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 both makes decisions and holds funds for hospital and community pharmaceuticals within NZ's public health system.
   - **PHARMAC** is a Crown entity governed by a Board accountable to the Minister of Health. **PHARMAC's objective** is to secure for eligible people in need of **pharmaceuticals**, the best health outcomes that are reasonably achievable from **pharmaceutical** treatment and from within the amount of funding provided.

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

   - Gut Cancer Foundation has not had direct experience working with PHARMAC, however we represent a group of patients that has been directly impacted by PHARMAC's current model and work closely with/ represent the interests of clinicians that are directly affected in the following ways. Both these groups have represented their experiences of working with PHARMAC as follows:
   - The groups we represent are increasingly frustrated by their communication with PHARMAC; letters/emails are left unanswered or are answered via obfuscation.
   - PHARMAC is a passive obstructer of funding rather than an organisation actively seeking to fund new medicines to assist with the best health outcome for NZers

within their limited budget. NZs GI cancer patients are no longer receiving international best practice medicines and New Zealand medical oncologists are regularly treating patients off ASCO/NCCN/ESMO or even Australasian treatment guidelines.

- We are increasingly frustrated by for example, "pinging" drug decisions between CATSOP/PTAC, poor use of data to refute clinicians requests for funding of specific medicines, slow uptake of bio-similars to allow for cost-savings and expanded indications, and using PHARMAC processes to 'block funding' e.g. NPPA process.

- In terms of the NPPA process, there is previous correspondence about this issue in particular and raltitrexed access is a great example. This is a medicine used occasionally in New Zealand for those intolerant of other fluoro-pyrimidines due to cardiac toxicity or pre-existing disease. A smattering of NPPAs were approved – no more than 1-2/year for some years. Without warning 2 NPPAs were declined as "not rare enough" and an erroneous figure of potentially 10000s people per year bandied around in email correspondence. A funding application was requested and submitted by the Gastro-Intestinal Special Interest Group (GISIG). As this application received an "approve with low priority" recommendation, patients will not gain access – as PHARMAC rarely provides funding for 'low priority' medicines – we are still waiting for many with a 'medium to high' recommendation in oncology and the NPPA system is no longer applicable to drugs that have been through PTAC/CATSOP review.

- Cetuximab demonstrates the "pinging" of decisions and poor use of data. This drug has been standard of care for more than a decade in a sub-set of patients with colorectal cancer. Our original application was declined as the benefit was felt to be too small and the applicable population too large. Over time, this sub-set of patients who benefit has been more clearly defined with proportionally greater survival benefit to a smaller group of patients. Although international practice is to only use cetuximab in this smaller population despite the pre-existing more broad approvals, one of the reasons for declining the most recent application was due to our proposed selection criteria being smaller than approvals in other jurisdictions.

- For more than a decade, the addition of anti-her 2 therapies to chemotherapy has been used internationally to provide a significant survival benefit to a sub-set of patients with gastric cancer. Bio-similar anti-her-2 therapies that can be used in place of Herceptin (trastuzumab) have been available and in use in the private sector for more than a year with significant cost-savings. PHARMAC do not appear to have actively pursued how the use of an anti-her-2 biosimilar could allow more cost-effective therapy for the small proportion of gastric cancer patients appropriate for anti-her-2 therapy and potentially cost savings across the board as trastuzumab use in breast cancer represents the 5th greatest gross spend on one medicine. Instead they put GISIG and consumers through a consultation in order to remove the possibility of funding for Herceptin (trastuzumab) from the application process.

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

- PHARMAC's functions were Potentially appropriate 25 years ago (when Pharmac was first created) – but it is questionable whether this mandate remains 'fit for purpose' in these rapidly changing times (eg: success of early access schemes, rapid advances in medication, advances in immunotherapy etc)

Ultimately and fundamentally, PHARMA is hampered/restricted by the 'amount of funding provided' and does not provide enough weight towards the economic value of a human life.

- PHARMACs processes are not transparent. It is impossible to tell when a medicine might be funded and often it feels like PHARMAC is more interested in getting the 'best deal' regardless of how long this takes and how many people have poor outcomes or die as a result of any resultant delay.

Clinician applications/requests for medicines are often not loaded on to the application tracker which is frustrating and disrespectful to the amount of work this takes.

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?

- It is not possible to measure PHARMACs processes currently as they are either invisible to non-PHARMAC employees or are not benchmarked in a way that matters to consumers or clinicians. We need to measure input (spend on drugs) per outcomes in actual patients. "total prescriptions" "total retail spend" does not provide any indication as to whether PHARMAC is meeting its goal of health benefits.

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

- Inequity of values used when budgeting (eg: health vs road). Treasury's own CBAx model shows the inequity in valuing health. https://www.treasury.govt.nz/publications/guide/cbax-spreadsheet-model-0 (go to the 'impacts database' tab)

In this model, the Ministry of Transport values a Statistical Life at $4,560,000.

If Pharmac was working with real-world numbers, and valuing life at the same value as the transport sector then the medicines calculations would be very different. Many more medicines would qualify for funding - which would address the problem 'the amount of funding provided' under its statutory purpose. Instead, the way it is currently organised, the calculations are designed so that medicines don't qualify for funding - so the amount

of funding provided isn't the issue. Essentially, to fit within the Pharmac envelope, the value of life is distorted to be artificially low.

- Rapid Access Scheme - Previously proposed and accepted as a potential solution. This seems to have slipped off the radar – and should now be included in this review.

There needs to be a timebound element in Pharmacy's processes. It's unacceptable for NZers to wait an unknown length of time for Pharmac to complete their deliberations. This can then feed into a metric on timeliness to approval that would help to bring NZ into line with Australia and other OECD nations for speed of assessment/approval of new medicines.

- PHARMAC does not appear to listen to its own experts. CATSOP is a group of motivated clinicians with broad experience and skill sets. Their decisions regarding appropriateness of funding do not seem to particularly influence whether or not a medicine is actually funded.

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?

European Medicines Agency (EMA) has a structured way of assessing the utility or otherwise of systemic therapy for cancer. This takes into account the trial data in terms of evidence but also the strength of that data.

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?

- GCF strongly endorse the need for a full overhaul of the Pharmac process (to address the issues we've raised) and given budget is out of scope we are calling for the review committee to advise Government that a budget increase is urgently needed. The government should call on Pharmac to provide the cost estimate to fund all medicines in line with international best practice.

- PHARMAC should act as part of the health system as a whole. The idea of assessing health technologies/pathways as a package of care is more attractive than looking at medicines in isolation. Testing for patient selection, monitoring for benefit, clinician time – medical, nursing and pharmacists, for example, all need to be included in the assessment of risk/cost/benefit. This was exemplified by the effect of funding immunotherapy, which overnight required increased clinical FTE for assessing patients, and staff and space for providing infusions, which fell to each

DHB. The drug costs and the clinical processes should have been introduced and funded together. Inequity inevitably occurred.

- Tight regulation of high cost medicines assumes that clinicians can't be trusted to use these medicines appropriately. Low-cost medicines, however, can be given to many people without oversight. Ten thousand dollars is still ten thousand dollars if it is spent on one person for great purpose or split over 100 people for a small or negligible benefit.

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

- It would be useful if PHARMAC were a proactive/outward looking system which engaged with local and international experts to ensure NZ patients were not 'missing out' compared with similar jurisdictions rather than a reactive drug company pushed system.

- Individuals within PHARMAC have on occasion sought to engage with clinicians directly. These relationships are often short-lived as PHARMACs staff turnover precludes long-lived connections.

- Clinicians, patients and their advocates and drug companies go "cap in hand" asking for funding. A sector wide approach ranking investments/potential health gains and then measuring them would assist in ensuring that access was fair and equitable.

- The inclusion of health psychologists at every step of decision making – rather than rely on patchy engagement with consumer groups we would recommend a team of health psychologists work with PHARMAC with a sole view that focuses on patient and whanau acceptability on medicines/treatments being considered for funding – considerations such as adherence, mode of administration, side effects – all of the things likely to impact of efficacy.

- Furthermore PHARMAC should FUND adherence support programmes to ensure NZ patients eligible for funded medicines have the best and supported chance of gaining an optimal outcome.

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

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?

- In gastrointestinal cancers, Maori are disproportionately affected by gastric cancer and hepatocellular carcinoma. These are two cancers for which New Zealand patients treated in the public sector are unable to receive best practice medicines despite similar medicines being available for similar benefit in other cancers.

There are NO funded therapies for hepatocellular carcinoma. Hepatocellular carcinoma is more likely in deprived populations due to its pathogenesis related to obesity and diabetes (non-alcohol fatty liver disease), alcohol overuse syndromes and viral hepatitides. Sadly, these precursor illnesses are suffered by Maori, Pacific Island and refugee communities disproportionately. This is a disease, at least in part, a direct consequence of health inequities which PHARMAC currently perpetuates.

Cancer registry data suggests a 5x greater risk of hepatocellular carcinoma in Māori men compared with non-Māori men, the rate is 3x in Māori women compared with non-Māori women.

Chamberlain et al., Aust N Z J Public Health, 2013 Dec;37(6):520-6. doi: 10.1111/1753-6405.12108.

- Immunotherapy agents nivolumab and pembrolizumab have been funded for treatment of metastatic melanoma for some years. Compared with immunotherapy data in melanoma, the combination of atezolizumab and bevacizumab in hepatocellular carcinoma has been demonstrated to have similar response rates, greater median progression free survival and better hazard ratio for OS (HR=0.66 cf HR=0.73).

Finn et al., N Engl J Med 2020; 382:1894-1905.

There is no equitable explanation for why the treatment of these two cancers that affect different populations are funded so differently.

- Trastuzumab has been funded for the treatment of metastatic breast cancer for many years. Treatment improves overall survival (HR 0.82) – extending life by between 5 and 8 months. Trastuzumab is not funded for patients with Her-2 over-expressing gastric cancers despite treatment for those with IHC-3+ disease improving overall survival (HR=0.66) – extending life by greater than 5 months.

Bang et al., Lancet 2010; 9742; 687-697.

There is no explanation as to why breast cancer and gastric cancer patients are not able to access equally useful medicines apart from that of institutional racism.

10. How can PHARMAC achieve more equitable outcomes? • As above, PHARMAC has the ability to provide equitable outcomes by ensuring that those who suffer a disproportionate burden of cancer have access to best practice therapies. Noise and political expedience must be outweighed by science.

Additional feedback

Is there anything else that you think the Review Panel should consider?

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.

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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.