's functions for it to provide advice on what the overall funding level should be for New Zealand to ensure world class access to effective treatments. There should be a benchmarking and horizon scanning process to ensure that the level of access to treatment is similar to other comparable countries. We think that advice on budget size to shareholding Ministers on what additional funds could offer in terms of health gains is a critical role that PHARMAC must start to perform. We wish to thank the panel members and everyone involved in the review for this important mahi. We welcome the opportunity to provide more feedback after the interim report is released.

Contact information

Your feedback is important to us. If you are comfortable for us to get in touch if we have any questions or points of clarification regarding your feedback, please provide your name and contact email address below.

Name	Lucy Elwood
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Organisation	Cancer Society

If you do not want your personal details to be shared for any other purpose (for example if we receive a request for information under the Official Information Act) please signal this using the box below.

☐ I do not want my personal details to be shared for any purpose other than this review.

Thank you for providing your feedback.

Tēnā koe mō tō tuku urupare mai.