New Zealanders for HEALTH RESEARCH
Ngā Tāngata o Aotearoa mō te Rangahau Hauora

NZHR Submission on the PHARMAC Review

Introduction

New Zealanders for Health Research (NZHR) was established in November 2015 to bring about increased investment in health research from government, industry and philanthropy. We believe that health research saves and improve peoples' lives, and directly and indirectly contributes to New Zealand's economic prosperity. We are therefore committed to ensuring that health research is fully valued, that it is embedded as an essential component of New Zealand's health system, and there is a level of investment in health research which results in the best possible health, productivity and economic returns.

NZHR believes that PHARMAC, as an integral component of New Zealand's health system, should be strengthening its support for the country's health research and innovation ecosystem, and we welcome the PHARMAC review as an opportunity to recommend how this should occur.

NZHR recommendations

1. *PHARMAC takes steps to reduce the time it takes to assess, prioritise and fund new treatments so as to retain a sufficiently long on-patent period to avoid disincentivising company investment in clinical research*

2. *PHARMAC's decision making processes, its cost benefit model, and decisions themselves transparently take into account any impact on clinical research including clinical trials, and the flow on patient outcome improvements and cost savings that could result from such research*

3. *PHARMAC be required to actively engage with and positively respond to both the imperatives of the New Zealand Health Research Strategy and the emerging expectations of the wider research, science and innovation ecosystem*

4. *PHARMAC's analysis of therapies' costs and benefits to society is set out openly and transparently so that it can be held accountable for the quality of its decision making and enhance the prospects of more clinical research being translated into clinical practice*

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Background

The Government has determined to undertake a review of PHARMAC. The purpose of the Review and the recommendations it makes "are to ensure that New Zealanders can have confidence that PHARMAC makes the best contribution it can to improving health outcomes for all New Zealanders, particularly Māori and Pacific peoples, as part of the wider health and disability system".

According to its Terms of Reference[1] the Review will help to address the concerns some have about PHARMAC – especially in regards to funding of new expensive medicines for hitherto untreatable conditions – "while providing an opportunity to ensure PHARMAC is well-positioned to make the best contribution it can to future health needs given the rapidly changing global, societal and technological changes. The review will also be timely as it will be informed by government decisions around health system reforms and take these into account in considering the ongoing role of PHARMAC".

The Terms of Reference also state that this Review will help to ensure that the public can have confidence in the work of PHARMAC by investigating and making recommendations on two key issues:

1. How well PHARMAC performs against its current objectives and whether and how its performance against these could be improved.
2. Whether PHARMAC's current objectives (with emphasis on equity for Māori and Pacific peoples) maximise its potential to improve health outcomes for all New Zealanders as part of the wider health system, and whether and how these should be changed.

The Review will be undertaken by a panel comprising Sue Chetwin (Chair), Professor Sue Crengle, Dr Tristram Ingham, Frank McLaughlin, Heather Simpson, and Leanne Te Karu.

Mandate for PHARMAC involvement in health and medical research

PHARMAC should engage with New Zealand's health research and innovation ecosystem for the following reasons: it is legislatively required to do so; there are implied imperatives in New Zealand's Health Research Strategy; engagement is consistent with recent Productivity Commission recommendations; to demonstrate responsiveness to public expectations; and to contribute to translating results of medical research into clinical practice.

Legislative requirements

Although there is currently no requirement for health and medical research to be embedded within the health system generally, nor as yet any evidence that this will be a required component of the future reforming and reformed health system[2], NZHR notes

[1] Terms of Reference for the PHARMAC Review Committee (health.govt.nz)
[2] Our health and disability system: Building a stronger health and disability system that delivers for all New Zealanders. DPMC White Paper April 2021. https://dpmc.govt.nz/sites/default/files/2021-04/heallth-reform-white-paper-summary-apr21.pdf

that by way of contrast section 48 of the New Zealand Public Health and Disability (NZPHD) Act[3] requires PHARMAC to perform a range of functions including "to engage as it sees fit, but within its operational budget, in research to meet [its] objectives...". The PHARMAC Board Governance Manual[4] elaborates by affirming that "research is part of PHARMAC's role in gathering information on pharmaceuticals so as to make informed funding decisions. PHARMAC can also conduct, or partner with other organisations to conduct, research to determine whether steps are needed to address its statutory objective".

New Zealand Health Research Strategy (NZHRS) 2017 - 2027[5]

The NZHRS is a whole of government strategy which applies to the health system in its entirety, and all aspects of health and medical research. PHARMAC, as a Crown Entity and a significant component of the health system, is not exempt from the NZHRS, and NZHR draws particular attention to the following imperatives:

"A world-leading health research and innovation system has a vibrant research environment in the health sector. The health sector is a key part of New Zealand's national innovation system, performing research, generating knowledge and making the most of innovations. All levels of care… [including PHARMAC]… have a role to play in the health research and innovation system." NZHRS Strategic Priority 2, page 16; (NZHR's parentheses.)

"For health service agencies to achieve their objectives of improving health and reducing inequities, they need a strong evidence base. In turn, to achieve this evidence base, they need an environment and culture of enquiry and innovation with research integrated into health care systems and population health initiatives." NZHRS Strategic Priority 2, Action 5, page 16

"Clinical research in New Zealand could be strengthened by … improving the environment for clinical trials and promoting industry investment." NZHRS Strategic Priority 2, Action 6, page 17

"The Government will seek to increase the number of partnerships between industry … and health sector agencies…" NZHRS Strategic Priority 4, Action 9, page 23

Productivity Commission "Frontier Firms" report[6]

This report states that "District Health Boards (DHBs) are hugely important in New Zealand's health system, yet most are inactive in supporting healthtech innovation. As a result, opportunities for mutual benefits for the healthtech sector and for productivity and accessibility within the health system are being lost. The main reasons for lack of

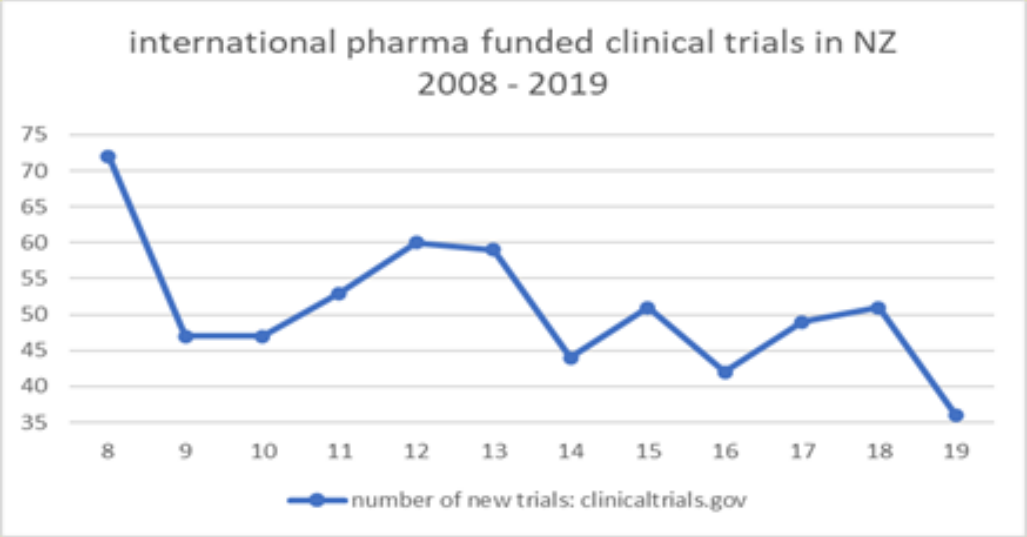
[3] New Zealand Public Health and Disability (NZPHD) Act. 2000. https://www.legislation.govt.nz/act/public/2000/0091/latest/DLM80051.html
[4] PHARMAC Board Governance Manual. 2019. https://pharmac.govt.nz/assets/2019-PHARMAC-Board-Governance-Manual.pdf
[5] New Zealand Health Research Strategy 2017 – 2027. June 2017. Ministry of Health and MBIE. https://www.health.govt.nz/system/files/documents/publications/nz-health-research-strategy-jun17.pdf
[6] New Zealand Productivity Commission. April 2021. New Zealand Firms: Reaching for the Frontier. Final report. https://www.productivity.govt.nz/assets/Documents/Final-report-Frontier-firms.pdf

support from DHBs are their lack of mandate and incentive to participate in innovation, the lack of targeted innovation funding, and rigidities in their procurement processes. Also, health policy provides no effective strategy on innovation and learning to guide DHBs.".

The report goes on to say that "Government should…improve the mandate, funding and incentives for DHBs to participate in the healthtech innovation ecosystem. This change would be to the mutual benefit of the healthtech sector, and the efficiency, effectiveness and accessibility of New Zealand's health and disability system".

Healthtech is defined by the Productivity Commission as including medical devices; digital health and IT products; and diagnostics and therapeutics. NZHR argues therefore that the Productivity Commission observations are also applicable to PHARMAC as another "hugely important" component of New Zealand's health system, and that as a government agency it too should be contributing to, rather than detracting from, funding and incentives for participation in the health innovation ecosystem.

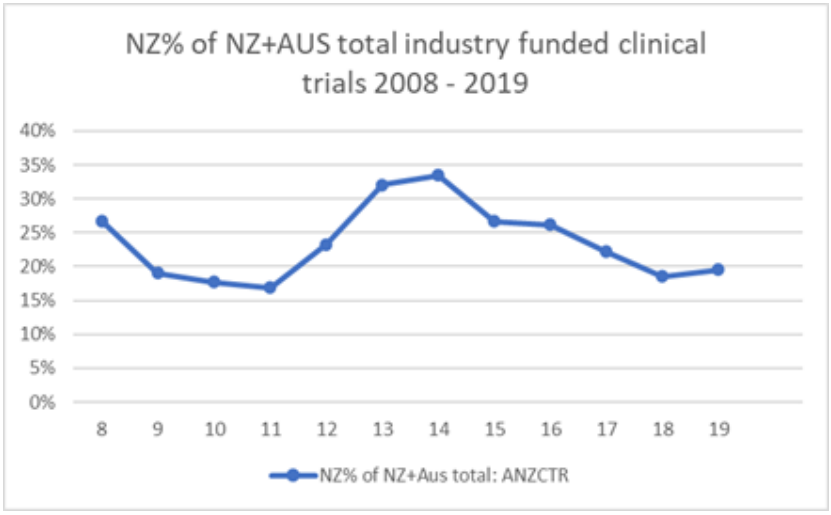
Yet NZHR's analysis of the USA clinical trials register[7] indicates that multinational pharmaceutical companies which operate in New Zealand have since at least 2008 been progressively excluding New Zealand locations as trial sites for international trials, as illustrated in the graph below.



New Zealand representatives of these companies have advised that this is at least in part attributable to PHARMAC's disincentivising purchasing and rationing practices. While NZHR fully appreciates the need for PHARMAC to purchase pharmaceuticals for the best possible price we also believe that PHARMAC should be transparently factoring the resulting loss of clinical research capability into its decision making and cost benefit analyses, and should also be seeking to identify how it can replace its disincentivising practices with alternative compensatory incentives to invest in clinical research.

Furthermore, New Zealand has been losing its share of the combined commercial Australia New Zealand clinical trials market, as illustrated on the following page.

[7] https://clinicaltrials.gov/



Public expectations

NZHR's opinion polling[8] consistently suggests a high level of public support for clinical trials, with the most recent 2020 poll[9] reporting that 71% of respondents agreed that it is important that New Zealanders are able to participate in clinical trials, 72% said they would be willing to participate in a clinical trial of a new medicine if they had a condition it might be able to treat, 65% agreed that there should be more opportunities for New Zealanders to participate in clinical trials for new medicines, and 62% agreed that participating in clinical trials for new medicines is as important as donating blood. Yet only 12% of respondents had ever been asked to participate in a clinical trial, and only 8% reported that they had ever actually participated. Furthermore, a separate investigation of cancer patients' experiences of clinical trials[10] reports that although 86% said that they would consider going on a clinical trial only 19% had done so.

Furthermore, clinical trials have direct health benefits for participating patients irrespective of the efficacy of the therapy under investigation, and financial benefits for participating hospitals[11].

PHARMAC's apparent disincentivisation of the carrying out of clinical trials clearly runs counter to public expectations, imperatives to deliver services consistent with best possible standards of care, and DHB's requirements to drive down costs.

Translating results of medical research into clinical practice

NZHR is frequently told by medical researchers of research that has been conducted in New Zealand and/or overseas which points to the efficacy of a therapy which is available in other countries but not in New Zealand. We are also aware from talking to health

[8] NZHR. New Zealand Speaks! Opinion polls 2017 - 2020
[9] NZHR. New Zealand Speaks! 2020 Kantar NZHR opinion poll. https://www.nz4healthresearch.org.nz/wp-content/uploads/2020/08/NZHR-Report-2020-GENERAL-EDITION-PRINT_newlogos-final.pdf
[10] Yeojeong J, Jameson M et al; Investigating strategies to improve clinical trial opportunities for patients with cancer in New Zealand— INSIGHT. NZMJ. 12th July 2019, Volume 132 Number 1498
[11] NZHR. Clinical Trials in New Zealand: a discussion paper. 2019. https://www.nz4healthresearch.org.nz/wp-content/uploads/2019/02/Clinical-trials-in-New-Zealand-NZHR-op-ed-130319-V2.pdf

consumer stakeholders of the negative life impacting consequences this has for those who are denied access to such treatments and their family/whanau.

NZHR also understands that such therapies can be sometimes very expensive and that PHARMAC engages in cost benefit analyses to assist in determining whether they should be funded. In the past PHARMAC has said that its cost benefit analyses are constrained by its legislation which only permits PHARMAC to consider cost benefits that may accrue to the health system. However PHARMAC's Operating Policies and Procedures[12] include as one of its factors for consideration "health related costs and savings…to the wider society".

Feedback from stakeholders suggest that the way in which PHARMAC arrives at its funding decisions lacks transparency, and it is difficult to understand how (or even whether) it takes into account savings to the wider society. NZHR believes that if its processes in this regard were to be more transparent there would be a greater likelihood of some therapies being funded to the benefit of its recipients, it would enable producers of such therapies to pitch their funding applications in a way that's consistent with PHARMAC's cost benefit expectations, and would enable consumer and clinician scrutiny and better understanding of PHARMAC's eventual decisions.

NZHR's response

NZHR's response addresses five out of ten of the Review's Terms of Reference which are of relevance to the extent to which PHARMAC's practices impact upon health and medical research, as follows:

Term of reference	NZHR's response
The timeliness of PHARMAC's funding decisions, including both: • the time taken to assess and prioritise treatments for funding; and • the time it takes for a treatment to be funded	The combined time it takes to assess, prioritise and fund new treatments often results in decisions being made which are very close to the expiry of the treatment's patent period. This acts as a disincentive for pharmaceutical companies to invest in clinical trials for such treatments as it makes it more difficult to recoup their R&D costs.
How transparent and accessible to the public PHARMAC's decision making processes are.	Decision making processes do not appear to be as transparent as they could be, especially in respect of whether and the extent to which there any detrimental flow on impacts on clinical research, and associated lost health outcome, cost saving and economic opportunities. Decision making also lacks transparency in respect of assessing the costs and benefits to society, potentially compromising the translation of research results into clinical practice and patient wellbeing
The model PHARMAC uses to assess benefits	Similarly, the model itself does not take into

[12] PHARMAC. Operating Policies and Procedures Manual 4th Ed. https://pharmac.govt.nz/medicine-funding-and-supply/the-funding-process/policies-manuals-and-processes/operating-policies-and-procedures/

Term of reference	NZHR's response
and costs that informs its decisions, whether it remains fit for purpose and consideration of alternative assessment models used internationally.	account of whether and the extent to which there any detrimental flow on impacts on clinical research, and associated lost health outcome, cost saving and economic opportunities
Whether decisions taken by PHARMAC adequately consider impacts on other parts of the health system	Again similarly, the decisions taken by Pharmac do not adequately consider whether and the extent to which there any detrimental flow on impacts on clinical research, and associated lost health outcome, cost saving and economic opportunities
How effectively PHARMAC collaborates with other health sector agencies (including the Ministry of Health, DHBs, PHOs and others) to improve health outcomes and implement government policy, and PHARMAC's role alongside these in the wider health system.	It appears as though PHARMAC has been permitted to be siloed off from the rest of the health system (it is barely referenced in the report of the Health and Disability System Review[13], and not featured in the health system diagram in the subsequent health reforms White Paper)[14]. NZHR believes PHARMAC should be engaging with both the rest of the health system and the wider research, science and innovation ecosystem to ensure that is both benefitting from and maximising the contribution it can make to the development of New Zealand's clinical research capacity and capability.

Recommendations

NZHR recommends that:

PHARMAC takes steps to reduce the time it takes to assess, prioritise and fund new treatments so as to retain a sufficiently long on-patent period to avoid disincentivising company investment in clinical research

PHARMAC's decision making processes, its cost benefit model, and decision's themselves transparently take into account any impact on clinical research including clinical trials, and the flow on patient outcome and cost savings that could result from such research

PHARMAC be required to actively engage with and positively respond to both the imperatives of the New Zealand Health Research Strategy and the emerging expectations of the wider research, science and innovation ecosystem

PHARMAC's analysis of therapies' costs and benefits to society is set out openly and transparently so that it can be held accountable for the quality of its decision making and enhance the prospects of more clinical research being translated into clinical practice

[13] Health and Disability Systems Review. Final Report / Pūrongo whakamutunga. 2020. https://systemreview.health.govt.nz/assets/Uploads/hdsr/health-disability-system-review-final-report.pdf
[14] Our health and disability system: Building a stronger health and disability system that delivers for all New Zealanders. DPMC White Paper April 2021. https://dpmc.govt.nz/sites/default/files/2021-04/heallth-reform-white-paper-summary-apr21.pdf

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NZHR constituency

In developing this submission NZHR has consulted with its partners and members as set out below (and from whom we derive 100% of our funding).

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16th July 2021

NZHR partners and members

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