

9 December 2021

**Submission to the Pae Ora Legislation Committee**  
*on the*  
**Pae Ora (Healthy Futures) Bill**

**Introduction**

The Chronic Lymphocytic Leukaemia Advocates New Zealand Trust (CLLANZ) Trust was established in 2019 by the late Dr Neil Graham to improve survival and quality of life for New Zealanders living with [Chronic Lymphocytic Leukaemia \(CLL\)](#) and related blood cancers. We are a member of an international 34-country network [CLL Advocates Network \(CLLAN\)](#) that works together and shares resources.

CLL is a life-threatening blood, lymph node and bone marrow cancer that usually progresses over time. Around 2000 New Zealanders live with CLL, of whom around 80% are aged over 60.

CLLANZ [cladvocates.nz](http://cladvocates.nz) was set up specifically to advocate for fair and equitable access to effective treatments for CLL patients with high unmet needs, treatments that are standard of care throughout the developed world.

While effective treatment remains unfunded, NZ patients in desperate need have the choice of self-funding, seeking public charity, getting onto a clinical trial, moving countries, or facing death or a greatly diminished quality of life.

As a small group of volunteers we have worked hard to represent these New Zealanders and to pursue funding of the treatments they need. This work was led by our Founder and Executive Director, also a CLL patient, Dr Neil Graham, who passed away on 16 November 2021. Among the many CLLANZ initiatives he had underway, Dr Graham had fully intended to write a submission on this bill, so we, the Trustees, resolved to do this in his place.

**Our concerns about the Pae Ora Bill**

CLLANZ strongly supports the Bill's purpose set out in Part 1, 3, in particular its clear emphasis on achieving equity and protecting, promoting and improving the health of *all* New Zealanders.

We note and support in Part 1, 7 (1) the following health system principles:

- (a) the health system should be equitable, which includes ensuring Māori and other population groups—
- (i) have access to services in proportion to their health needs; and
  - (ii) receive equitable levels of service; and
  - (iii) achieve equitable health outcomes:

We are very concerned, however, that there is no requirement for our 26 year-old medicines procurement agency to be bound by the objectives and principles of the Pae Ora Bill outlined above, and to be part of the 'modern, compassionate and responsive health system' the Government is seeking to create.

The principles and objectives are not reflected in Part 3, Subpart 1 – Pharmac, section 61, (1) (a), which leaves Pharmac's statutory objective with its dominant, narrow focus on cost saving quite unchanged. In fact Pharmac is expressly exempted from complying with the Pae Ora principles in Part 1, Section 7, (4) of the Bill.

This is inexplicable, and raises a number of concerns, summarised below, which we wish to bring to the attention of the Committee.

## **Key points**

### ***1. A modern medicines policy should be an integral feature of the new, high-performing health system envisaged by the Bill***

Medicines and medical technology are critical contributors to health and optimal health outcomes, as seen so clearly in the current Covid-19 pandemic.

The Pae Ora reforms are an opportunity to embrace and adopt the central features of an effective medicines policy that will contribute to optimising health outcomes, and get New Zealand into step with international best practice. Some key features of a modern medicines policy are as follows:

- It should be aligned with and supportive of the new health system's wider social wellbeing approach, including timeliness, speed and equity of access to modern medicines. But Part 1, Section 7, (4) exempts Pharmac from being concerned with these matters.
- Meaningful engagement and timely, genuine consultation with consumers should be hallmarks of the policy. But again Part 1, Section 7, (4) exempts Pharmac from this. Pharmac need only consult when it 'considers it appropriate to do so' (Part 3, Subpart 1 – Pharmac, section 63).
- Budget setting for medicines needs to bear a relationship to actual need (e.g. the 73 medicines currently sitting on Pharmac's options for investment list), and should also factor in social costs and benefits. But the Bill affirms in Part 3, Subpart 1 – Pharmac, section 61, (1) (a) that Pharmac must continue to secure medicines from within a fixed budget.

- The amount of funding for medicines as a proportion of health spending needs to be brought into line with comparable OECD countries. It should be determined by Health NZ as an appropriation in Vote: Health, allowing proper scrutiny of how resources are allocated among health services. This is not contemplated by the Bill.
- An effective medicines policy also needs to be forward-looking, assessing and planning for the new generation medicines and technologies that are on the horizon and actively attracting innovation to New Zealand. There is no scope for this in Pharmac’s statutory functions, in Part 3, Subpart 1 – Pharmac, section 62 (1).
- In carrying out its functions, Pharmac should be required to reflect the principles of Te Tiriti o Waitangi and address the need for greater equity of access to medicines for Māori. Its current narrow limitation to health considerations rather than the wider social and economic impacts of its decisions are likely to be impacting more heavily on people who are already disadvantaged in the health system, including Māori, Pasifika and disabled people.

Instead of seizing this opportunity to transform Pharmac into a responsive, modern medicines funding agency, the Bill as it stands cements the current anachronistic Pharmac model into the new legislative framework, appearing to run counter to the healthy futures for New Zealanders that the Bill is intended to achieve.

## **2. *Omitting Pharmac reforms from the Bill compounds the effects of excluding access to medicines from the Health and Disability System Review***

The scope of this major review noted that:

*‘The goal for the New Zealand Health and Disability System, as currently set out in legislation is that it is strong, effective and delivers equitable health outcomes for all New Zealanders. The Review will investigate where the system is not currently achieving this core equity goal, and understand the drivers of this (whether it be service delivery, or the broader social determinants of health).’*

It is hard to imagine how the Review could have performed this task without considering the role of access to medicines in wellbeing. But as its recommendations form the basis of the Pae Ora Bill, it is not surprising but most regrettable that this key issue was also omitted here.

**3. *The Bill should not proceed until the report of the Independent Pharmac Review Panel has been published***

CLLANZ, along with over 100 other submitters put a great deal of time in good faith into contributing to this review. We made a substantial submission [https://clladvocates.nz/wp-content/uploads/2021/08/CLLANZ\\_Submission-\\_to\\_Pharmac\\_Review\\_Panel-\\_160721.pdf](https://clladvocates.nz/wp-content/uploads/2021/08/CLLANZ_Submission-_to_Pharmac_Review_Panel-_160721.pdf) , attended and contributed to the Panel's workshop for patient advocacy groups, and CLLANZ Executive Director Dr Neil Graham, haematologist and Malaghan Institute Research Fellow Dr Rob Weinkove, and CLLANZ Trustee Dr Ben Schrader, all appeared before the Panel on behalf of CLLANZ to present the submission.

This was a serious and very considerable effort on the part of very busy, professional people volunteering their time, but was done because we had confidence that this review was to be taken seriously.

It is therefore insulting to all who took part that the Pae Ora legislation is advancing through the House with Pharmac's narrow objectives completely untouched and no regard at all to what the Review Panel may recommend.

**4. *The interim report of the Independent Pharmac Review Panel is further evidence that the Bill should not proceed until the final report is published.***

- Some time after submissions opened on the Pae Ora Bill the interim report of the Pharmac Review Panel was released (on 2 December). We understand the report had been sitting with the Minister of Health for several weeks prior to this, so presumably its findings could have been factored in to the development of the Bill. No explanation was given as to why this did not happen or for the timing of its release.
- We understand the final report, which will include recommendations, will be received by the Minister on 28 February, and released some time after that.
- Recommendations are expected to cover its governance arrangements and legislative requirements in terms of the new health system.
- As the Committee will know, the Panel reports that it could not make a meaningful analysis of Pharmac's performance as it 'zealously guards information' and has a 'fortress mentality'.
- Lack of data gave rise to comments like the following: "*We are unable to see and measure the links between inputs, impacts, outcomes, and the long-term objective of achieving the best health outcomes possible from its budget.*"

- Notwithstanding the withholding of data, the report paints a damning picture of Pharmac’s decision-making processes.
- For the sake of completeness we include the following summary from the message from the Panel Chair Sue Chetwin:

*‘Stakeholder engagement and an initial assessment of Pharmac decision-making processes show:*

- *Pharmac is underperforming in helping to remove inequitable health outcomes*
- *Its prioritisation approach appears to disadvantage Māori, Pacific people, disabled people and those with rare disorders*
- *Te Tiriti o Waitangi principles are largely unseen in decision-making processes*
- *There may be an excessive focus on containing costs - and a concern the cost-saving model may not be the right one to meet future health needs*
- *Decision making is opaque and is perceived as being slow*
- *Engagement with consumers and patient advocacy groups needs to be more meaningful*
- *Convoluting procurement processes put off pharmaceutical companies*
- *A perception New Zealand is falling behind other developed countries*

*The panel notes the health and disability reforms provide an opportunity for Pharmac to work in a more integrated way to contribute to better health outcomes for all New Zealanders.*

*In the next phase the panel will:*

- *Make recommendations following the observations made in this report to support Pharmac to become more effective*
- *Look at Pharmac’s legislative requirements in terms of the new health and disability system and the Pae Oranga Bill (Healthy Futures)*
- *Make recommendations on Pharmac’s governance arrangements*
- *Address outstanding aspects of the terms of reference*
- *Look further at funding for people with rare disorders*
- It is clear that the Panel’s recommendations are likely to suggest significant amendments to Pharmac’s statutory objectives and functions and these should inform the Committee’s work and be considered before the Bill moves from the select committee stage.

**5. In evaluating whether the role of Pharmac should be preserved as is or reformed in line with the principles of the Pae Ora Bill, we ask the Committee to consider and bear in mind the painful legacy of recent years of the countless patients and their loved ones who have battled for life-saving treatments but been beaten by the system.**

(1.) We ask you to note these brief facts from The Medicine Gap <https://themedicinegap.co.nz/>, a collective voice for the thousands of New Zealanders who need help to stay well or to stay alive:

*'In the last two years alone, New Zealanders have submitted 24 petitions to Parliament amassing over 400,000 signatures, seeking funding for a broad spectrum of lifesaving, life-transforming, or life-extending drugs.'*

*Many New Zealanders who try to effect change by advocating for help or medicines support from Pharmac or the Government do so at a very vulnerable time in their lives.*

*They, or their loved ones are often ill or trying to come to terms with a life-threatening or terminal diagnosis. Often, they are lone voices calling for change or help. Always, it is a David versus Goliath battle.'*

(2.) The following is a brief summary of a case study from our own experience, which illustrates many of the points raised in this submission.

- As noted in our introduction, CLLANZ together with clinicians and individual patients has made strenuous efforts in recent years to get help to get urgently needed medicines, to advocate for change, to engage with Pharmac, and to participate in any 'consultation' opportunities.
- In particular we have been advocating for a long-awaited and sorely needed medicine ([Ibrutinib](#)) for CLL patients with high unmet needs, that is standard of care in over 45 countries, is recommended treatment in current international guidelines, and has been approved in NZ for 6 years, but is still not funded.
- Our efforts have ranged from provision of information and extensive data through letters, emails, meetings with Pharmac, marches, petitions, and presentations to the Health Committee. But our experience has been that all of that effort including serious, very well-informed pleas from clinicians desperate to be able to offer this treatment to patients, has gone unheard and counted for nothing.

- Over six years of PTAC and CaTSOP committee meetings on ibrutinib there have been 20 widely vacillating outcomes, ranging from decline, medium, low, high, no decision and defer. See the record of this here [Appendix 1](#)
- In the end we can only assume that price is all that matters, and people die waiting, while Pharmac spends years waiting for the price to go down or cheaper options to appear.

## Recommendations

We submit that:

1. The current Pharmac model as enshrined in the Bill is no longer fit for purpose and is not achieving equitable, optimal health and wellbeing outcomes from medical treatments for New Zealanders.
2. Pharmac's current statutory objectives strictly confine the organisation to a narrow focus on cost containment which does not produce optimal outcomes and has multiple negative flow on impacts such as:
  - a. unnecessarily long delays in funding medicines
  - b. not improving equity of access to good health
  - c. limiting outcomes to what are 'reasonably' achievable, as opposed to the best achievable
  - d. not taking account of wider social costs and benefits
  - e. opaque decision-making processes that leave consumers with no certainty regarding medicines funding, and
  - f. rendering consumer consultation somewhat pointless.

The requirement to contain costs and manage resources in any event applies to all government health entities and does not need to be additionally spelled out for one particular entity.

3. The confines of the current statutory objective prevent Pharmac from moving with the times and adopting a responsive modern medicines strategy that has social wellbeing, timeliness, speed and equity of access at its heart, is genuinely consultative, is abreast of new generation medicines and technologies and is in step with international best practice.
4. The Bill inexplicably exempts Pharmac from complying with the Pae Ora principles, a critical feature of the new health system.

We recommend that:

5. Pharmac's statutory objectives in Part 3, Subpart 1 – Pharmac, section 61, (1) (a) be amended to remove the narrow focus on cost containment, by removing the words **'and from within the amount of funding provided'** and the word **'reasonably'**, and that an additional objective be added **'to achieve improved social wellbeing through timeliness, speed and equity of access to medicines for New Zealanders.'**
6. Pharmac's express exemption in Part 1, Section 7, (4) from complying with the Pae Ora principles be removed from the Bill.
7. To foster meaningful engagement and timely, genuine consultation with consumers, the words **'when it considers it appropriate to do so,'** be removed in 'Pharmac to consult in implementing objectives and performing functions' (Part 3, Subpart 1 – Pharmac, section 63).
8. Finalisation of the Committee's report back to the House of the sections of the Bill relating to the objectives and functions of Pharmac be deferred until after the final report of the Independent Pharmac Review Panel is received.

The Trustees

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