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The Royal Australasian College of Physicians' submission to the Ministry of Health

Provide your feedback on the PHARMAC review

Hōngongoi 2021

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to submit feedback to the Ministry of Health on the review of PHARMAC (the Review).

The RACP works across more than 40 medical specialties to educate, innovate and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society. By working together, our members advance the interest of our profession, our patients and the broader community.

Consultation Questions

1. What is your understanding of what PHARMAC does?

PHARMAC's objective, as outlined in statute, is to secure for eligible people in need of pharmaceuticals, the *best health outcomes* that are reasonably achievable from pharmaceutical treatment, from within the amount of funding provided[1].

Practically, PHARMAC's primary role is in the management of the pharmaceutical schedule – a list of publicly subsidised pharmaceuticals, sourced from within PHARMAC's fixed budget[2]. In the development of this list, PHARMAC is unique internationally, as it manages all aspects of decision making in the assessment and listing of publicly subsidised medicines, alongside negotiating prices with suppliers within its capped budget. As such, it is reliant upon the government of the day, in determining its capability.

Due to PHARMAC's success in constraining costs for pharmaceuticals, its remit has expanded over the years of its operation. In 2001, assessments and funding decisions associated with cancer drugs began to be overseen by PHARMAC, followed by national contracting for the influenza vaccine[3]. PHARMAC undertook the wider management of the national immunisation schedule in 2012, and in 2013 the management of hospital medical devices was added to its remit[4]. While District Health Board's (DHBs) retain the autonomy to decide the specific hospital medical devices to be used in their services, these devices are selected from a national medical devices list, maintained by PHARMAC.

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

Generally, the RACP as an organisation has had a productive working relationship and dialogue with PHARMAC. The College has been a regular submitter to PHARMAC consultations on a variety of pharmaceuticals and medical devices, as well as regulations overseen by the Agency. Despite this, the RACP has recently expressed areas of significant concern regarding PHARMAC's

[1] New Zealand Government. New Zealand Public Health and Disability Act [Internet]. Wellington: New Zealand Government; 2000. Accessed 12 July 2021. Available from: https://www.legislation.govt.nz/act/public/2000/0091/latest/whole.html#DLM80878.
[2] Gauld R. Ahead of Its Time? Reflecting on New Zealand's Pharmac Following Its 20th Anniversary. Pharmacoecon Open [Internet]. 2014; 32(10): 937-942. Accessed 12 July 2021. Available from: https://pubmed.ncbi.nlm.nih.gov/24906479/.
[3] PHARMAC. History of Pharmac [Internet]. Wellington: PHARMAC; 2021. Accessed 12 July 2021. Available from: https://pharmac.govt.nz/about/what-we-do/pharmac-history/.
[4] PHARMAC. Growing our role in medical devices [Internet]. Wellington: PHARMAC; 2020. Accessed 12 July 2021. Available from: https://pharmac.govt.nz/hospital-devices/about-our-role-in-device-management/.

commitment to equity. For example, the RACP's 2020 submission on the Funding of Type 2 Diabetes Medicines explored failings in the proposal to address persistent inequities of access across Aotearoa NZ[5]. We have also identified PHARMAC's lack of commitment to its bold goal of eliminating inequities in access to a selection of medicines as problematic[6].

The RACP believes that PHARMAC must take a prominent leadership role in realising health equity in Aotearoa NZ, and as such, further commitment is required.

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

A model focused on efficiency within a fixed budget inevitably trends towards supporting major societal groups. As a consequence, these models will tend to cater less well, if at all to the rights of marginalised and overburdened communities. For PHARMAC, this has manifested in a system where Māori and Pacific people, people with fewer resources, and people with rare disorders face challenges in accessing medicines, over and above existing barriers to accessing diagnostic and primary health care services[7] [8]. This is discussed further in response to consultation question five.

The substitution of generic pharmaceuticals, in pursuit of cost efficiency benefits, has also been controversial. Whānau have reported that generic substitutions have harmed their health, across conditions such as epilepsy, and depression[9] [10]. Negative perceptions from pharmacists, both of generic medicines and of PHARMAC's strategies for the communication of generic substitutions, have also been found. Over two-thirds of pharmacists responding to a study, reported that they were unsatisfied with the brand change information provided, with concerns about quality prominently featured[11].

More widely, PHARMAC's model does not provide timely access to some clinically effective drugs. Effective medicines, available in other comparable countries, may not become available in Aotearoa NZ for some time, due to concerns over their impact on PHARMAC's budget, or the availability of other, less effective medicines in their area[12]. Harm due to lack of medicine availability has been

[5] The Royal Australasian College of Physicians. The Royal Australasian College of Physicians' submission to PHARMAC Funding of Type 2 Diabetes Medicines [Internet]. Wellington: The Royal Australasian College of Physicians; 2020. Accessed 12 July 2021. Available from: https://www.racp.edu.au//docs/default-source/advocacy-library/racp-pharmac-submission-funding-of-type-2-diabetes.pdf?sfvrsn=498ef41a_8.
[6] The Royal Australasian College of Physicians. The Royal Australasian College of Physicians' submission to PHARMAC Changes to Advisory Committees [Internet]. Wellington: The Royal Australasian College of Physicians; 2021. Accessed 12 July 2021. Available from: https://www.racp.edu.au//docs/default-source/advocacy-library/racp-submission-to-pharmac-changes-to-advisory-committees.pdf?sfvrsn=197bfc1a_4.
[7] Babaar S B, Francis S. Identifying priority medicines policy issues for New Zealand: a general inductive study. BMJ Open [Internet]. 2014; 4. Accessed 12 July 2021. Available from: https://bmjopen.bmj.com/content/4/5/e004415.
[8] Health Quality & Safety Commission. Health service access: key findings 2019 [Internet]. Wellington: Health Quality & Safety Commission; 2019. Accessed 12 July 2021. Available from: https://www.hqsc.govt.nz/assets/Health-Quality-Evaluation/Atlas/Health-service-access/Atlas_Healthcare_Service_Use_Infographic_20200608.pdf.
[9] Espiner G. Epilepsy medication switch may have contributed to deaths – neurologist [Internet]. Wellington: RNZ; 2021. Accessed 12 July 2021. Available from: https://www.rnz.co.nz/news/national/437659/epilepsy-medication-switch-may-have-contributed-to-deaths-neurologist.
[10] Maude S. Anti-depressant swap: Sufferers claim generic drug is harming their condition [Internet]. Wellington: Stuff; 2018. Accessed 12 July 2021. Available from: https://www.stuff.co.nz/national/health/101628317/antidepressant-swap-sufferers-claim-generic-drug-is-harming-their-condition.
[11] Babar Z U, Polwin A, Kan S W Amerasinghe S, McCarthy S, et al. Exploring pharmacists' opinions regarding PHARMAC's interventions in promoting brand changes. Res Social Adm Pharm [Internet]. 2015; 11(1): 96-110. Accessed 12 July 2021. Available from: https://www.sciencedirect.com/science/article/abs/pii/S1551741114000357.
[12] Cumming J, Mays N, Daubé J. How New Zealand has contained expenditure on drugs. BMJ [Internet]. 2010. Accessed 12 July 2021. Available from: https://pubmed.ncbi.nlm.nih.gov/20483927/.

highlighted by organisations such as the Diabetes Foundation Aotearoa, Breast Cancer Foundation NZ, and others, in submissions to PHARMAC[13] [14].

While we agree that there are clear benefits to PHARMAC's fiscally prudent model, there are aspects of cost which fall unevenly and inequitably. PHARMAC engages with global corporations whose terms, influences and motivations may sit at odds to those of a national pharmaceutical procurement agency. Further, the costs to whānau unable to access medicines which could significantly improve quality of life, social connection and productivity are under-calculated or analysed.

PHARMAC is also reliant on the government of the day, as its level of resource is determined through the annual budget process. While PHARMAC is generally identified as an apolitical agency which benefits from a relative national consensus of non-interference, when viewed in context, this is not true. In recent years this has become more prominent, with parties pledging to increase funding in specific areas, with the aim of garnering further political support[15]. This contributes to a climate in which PHARMAC is reliant upon the government of the day and expected to negotiate with corporations of a far larger scale, to achieve *the best health outcomes*.

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

The effectiveness of PHARMAC's assessment methods and negotiation tactics in constraining the cost of pharmaceuticals has been widely recognised. This perception is consistent across key informants in Aotearoa NZ throughout the medical sector, politics, and other relevant areas. The RACP agrees that cost management is the key benefit of PHARMAC's current approach[16].

Comparatively, it has been estimated that if Australia could achieve the same prices for pharmaceuticals as PHARMAC has achieved in Aotearoa NZ, savings of up to $A1.7 billion a year could be realised[17]. This, when viewed in context with significant increases in prescriptions per capita, illustrates the achievements of PHARMAC's model.

Cost is interpreted narrowly as financial expenditure only. PHARMAC's purpose, as set out in legislation, states its ambit is contracting and procuring pharmaceuticals (and medical devices) for the best health outcomes. Improved health outcomes implies a holistic interpretation incorporating physical, social/familial, mental/emotional, and spiritual/cultural dimensions of health and wellbeing.

[13] Scoop. NZ's Slow Medicine Uptake Leads To 800 Diabetes Deaths Each Year [Internet]. Auckland: Diabetes Foundation Aotearoa; 2020. Accessed 12 July 2021. Available from: https://www.scoop.co.nz/stories/GE2006/S00103/nzs-slow-medicine-uptake-leads-to-800-diabetes-deaths-each-year.htm.
[14] Breast Cancer Foundation NZ. Are we falling behind Australia in terms of access to new cancer drugs? Our reply to PHARMAC's report [Internet]. Auckland: Breast Cancer Foundation NZ; 2021. Accessed 12 July 2021. Available from: https://www.breastcancerfoundation.org.nz/news-articles/article/are-we-falling-behind-australia-in-terms-of-access-to-new-cancer-drugs-our-reply-to-pharmac-s-report/5.
[15] Scoop. Better Funding For PHARMAC [Internet]. Wellington: New Zealand National Party; 2020. Accessed 12 July 2021. Available from: https://www.scoop.co.nz/stories/PA2009/S00140/better-funding-for-pharmac.htm.
[16] Ragupathy R, Tordoff J, Norris P, Reith D. Key informants' perceptions of how PHARMAC operates in New Zealand. Int J Technol Assess Health Care [Internet]. 2012; 28(4): 367-373. Accessed 12 July 2021. Available from: https://pubmed.ncbi.nlm.nih.gov/23062515/.
[17] Wilkinson B. Pharmac: The Right Prescription? [Internet]. Wellington: The New Zealand Initiative; 2020. Accessed 12 July 2021. Available from: https://www.nzinitiative.org.nz/reports-and-media/reports/pharmac-the-right-prescription/.

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

Barriers to accessing medicines and devices in Aotearoa NZ come in many forms. By design, PHARMAC's model bars access to clinically effective medicines available in other parts of the world, either due to process, negotiations with pharmaceutical companies and their subsidiaries or an identification that funding is not cost effective in the context of PHARMAC's limited budget.

Despite subsidies for medicines, cost is a barrier to access for whānau in Aotearoa NZ. The main barrier to accessing prescriptions, is through appointment costs[18]. 17 per cent of respondents to a Health Quality and Safety Commission survey reported that they had not visited a general practitioner or nurse in the past 12 months, due to cost. Costs due to travel are a compounding factor, with particular impacts upon access to healthcare for children[19]. Ultimately, subsidies that reduce the cost of prescription medicines cannot have their intended effect if appointments with healthcare practitioners are inaccessible, or if the structural and institutional racism built into our health system is enabled to continue. Material disadvantage results, with Māori and Pasifika receiving fewer prescriptions overall[20].

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

Due to PHARMAC's design, and the comparative benefits it delivers with on cost, it is difficult to assess whether systems used overseas, which deliver better outcomes in some areas, are applicable to Aotearoa NZ. Furthermore, this consideration relies on the context of the wider health system, including comparisons between user pays and insurance schemes, against our current public health system model.

The Scottish Medicines Consortium

PHARMAC is unique in its multiple roles as funder, negotiator and evaluator (insofar as clinical evidence is applied to a case for funding) for medicines and devices. Other countries, including those frequently-cited "comparator countries" of the United Kingdom, Australia and Canada have separated these roles; most notably resourcing and funding, from supply negotiations and clinical evidence assessment.

The Scottish Medicines Consortium (SMC) offers a multidisciplinary model incorporating many forms of expertise, including clinical, pharmacological, health economics, industry and lived experience. The SMC is situated within Healthcare Improvement Scotland and this organisational framing supports the goals of continuous quality improvement and innovation while providing advice on the efficacy and patient benefits of new or existing pharmaceuticals[21].

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[18] Health Quality & Safety Commission. New data shows cost as the main barrier to accessing health services [Internet]. Wellington: Health Quality and Safety Commission; 2019. Accessed 12 July 2021. Available from: https://www.hqsc.govt.nz/our-programmes/health-quality-evaluation/news-and-events/news/3786/.

[19] Bidwell S. Improving access to primary health care for children and youth: a review of the literature for the Canterbury Clinical network Child and Youth Workstream [Internet]. Christchurch: Canterbury District Health Board; 2013. Accessed 12 July 2021. Available from: https://www.cph.co.nz/wp-content/uploads/accessprimarycarechildrenyouth.pdf.

[20] Mauri Ora Associates. He Ritenga Whakaaro:
Māori experiences of health services [Internet]. Auckland: Mauri Ora Associates; 2016. Accessed 12 July 2021. Available from: https://members.mauriora.co.nz/wp-content/uploads/2016/04/He_Ritenga_Whakaaro-1-13-17-23.pdf.

[21] Scottish Medicines Consortium. A guide to the Scottish Medicines Consortium. Glasgow: Health Improvement Scotland, Scottish Medicines Consortium; 2018. Available from https://www.scottishmedicines.org.uk/media/3574/20180712-a-guide-to-the-scottish-medicines-consortium.pdf. Accessed 13 July 2021.

The New Drugs Committee's (NDC) rapid review of available clinical and efficacy data, which supports SMC decision-making, is a mechanism which can disrupt the established, yet often protracted, model of efficacy assessment applied in public health systems worldwide. The NDC assessment is undertaken in around 18 weeks and can reduce the time between the submission of an application and guideline publication for some medicines, although cancer medicines are a notable exception[22].

The SMC's horizon scanning role should be explored for its applicability to PHARMAC[23]. While all organisations should engage in prudent horizon scanning as part of its planning process, SMC engages directly with the Health Board level to support improved budgetary and fiscal responsibility, clinician and Board engagement, planning and ultimately population outcomes. This model could significantly improve connections and transparency between clinical leadership, PHARMAC and the pharmaceutical industry.

Rare diseases

It has been comprehensively shown that PHARMAC funds a small diversity of drugs for rarer conditions, in comparison to other nations. In the case of cancer drugs, studies show that PHARMAC funded 25 per cent of studied drugs, with Canada funding 54 per cent, and the US, Finland, France, Germany and Sweden all funding over 90 per cent[24]. This is endemic to the design of PHARMAC, due to the extensive Health Technology Assessment process required, and the need to demonstrate a cost-benefit that outweighs the impact of the drug in question on PHARMAC's fixed budget[25]. Indeed, even in the evaluation of the Request for Proposal (RFP) process, which was intended to improve funded access to medicines for rare disorders, it was noted that had funds allocated through this process been spent in PHARMAC's standard schedule funding application pathway, greater benefits could have been achieved[26]. Following this, the RFP process was disestablished, and replaced with a new principles-based approach, which has consistently been met with dissatisfaction from stakeholders within a broad range of healthcare and policy institutions[7]. This demonstrates the fundamental trade-offs within PHARMAC's design.

Alternative approaches proposed overseas place greater emphasis on equitable treatment for all[27]. Economic analysis based on the principle that in the absence of alternative treatment, patients with life-threatening diseases should receive therapy irrespective of cost, are at the heart of this approach. While Aotearoa NZ is a small nation that may not have the liberty of employing a principle such as this in many cases, further consideration of the ethical issues inherent in denying funding for needed medicines could be further integrated into PHARMAC's processes.

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[22] Ford JA, Waugh N, Sharma P, Schulper M, Walker A. NICE guidance: a comparative study of the introduction of the single technology appraisal process and comparison with guidance from the Scottish Medicines Consortium. BMJ Open [Internet]. 2012; 30(2): e000671. Available from https://pubmed.ncbi.nlm.nih.gov/22290398/. Accessed 13 July 2021

[23] Scottish Medicines Consortium. Horizon scanning. [Internet]. Glasgow: Healthcare Improvement Scotland; Scottish Medicines Consortium; not dated. Available from https://www.scottishmedicines.org.uk/about-us/horizon-scanning/. Accessed 13 July 2021.

[24] Cheema, P., S. Gavura, M. Migus, B. Godman, L. Yeung, M. Trudeau. International Variability in the Reimbursement of Cancer Drugs by Publicly Funded Drug Programs. Curr Oncol [Internet]. 2012; 19(3): 165–176. Accessed 12 July 2021. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3364777/.

[25] Kelley L T, Tenbensel T, Johnson A. Ontario and New Zealand Pharmaceuticals: Cost and Coverage. Healthc Policy [Internet]. 2018; 13(4): 23-34. Accessed 12 July 2021. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6044260/.

[26] Grant Thornton. Evaluation of PHARMAC's commercial approach to fund medicines for rare disorders [Internet]. Auckland: Grant Thornton; 2017. Accessed 12 July 2021. Available from: https://pharmac.govt.nz/assets/2017-06-final-Grant-Thornton-evaluation.pdf.

[27] Panju A H, Bell C M. Policy alternatives for treatments for rare diseases. CMAJ [Internet]. 2010; 183(17): 787-792. Accessed 12 July 2021. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2988562/.

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

Our College wants to see whānau and communities with a greater understanding of PHARMAC's role, and the context in which PHARMAC operates. The COVID-19 pandemic could be a catalyst to relate these narratives: there is a greater level of public familiarity with the language of infectious diseases, vaccines, and public health measures. The roles played by globalised pharmaceutical companies, notably those that have successfully patented vaccines, and recorded significant profits and growth in share prices, should be openly and transparently reported, to generate increased public discourse and engagement[28] [29].

The profit-driven ethos of pharmaceutical corporates cannot be reconciled easily with PHARMAC's goals of providing safe, quality and affordable medicines to whānau and communities – equitable socialised medicine. PHARMAC negotiates on behalf of Aotearoa NZ with powerful companies in a globalised market using a finite purse of public funding. How these corporates harness political economy, intellectual property and global trade – and its impact on PHARMAC's responsibility to get the best health outcomes should be communicated to the public.

In the future, PHARMAC should become a more transparent and responsive organisation. Despite the comparative advantages of PHARMAC's operations to this point, large proportions of the health sector in Aotearoa NZ identified budget as its first concern in funding medicines, at the cost of improvements in other areas[30]. Organisations such as the Cancer Society have criticised PHARMAC for a lack of transparency, and that because of this, patients are not getting what they need[31]. While PHARMAC has made changes to increase transparency such as removing open applications that are unlikely to be funded, the organisation continues to be shrouded in a degree of distance that is problematic[32].

PHARMAC needs to improve the way in which it interacts with actors in our health system, including prescribers, pharmacies, researchers, whānau and communities.

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

Our members have expressed concern over the position of child-centred clinicians, and PHARMAC's responsiveness to their need for medicines applicable to the paediatric age range.

Recent proposals by PHARMAC to end an exemption which guaranteed children with cancer access to drugs needed for treatment have been criticised by both the Children's Commissioner and

[28] Savage L. The pandemic will continue until we break pharma's monopoly and end vaccine apartheid. Jacobin [Internet] 13 July 2021. Available from https://www.jacobinmag.com/2021/07/pandemic-covid-vaccine-distribution-big-pharma-apartheid-corporate-profits-2078. Accessed 14 July 2021.
[29] Helmore E. Pfizer pushes for US booster shots as WHO says greed is driving vaccine disparities. The Guardian [Internet]. 12 July 2021. Available from https://www.theguardian.com/world/2021/jul/12/coronavirus-pfizer-booster-vaccine-who-disparities. Accessed 14 July 2021.
[30] Babar Z U D, Ali A, Kim C, Mcintosh J, Namdas M S, et al. Access to subsidised medicines, cost of medicines and health outcomes: exploring general practitioners' perceptions and experiences. J Pharm Policy Pract [Internet]. 2015; 8. Accessed 12 July 2021. Available from: https://joppp.biomedcentral.com/track/pdf/10.1186/2052-3211-8-S1-O6.pdf.
[31] 1 News. Cancer Society critical of Pharmac saying they 'lack accountability, lack transparency, are slow' [Internet]. Auckland: 1 News; 2019. Accessed 12 July 2021. Available from: https://www.tvnz.co.nz/one-news/new-zealand/cancer-society-critical-pharmac-saying-they-lack-accountability-transparency-slow.
[32] Bennett L. Pharmac changes funding processes for greater transparency [Internet]. Auckland: New Zealand Herald; 2019. Accessed 12 July 2021. Available from: https://www.nzherald.co.nz/nz/pharmac-changes-funding-processes-for-greater-transparency/V5QZGWSIUQGGYKGYI4EJRAU444/.

leading cancer experts, leading to questions over PHARMAC's approach[33] [34]. The lack of a Pharmacology and Therapeutics Advisory Committee (PTAC) sub-committee dedicated to paediatrics reinforces this perception[35]. To improve responsiveness, and in conjunction with other reforms to the manner of PHARMAC's operation, the establishment of either a committee dedicated to paediatrics, or a guarantee of paediatric positions through other committees, should be considered.

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

The New Zealand Health and Disability System Review determined that to improve outcomes, we need to ensure consumers, whānau and communities are the heart of our health system. PHARMAC focuses on the management of budget as its first priority, over whānau wellbeing. As such, if PHARMAC is to embody this ethic, reorientation is required.

Centralisation of DHB's, and the creation of a single overarching national agency, Health NZ, will present a new challenge for PHARMAC[36]. A single point of action, responsible for the planning and commissioning of services, is likely to reduce fragmentation and provide more consistency throughout Aotearoa NZ. For PHARMAC, this may mean a greater deal of reliability in planning, and further guarantees on economies of scale for funded medicines.

Establishment of the Māori Health Authority, and the justifications given for its commissioning authority, may have implications for PHARMAC's place in the health and disability system[37]. PHARMAC, in its current form, is not conducive to self-determination for whānau Māori. As it holds sole funding assessment power, it can close the door to any medication, even those considered to be desirable for the improvement of health outcomes for Māori. In the future, this may hamstring the ability of the Māori Health Authority by removing its ability to bring to Māori truly appropriate care, and the medicines needed to live long and healthy lives. In a new look health and disability system, power should be shared, and that means that PHARMAC must change.

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

In a world where Māori and Pacific people are still two to three times more likely to die of conditions that could have been avoided if effective and timely health care had been available, an unreformed PHARMAC fundamentally cannot be reflective of the principles of Te Tiriti o Waitangi, because its model, policies and practices were never designed to be[38].

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[33] Espiner G. 'Intimidating' Pharmac move may lead to child cancer drug delays [Internet]. Wellington: RNZ; 2021. Accessed 12 July 2021. Available from: https://www.rnz.co.nz/news/national/441940/intimidating-pharmac-move-may-lead-to-child-cancer-drug-delays.

[34] Espiner G. Don't play sick children off against each other - Children's Commissioner tells Pharmac. Wellington: RNZ; 2021. Accessed 12 July 2021. Available from: https://www.rnz.co.nz/news/national/441704/don-t-play-sick-children-off-against-each-other-children-s-commissioner-tells-pharmac.

[35] PHARMAC. PTAC Subcommittees [Internet]. Wellington: PHARMAC; 2021. Accessed 12 July 2021. Available from: https://pharmac.govt.nz/about/expert-advice/ptac-subcommittees/.

[36] Department of Prime Minister and Cabinet. The new health system [Internet]. Wellington: Department of Prime Minister and Cabinet; 2021. Accessed 12 July 2021. Available from: https://dpmc.govt.nz/our-business-units/transition-unit/response-health-and-disability-system-review/information.

[37] Kerr F. Self-determination at the heart of new Māori Health Authority [Internet]. Wellington: Stuff; 2021. Accessed 12 July 2021. Available from: https://www.stuff.co.nz/pou-tiaki/300282517/selfdetermination-at-the-heart-of-new-mori-health-authority.

[38] Ministry of Health. Health and Independence Report 2016 [Internet]. Wellington: Ministry of Health; 2016. Accessed 12 July 2021. Available from: https://www.health.govt.nz/publication/health-and-independence-report-2016.

PHARMAC has previously acknowledged that not all New Zealanders are achieving 'best health outcomes' from medicines funded[39]. We agree with PHARMAC's conclusion that the social determinants of health, structural and system-level barriers lead to inequitable health outcomes across the population.

Structural barriers impacting PHARMAC's ability to reflect the principles of Te Tiriti include medicines funding not keeping pace with health spending, the undercounting of social costs and benefits in funding decisions, decision making on budget setting being unclear, and the slow nature of current funding appraisal processes[40]. These factors are compounded for Māori, who are already systematically disadvantaged throughout the Aotearoa NZ health system, as found both in the Waitangi Tribunal's *Hauora* report, and the New Zealand Health and Disability System Review[41] [42]. Embodiment of Te Tiriti means the facilitation of tino rangatiratanga and mana motuhake for Māori, which is largely incompatible with how PHARMAC operates in the current environment, due to its place as the sole decision-maker and negotiator for medicines and related products in Aotearoa New Zealand[43].

11. How can PHARMAC achieve more equitable outcomes?

The route that PHARMAC takes to achieve more equitable outcomes is dependent on perspective. If the outlook taken is to achieve more equitable outcomes within PHARMAC's current model, addressing medicines access equity with strident action is key. Renewed commitment to the goal of eliminating inequities in access to medicines by 2025 should drive PHARMAC's planning and actions in the years to come. Many of the key barriers faced are outlined in PHARMAC's document *Achieving Medicine Access Equity in Aotearoa New Zealand – Towards a Theory of Change*, but they need commitment from the organisation, and from the wider health system to their achievement. However, this cannot alter that fundamentally, PHARMAC holds a role as the sole decision-maker and negotiator for medicines and related products in Aotearoa NZ, which is incompatible with a true reflection of mana motuhake and tino rangatiratanga for Māori.

An alternative perspective that aims to truly reconcile the way medicines and medical devices are funded in Aotearoa NZ, would involve the reconstitution of PHARMAC through a model which truly reflects co-governance, and autonomous decision-making by Māori, for Māori. This is not without precedent, with the recent establishment of the Māori Health Authority and its power to autonomously commission services providing a practical example[37]. However, a model such as this may compromise the comparative advantages of PHARMAC's model as previously discussed, through the shedding of its role as the sole arbiter of pharmaceutical funding and approvals in Aotearoa New Zealand.

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[39] PHARMAC. Achieving Medicine Access Equity In Aotearoa New Zealand Towards A Theory Of Change [Internet]. Wellington: PHARMAC; 2019. Accessed 12 July 2021. Available from: https://pharmac.govt.nz/assets/achieving-medicine-access-equity-in-aotearoa-new-zealand-towards-a-theory-of-change.pdf.

[40] Krieble T. A new generation medicines policy Improved access and equity for New Zealanders NZIER report to Medicines New Zealand [Internet]. Wellington: NZIER; 2020. Accessed 12 July 2021. Available from: https://nzier.org.nz/publication/a-new-generation-medicines-policy-improved-access-and-equity-for-new-zealanders.

[41] Waitangi Tribunal. *Hauora* Report on Stage One of the Health Services and Outcomes Kaupapa Inquiry [Internet]. Wellington: Waitangi Tribunal; 2019. Accessed 12 July 2021. Available from: https://forms.justice.govt.nz/search/Documents/WT/wt_DOC_152801817/Hauora%20W.pdf.

[42] New Zealand Health and Disability System Review. Final report / Pūrongo whakamutunga [Internet]. Wellington: New Zealand Government; 2020. Accessed 12 July 2021. Available from: https://systemreview.health.govt.nz/final-report/download-the-final-report/.

[43] PHARMAC. About [Internet]. Wellington: PHARMAC; 2021. Accessed 12 July 2021. Available from: https://pharmac.govt.nz/about/.

Conclusion

The RACP thanks the Ministry of Health for the opportunity to provide feedback on this consultation. To discuss this submission further, please contact the RACP's Aotearoa NZ Policy and Advocacy Unit at policy@racp.org.nz.

Nāku noa, nā

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