HEALTH

PHARMAC

The right prescription?

Bryce Wilkinson
Foreword by Timothy Hanlon

THE NEW ZEALAND INITIATIVE

Published by
The New Zealand Initiative
PO Box 10147
Wellington 6143
New Zealand
www.nzinitiative.org.nz

ISBN
978-0-9951208-8-4 (print)
978-0-9951208-9-1 (online)

RR59

Designed by Angela Whitney,
www.angelawhitney.com

Printing arranged by True North New Zealand Ltd

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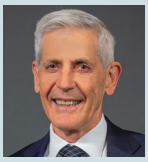
About the New Zealand Initiative

The New Zealand Initiative is an independent public policy think tank supported by chief executives of major New Zealand businesses. We believe in evidence-based policy and are committed to developing policies that work for all New Zealanders.

Our mission is to help build a better, stronger New Zealand. We are taking the initiative to promote a prosperous, free and fair society with a competitive, open and dynamic economy. We are developing and contributing bold ideas that will have a profound, positive and long-term impact.

ABOUT THE AUTHOR



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ACKNOWLEDGEMENTS

The author acknowledges and thanks all those who have generously assisted with this research and the preparation of this report. In particular he thanks Dr Oliver Hartwich, Dr Eric Crampton, Aimee Bourke, Alison Cossar, Bronwyn Croxson, Sarah Fitt, Dr Timothy Hanlon, Dr Graeme Jarvis, David Moore, Samuel Rees-Thomas, Roger Styles, Carston Schousboe and Lisa Williams. The author is solely responsible for the opinions expressed in this report and any errors and omissions.

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Foreword

Before leaving my role as a clinical director at one of London's largest academic health care organisations, I was at a meeting with a senior director at the UK Department of Health. When he heard that I was moving to New Zealand, he commented on his fascination with the model that is the New Zealand Pharmaceutical Management Agency (Pharmac) and its considerable success at keeping the list price of medicines well below the average paid in many other OECD nations. He commented that, of course, it is possible to do 'these things' (meaning control prices) in a smaller economy – and then continued on with the business we had set out to discuss. That comment, which was almost an aside, piqued my interest in Pharmac considerably.

Since arriving in New Zealand a couple of years ago, I have found that people here, in general and unlike in many countries where I have lived and worked, have a reasonably well-informed view of Pharmac and what it does and achieves for the New Zealand economy. I have found it quite remarkable and I have often questioned myself as to whether I would encounter such well-informed views of the United Kingdom's National Institute for Health and Care Excellence (NICE); I doubt it very much. Pharmac, it would seem, is ingrained in the nation's psyche – and with good reason.

Since its inception, Pharmac has done a remarkable job of keeping spending on pharmaceuticals as low as anyone could possibly imagine. If that were the only measure of importance, then I would conclude this foreword by saying that Pharmac has done an excellent job, add my congratulations and that, as they say, would be that.

However, there are other matters of great importance where Pharmac's achievements and approach should be questioned and examined further. Matters that go well beyond fiscal control of medicines expenditure and raise questions that Kiwis should ask to be confident they are receiving the best treatments and achieving year-on-year improvements in health outcomes. I wish to highlight a number of key issues this excellent and well-written report examines.

One major issue the report addresses is that the universal subsidy is a solution for a problem that is not clearly described. I agree. I would go further to say it is likely to lead to waste and even a trivialisation of medicines. I have witnessed this in my own work in the public health care delivery sector in stark contrast to the private health care delivery sector, where every item consumed is subject to scrutiny. This does not even consider the environmental impact of medicines waste, which is a pressing international issue.

A second major issue is data, or specifically the lack of it. How good is Pharmac at what it does compared to other countries? No one really knows. Whilst some 'before and after' comparative data exists, there is no systematic benchmarking. This report points to the lack of up-to-date and publicly available data on Combined Pharmaceutical Budget (CPB) spending. The only real game in town is health outcomes data that would allow a cost-benefit analysis of the vast investment in pharmaceuticals. Pharmac's decisions need to be assessed against this criterion.

A third major issue is the sole supplier or sole subsidy solution currently favoured by

Pharmac. The production of pharmaceuticals is increasingly global in nature, particularly the source of the active pharmaceutical ingredient (API). The Covid-19 pandemic (as at the time of writing) has brought the fragility of the global market into sharp relief and gives cause for governments to be thoughtful about reliance on any single supplier solution as it amplifies any vulnerabilities in the supply chain. When faced with supply problems (which are perennial in the supply of pharmaceuticals), any short- to medium-term alternative arrangements rely on good relationships with the pharmaceutical industry. If these relationships are strained (or at least transactional rather than cooperative), they make these vulnerabilities even more concerning, which leads to my final point.

The fourth major issue is the important relationship that exists (or should exist) between the patient (the consumer of the medicine), the provider of the healthcare (and the medicine), and the pharmaceutical industry (the originator of the medicine). It is my contention that achieving optimal outcomes from the significant investment that medicines represent requires all parties to be full partners in the endeavour, so to speak. Anyone with any knowledge of the pharmaceutical industry knows that the aim is not just to sell maximum units of stock but to see maximum appropriate use of the company's products. It is in no one's interest to have a medicine used in the wrong patient group, which does not deliver the promised outcomes, and which may result in adverse reactions. A culture of cooperation is required to achieve medicines optimisation centred on patient benefit and health system sustainability. This is in everyone's interest. This will be no truer than the mainstreaming of the expensive biological immunotherapies for cancer treatment, in the main. These treatments are seen as a step change in treatment but they come at a significant cost, which may need to be budgeted over a number of years rather than in-year. How can this be achieved other than through a cooperative conversation between the health care sector and the pharmaceutical industry?

This report could pave the way to a shift that would see New Zealand leading the world in industry/health cooperation and appropriate early adoption of innovative and ground-breaking medicines combined with a national conversation about the role of the universal pharmaceutical benefits subsidy, the size of the CPB and the role of private contributions that will be needed to achieve the health outcomes all New Zealanders deserve.

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Executive summary

This report examines the strengths and weaknesses of New Zealand's arrangements for prescription medicines. Central to them is the Pharmaceutical Management Agency, Pharmac, a Crown entity. Among OECD member countries, Pharmac is "unique" in combining "clinical, economic and commercial aspects, and decision-making within a fixed budget for subsidising pharmaceuticals."[1] Other member countries commonly separate these roles and may have more open-ended budgets.

Perhaps the greatest strength in New Zealand's arrangements compared to elsewhere is that, from its inception in 1993, Pharmac has focused on achieving radically lower prices for many pharmaceutical medicines within a tight budget. For a time at least, those low prices attracted envious international attention. That focus reflects the clarity of its statutory objectives.

Under Pharmac's watch, the annual per capita number of filled prescriptions in New Zealand has risen markedly as unit medicine prices have fallen. Overall, pharmaceutical subsidy spending has not risen relative to GDP. In contrast, Australia is spending a lot more than New Zealand absolutely and as a percentage of GDP in subsidising prescription medicines. Yet, annual filled prescriptions per capita in Australia are now appreciably lower than in New Zealand. Prior to 2010, it was the other way around.

It is an open question whether Pharmac can sustain its superior low-price performance. It is not systematically benchmarking its price performance against that of top medicine procurers in other countries. District Health Boards (DHBs), the Ministry of Health and Treasury should be ensuring that Pharmac does so.

Another concern is that a fixed subsidy budget and a focus on low price might be at the expense of user choice and adoption of innovative new medicines. Pharmac's ability to fund new medicines each year depends considerably on its ability to achieve lower prices each year for some existing medicines.

The most serious weakness with current arrangements is that no one really knows whether they are improving health outcomes, let alone the overall wellbeing of Kiwis. The health gain relative to not having the medicine is assessed, but the degree to which it would be consumed if not subsidised is not known.

The report rebuts the view that to fail to subsidise a medicine is to deprive New Zealanders of its benefits. It finds no undue non-price barriers to New Zealanders' access to registered medicines. Why subsidise what medical professionals might advise people to buy anyway?

The lack of clarity about what the subsidies are meant to achieve creates an insoluble problem for public administration and accountability. It means Pharmac cannot do a meaningful wellbeing assessment of its subsidy decisions. Nor can anyone else.

Subsidies for people not in financial need are costly. They invite over-prescribing and waste. Pharmac's current 100% subsidy policy and the Ministry of Health's policy of limiting the standard prescription charge to $5 heightens the concern. The system creates expectations that a limited budget can never satisfy. Some suppliers, prescribers and consumers will always be aggrieved.

The subsidies disempower consumers. Consumers are no longer the piper calling the tune. Government provision displaces more flexible private arrangements. Prescriptions are biased towards the subsidised medicines that may not otherwise be the best option for individuals. To keep spending from blowing out, governments must limit access.

Nor is there a general affordability problem. The average annual cost per household of the government subsidies for prescription medicines is about $1040. Most families could pay for this out-of-pocket even if taxes were not lowered commensurately. It is cheaper for people to pay their bills directly rather than through the tax system. Private health insurance policies exist to pool the risks of much higher costs in any given year. The coverage is limited by fine print in the policies, but coverage under Pharmac is limited too.

Cash is generally the best form of assistance for those in financial need. Cash is empowering and enhances choice and flexibility relative to assistance in kind. Some private insurance policies provide a cash option.

For such reasons, there should be a presumption against subsidising those not in financial need and in favour of a cash option for those in financial need. Future reviews of the subsidy budget should clearly identify the public policy reasons for departing from this presumption.

The same presumption should be applied to future reviews of the maximum prescription charge for those not in financial need. Fiscally constrained governments in a post-Covid-19 world will need to reprioritise spending.

One aspect meriting further consideration is the degree to which less reliance on taxes to pay for medicines might reduce Pharmac's commercial clout. A gradual rather than radical shift towards less reliance on the tax system would manage this risk.

A deep consequence of the failure to identify the problem for which the subsidies are the remedy is that Pharmac does not know what arrangements people would have made to obtain the medicines they need in the absence of subsidies.

By default, Pharmac's decisions have a therapeutic efficiency health system focus, with a strong fiscal bias. The pressures on Pharmac to broaden the factors it takes into consideration, such as socio-economic disparities, do not address the deep problem but rather risks exacerbating controversy by making its decisions more clearly political rather than technical. The trend could undermine Pharmac's evidence-based rigour and focus. A better option might be to let Pharmac keep on doing what it does well – maximising potential therapeutic efficacy within a limited budget.

Abbreviations

ACC	Accident Compensation Corporation
BIM	Briefing to the Incoming Minister (post-election)
CPB	Combined Pharmaceutical Budget
CPI	Consumer Price Index
DHB	District Health Board
NPPA	Named Patient Pharmaceutical Assessment
NZPS	New Zealand Pharmaceutical Schedule
PBS	Australian Pharmaceutical Benefits Scheme
Pharmac	Pharmaceutical Management Agency
PTAC	Pharmacology and Therapeutics Advisory Committee
QALYs	Quality-adjusted remaining years of life
RHA	Regional Health Authority

Introduction

… governments or compulsory schemes finance nearly 55% of retail pharmaceutical spending in OECD countries, albeit with wide variations.[2]

The New Zealand Initiative's mission is to help create a competitive, open and dynamic economy and a free, prosperous, fair and cohesive society. Governments can do much to help or hinder the achievement of these goals. Good governance, well-designed state institutions, modest tax and regulatory burdens on citizens, good oversight of the adequate provision of public goods and excellence in public administration – all matter a great deal.

This report examines the strengths and weaknesses of New Zealand's arrangements for accessing prescription medicines. The quality of these arrangements matters for community wellbeing.

Government subsidies for prescription medicines dominate New Zealand's arrangements. While they benefit those in financial need, subsidies also invite waste and create many problems for government administrators, suppliers, prescribers and consumers. The amount of subsidy and its allocation are inherently contentious.

Effective public administration can minimise waste in the application of these subsidies. Central to their administration are the Community Pharmaceutical Budget (CPB) and the Pharmaceutical Management Agency (Pharmac), a Crown entity. The CPB dictates the fiscal cost of the subsidies. Pharmac determines which medicines are to be subsidised and to what degree.[3]

This report also highlights the tension between the open-ended demands for a greater subsidy and the reality of a finite budget. Other factors exerting pressures on current arrangements include an ageing population and the development of new, high cost, innovative and effective medicines. The fiscal pressures arising from the response to Covid-19 also presage a reassessment of spending priorities.

Governments' responses to the pressures on current arrangements will be some combination of tighter restrictions on access to subsidies, a bigger subsidy budget and/or greater recourse to private funding. The best combination for Kiwi wellbeing is a matter for analysis and debate. This report contributes to that debate.

New Zealand's current arrangements are an evolving policy choice. Health policy is political football – a contest between ideology, interest group pressures, and fiscal cost. It can change with a change in government or even a Minister.[4]

From an international perspective, there is nothing sacrosanct about New Zealand's current funding mix. Funding options for prescription medicines include government subsidies, compulsory insurance, voluntary private insurance, and recourse to personal, family and charitable resources. The prevailing combinations vary greatly across countries and can change through time.

A 2018 report by the Organisation for Economic Co-operation and Development (OECD) assessed the funding combinations for prescription medicines across 24 member countries in 2016. Each country had its own mix of voluntary and compulsory means. The proportion of funding from voluntary sources was lowest for Germany (6%) and highest for Mexico (100%), followed by Canada (57%).[5]

The median proportion paid from voluntary sources was 32%. For Australia, it was 24%.[6]

Major changes in funding mixes can occur over time. New Zealand's most radical change occurred in 1941 when universal prescription medicine subsidies first took effect. Obamacare (the Affordable Care Act) recently saw the United States adopt mandatory insurance.

The following chapters assess New Zealand's arrangements and consider how they might usefully evolve.

CHAPTER 1

Pharmac – Background and role

New Zealand is unique in creating a management agency that combines clinical, economic and commercial aspects, and decision-making within a fixed budget for pharmaceuticals.[7]

New Zealand before Pharmac

Government subsidies for prescription medicines were foreshadowed in New Zealand's radical *Social Security Act 1938*. The subsidies took effect on 5 May, 1941. Kiwis were "entitled to receive, without cost to themselves" all prescribed medicines that conformed to the Act.[8] Entitlement was not means tested.

This policy choice needs to be seen in the context of a broad ideological move internationally that invoked the cradle-to-grave concept for state welfare. Nor was Australia immune. Its subsidies for medicines date back at least to 1948–49. The ongoing fiscal costs and administrative rationing problems were left for future governments to wrestle with, as they have – with difficulty.

Subsidies for prescription medicines are provided for under the *New Zealand Public Health and Disability Act 2000*. They are available to all, regardless of financial need.[9]

The purpose statement in the 2000 Act does not identify the problem remedied by subsidies for medical services for people not in financial need. Instead, it requires that several open-ended health-service objectives be pursued "to the extent that they are achievable within the funding provided." The invidious implication is that to deny an increase in funding is to deny a health benefit.

The reasons for creating Pharmac can be readily inferred from a critical audit in 1992 of the Department of Health's administration of the subsidies. In this audit, the Controller and Auditor-General documented many administrative failures by the Department of Health to control the price of medicines and their growing use.[10]

The audit reported that prices for 58 of 74 subsidised medicines in New Zealand were greater than their prices in Australia. For 27 of these 58 medicines, New Zealand prices were over 50% more expensive.[11]

The formation of Pharmac also needs to be seen in the context of the then government's drive to improve accountability for the state's dual roles as a major funder and provider of health services by separating those roles institutionally.[12] Four Regional Health Authorities (RHAs) were set up as purchasing agencies. Local health board providers were set up as 23 Crown Health Enterprises. Pharmac was initially a joint venture owned by the four RHAs.[13]

As part of this change, RHAs were required from the outset to keep within fixed annual budgets for their overall spending. In addition, they took over responsibility from the Department of Health for managing health subsidy spending. That meant Pharmac was required to keep spending within a pre-set annual budget, the CPB. Until then, spending on subsidised pharmaceutical and other health benefits had been open-ended, or 'demand-driven' in Treasury terminology.

Pharmac's historical account of its own formation stresses the need to reduce the growth in government spending on prescription medicines.[14]

Pharmac's statutory objective

Pharmac commenced business in July 1993. It manages government-funded medicines dispensed by community pharmacies.[15] It had, and has, sole authority for determining which medicines will receive government funding. It lists subsidised medicines and therapeutic products in the New Zealand Pharmaceutical Schedule (NZPS).

Pharmac's prime statutory objective was, and 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.[16]

Best health outcomes

In deciding whether to permit a medicine to be subsidised, Pharmac is advised by the Pharmacology and Therapeutics Advisory Committee (PTAC).[17] The committee includes external clinical experts in relevant fields. It advises Pharmac on epidemiology, disease, current clinical practice, impacts on clinical practice and health outcomes from clinical trials. Pharmaceutical suppliers must provide evidence of such gains in support of their subsidy applications.

PTAC recommends what medicines are therapeutically worthy of subsidising. In doing so, it must consider their cost and Pharmac's funding criteria. From July 2016, these have been far-reaching, multi-tiered and multi-faceted "Factors for Consideration."[18] How Pharmac is to decide between the multitude of potentially conflicting and subjective considerations is unclear. (Prior to July 2016, Pharmac's decision-making criteria comprised nine (conflicting) considerations.)[19]

The lack of an overriding measure to assess trade-offs between these conflicting considerations makes decision-making formally arbitrary and non-transparent. The decision in any one case may implicitly put different weights on the same considerations to the weights in another case. The weights could change with a different composition of decision-makers. This is not a criticism of PTAC or Pharmac. Any other administrative arrangement would face the same problem. It is a systemic weakness.

Reasonably achievable

In assessing PTAC's recommendations, Pharmac uses health cost-utility analysis to inform its decisions.[20] The formal analysis uses an internationally accepted measure of health benefit – the effect on Quality-Adjusted Remaining Years of Life (QALYs).[21] Pharmac is more likely to subsidise a medicine with a higher ratio of its assessed health benefit to cost, but that decision also depends on whether doing so would keep total subsidy spending within the CPB limit. Conceivably, a very high cost pharmaceutical treatment could be ruled out despite having a high benefit ratio.

An underappreciated point is that QALYs gains are based on trial information where the control group may receive standard treatment for a condition.[22] Any additional health gains should be assessed relative to the additional cost. A deeper point is that this calculus does not identify the health gains from subsidising a medicine. They depend on what people would do or buy otherwise. Lack of information about that makes subsidy decisions deeply problematic.

Cost assessment is another problematic issue. Costs of what type and to whom? Pharmac considers the fiscal costs to all aspects of Vote Health from providing medicinal treatment, along with any out-of-pocket costs to the patient. It also considers fiscal savings from avoided health system costs, such as avoided surgery. It does not take into account lost wages due to sickness.[23]

Given these ambiguities and informational problems, Pharmac is obliged to make hard and sometimes controversial choices.

Within the amount of funding provided

Pharmac reports that it has consistently kept pharmaceutical spending within budget since its inception.[24] It performs this budget-focused role by determining which pharmaceutical medicines will be subsidised by the CPB. The CPB is used to subsidise community medicines, vaccines, haemophilia treatments, all hospital medicines and some medical devices.[25] Pharmac manages the CPB on behalf of District Health Boards (DHBs).

Pharmac and the DHBs, jointly where possible or separately otherwise, recommend a budget level for the CPB for the next financial year to the Minister of Health. The Minister determines its actual level on the advice of the Ministry of Health.

Budget bid recommendations released by Pharmac under the *Official Information Act* suggest unanimous recommendations are common, and budget bids normally assure the Minister that the amount bid would allow for all medicines offering "very good" value for money to be subsidised along with "some good value" investments.[26] Presumably, officials do not recommend that all 'good value' investments be funded because they do not think the government would approve the needed funding. That suggests the budget is too small or the subsidy bar too low.

As part of this process, Pharmac ascertains in conjunction with the DHBs a three-year funding path for CPB spending for planning and contingencies. That understanding, in conjunction with a CPB Discretionary Pharmaceutical Fund established by the Ministry of Health, gives Pharmac some flexibility in smoothing 'unders and overs' across financial years.[27]

Pharmac's price negotiation techniques

Pharmac a subsidy gatekeeper

Pharmac acts as a cross between gatekeeper and procurer.[28] As a gatekeeper, it determines which products get subsidised. It is not a procurer in that it does not buy medicines itself. But it does contract supply conditions as part of its price negotiations. DHBs and retail pharmacies are the procurers. Retail pharmacies pay no more than the price the supplier has negotiated with Pharmac and can claim no more from Pharmac than the subsidy.

Pharmac seeks to actively manage markets for pharmaceutical medicines, with a keen eye on the duration of remaining patent lives. It uses a wide range of commercial strategies to get the best price.[29] From inception, its techniques included tendering; a focus on generic medicines, where available; and reference pricing.[30] Reference pricing imposes part charges on users of competitive medicines which cost more than the fully subsidised product.

What determines an acceptable price?

An acceptable price is one which provides health benefits relative to cost that are sufficiently superior to other spending options.

Obviously, the lower the price, the more QALYs Pharmac can hope to achieve from an unchanged CPB. But if Pharmac underspends the CPB by holding out for an ever-lower price, it will fail to achieve its statutory objective.

The price seen by the end-user is usually merely the co-payment prescription charge. This is not set by Pharmac but by politicians and is a Ministry of Health responsibility. The standard out-of-pocket co-payment charge is $5 for most prescription medicines.[31]

Today, Pharmac has largely abandoned reference pricing. Pharmac is increasingly tendering for sole subsidy status within a given therapeutic category.

In the March 2020 edition of the NZPS, sole supply medicines accounted for 163 (63%) of the 259 distinct therapeutic categories for listed community medicines. The number of brands of medicine accorded sole subsidy status was 19% higher than in the January 2016 edition. In the March 2020 edition, 94% of brands of community medicines were fully subsidised, as were all but five of the 193 chemicals on the forms that authorised prescribers must use to access the subsidy.

Mark-ups for patented medicines can be large and variable for sound economic reasons.[32] Pharmac reports that price reductions of more than 90% have occurred after patents expire.

Pharmac can also achieve price reductions for branded medicines by negotiating on the basis that on the evidence the gain in health benefits a medicine offers is not commensurate with the additional cost. It now achieves its greatest additional cost savings by fostering competition for innovative medicines.[33]

Source of Pharmac's commercial clout

Pharmac's power to deny access to the subsidy unless the supplier offers an acceptable price gives it major commercial clout. Subsidy status has commercial value. Consumers naturally prefer a 'free' product to one they must pay extra for, and they have Pharmac's assurance that the subsidised product is effective. Those doing the prescribing would need a good reason to advise their patients not to use the fully subsidised product. Fully subsidised status may allow a much higher market share to be achieved, justifying discounts or rebates for bulk supply.

Pharmac can also tell the supplier of a new therapeutic medicine that it will not include it in the subsidised list unless its price at least matches the cheapest existing medicine in that category. The manufacturer will likely make a case that this is unreasonable as the new medicine is superior in some respects, say, therapeutic efficacy, convenience of application, or diminished adverse side-effects. Pharmac will listen, but it has the option of rejecting these as material gains.[34]

Also, time is money, particularly to the supplier of a product that will lose much of its commercial value when it goes ex-patent. Pharmac can take a longer view. It does have to worry that delayed access means forgone QALYs during that period, but it can balance this against future QALYs gains if it gets a lower price in the end. The lower the price, the more therapeutic units Pharmac can fund from a fixed budget.

Pharmac's scope adds to its bargaining power. It sits across all subsidised medicines for all ailments. It can do deals across therapeutic groups. It can say, "If you lower your price by X% for the subsidised medicine you are supplying in therapeutic category A, we will put your new medicine for therapeutic category B on the subsidy list as long as that price is right too." Pharmac would offer such a deal to achieve an overall QALYs gain per dollar with minimal budget impact.

Pharmac can also seek to negotiate risk-sharing arrangements. It can do a deal where the supplier takes the risk that the uptake of a medicine in a budgetary year exceeds an already decided dollar amount. Such contracts help Pharmac be more confident that overall spending will neither exceed nor fall short of the CPB.[35]

In all such cases, Pharmac's commercial clout increases as patents approach their expiry date and the supply of generic competitors becomes imminent.[36]

Commonly, the price Pharmac negotiates for branded medicines is achieved via an agreed rebate arrangement for supply at a price listed in the NZPS that may be an international wholesale market list price. The rebates are usually

commercially sensitive and unpublished. The secrecy of the rebate quantum makes the price listed in the NZPS a rather notional concept.[37]

The contracting suppliers pay the rebate to Pharmac, which transfers the funds to DHBs since they have paid the list price out of the CPB. The charge on the CPB is the net amount. Pharmac publishes the total summed value (gathered from all suppliers) of all the rebates paid into the CPB. Rebates on individual medicines are commercial secrets.

How Pharmac funds new medicines within budget

Currently, costly new treatments are available internationally for some conditions, including cancer, rare disorders and multiple sclerosis. With a tight budget constraint already largely committed to subsidising existing medicines, Pharmac can only fund new medicines if it subsidises less of something else, or if the CPB is increased following the process described above.

To fund very expensive new treatments out of a largely committed budget is a big challenge. For those afflicted the stakes are high. Securing subsidised access may be an intensely personal and emotional matter. The absence of a policy purpose of the subsidy creates an expectation that taxes have been taken to meet people's open-ended medicinal needs. Disappointment, disillusion and anger at the margin are intrinsic to this structure.

Only by being hard-headed in commercial negotiations over price, year in year out, can Pharmac make room in a tight budget for funding costly new medicines. That fiscal imperative risks generating more combative relationships with suppliers than would normally be mutually beneficial.

Each year, Pharmac also budgets for exceptional cases that justify recourse to unlisted medicines. This Named Patient Pharmaceutical Assessment (NPPA) policy is part of Pharmac's broader Exceptional Circumstance Framework.[38] Funding for the NPPA also comes out of the CPB.

CPB spending in perspective

CPB spending is a minor portion of total health spending. Government spending from the CPB was 0.36% of GDP in the year ended June 2018.[39] Central government spending on health was 5.9% of GDP in the same year. This excludes the Accident Compensation Corporation (ACC) and local government spending.

CPB spending is low relative to voluntary spending on health by households. OECD statistics for such spending in New Zealand put voluntary spending at 1.9% of GDP in 2019.[40] Of that, out-of-pocket spending accounted for 1.2% of GDP. Some portion of this out-of-pocket spending will have been on medicines.

Out-of-pocket spending on health commonly exceeds other forms of voluntary spending across OECD member countries. This was so for 22 of 24 member countries tabulated by the OECD in 2018.[41] The two exceptions were Canada and Slovenia. Their proportions of total health spending funded by voluntary health care payment schemes were 36% and 34%, respectively. These proportions are outliers. The median proportion across the 24 countries was only 1%. Australia was close to the median. Its voluntary funding through health care payment schemes contributed 1% to all funding against 23% for out-of-pocket funding. Only 10 of the 24 countries had a greater proportion than Australia's 1%.

The member countries heavily subsidising prescription medicines include Australia, New Zealand, Spain, the United Kingdom and Sweden. The OECD's 2018 report found that governments in Spain, Australia and Sweden subsidised at least 70% of spending on prescription medicines.[42]

Other member countries, particularly European countries, fund heavily through compulsory insurance arrangements.

Concluding points

Pharmac's establishment derives from the broader institutional reforms of New Zealand's health system aimed at improving accountability for purchasing and delivery. As the last surviving remnant of that drive, its continuance is a tribute to its achievements, and owes much to the continuance of its relationship with DHBs.

Pharmac's governing legislation obliges it to focus on fiscal control and therapeutic efficacy. These (necessary) constraints define its silo. It cannot focus on non-health aspects of wellbeing or on real resource constraints, as distinct from fiscal constraints.[43]

CHAPTER 2

Pharmac's performance

Pharmac's performance is debated and final judgement depends on perspective and experiences. On a range of indicators, the agency has performed admirably.[44]

Performance evaluations are a comparative exercise. There are many possible benchmarks. Performance may be good against one yardstick and bad against another. The primary public policy questions concern how well Pharmac has performed its statutory role and how useful that role is.

Cost and price performance

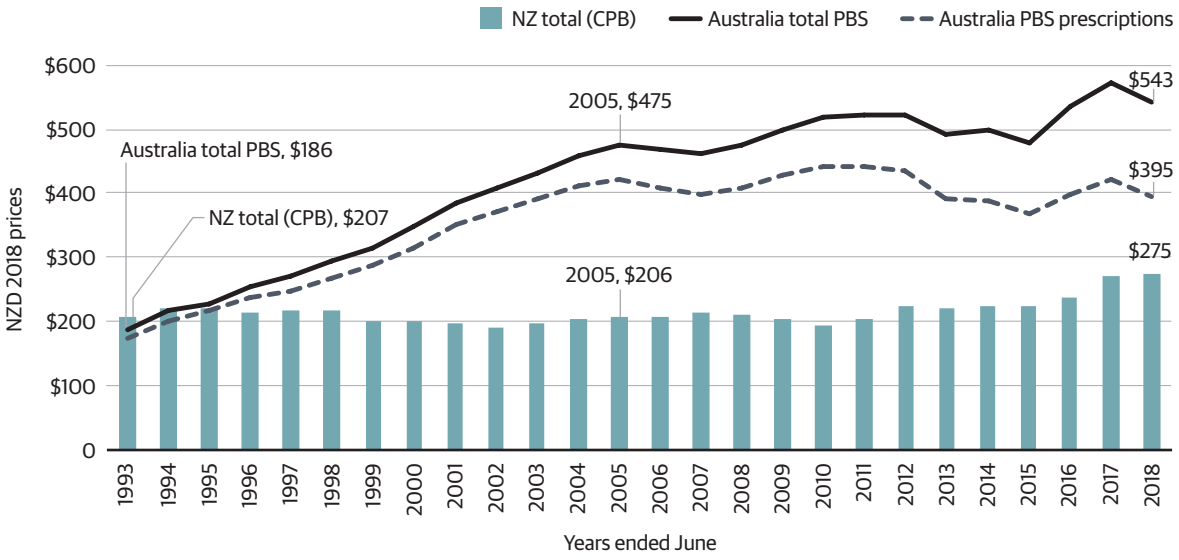
Cost control

> There is no doubt that Pharmac tries to achieve the very best prices for the medicines it funds, while ensuring availability of a wide range of medicines within a relatively small budget.[45]

Pharmac's early success in reducing medicine prices since it was established in 1993 is remarkable. Figure 1 shows its performance both absolutely and relative to Australia.[46] For New Zealand, the figure shows annual government spending (before rebates) through the CPB since 1993 expressed in 2018 dollars per capita using the all-groups Consumer Price Index (CPI). For Australia, the figure shows sharply increasing federal government spending per capita under its Pharmaceutical Benefits Scheme (PBS) also in 2018 dollars using the Australian CPI and converted to New Zealand dollars using the average exchange rate between 1993 and 2018 (using the Reserve Bank of New Zealand's statistics).[47]

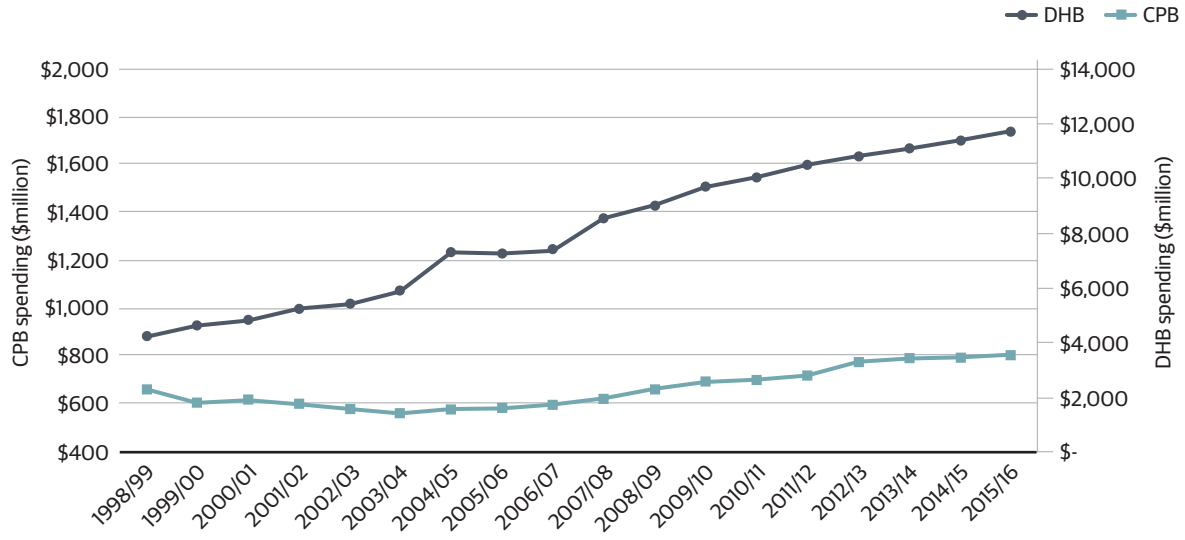
Between 1993 and 2005, CPB real spending per capita in New Zealand fell while PBS spending in Australia more than doubled. Australia's post-2005 spending indicates it was a late starter with effective measures to control spending.

Figure 1: Pharmaceutical subsidy comparison between New Zealand and Australia (1993–2018)



Source: Compiled by the author based on ABS statistics for Australia and OECD (Pharmac-sourced) statistics for New Zealand, and Reserve Bank of New Zealand exchange rate statistics.

Figure 2: DHB spending vs CPB spending (1999–2016)



Source: Pharmac, "Briefing to the Incoming Minister of Health" (8 November 2017), 10.

The comparison in Figure 1 understates the degree to which Australians are spending more. Out-of-pocket charges for prescription medicines are also significantly higher in Australia than in New Zealand.[48]

Pharmac's success in keeping spending growth low and within budget is even more remarkable when compared to the fiscal performance of DHBs. Collectively, DHBs notoriously outspend their budgets, knowing that governments are reluctant to punish them.[49] Figure 2 compares the growth in total government spending on DHBs with that in the CPB.

Pharmac's success in negotiating lower prices (see the next subsection) and thereby increasing volumes under a tight budget constraint induced governments to progressively add to its tasks, and thereby its budget.

CPB spending has tracked upwards since the mid-2000s (see Figures 1 and 2). Part of the reason for the growth is Pharmac's expanding role. Table 1 summarises its added responsibilities since 1993.

Table 1: Timeline of Pharmac's additional tasks

1993	Community medicines
2002	Off-patent hospital medicines and cancer basket, procurement and national contracting added as new functions
2004	Influenza vaccine
2011	Hospital cancer medicines
2012	All other vaccines (in addition to influenza)
2013	Hospital medicines (partial), haemophilia treatment
2014	First contracts for hospital medical devices (not CPB funded)
2018	CPB includes all DHB spending on hospital medicines

A 2018 report by the New Zealand Institute of Economic Research (NZIER) found the proportion of the CPB budget allocated to subsidising community pharmacy medicines declined during these years.[50]

Pharmac's role in 2019 includes:

- managing and maintaining the NZPS – the list of prescription medicines and therapeutic products subsidised by the government;

- managing the CPB – the funding of community pharmaceuticals, hospital pharmaceutical cancer treatments, vaccines, and haemophilia treatments;
- managing the medicines and related products used in public hospitals;[51]
- considering funding applications for people with exceptional clinical circumstances;
- promoting the responsible use of pharmaceuticals; and
- engaging in relevant research.

Pharmac is also taking responsibility for purchasing medical devices for DHBs, and is increasingly involved in effective access to subsidised medicines for Maori and Pacifika ethnicities.

This expanded scope is not the only reason for the rise in CPB spending shown in Figure 2. The fifth Labour Government raised the demand for subsidised medicines by lowering patient co-payments, and by expanding the number and types of authorised community prescribers to include midwives and nurse practitioners. It also increased CPB funding.

Figure 1 shows gross spending by the CPB. Rebates are repaid into the CPB, so net spending growth is even less than shown in Figure 1. Figure 3 shows the significance of those rebates in recent years, expressed as a percentage of GDP.

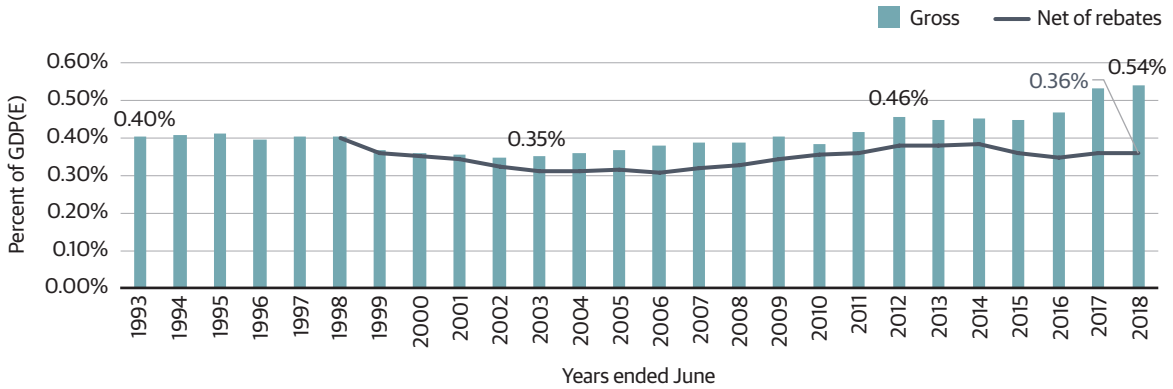
In the year ended June 2018, gross spending from the CPB was 0.54% of GDP but only 0.36% of GDP net of negotiated rebates. Expressed differently, the rebates eliminated 33% of the listed cost of CPB medicines that year.

Gross PBS spending in Australia in the year ended June 2018 was 0.63% of GDP and gross spending on prescription medicines was 0.46% of GDP.

Medicines Australia estimated that discounts through rebates were much less significant in Australia than in New Zealand. Figure 4 compares the rebates between the two countries from the financial years ended 2012 to 2017. Back in 2012, the rebate in Australia represented an average discount of 2% compared to 17% for New Zealand. By 2017, the discount for Australia was 12 times greater at 24% while that for New Zealand had almost doubled to 33%.

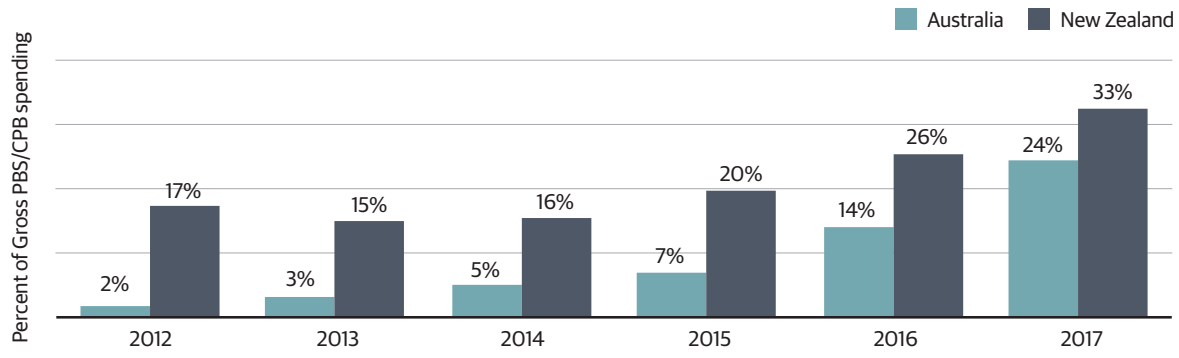
These rebate comparisons strengthen the conclusion from Figure 1 that the advent of Pharmac saw much greater budgetary constraints in New Zealand than in Australia.

Figure 3: Pharmaceutical community budget as a percentage of GDP (1993–2018)



Source: OECD, "Health Statistics 2019: Definitions, Sources and Methods – Pharmaceutical sales" (2019), www.oecd.org/health/health-data.htm.

Figure 4: PBS/CPB rebates for Australia and New Zealand, percentage of gross spending (2012–17)



Source: Medicines Australia: Federal Budget Submission 2018, Pharmac (OECD).

Price negotiating performance

Commercial confidentiality makes it hard to assess just how low prices are for pharmaceutical medicines in New Zealand compared to other countries. The OECD has commented on the lack of transparency globally in the pricing of pharmaceuticals.[52]

As mentioned above, government spending on subsidising medicines in New Zealand prior to Pharmac's formation was markedly higher than in Australia, overall.

Pharmac's formation changed that. A major study in 2000 by the (Australian) Productivity Commission found that listed prices in New Zealand were marginally lower on average than those in Australia for 150 pharmaceuticals.[53] Prices were much higher on average in Canada, Sweden, the United Kingdom and the United States. This study did not take rebates into account, but Figure 3 indicates that overall they were not material for New Zealand in 2000.

More recent studies have pointed to even greater relative price gains for New Zealand, at least in particular cases. An American firm compared prices in 2006–07 for 30 patented and generic drugs in nine countries.[54] A 2014 article in *PharmacoEconomics* by Robin Gauld summed up its findings:

> In comparative terms, New Zealand pays the lowest prices amongst high-income countries for a list of 30 "most prescribed" medicines – around one-third of the costs for the USA and 70% of Australian and British prices. There are numerous examples of individual New Zealand pharmaceutical prices and patient co-payment amounts that other countries and their citizens might only dream of.[55]

Unsurprisingly, Australians took notice of such differences in pricing outcomes. A March 2013 report by Melbourne's Grattan Institute,[56] a policy think tank, compared prices paid for 75 pharmaceuticals in Australia under its PBS scheme with those paid by Pharmac. The results were devastating from an Australian taxpayer perspective. They were paying prices not just a few percentage points higher but in multiples of 5, 10, 20, 30 or more than New Zealand prices.

The medicine Atorvastatin provided a dramatic example. The Australian price in October 2012 was $A51.59 for 30 40mg tablets. The equivalent New Zealand price for 90 tablets was equivalent to $A5.80 – roughly a 30-fold price differential. Australians spent $A700 million on this medicine in 2011–12. One-thirtieth of that is $A23.3 million.

All up, Grattan Institute estimated that Australians could be saving around $A1.7 billion a year if they paid New Zealand prices.

Yet another indicator is the government subsidy cost per prescription. In Australia, PBS payments per prescription averaged $A13.22 in 1993 and $A43.92 in 2017 (years ended June). In New Zealand, the average payment in 2017 was $18.35 net of rebates and $27.55 gross of rebates. The 1993 (gross and net) average in New Zealand was $24.30.[57] In short, the gross nominal dollar per prescription rose four-fold in Australia between 1993 and 2017, while the nominal cost in New Zealand fell on a net basis and rose by about 10% on a gross basis.

Prescriptions per capita provide another comparison. In Australia, they rose 30% from 6% in 1993 to 8.1% in 2017 (years ended June). In New Zealand, they rose 90% (from 5.1% to 9.6%). The crossover year, when New Zealand's prescription per capita ratio first exceeded Australia's, was the year ended June 2010. But for Pharmac's price achievements, that outcome is the opposite of what might have been expected under New Zealand's much tighter spending controls.

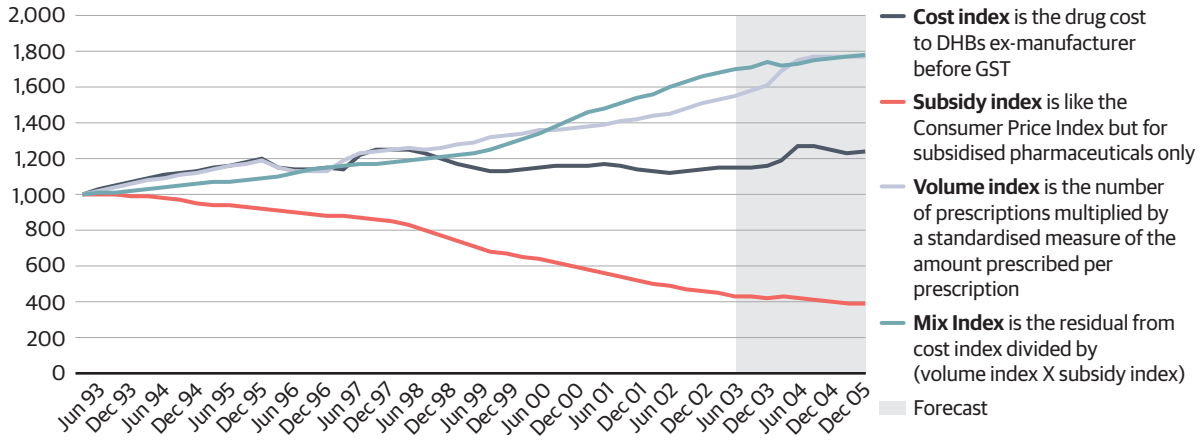
Given New Zealand's higher prescriptions per capita in 2017/18, it is remarkable that subsidised CPB spending per capita in the year ended June 2018 was 22% lower than in Australia (see Figure 1).

Australians were not the only ones interested in "the New Zealand model." An earlier independent assessment published in the *British Medical Journal* in 2010 reported that a 2006 analysis by the Canadian government had found that "the price of generic drugs in New Zealand is less than a quarter of the price in Canada and that patented drugs are 20% cheaper."[58]

Gauld observed in 2014, in relation to such factors, that Pharmac has "emerged as something of an international role model for evidence-informed decision making."[59] This view is controversial.[60]

Pharmac's annual reviews provide its own assessments of what it is achieving. During its first decade, price reductions allowed volume growth to markedly exceed nominal spending growth despite the increased proportion of spending on more expensive medicines (see Figure 5).

Figure 5: Pharmac's volume and price indices (1993–2005)



Four-quarterly moving averages | Base: Four quarters ending June 1993 = 1,000

Source: Pharmac, "Annual Review 2003" (Wellington: New Zealand Government, 2019), 3.

The red line tracks Pharmac's **subsidy index**. This is a chain-linked, expenditure-weighted nominal price index for CPB spending (net of rebates) on pharmaceuticals. It measures the extent to which unit prices for subsidised medicines have been reduced since 1993 in dollar-of-the-day terms. Lower unit prices per pharmaceutical reduce the subsidy index. Subsidised medicines are mostly prescription medicines.[61]

The blue line tracks Pharmac's **volume index**. This is the product of the cumulative growth in the number of filled prescriptions from the base year and a units per prescription index.[62] As such, it is a measure of the increases in prescribed active therapeutic ingredients.

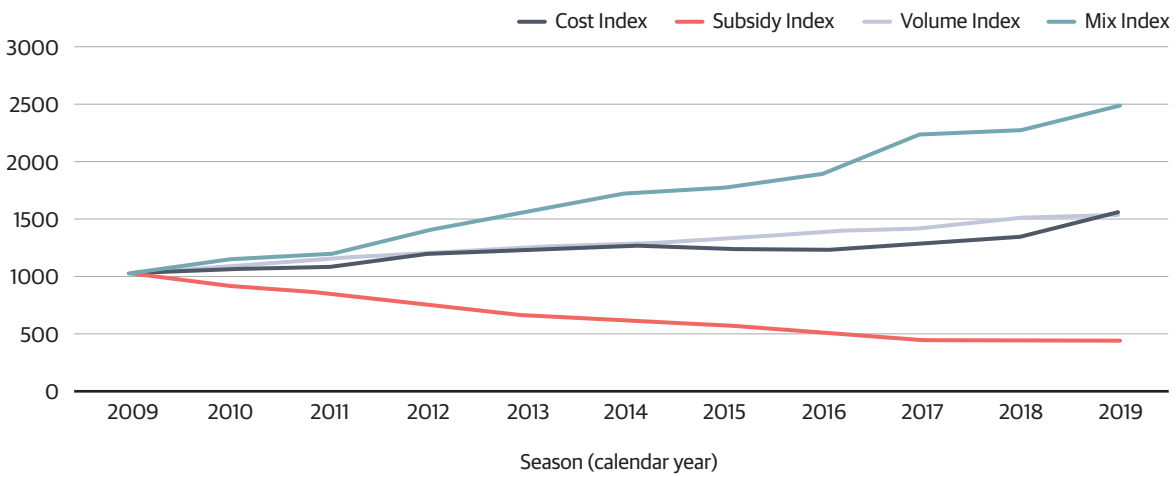
The black **cost index** line is an index of all nominal CPB spending net of rebates. This index has risen much less than the rise in the volume index because of the fall in the subsidy index.

The **mix index** is the cost index divided by the product of the subsidy and volume indices. Its rise indicates a trend of prescribing increasingly more expensive products during this period. A halving of the subsidy index in a decade of continuing CPI inflation is remarkable.

The experience during the decade to 2019 suggests a somewhat different story. Volume growth has matched nominal spending growth, although the rise in the latter includes expansions in the scope of activities funded through the CPB, overstating the growth in spending on community pharmaceuticals. The fall in the subsidy index has been offset by the rise in the mix index. The composition of the mix is different from that in Figure 5 due to the addition of vaccines, PCT and haemophilia spending, among others. The subsidy index halved again, but the rate of decline slowed towards the end of the last decade (see Figure 6). The upshot was an overall 50% lift in volume and nominal cost. Per capita filled prescriptions rose further.

An important qualification is that these figures do not benchmark New Zealand's outcomes against those achieved elsewhere. That absence makes Pharmac's quantified "before and after" estimates of the fiscal savings from its efforts suspect as a performance indicator. For example, pharmaceutical prices for a medicine can fall globally as patents expire.

Figure 6: Pharmac's volume and price indices (2009–19)



Source: Pharmac, "Annual Review 2019" (Wellington: New Zealand Government, 2019), 24.

Pharmac's 25-year history cites its first chief executive as reporting that of all the performance benchmarks he was using:

> The only group that has been able to be as effective as Pharmac is the Veterans Affairs in America, where they directly purchase their pharmaceuticals; they are very clever about it.[63]

However, Pharmac in response to an OIA request for more details said in December 2019 it possessed no detailed information. This is disappointing. If Pharmac is not systematically benchmarking its performance against others, it cannot really know whether it is improving or falling back.

Pharmac's skill in assessing therapeutic value

Competitive and regulatory pressures on pharmaceutical companies are intense. They must try to maximise the degree to which they can use patents to hold out against competition. Time is precious. They must market to everyone from expert professional procurers to single practice professional prescribers, individual retail pharmacists and the general public. Most of these target customers lack the time and expertise to assess whether one medicine really is therapeutically superior.

It is easy to see how that situation could lead to a proliferation of minor variations of existing drugs being marketed as new drugs with proven therapeutic powers.[64] It can also lead to marked differences in subscribing behaviour from one entity to another.[65] Pharmac uses an expert committee to assess and advise on the extent to which medicines really offer therapeutic gains.

The significance of the need for this expertise is illustrated by an international finding in the 1990s: about 85–90% of new drugs "provide few or no clinical advantages for patients."[66]

It is also indicated by evidence of big variations in subscribing practices and medicine costs across the regional health authorities prior to the formation of Pharmac.[67]

Pharmac's budget constraint gives it a stronger incentive than otherwise to spend the CPB on effective medicines. Research by Jacqueline Cumming from the Victoria University of Wellington provides supporting evidence. She found that of 10 drugs deemed by the UK's National Institute for Health and Care Excellence (NICE) between 1996 and 2005 to be least cost effective, only five were approved for funding in New Zealand as against six in Australia and all 10 in the UK.[68]

Assessment

Pharmac's early achievements in reducing unit prices for many effective therapeutic medicines are both enormously impressive and globally remarkable. New Zealanders are consuming far more medicines of proven therapeutic worth than with the same subsidised spending under pre-existing arrangements. Pharmac's early performance in reversing the initial higher price paid than in Australia is particularly commendable.

Nevertheless, Pharmac's measures of performance in achieving lower prices are of a "before and after" nature. Such price comparisons do not show relative performance. Absent measures of relative performance, Pharmac's current performance cannot be accurately assessed.

Pharmac's annual reviews since 1993 demonstrate an ongoing intense focus on performing against its objective. Much credit for the sustained nature of that focus should go to those who set its initial statutory objective, and to the founding leaders and staff. The latter clearly established a culture of rigour and commitment strong enough to survive many changes of government

and circumstances. The contrast between the strong focus on value for money in Pharmac's Briefing to the Incoming Minister (BIM) in 2017 contrasts sharply with the Ministry of Health's lack of any such focus in its briefing.

The absence of a politically significant local industry manufacturing pharmaceutical medicines has surely helped Pharmac and the government to focus on budgetary control.[69] Pharmac could focus on reducing prices with no political concerns about industry layoffs and redundancies.

A single overriding objective helps focus the mind. Managers cannot manage purposively if their overall objective is unclear. Sir Peter Blake when leading the New Zealand syndicate's 1995 challenge to win the America's Cup reportedly asked "will it make the boat go faster" of every proposal. Such a focus disposes of many diversions and much trivia.

The robustness of the budget setting process is another factor. Pharmac is the agent of DHBs. It is effectively spending their money. When DHBs and Pharmac jointly recommend the CPB spending level to the government, DHBs know that the government is also setting its overall funding budget at the same time. If the government has a figure in mind for the total DHB budget, as the Minister of Finance likely does, a larger budget for the CPB likely means less money for the DHBs to spend on their core business – funding public hospitals. So the parties to the recommendation are confronted with deciding the value to the DHBs of spending on public hospitals.

A further factor is that Pharmac is unusual in combining the roles of assessing clinical efficacy and pricing in one organisation.[70] That opens it up to criticisms relating to secrecy and delays, but it is likely also important to unite both aspects by the single overriding value-for-money purpose. One can imagine a clinical expert's focus sharpening when a colleague says, "Now wait a minute, if this medicine is only marginally more therapeutic but costs 10% extra, we will not be able to subsidise it. Are you sure it is only marginally better?" Such conversations are likely to be more effective between colleagues with a common purpose.

In addition, Pharmac's judgment has been largely supported politically. Few decisions have been changed by politicians.[71] This is likely to change if Pharmac's decisions are seen to be political rather than technocratic.[72] External reviewers have noted other contributing factors.[73]

CHAPTER 3

Criticisms and issues

… an excessive focus on price and an inability to take advantage of the opportunities presented by new medicines can be costly to the health system. These effects are both attributable to the constrained budget under which Pharmac operates.[74]

Pharmac's gatekeeper role is inherently controversial. To keep expenditure within a largely static budget constraint forces it to defer, or less commonly reject, subsidising many medicines which are therapeutically effective.[75] Those can be tough calls – and may even be considered an affront to suppliers and prescribers (and their patients).

Pharmac has been subject to strong criticism from the pharmaceutical industry, medical professionals and aggrieved consumers since its inception. This chapter focuses on criticisms of a professional nature. Appendix 1 identifies and comments on criticisms by medicine consumers and others.[76]

Professional concerns include:

- an excessive focus on low cost medicines with a concomitant unduly limited range of subsidised medicines for treating specific conditions;
- New Zealand falling behind the evolving technology frontier embodied in new, innovative medicines, with delays in listing decisions being an aggravating factor. An associated concern is reduced incentives to provide more than basic product support in New Zealand;
- failure to subsidise deprives New Zealanders of access, reducing health wellbeing; and
- the problematic basis for centralised health wellbeing assessments and, more importantly, the absence of a broader wellbeing focus for decisions.

The issues of lowest cost and narrow range

Industry professionals criticise Pharmac for being overly focused on fiscal savings and achieving low prices at the expense of health outcomes. Those criticisms are largely continuing.

Dr Pippa MacKay's editorial in the *New Zealand Medical Journal* in 2005 illustrated these concerns. At the time, she was chair of the then-Research Medicines Industry Association of New Zealand, an interested party. Her editorial followed a 1999 letter in which she asserted Pharmac's focus on achieving lower prices was at the expense of patient safety: "… consultation with the medical profession was cynical, and bureaucratic requirements were smothering prescribers."[77] Her subsequent 2005 editorial concluded that things were worse – Pharmac had become even more combative and aggressive in its cause of keeping prices and costs down.[78] This had negative effects on industry participation and support services for New Zealand. She was particularly concerned that its 'sole subsidy' policy was making medicine supply chains vulnerable.[79]

That the range of subsidised medicines is more limited in New Zealand than in many other OECD member countries seems beyond dispute. A recent assessment by US health care multinational IQVIA compared the range of new medicines (excluding generics) listed in New Zealand for eight priority conditions, and a ninth 'catch-all' category, across 20 OECD member countries between 2011 and 2017.

A news media article summed up its findings as follows:

> New Zealand … had the lowest number of publicly funded medicines in the OECD, with all other countries having between three and 10 times more publicly funded medicines than us.[80]

The report identified 304 new medicines during this period. Only 98 of those were registered in New Zealand and only 17% were subsequently listed. For Australia, the corresponding figures were 150 and 55%.

The issue more likely to be disputed, and worthy of more research, is the degree to which the range of therapeutic equivalent medicines is materially narrower in New Zealand. Pharmac's decisions about these matters are informed by expert assessments of the degree of therapeutic equivalence between competing products. Even if that range is not narrower, there may yet be 'second-order' differences between near equivalent medicines which affect users differentially.

There are many aspects to subsidy decisions that go beyond simple therapeutic equivalence. Newer medicines can be accompanied by innovative application methods and/or complementary innovative medical devices. A medicine that can be self-administered orally is a different product from one of similar therapeutic efficacy that must be administered in a hospital or clinic. Which product people value more depends in part on their circumstances. Of course, Pharmac recognises the relevance of these and many other funding considerations, but it cannot hope to satisfy all needs and must make overall calls about the trade-offs. A senior industry representative said in a private conversation that perhaps 40–50% of prescribed medicines suffer from this problem. Right or wrong, that estimate reflects deep expert concern.

The public policy question for Pharmac and its critics is whether the health losses from channelling spending into a limited range of subsidised medicines with a one-size-fits-all effect are outweighed by the potentially great reductions in the social cost of supply, under tendering for sole listing status.

Pharmac's incentive is to get the greatest statistically expected health gains from a given fiscal budget. On the evidence, there is a sharp trade-off between price and range of subsidised products. Pharmac can greatly reduce the average cost of supply by auctioning off or negotiating the right to be the sole recipient of the subsidy. But doing so distorts relative social costs and penalises choice. The epilepsy example documented in Appendix 2 illustrates how dramatic these gains can be.

Lower prices represent a gain in national income when the suppliers are foreign-owned.[81] (Note that in sole supply situations the subsidised price is the net price. Rebates are largely restricted to patented products.)

The balancing consideration then is the scale of the health wellbeing losses from the reduced range of subsidised medicines. This is primarily a matter for empirical examination. Is there actual evidence that Pharmac is underestimating the benefits from wider subsidised access to the detriment of Kiwi health?

One approach to answering this question is to search for aggregate evidence that New Zealanders' health and wellbeing is worse relative to other countries than would be expected based on differences in spending on pharmaceuticals per capita, holding other aspects constant.[82] A more direct cross-country approach would be to seek evidence that countries subsidising a wider range of medicines tend to have better outcomes, holding other factors constant.

Such approaches are imperfect. Many factors unrelated to prescription medicines affect New Zealanders' overall wellbeing. It is hard to isolate these effects from those of prescription medicines in cross-country comparisons.

A different approach is to narrow the focus to the medicine options available for treating a specific condition and assess statistically expected outcome differences across countries. A group of nine analysts employed by Pharmac or with connections to it adopted this approach.

The analysts compared outcomes from medicinal treatments in New Zealand with those in Australia, which subsidises a wider range of cancer medicines than New Zealand. They used clinical trial data to quantify the expected health gains from cancer medicines funded in Australia, but not across the Tasman. They assessed whether the difference between those gains and those expected from the medicines funded in New Zealand could be expected to be meaningful. They used the American Society of Clinical Oncology Cancer Research Committee's (ASCO-CRC) recommended targets for clinically meaningful health gains and reported that:

> … most of the additional medicines funded in Australia do not deliver clinically meaningful health gains as defined by the ASCO-CRC guidance. This suggests New Zealand is not missing substantive opportunities for improvements to New Zealand's cancer survival rates through additional medicines funding.[83]

From this, they concluded that Kiwis were missing little from the country's narrower focus on therapeutic value per dollar, which frees up funding for delivering additional health benefits elsewhere with the CPB.[84]

Some oncologists have strongly disputed this conclusion, pointing out its limited and arm-chair nature.[85] The robustness of its merely "suggestive" conclusion should be questioned.

The challenge for critics is, of course, to provide a more robust study that reaches the opposite conclusion. The debate is essentially empirical, and the research problem difficult. Simply asserting superior overall therapeutic benefits from the given budget by funding a greater range of medicines is not evidence. The research challenge is to do better.

Pharmac's approach favours older, less innovative medicines

A related prominent professional criticism is that the focus on low price means a focus on dated generic medicines at the expense of newer, innovative patented medicines.[86] At the same time, the current sole subsidy policy limits patient and prescriber choice as between alternative medicines for treating the same condition. Other suppliers could lose interest in New Zealand, offering little more than basic product support for unsubsidised medicines.

In principle and intention, Pharmac should list new, more costly medicines where the gains in therapeutic benefit exceeds the increase in health system cost. In practice, its default proposition is to list a new medicine only if it costs less than the existing fully subsidised medicine for that condition.

This is probably best read as an opening negotiating position, but it does create a presumption against a new, more costly medicine, and perhaps a culture oriented that way. In practice, Pharmac clearly is prepared to list a dearer medicine instead of a cheaper one if the additional therapeutic benefits justify doing so. One example is the decision to replace the hepatitis C medicine Viekira Pak (+/- RBV) by Maviret from February 2019.[87]

Even so, the criticism has a point. A new medicine may be too costly to be funded by a heavily committed budget even if its net benefits

are superior to less costly ones which can be funded within the budget constraint. Also, a new medicine might have benefits not captured by the limited range of cost savings relevant to Pharmac's decision criteria.

Another aspect of this concern is the time it can take to make listing decisions. Richard Milne, associate professor at the University of Auckland, and Michael Wonder, an Australian consultant health economist, reported in 2011 that on average it had taken 33 more months for New Zealand to list 59 new medicines for subsidisation than in Australia. This covered all the new medicines listed in both countries between 2000 and 2009. On average, the drugs were registered nine months later in New Zealand, making the average further delay relative to Australia between registration and listing 24 months.[88] (See Appendix 1 for further discussion.)

The authors said delays mean forgone health benefits and they repeated this point in their subsequent reply to Pharmac's response.[89]

A 2019 assessment by US health care multinational IQVIA found that between 2011 and 2017, it took an average of 512 days (17 months) from the day of registration to get a new medicine listed in New Zealand compared to an average of 233 days for 20 OECD member countries. In addition, New Zealand did not register any new medicines during those years for five of eight priority conditions.[90]

New Zealand's model makes some relative delay understandable. It would be surprising if it did not take long to get a new medicine subsidised in New Zealand than in countries taking a less single-minded, and perhaps more collaborative, approach to negotiating price. The norm internationally is for the entity approving a new medicine for the subsidised list to be separate from the entity responsible for budget control.[91] That arrangement complicates the situation of any fiscal gatekeeper trying to withhold supply to drive down prices. The patient is entitled to the subsidised supply; the supplier has been given the necessary authorisation; and the budget is somewhat open-ended (i.e. demand driven). To deny funding is to dash raised expectations.

In contrast to this norm, Pharmac can say to the supplier: "Our assessment is that we cannot justify subsidising your product because on the evidence provided, its therapeutic gains are not worth the cost. What can you propose to overcome that difficulty?" Not only can it say that, its pre-set budget and statutory objective oblige it to take such an approach.

Naturally, the subsequent commercial bargaining takes time, and there is no guarantee the price/therapeutic efficacy barrier will be overcome. It takes two to reach a deal. Nor can the speed of a negotiation be dictated by Pharmac. There may be strategic issues for the head offices of the major pharmaceutical companies to consider.

From the outside, no deficiency is obvious in Pharmac's incentives to balance the conflicting considerations optimally. If there were evidence it was not considering the health losses from stringing out commercial negotiations, that would be a concern. Pharmac should be accountable for justifying the delays that do occur, notwithstanding issues of commercial confidentiality.

In short, longer delays for listing are intrinsic to the New Zealand model, but the question of whether their extent is excessive remains open.

Pharmac recently commenced assessing a promising new medicine for listing at the time of application for registration in the case of rare disorders and cancer medicines.[92] That could reduce delays compared to waiting for the listing application. There may be scope for making that approach more general.

Failure to subsidise deprives New Zealanders of access

A strident criticism, and deeply held view, is that if a medicine is not subsidised, Kiwis are deprived of its benefits. This is a confusion of terminology. Taken literally, it claims that New Zealanders would be deprived of cars, food, clothing and housing if these were not subsidised.

This research has identified no legal barriers to accessing safe, unsubsidised therapeutic medicines. Suppliers are free to import, advertise and market unsubsidised MedSafe-approved medicines. Also, it is legal for authorised prescribers to prescribe them.

Many medicines are cheap relative to average household incomes. People already pay cash for pharmaceutical products bought at local community pharmacies and supermarkets.

Insurers are free to offer insurance policies that would pool risks and fund unexpectedly large costs for policy holders. Indeed, they are actively doing so. About 28% of working-age New Zealanders are covered by private health insurance, according to a 2017 KPMG report.[93]

In 2006/07, private health insurers paid for $33.3 million of spending on "pharmaceuticals and other medical non-durables." Out-of-pocket spending was 14.7 times higher at $522.2 million. CPB spending net of rebates was $598 million. Total public sector spending, including hospital medicines, was $1.05 billion. Regrettably, more recent official statistics do not appear to exist. Nor has this research been able to find any recent information about the proportion of prescription medicines paid for out-of-pocket or via private insurance.[94]

Some insurance policies cover medicines not subsidised through the CPB. Presumably, the main constraint on their role is commercial – customer demand is limited at the premiums insurers would need to charge.

Private insurance is not a panacea. It cannot be expected to fund the cost of treatments for pre-existing conditions.[95] These situations present a funding problem, not an insurance problem. Bad policymaking can confuse the two.

Nor can private health insurance policies offer open-ended benefits *en masse*. For premiums to be affordable, they must offer policies with limited coverage. The government faces the same constraint in the form of the amount that people are willing to pay in taxes. The limits to the CPB's scope reflects resource scarcity.

Is private insurance not paying a larger role because people cannot afford the premiums or are the medicines Pharmac is subsidising seen by users and their prescribers as reasonably satisfactory for their needs?[96] That question warrants further research.

A related criticism is that Kiwis have access to too narrow a range of subsidised medicines because the subsidy budget is too small and Pharmac is culpable unless it consistently recommends a larger budget.[97]

This complaint is somewhat justified. In response to an OIA request, Pharmac published extracts from its budget recommendations in 2017–19. The following comment appears to be representative.

> Usually Pharmac can make all of the investments that represent very good value for money and some investments that represent good value for money on behalf of DHBs. ... Investments that Pharmac consider very good value are those that represent significant health gains, and/or those that provide savings or added benefit for the health system overall even if they result in a cost to Pharmac.[98]

Nothing in this advice makes Pharmac look neglectful or irresponsible. It is not its job to advocate greater DHB spending on medicines if it thinks the money could be better spent elsewhere in the health system. As an agent of DHBs, Pharmac must be aware of the DHBs' broader concerns and responsibilities to serve the public. For example, surgery and radiation are important for treating many cancer conditions.[99]

Whether New Zealanders are better off is unknown

Three related concerns come under this heading:

1. Pharmac is focusing on fiscal costs at the expense of health benefits;
2. QALYs are an imperfect measurement of health benefits; and
3. Neither health wellbeing nor overall wellbeing is being satisfactorily addressed.

The first concern was expressed by Hogan in the quote at the start of this chapter.

The criticism has real force, although the problem is with Pharmac's statutory objective. The cut-off for subsidising medicines is determined by a fiscal constraint rather than the marginal value to the community.[100] That situation represents a potential welfare loss for New Zealanders. If the criterion for listing a medicine were based on a threshold for, say, QALYs per dollar that was similar year in year out, the annual budget would be more flexible. Pressures would remain, however, to lower the threshold ratio. Ultimately, the issue is the budget constraint.

Pharmac's statutory objective also gives it a therapeutic value focus rather than a wellbeing focus. People trade health wellbeing against non-health facets of wellbeing. Pharmac cannot do so. If some people do not access available beneficial health services, that Pharmac's concern regardless of the reason. But perhaps the reason should matter.[101]

The second concern is also valid. QALYs are indeed an imperfect measure of health gains from a medicine. The weights accorded to different degrees of health impairment in calculating QALYs are contentious. For example, a sedentary person would likely evaluate an extra year of life sitting in an arm-chair differently from an active person, and a concert pianist would value the loss of flexibility in a wrist differently from an average person. A central authority must estimate an average value. That is not good for those whose valuations are outliers. The greatest good for the greatest number is not the greatest good for all.

Moreover, the wider the definition of health gains, the more problematic it is for Pharmac to assess them. Some aspects can be psychological and deeply subjective. To make its task manageable, Pharmac limits the scope of estimated health benefits:

> When estimating QALYs, only the impact on health-related quality of life is measured, as opposed to taking into account all factors that may affect a person's general quality of life.[102]

Given such difficulties, Pharmac does not rely on QALYs rankings in making decisions. They are instead an input into Pharmac's Factors of Consideration.[103]

However, the Factors of Consideration blur rather than resolve the difficulties with QALYs. Their diverse considerations pull in different directions and their relative importance is subjective and likely inconstant over time:

> The Factors are not weighted or applied rigidly, and not every factor is relevant for every funding decision Pharmac makes. This is because the situation for one assessment may require quite different considerations

> compared with another. Funding decisions are made relative to other options, and the context within which decisions are made is constantly changing.[104]

Pharmac's decision-makers no doubt do their best to weigh these factors and reach a reasonable agreement about the overall balance – and thereby the immediate subsidy decision. But a different group at the table might have weighed the factors differently and reached a different decision.

On the cost side of the QALYs per dollar assessment, there is a fundamental tension between Pharmac's desire to see greater emphasis on patient autonomy[105] and its decisions to exclude from its cost calculations lost wages, premature mortality and pain and suffering from treatment.[106] The postulated ethical premise is that to include these costs would be to bias calculations against those not in the labour force.

That premise appears to be more political than ethical. Some households would surely place a high priority on the family breadwinner able to work again. Lost wages might matter more to them than to Pharmac.

The contrast between ACC's incentives and Pharmac's is instructive. ACC has a strong fiscal incentive to use medical services to expedite an injured worker's return to the workforce. Doing so reduces ACC's liabilities to pay an income-related benefit. Pharmac does not have this incentive.

The point here is not whether Pharmac or ACC must be wrong. It is that government agencies must be given a direction and they should adhere to it. The important questions are what this directive incentivises the agency to do and whether those incentives are correct.

The third concern is also valid. Pharmac (and indeed the Ministry of Health) does not focus on overall wellbeing. Pharmac exists to assess the therapeutic efficacy of subsided pharmaceutical medicines. It does not focus on wellbeing because it does not know, and is not required to know, to what degree people would spend their share of the subsidy money differently, if they could.

Therapeutic value for money is not the same as wellbeing value for money. The cost to the health system is not the same as the cost to the community, consumer and family. The lowest-cost medicine is likely not a perfect substitute for alternative medicines and embodied treatments. Given the choice, consumers would likely spend the same money on a different mix of medicines, or in some other way. While many might spend it less well, it would be their money and their health.

Universal subsidies distort choices and invite wasteful use. People might prefer the money to the subsidised commodity, but they do not get that choice. They and their specialist adviser may strongly prefer an unsubsidised treatment, but they must pay taxes for the subsidised product regardless. Prescribers may feel driven to prescribe the sole subsidised medicine even if it is not the best option for the patient's condition. By thus distorting demand and use, universal subsidies suppress information about the diversity of the population's preferences and priorities. That makes it hard for those responsible for subsidies to know the difference they are making.

The following questions serve to illustrate the difficulties. What mix and volume of prescription medicines would be consumed and under what alternative arrangement? Would Pharmac still be a bulk purchaser for DHBs, and could it also act as a bulk purchaser for private hospitals, private insurers or community pharmacists? Or would a range of bulk purchasers emerge? Would the government mandate purchasing insurance if there were no subsidy system, and if so, what would be the mandated cover? What substitute

arrangements would be made to help those with expensive pre-existing conditions that private insurance does not cover? What would be the alternative welfare arrangements to address these and other affordability problems? Would such assistance give recipients a cash-out option?

Pharmac cannot hope to answer these questions and should not be asked to. It is a problem for those assessing the subsidies' intended goal and whether Pharmac's statutory objective is fully aligned with that purpose.

The conclusion that no one can really know how much the subsidies have improved the health status of New Zealanders was informed by an extensive assessment by University of Canterbury economists Alan Woodfield, John Fountain and Pim Borren (see Appendix 3).[107]

Assessment

There are fundamental problems with current arrangements. The difficulties are inherent in the lack of clarity as to what the subsidy system is intended to achieve. Pharmac's statutory objective gives it a fiscal focus. The alternative of a health or wellbeing focus is impractical given the lack of clarity about what people would have done otherwise.

The more Pharmac is pressured to base its decisions on contentious, broad welfare considerations rather than narrow therapeutic efficacy relative to cost, the more political its decisions may be and the harder it will be for it to defend its decisions on technical grounds.

Financial affordability for very low-income households or those with very costly conditions is best seen as a welfare state benefit issue. It is addressed further in Chapter 4.

CHAPTER 4

Evaluation of the issues

The previous chapters established that Pharmac's activities in administering the subsidy regime have produced major cost savings for New Zealanders, and these represent a national income gain. They also established that the subsidy regime is inherently controversial and distortive. The true health and wellbeing gains are not known.

Evaluation framework – Private good vs public good

The central question of what the problem is with private arrangements for which the subsidies are the remedy is particularly pertinent because prescription medicines are a private good, as are food, clothing and housing. First, their use is rivalrous. The pill that you, the reader, swallow cannot in general benefit anyone else. Second, access is easily excludable. Supply can be withheld from those who do not meet any restrictions (e.g. meeting the supplier's price or government's criteria for importing and domestic sale).

Those two attributes create a presumption in favour of competitive unsubsidised provision, along with a welfare safety net to alleviate affordability problems.

(The contrast is with public goods, such as communicable diseases. One person's failure to inoculate or self-isolate can harm others by infecting them. Compulsion may be needed, subsidy or no subsidy.)

Problems with subsidising private goods include:

- the distortions introduced to private choice from altered relative prices, thereby potentially producing a poor fit between what is consumed and might have been consumed;
- the costs to the community of measures to collect and avoid taxes and of decisions that increase one's likelihood of being able to take advantage of the subsidy;[108]
- flawed bureaucratic and political decision-making, no matter how well-meaning, due to incentive and information problems;
- regulatory creep. (Subsidies invite over-use, waste and other unintended consequences. To limit their fiscal cost and emerging unintended consequences, governments are compelled to take supplementary measures to limit use and thereby individual freedom of choice.)[109]

Pharmac is incentivised by its statutory objective to have a fiscal cost/therapeutic efficacy focus. That is not necessarily the focus of those whose money is being spent.

Public policy arguments that might be put forward for subsidising medicines of a private good nature despite such drawbacks include:

- Egalitarianism – no one should be denied treatment for money reasons;
- Monopoly – patented medicines are over-priced;
- Paternalism (merit good) – people do not do what is best for themselves;
- Lack of knowledge – people do not know what is best for themselves.

All four arguments are weak. The first three are general. New Zealand governments do not subsidise necessary food, clothing or housing for those who can afford to buy them. On the monopoly aspect, Chapter 2 shows the effectiveness of disciplined procurement

in reducing prices. In any case, subsidies for the purchase of a monopoly good surely benefit the monopolist. Appendix 3 elaborates on these aspects.

The affordability issue

Nothing in the assessment to this point questions the case for targeted assistance for those in financial need. For self-competent adults, cash assistance is preferable to benefits in kind. The social welfare system administered by the Ministry of Social Development and Work and Income independently provides cash assistance for affordability issues arising from health and disability. They include provision for emergency benefits and living payments to supporting carers.[110]

The average household can afford the average cost of pharmaceutical medicines.[111] In the year ended June 2019, net CPB spending was $985 million, which represents on average $21 per filled prescription.[112] DHB distribution costs to pharmacies of $400 million would lift the average to $29. The most common out-of-pocket payment to the pharmacist is $5.[113] There were 10 filled prescriptions per capita per annum on average. That puts the average annual cost at around $375 per capita or $1040 per household (GST inclusive) if people paid directly rather than through the tax system. This is not crippling for the average family, even in the unlikely event the government treats all fiscal savings as a tax grab. For example, the annual average family food bill is about $10,000.[114]

In any one year, a minority of households could incur potentially crippling medicinal costs. On Pharmac's figures, 20% of patients account for 91% of the annual cost of prescription medicines in any year.

The affordability issue arises with respect to those who cannot obtain insurance cover because of pre-existing conditions or severe financial need. About 5% of the population cannot afford visits to a general practitioner, let alone accumulate savings or fund insurance premiums.

The welfare state exists to support those in financial need. There is indeed a stigma to eligibility conditions requiring proof of need. This is real, but it is also commonplace, applying to almost all working-age welfare benefits. The Community Services Card provides ongoing special assistance to those who qualify in a relatively discreet way.

On the one hand, the social sanction of the stigma improves the incentives to self-provide. On the other hand, the imposition of conditions is demeaning to those for whom adequate self-provision was never an option. People can differ as to where they draw the balance. Under a system of voluntary charitable assistance, there is scope for people to exercise their own preferences without imposing them on others. A state-directed system is much more coercive. The issue is about where to find the balance for a state safety net, not its existence.

In contrast to medicine subsidies, most welfare assistance in New Zealand is targeted. Eligibility depends on satisfying thresholds of need. An instructive precedent for a targeted safety net relating to health care in New Zealand is the Residential Care Subsidy. This subsidy provides major support for elderly citizens needing long-term residential care in a hospital or rest-home. Access to this subsidy is both means- and asset-tested.[115] Those above the threshold must pay the full weekly cost of the residential care, up to a Maximum Contribution.[116] Those with nothing get free care. No Kiwi needing long-term residential care needs to die destitute under a bridge.

The political case for pharmaceutical subsidies

Whereas the public interest case for current arrangements is weak, the political case is clear. Incumbent interests and public expectations support their continuance and even their enhancement. Redistribution favours some groups at the expense of others, so why would the former want that to change?

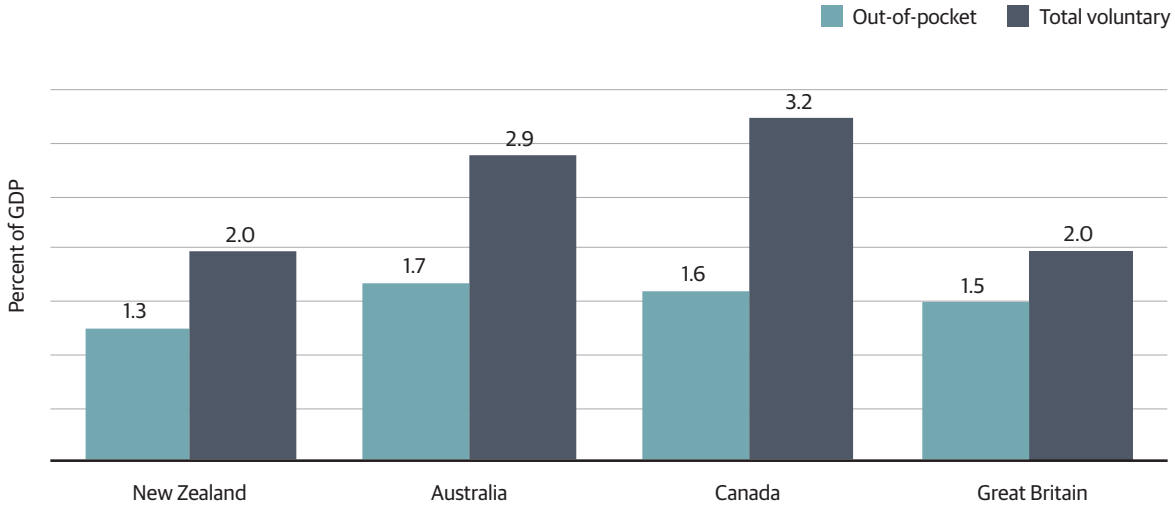
There is an argument that subsidies for medicines are politically sustained because median voters rationally vote in subsidies for themselves if they think the burden of the taxes to fund them will fall disproportionally on higher or lower income groups.[117] However, median voters can vote for redistributive taxation in their favour independently of funding for health care, so this proposition is not persuasive as it stands.

Subsidies for medicines with patent protection can be expected to have the support of patent holders. The opposite would apply to policies aimed at opening patent holders to competition. Countries in which pharmaceutical companies are significant employers may have enough political clout to support policies for expanding local demand for their products, but not for policies to enhance competition.

The political case for extensive government involvement has proven to be near irresistible among prosperous countries. Even so, there are substantial differences across these countries in the degree of involvement and its nature. New Zealand's current arrangements are a policy choice.

New Zealand is placed towards the bottom end of the international spectrum for its use of voluntary payments to fund and allocate health services.[118] (Of 49 countries in the OECD's database for 2016, only 12 had less out-of-pocket spending on (total) health services as a percent of GDP than New Zealand's 1.3%. Australia was the median country with 1.7%. Adding other private spending (e.g. by private health insurance) brought New Zealand's voluntary spending on health services in 2016 up to 2.0% of GDP, compared to a 49-country median of 2.3%. Figure 6 compares New Zealand's funding on these two measures with the funding in Australia, Canada and Great Britain.

Figure 7: Voluntary funding of health services (2016)



Source: OECD, "Health spending (indicator)" (2019), doi: 10.1787/8643de7e-en.

(In 2018, voluntary funding in Australia and Canada was 30–31% of all health spending as against 23% for Great Britain and 21% for New Zealand. The median (for only 36 countries with 2018 data) was 25%. Norway was lowest at 15%, Mexico highest at 49%.

There is also considerable variation within countries across time. For example, the share of voluntary funding of health services fell in the United States from 51.2% in 2013 to 15.8% in 2014, according to OECD statistics. Presumably, this reflects the impact of Obamacare.

Sources of growing pressure on the system

> The forces that have shaped Pharmac over the last 25 years – huge demand for medicines on constrained budgets, rapidly evolving technology and the economics of the global medicines market – will greatly influence its next 25 years too.[119]

A growing and ageing population, the advent of expensive but effective treatments for cancer and some other conditions, and Pharmac's expanded role and pressures promise to compound the weakness in the current arrangements identified in Chapter 3.

Filled prescriptions per of head of mean population rose from 8.2 in 2009 to 9.7 in 2019. During these 10 years, 204 new medicines were added and there were 242 expansions of subsidy scope. Treasury's long-term fiscal projections to 2060 show health spending rising even more sharply as a percentage of GDP than spending on national superannuation for an ageing population. The rising per capita demand puts real pressure on Pharmac each year to fund the budgetary room to list new medicines or expand access to existing medicines.

Under a static budget, funding the medicinal demands of a growing and ageing population requires cutting unit supply costs each year. Currently, Pharmac must find annual savings on the order of $40-$70 million to keep up with funding the growing demand for existing subsidised medicines. To fund new medicines or expand access for existing medicines requires bigger savings, or a bigger budget.[120]

Nor will it be possible for Pharmac to answer questions about overall health and wellbeing outcomes satisfactorily. The intensity of interest in these questions has been rising and may continue to do so. This shift is reflected in the previous elected Government's cross-agency social investment approach, the current Government's "first wellbeing budget" and Treasury's Living Standards Framework. These forces are pushing against government silos and the CPB.

In response to external political developments, Pharmac has been drawn into political matters. Thus, Pharmac's 2019 Annual Review said it aims to "eliminate inequities in access to medicines by 2025." It interprets this to mean "everyone should have a fair opportunity to access funded medicines to attain their full health potential, and no one should be disadvantaged from achieving that potential."[121] But what if the budget for funded medicines is not large enough? And what is wrong with achieving one's full health potential without access to funded medicines?

Worse, its measure of success is not health equality in the sense of equal treatment but equality of health outcomes for Maori, Pacifika peoples, refugees, those in isolated regions and folk living in high socioeconomic deprivation:[122]

> Health equality is 'sameness.' Health equity "better recognises that people differ in their ability to attain or maintain health" and that consequently "equitable outcomes in health may require different (i.e. unequal) inputs to achieve the same result." Pharmac recognises that to achieve equal outcomes, unequal input is required and that this requirement is the application of equity.[123]

It would be hard to conceive of a more politicised and less achievable goal for Pharmac. Health outcomes depend on many things outside Pharmac's control, including lifestyle choices. Even the state welfare system does not think it can achieve equal outcomes. Why not just do what the Ministry of Social Development does – give people the cash? Then providers can emerge which can better tailor the delivery of services to the needs of different groups.

Increases or decreases in the CPB

Increases in the CPB would ease this funding pressure and should increase prescriptions per capita further. What it would not do is stop the controversy over wellbeing benefits, pricing and medicine choices. The bigger the role of government in forcing people to pay for prescription medicines through their taxes, the bigger the likely controversy about its performance.

If the CPB were reduced, to what extent would medicine prices be higher because Pharmac had less commercial clout? That issue needs more analysis and debate.

Discounts for bulk supply can be negotiated without any need to subsidise the purchased products. In the extreme case of the absence of a universal subsidy for prescription medicines, DHBs might as well still use the advantages of prudent buying and negotiating so discounts for bulk supply can be achieved without any subsidies for the products thus purchased. They can be worth achieving even if none of the gains are used to boost health spending.

But there are far more pragmatic options. Even just holding the budget steady as the population grows and ages would likely see greater recourse to independent provision through some combination of out-of-pocket spending and private insurance.

Assessment

Pharmac's expanded scope and ambitions seem likely to distract it from its core function. The case for sound professional decision-making in medicine procurement is core and self-evident. The case for subsidising medicines at all, let alone at 100%, regardless of financial need is not. People do have private insurance options for pooling risks.

It is easier for Pharmac to negotiate discounts for bulk supply based on the greatest potential therapeutic efficacy per dollar than assess overall health benefits for those using these medicines compared to what might have happened otherwise. The narrower goal at least offers greater clarity and accountability, despite its limitations.

A policy tension arises because Treasury's Living Standards Framework and cost-benefit primer would not permit this narrow approach. A cost-benefit analysis would require the best forgone alternative to the subsidy be identified and analysed. That requirement brings to the fore the question of what problem the subsidies are solving.

Pharmac's job is to administer the subsidy system as best it can, not to question it. It is Treasury's and the Ministry of Health's job to both look beyond the silo and assess the value to the community of the subsidy system and advise its Ministers accordingly.

Failing this examination, the expanding scope of governments' ambitions for Pharmac risk increasingly politicising it. It is bound to fail to achieve equal health status outcomes for Maori, Pacifika peoples and those with low socioeconomic status by 2025. The relatively poor health outcomes of some groups are symptomatic of problems far beyond Pharmac's ability to offset. Trade-offs must be made when the government sets budgets. Would governments

rather see better health outcomes for prisoners or better work-skill outcomes? Would prisoners be healthier in jobs when released from prison or back on welfare? Like all things, Pharmac must live with the consequences of such political decisions and do the best it can in its silo with the resources it has.

To provide efficient procurement of pharmaceutical medicines on behalf of DHBs is to provide a valuable service to the community. It is a narrow role, but there is nothing wrong with specialisation.

This report has identified shortcomings in current arrangements. At their heart is the problem of not knowing what the problem is for which the subsidy is the remedy. That is a problem for the Treasury and the Ministry of Health to assess, as lead policy advisers.

In the absence of a clear public policy case for the subsidy, there should be a presumption in favour of a policy direction that expands the scope for individual choice when opportunities to do so arise. Cash for those in financial need and lower subsidies for everyone else would likely raise overall wellbeing compared to current arrangements.

The growing pressures on the CPB from a growing and ageing population and the advent of very expensive treatments strengthen the case for seeking alternative sources of funding to the CPB. Greater recourse to user charges and private insurance have potential.

Conclusions

In the past, Pharmac provided an outstanding example within the public sector of what can be achieved when an agency is given a relatively clear and single overriding objective, narrowly interpreted, and develops a culture focused on achieving that objective. There is a general message here for the design of government agencies.

Above all, Pharmac is to be applauded for the low prices it has achieved for imported pharmaceutical medicines and for the rigour and discipline it has brought to its task. Lower prices for imported products increase national income. The successful application of such techniques has allowed Kiwis to markedly increase the per capita volume of prescription medicines consumed since 1993 without increasing spending relative to GDP.

Pharmac should systematically benchmark its performance against that of top medicine procurers in other countries. DHBs, the Ministry of Health and Treasury should ensure that it does.

The concern that current arrangements are biased against introducing costly innovative new medicines has some merit. Pharmac may not have room for them in the budget even if they are worthy of inclusion. Pharmac could reduce this concern by repeatedly demonstrating and reminding the public that it does list new medicines on their merits, even when the cost is greater than for an existing subsidised product.

A more serious weakness with current arrangements is that no one knows whether these are improving health outcomes, let alone the overall wellbeing of New Zealanders. Taking people's money in taxes and dictating which medicines to spend it on disempowers taxpayers.

This weakness manifests itself in various ways. Current arrangements create open-ended expectations Pharmac can never fully satisfy. One symptom is endless pressure to increase the subsidy budget because 'more is always better.' People can say their taxes entitle them to a say in what is subsidised. Anger, distress, disillusion and political agitation are understandable recurring consequences. This sense of entitlement weakens civility, self-reliance and resilience.

The weakness reflects a lack of clarity about the subsidy's policy rationale. The problem with private arrangements for which the CPB is the remedy is unidentified. As a result, no one can know whether a higher or lower level for CPB spending would be good or bad for overall wellbeing.

In the absence of a public policy case for the subsidy, there should be a presumption against subsidising those for whom affordability is not a problem. It is cheaper to pay for private goods directly rather than through the tax system.[124] For those for whom affordability is a problem, there should be a presumption in favour of cash assistance.

Pharmac could still negotiate bulk discounts with a smaller CPB. Perhaps Pharmac would have less clout because there would be greater fragmentation of procurement. That might mean smaller discounts and less of a national income gain.

The extent of this concern merits further analysis and debate. Benchmarking against countries that do not rely much on pharmaceutical subsidies should be informative. Conceivably, private hospitals and insurers could also hire Pharmac to negotiate on their behalf in the common cause. (That is if Pharmac were permitted to

supply its services on a commercial basis; DHBs were not too anti-competitive; and any conflicts of interest for Pharmac could be managed.) Pharmac could even become an entity that contracted its negotiating skills and accumulated information internationally.

A more diverse structure could also allow greater scope for cooperation between suppliers and users whose mutual benefits might not be obvious to outsiders. Government and state agencies would still be responsible for spending taxpayer money well and welfare assistance, but people would be freer to spend more of their own money as they see fit.

Given the existing policy preference to provide the subsidy in kind, one option for better targeting would be to increase the standard $5 co-payment for prescription medicines to something closer to the rate charged in Australia. Existing lower payments for those in need could be retained. The cap for annual spending per household also could be retained in some form.

The state must also continue to be responsible for public health issues, for example, the efficacy and coverage for immunisation programmes. Arguably, the less involved it is in private good matters, the better it could focus on such important tasks.

This research has not found significant non-commercial barriers to a greater role for private insurance. The most likely factors holding back greater recourse to insurance cover are pre-existing conditions and CPB subsidies in kind that pool the risks via the tax system.

A greater role for private insurance would see a richer menu of policy offerings. Kiwis would have a wider range of choices for pooling risks of costly medicinal treatment than under the current New Zealand model. Tax burdens could be lower, but medicine costs could be higher because of the reduced economies of scale when moving away from sole subsidy status.

A modest recommendation in this respect is for Pharmac and policymakers to look for opportunities to reduce the role for subsidies-in-kind with respect to pharmaceuticals. Greater recourse to part charges for medicines, private insurance and reliance on the broader welfare system to address issues of financial need would alleviate some of the concerns identified in this report with CPB.

Although not a focus of the report, this research has also identified concerns about the expansion of Pharmac's cost-reducing role in DHB hospital medicines and medical devices. If Pharmac were an agent of the DHBs for procurement, it would not dictate to them what they could or could not buy. Accountability is confused if hospital managers are responsible for patient care, but not for important elements of the delivery of patient care.

Pharmac's expanding role does risk drawing it increasingly into political matters, such as socioeconomic access issues. This could reduce its independence and has arguably already occurred. A narrow interpretation of the health wellbeing aspect of its statutory objective would see it focused on narrow therapeutic efficiency. The current broad interpretation of overcoming socioeconomic disadvantage loses that focus and invites overreach.

A final point is that the public needs the government to excel in its public health function. The 1918 influenza epidemic, the polio scares of the 1959s, the recent measles outbreak and Covid-19 all demonstrate the critical importance of that government function.

If government agencies and politicians were less distracted by the dissent and dissatisfaction induced by ill-justified subsidies for private goods, they could focus more on protecting the public from communicable diseases – and reduce taxes and public debt.

APPENDIX 1

More criticisms of Pharmac

This appendix lists and comments on some additional criticisms of Pharmac encountered in the course of this research. Although this review does not consider that some of these criticisms have force, they all have a welcome accountability aspect. They oblige Pharmac to explain to its political masters, suppliers and the public why its allocation decisions are in accord with its statutory objective. Public criticism and challenge are a necessary disciplinary check.

Pharmac is not subsidising the drugs my condition needs

A common criticism, in mainstream media and in submissions by individuals to parliamentary select committees, is that Pharmac has not approved a subsidy for a medicine the complainant wants subsidised. Those complaints commonly fail to recognise that with a given budget constraint, taxpayers can only spend extra money subsidising one medicine if they spend less on subsidising at least one other medicine. The complainants whose cases are picked up in the mainstream media are not asked to identify which medicines Pharmac should subsidise less.[125] In effect, they are arguing that the budget constraint should be eased. Pharmac does not set its budget.

Pharmac sometimes errs in assessing therapeutic efficacy

Assessing the validity of this complaint in any detail is beyond the expertise of the author and the scope of this report. Of course, Pharmac's experts have incomplete information. The experts in the pharmaceutical companies who have been assessing a new medicine for years should know more than Pharmac about its likely therapeutic efficacy. Pharmac's experts can only assess the evidence in front of them. It will naturally be incomplete and have an advocacy element. Statistically, it is inevitable that they will sometimes wrongly reject a subsidy application and sometimes wrongly accept one. No alternative structure or change of personnel would prevent that. It is intrinsic to the problem of incomplete information.

The open question is whether Pharmac is making such errors too often, statistically speaking. This study has not uncovered any evidence either way on that aspect.

Pharmac considers only costs to the CPB, ignoring fiscal costs elsewhere

As already mentioned, it is not true as a general proposition that Pharmac considers only the costs to the CPB, ignoring fiscal costs elsewhere. Nonetheless, this research has encountered strongly held industry views that Pharmac does put more weight on fiscal savings to the CPB than on savings elsewhere in the health system. It is plausible that this criticism has some validity given the budgetary emphasis in Pharmac's statutory objective.

Pharmac focuses too much on fiscal costs and too little on system net benefits

This criticism has real force. Pharmac's statutory objective clearly obliges it to have an overall fiscal focus. The cut-off threshold for subsidising medicines is determined by a fiscal constraint rather than by the opportunity cost to society. That situation represents a potential welfare loss for Kiwis. It is intrinsic to the binding budget constraint in the New Zealand model. If the criterion for listing a medicine were based instead on a threshold for, say, QALYs per dollar that was much the same year in year out, the annual budget would be more flexible.

Pressures would remain, however, to lower the threshold ratio. Ultimately, the issue is one of budget constraint.

No cut-off threshold for QALYs per dollar

Under current arrangements, the cut-off threshold for funding a new medicine has the potential to vary greatly annually.

Other things being equal, this is inter-temporally inefficient. Instead, the CPB should be expanded or contracted so it could fund all medicines satisfying much the same QALYs per dollar threshold from one year to the next.

The degree to which this is so is difficult to determine from the average statistics Pharmac publishes. For example, in its 2019 Annual Review Pharmac reported that:

> There were 118 quality-adjusted life-year (QALYs) achieved per $1 million spent for funded proposals, compared to 12 QALYs per $1 million for all available investment options...[126] The corresponding figures in its 2018 Annual Review were 238 and 42, respectively.[127]

It transpires that these statistics compare the expected QALYs gains for newly funded medicines in the financial year per million dollars of CPB spending on these medicines with the corresponding figures for those that might otherwise have been newly funded in that year.

The 2018 figure of 238 is much higher than the 118 figure in 2019, but the statistics do not reveal whether the cut-off figure in 2018 was higher than in 2019. The difference in the published figures is merely suggestive.

Pharmac could do a lot more to report on its assessment of the QALYs gains from its activities in other ways, too. It would be useful if it reported its assessed QALYs gains per dollar of overall health system costs.

Hidden costs in Pharmac's structure aggravate supply-side uncertainty

A volatile and ill-known cut-off threshold for accepting a subsidy application creates business uncertainty. Potential suppliers do not know how good the medicine needs to be in order to get it listed in the Schedule. This uncertainty must affect their decisions as to whether the cost of applying for registration in New Zealand to hopefully approve a subsidy application is worth the effort.

In the UK, the budget is more open-ended and the threshold for accepting an application for subsidisation is more predictable.

Other things being equal, community welfare would be higher if the CPB borrowed in such years to account for the high QALYs per dollar opportunities and ran surpluses in years with fewer such opportunities.

Pharmac's structure and operations are anti-competitive

Pharmac survived court challenges on anti-competition grounds in its early years. It is exercising monopsony power but in an insignificantly small portion of the world market. Pharmac is actively seeking competitive entry (particularly of generics) and pricing. If it had the power to ban the sale of registered medicines in New Zealand it was not prepared to subsidise, there could be a stronger case for an abuse of monopsony power – but it does not.

The Crown should have the right, like anyone else, to determine which medicines it will subsidise and by how much. How well it exercises that right is a different matter.

At the same time, it is unclear whether the special provisions favouring Pharmac in respect of the *Commerce Act* are needed.

Reference pricing cannot expect to achieve budget control

Pharmac's reference pricing strategy, where applied, is to subsidise every pharmaceutical in each therapeutic sub-group at the level of the lowest-priced one in that sub-group.[128]

A substantial assessment by economists from the University of Canterbury made the strong assertion that reference pricing and related measures could be expected to "have no sustained impact on curbing public drug spending." This was after reviewing the experience with reference pricing internationally, particularly in the European Union.[129] A central point was that open-ended subsidies with demand-driven budget spending amounted to an open cheque book unless accompanied by effective direct measures to curb demand. Implementing and sustaining constraints on prescribing practices and related aspects of demand would be a challenge.

Clearly, the New Zealand model has achieved sustained control of spending growth. What has made New Zealand's experience so different is the focused single-purpose value-for-money target and the power to achieve it (see Chapter 1). But the economists were correct about the need for demand-side measures. Limits to prescribing have been set and some oversight exercised.

Pharmac's success in this regard is even more impressive in the light of other countries' less successful experiences, as documented in the economists' study.

Pharmac's decisions lack transparency and cause uncertainty

The commercial aspects of Pharmac's role are at some cost to transparency and decision-making by pharmaceutical companies. Again, this is a criticism of the New Zealand model rather than of Pharmac unless it can be shown that Pharmac is failing to fulfil its statutory obligation in this respect. This research has not uncovered solid evidence that Pharmac is failing in this respect.

Pharmac's aggressive commercial role hides costs

Suppliers want to see their effective medicines used most effectively. They do not want to see them displaced by a competitor's inferior product. Relationships and trust between suppliers and purchasers are important, particularly when a product's quality cannot be accurately assessed before its use, and perhaps not even afterwards.

There is a mutual dependency between suppliers and purchasers of scale. Relationships are desirably based on trust, integrity and reciprocity when something unexpected disadvantages either side. (Most commercial contracts are 'relational,' that is, they do not cater for all circumstances and contingencies. For example, disruptions outside the control of the contracting parties might require a speedy response that could violate some contractual conditions. Quick resolution is easier where there is mutual trust.)

A strict auction market is more of an arm's length affair. Ideally, all alternative medicines offered in the auction would be identical in every respect, with price being the only distinguishing element yet to be determined. If the generic drug is identical to all the alternatives, it is likely to win at auction.

Any given situation only represents an approximation to that simplified ideal. In reality, security of supply chains, capacity to respond to unforeseen shocks, quality control, financial strength, logistical capacity, ease of application, education of prescribers and many other factors affect the QALYs gains from a preferred medicine.

If Pharmac were spending its own money, accountable only to itself, it could more easily assess the diverse merits of contending medicines and suppliers. The need for a public body when challenged to justify its decisions to DHBs and Ministers and ultimately taxpayers is a necessary but inhibiting constraint. It is

difficult to make decisions that cannot be readily defended publicly for fear of breaching libel or commercial confidentiality laws, to pick two examples. So, in practice Pharmac will have to find a balance between providing a good reason for difficult decisions and the real reasons. Most public organisations face this problem from time to time.

This is a matter of degree rather than of kind. Pharmac will certainly be taking supplier capabilities into account when deciding what to subsidise. Failing to do so would violate its statutory objective and blow up in its face when supply proves inadequate.

Pharmac should be doing more to fund cost-reducing R&D

Pharmaceutical companies' prime role is commercial. If they do not make adequate profits, they will not survive. That business model pushes them towards innovations that can be patented. Such innovations may be cost-reducing or cost-increasing relative to alternatives, but the latter is prevalent.

The current development of repurposed medicines is of a cost-reducing nature. It can extend the scope of the therapeutic application of medicines that are already approved for public use and are likely to be available in generic form. Where they are available generically, the benefits from such research will have more of a public good characteristic. All producers of the generic products can benefit from R&D even if none of them funded it.

Such developments should be of much greater interest to procurers, such as the DHBs (Pharmac), ACC and private health insurers than to for-profit pharmaceutical companies. Private philanthropists could also be interested.

Research in New Zealand based on repurposed medicine exists, but there is arguably a gap in public funding for this type of research.

For example, MBIE's multitudinous "funding and support programmes [that] aim to build a high-performing science and information system that will transform New Zealand …"[130] do not appear to encompass any programme capable of funding clinical trials for a project of a public good nature (i.e. of dubious commercial return). To illustrate, MBIE's website points to the government-funded Health Research Council's activities. However, the Council's maximum grants for projects and programmes do not allow funding for more than $1 million per year.[131] This is arguably too little to fund clinical trials of a scale that would impress international (or domestic) regulatory agencies.

Similarly, the government's Callaghan Innovation Fund has a commercialisation focus rather than a public good focus. The Marsden Fund is academically oriented, measuring its performance by journal citations rather than contributions to New Zealanders' health and wellbeing.[132] This is not to criticise these organisations – it is not their job to be all things to all people.

The evident difficulties in funding cost-reducing medical R&D in New Zealand do raise the question of whether medicine procurers and funders could be more active in ensuring that state funding for medical R&D is sufficiently supportive.

Pharmac is 'outside' the rest of the health system

Pharmac is not a health service delivery agency. It does not daily deliver in person to the needs of the individual patient or consumer. Its focus instead is on statistical therapeutic benefits for the greatest number. This is not a criticism. It goes with the territory. Civil engineers designing a road, a building or a dam must design to standards that balance greater cost against reduced statistical deaths and injuries. This must be done systematically and analytically. Spending on health care requires the same analytical balance.

This abstract analytical point of view can look callous to those inside the health system dealing with the plight of the sick individual. It behoves Pharmac to be sensitive in its communications in that respect.

A good system must have a good statistical focus on value-for-money, but it must also cater for differences and preferences in user needs. Pharmac has built considerable flexibility into its structure, but it cannot hope to provide the richness of the options of a competitive system. The more Pharmac's operations limit or distort individual choice, the greater the potential for conflict and political involvement. Pharmac's expanding role aggravates this risk.

APPENDIX 2

Sole subsidy example – Epilepsy

The scale of the financial gains from conferring sole subsidy status on one medicine is readily appreciated by looking at a recent example. Prior to 1 October, 2019, Pharmac was subsidising 100% of three alternative medicines for treating epilepsy. By tendering for sole supply (i.e. sole subsidy), it achieved a 92% reduction in the cost of one medicine, Logem, on 1 October, 2019.[133] Table 2 summarises the effect on relative prices.

Table 2: Indicative effect of sole supply on price differentials

NZPS listed supply costs for each of three medicines for treating epilepsy (56 tablets each of 100 mg)			
	Arrow-Lamotrigine	Lamictal	Logem
Supply costs as listed in the NZPS			
For 1 April 2019	$59.90	$79.16	$56.91
From 1 Oct 2019	$59.90	$79.16	$4.40
Changes in costs at 1 October			
In dollars	$0.00	$0.00	-$52.51
As percentages	0%	0%	-92%
Pharmac/CPB subsidy			
From 1 April 2019	$59.90	$79.16	$56.91
From 1 Oct 2019	$0.00	$0.00	$4.40
Price differences from Logem price			
April 2019 – supply cost excess	$2.99	$22.25	$0.00
April 2019 – charge to end-user	$0.00	$0.00	$0.00
October 2019 – charge to end-user	$59.90	$79.16	$0.00

The problem for users of the other two products was that their prices went from 100% subsidised to 100% unsubsidised. Someone wanting to continue to use, say, Lamictal for their condition saw their zero co-payment on 30 September skyrocket to $79.16 per packet from 1 October. The (pre-rebate) social cost differential at 20 September was only a fraction of that at $22.25. Users who believed that the newly unsubsidised tablets were superior for their situation were understandably angered.

By 18 December, 2019, more than 1300 people had applied under the NPPA exceptional circumstances scheme for a restoration of their subsidy; Pharmac approved more than 1200 of those applications. This degree of approval begs some questions.

The achieved priced reduction was extraordinary and the anticipated fiscal gain at the time of the decision appears to have been of the order of $10 million in net present value terms.[134]

Clearly, the unit cost of supply drops sharply with an increase in market share. This presumably reflects some combination of strategic considerations, and economies of scale and scope.

It is problematic that all three medicines were subsidised 100% in the NZPS for 1 April, 2019 (and in earlier versions). In principle, a better policy from a price distortion/patient choice perspective would have been to subsidise all three medicines at $56.91 from 1 April, 2019, leaving the co-payments for the other two medicines to reflect their social cost differentials.[135] That policy would have reduced the indicative (equally weighted) pre-rebate fiscal cost to the CPB from $65.32 to $56.91. This is a minute fiscal gain compared to what Pharmac achieved under the sole subsidy tendering option.

APPENDIX 3

Weak arguments for medicine subsidies

This appendix briefly canvasses some arguments for subsidising private goods or services. Readers wanting a more comprehensive discussion of these first-principle issues regarding subsidies for medicines could consult Woodfield, et al.'s 270-page analysis and the largely supportive subsequent commentary by Victoria University of Wellington economists Lewis Evans and Neil Quigley.[136]

'Merit good' paternalism

Paternalists argue that others do not know what is best for them and will not consume enough medical services unless the state obliges them to prepay through taxes or mandatory health insurance premiums.[137] That is not an affordability argument.

Such arguments are sometimes called 'merit good' arguments. Arguably, they are more applicable to education where over-consumption is less of a concern.

The fact that a good is being subsidised for no clear public policy reason does not make it a merit good. It may be subsidised simply because it was once politically expedient to do so and it subsequently became politically entrenched, as subsidies so commonly are.

The first problem with this paternalistic justification is that it is too unspecific. If people do not spend wisely on pharmaceuticals, why would they spend wisely on food, housing, education or anything else? The more philosophical question is to what degree the state is justified in taking coercive action to stop people from doing things that do not harm others. If people are not free to make poor decisions, what is freedom about? Paternalism and freedom tread different paths. John Stuart Mill's famous assessment was that people can be told what others think is good for them, but respect for individual autonomy precludes forcing them to change.[138]

A burden of proof must be applied to paternalistic coercive action if the domain for individuals to pursue goals of their own choosing without curtailing similar freedoms of others is to be protected. In general, one person's consumption of prescription medicines does not harm others. People can be informed of the benefits, but the case for coercing them by taxes or regulations is weak.

Egalitarianism

An egalitarian argument is that therapeutic medicines are good for those who need them, and issues of affordability should not preclude people from getting their benefit.

However, many things are good for people who need them, including food, clothing and housing. The welfare state exists to help people with affordability problems. It does not exist to subsidise those good things for everyone else.

Egalitarianism does not justify subsidies for those who do not need them. The state can only help those in financial need by taxing others. The egalitarian argument that a universal subsidy treats everyone as being in the same boat seeks to avoid this reality. Moreover, it is impossible to politically or financially stop the well-off from obtaining more health services than the government of the day funds for those in financial need. The rich will normally spend more on any given good or service than the poor, including health services, for the obvious

reason that they can afford to.[139] There is nothing intrinsically wrong with that under a system of liberty.

Health event uncertainty

Uncertainty about the magnitude of future costs does not justify a state subsidy. Private health insurance exists to pool fire-, accident- and health-cost risks. Health insurers in New Zealand are offering policies that cover some unsubsidised medicines.

Inability to assess therapeutic value

Technical complexity does not justify a state subsidy. No lay consumer needs to know anything technical about how computers or cars work to enjoy their capabilities. Nor do they need a government agency to deal on their behalf. Independent private specialists and consumer information agencies (worldwide through the internet) reduce problems of unequal information. Patients look to expert consultants and prescribers for professional advice.

Monopoly pricing due to patent protection

A monopoly is relevant to competition, but not to the subsidy issue. Patents confer time-limited monopoly rights on innovators for widely accepted reasons.[140] Such rights allow different prices to be charged in different market segments, where resale from one segment to another is difficult.[141] Pharmac's example demonstrates that existing patent rights need not stop commercial procurers with scale from achieving major discounts on posted prices.

Endnotes

1 Pharmac, "Briefing to the Incoming Minister of Health" (8 November, 2017), 6.

2 OECD, "Pharmaceutical Innovation and Access to Medicines," *OECD Health Policy Studies* (Paris: OECD Publishing, 2018), Chapter 1.

3 Of course, Pharmac must comply with statutory requirements, and the incumbent government has the power to over-ride its decisions.

4 For example, prescription co-payment charges were increased sharply from 1990 to 1992 to reduce fiscal pressures and increase cost awareness; the charges were reduced markedly in 2007 when opinions and circumstances changed.

5 OECD, "Pharmaceutical Innovation and Access to Medicines," op. cit. Annex 1.A. The table had no statistics for the United Kingdom, Mexico or New Zealand.

6 Regretfully, the official time series of prescription spending is not easy to find in New Zealand, if they exist at all. Some limited statistics can be gleaned from Pharmac's annual reviews and reports.

7 Pharmac, "Briefing to the Incoming Minister of Health," op. cit. 6.

8 For a description of developments and tabulated annual costs, see Official Yearbook, "Monetary Benefits" (1944), Website, Chapter 24, section 24.

9 "All" includes all citizens and permanent residents. For other categories of eligible persons, see Ministry of Health, "Guide to eligibility for publicly funded health services," Website.

10 The Audit Office, "Department of Health: Administration of the Pharmaceutical Benefits Scheme" (1992).

11 Ibid. 30.

12 Issues of fiscal control, fiscal deficits, and public debt were a priority at that time.

13 A new government, elected in 2000, abolished the Regional Health Authorities. Pharmac became, and remains, a stand-alone Crown entity with an independent board. See Pharmac, "Pharmac history," Website; and New Zealand Parliament, "New Zealand Health System Reforms," Research Paper, Website (2009). For an overview of the evolution of the instability of politicised institutional health system arrangements in New Zealand, see Robin Gauld, "One Country, Four Systems: Comparing Changing Health Policies in New Zealand," *International Political Science Review* 24:2 (2003), 199–218.

14 Pharmac, "A 25-year History (1993–2018)" (Wellington: New Zealand Government, 2019).

15 As distinct from supplies to hospitals and pharmacists other than those in community pharmacies.

16 *New Zealand Public Health and Disabilities Act 2000*, section 47.

17 Pharmac, "Pharmacology and Therapeutics Advisory Committee (PTAC)," Website.

18 The four key dimensions to the factors of consideration comprise need, health benefits, costs and savings, and suitability. The contribution of the medicine to individuals; families, whanau and wider society; and the "health system" must be considered under each dimension. Impacts on government health priorities; Maori health; and "population groups already experiencing health disparities" must also be considered. See Pharmac, "Supporting information," Website.

19 See Pharmac, "Decision Criteria review," Website. A year of life in perfect health has a QALYs value of 1. A year of life in less than perfect health is given a lower value in proportion to the degree of incapacity. The proper graduation of weights is contestable.

20 Pharmac explains its preference for QALYs as a measure of health gains on its website. Pharmac, "Estimating health benefits," Website.

21 Ibid.

22 They might, or might not, all receive the same alternative treatment.

23 Its reasons for excluding lost earnings and other indirect costs are explained in Pharmac, "Prescription for pharmacoeconomic analysis – Methods for cost-utility analysis," Website (2015), section 7.

24 Pharmac, "Purchasing medicines," Website.

25 Pharmac, "Setting and managing the combined pharmaceutical budget (CPB)," Website.

26 Under the *Official Information Act*, Pharmac has released copies of its and DHBs' joint budget bid

recommendations for the fiscal years ended 2016, 2018, 2019 and 2020. The first of these includes the comment that "[i]n previous years Pharmac has been able to make 100% of very good value for money investments within the allocated budget." Pharmac, "Accountability information: Pharmaceutical budget bid information," Website.

27 Pharmac, "Setting and managing the combined pharmaceutical budget (CPB)," op. cit.

28 Pharmac, "Purchasing medicines," op. cit.

29 Ibid. Pharmac lists eight purchasing strategies: negotiation; tendering; requests for proposals; alternative commercial proposals; reference pricing; rebates; expenditure caps; and multi-product agreements.

30 "Reference pricing means that all pharmaceuticals in any given therapeutic sub-group, to which Pharmac decides to apply reference pricing, are subsidised at the level of the lowest priced pharmaceutical in that sub-group." Pharmac, "New funding applications," Website.

31 The number of prescriptions a family would be charged in any year is capped at 20, and there is no charge for prescriptions for children under 14 years. Those who have a Community Services Card may pay even less per prescription. Ministry of Health, "Prescription charges," Website.

32 Patricia Danzon, *Pharmaceutical Price Regulation: National Policies Versus Global Interests* (The AEI Press, 1997), explains the role for discriminatory pricing when marginal cost pricing would only fund 30% of sunk costs.

33 Communication from Pharmac's chief executive.

34 A reviewer has pointed out that this process might disadvantage disease areas not covered by suppliers with large medicine portfolios.

35 Pharmac's contractual options are categorised in its 1995 annual review. Pharmac, "Annual Review 1995" (Wellington: New Zealand Government, 1995).

36 The degree to which prices fall when patents expire is a matter of some complexity. See Rena M. Conti and Ernst R. Berndt, "Four Facts Concerning Competition in U.S. Generic Prescription Drug Markets," NBER Working Paper No. 26194 (2019).

37 For an explanation of the economic rationale for secrecy, see Patricia Danzon, *Pharmaceutical Price Regulation*, op. cit.

38 Pharmac, "Exceptional Circumstances," Website.

39 See Figure 1. This figure excludes GST. The IQVIA 2019 report (Appendix 3) puts overall pharmaceutical spending in New Zealand at 0.9% of GDP, below the United Kingdom's 1.1% and Australia's 1.4%. The basis for its New Zealand statistics is unclear.

40 OECD, "Health spending (indicator)" (2019), doi: 10.1787/8643de7e-en. Note that OECD statistics relate to calendar years, but its statistics for New Zealand for 2018 might be on a June year basis.

41 OECD, "Pharmaceutical Innovation and Access to Medicines," op. cit.

42 Its list did not include the United Kingdom or New Zealand. The absence of comparable OECD official statistics on New Zealand is an indictment of New Zealand's statistical system. New Zealand is the only country out of 34 to not have supplied statistics for 2016. See OECD, "Pharmaceutical Innovation and Access to Medicines," op. cit. Figure 1.1: Retail pharmaceutical expenditure as a share of GDP.

43 For example, Pharmac's cut-off threshold for listing medicines in any given year is fiscally driven. If it happened to be a good year for achieving savings on existing medicines and a lean year for benefits from subsidising new medicines, the cut-off threshold could be unusually permissive that year.

44 Robin Gauld, "Ahead of its Time: Reflecting on New Zealand's Pharmac Following its 20th Anniversary," *PharmacoEconomics* 32:10 (2014), section 3.

45 Sarah Hogan, "Pharmac economic analysis and 'savings' claims," Background note produced for Medicines New Zealand, New Zealand Institute of Economic Research (2018).

46 Pharmac's figures exclude GST and DHB funding of distribution and dispensing costs.

47 Years ended June. The value was 0.8547. With thanks to Michael Reddell for the suggestion, purchasing power parity was not used to make the conversion because pharmaceuticals are largely imported goods in Australasia.

48 From 1 January, 2019, Australians pay $A40.30 for most PBS medicines or $6.50 if they have a concession card. See Pharmaceutical Benefits Scheme (PBS) Australia, "About the PBS," Website. In New Zealand, the standard charge for prescription medicine is between $5 and $15.

49 "DHBs are not necessarily encouraged to live within their fiscal envelopes and there is little to encourage them to apply proper asset maintenance programmes and adequately provision [sic] for on-going maintenance and care of their assets." Deloitte, "Budget 2019: Health – Searching for a concrete set of policy responses," Website. See also Jason Walls,

"The total District Health Board deficit $170m higher than Govt had previously admitted," *The New Zealand Herald* (12 November 2019).

50 Prince Siddharth, "Community Pharmaceuticals: Expenditure Trends," Report to Medicines New Zealand, New Zealand Institute of Economic Research (2018).

51 Pharmac is increasingly taking responsibility for managing public funding for DHB hospital medical devices. The government charged it with developing this role in 2012.

52 "[T]he costs and pricing structure of the pharmaceutical market are often opaque, and there are legitimate questions about the degree of innovation and value offered by certain increasingly costly new treatments." See OECD, "Pharmaceutical Innovation and Access to Medicines," op. cit. Executive Summary.

53 Productivity Commission, "International Price Differences," Research Report (Wellington: New Zealand Government, 2001), vii.

54 Pharmac, "Annual Review 2012" (Wellington: New Zealand Government, 2012), 10–11.

55 Robin Gauld, "Ahead of its Time: Reflecting on New Zealand's Pharmac Following its 20th Anniversary," op. cit.

56 Stephen Duckett, et al. "Australia's Bad Drug Deal: High Pharmaceutical Prices" (Melbourne: Grattan Institute, 2013).

57 The raw numbers for Australia from the Australian Bureau of Statistics (ABS) show a rise in the number of prescriptions from 106.2 million in 1993 to 198.4 million in 2017, while the Pharmaceutical Benefits Scheme (PBS) government prescription gross expenditures rose from $A1,403 million to $A8,447 million. Figures for Pharmac taken from its annual reviews show the number of filled funded prescriptions rose from 18 million in 1993 to 45.8 million in 2017, while CPB net spending (excluding GST and on everything, not just pharmaceuticals) rose from $445 million in 1993 to $849.6 million in 2017. Pharmac's gross spending in 2017 was $1,262 million. The $24.30 figure for New Zealand for 1993 comes from Jacqueline Cumming, Nicholas Mays and Jacob Daubé, "How New Zealand Has Contained Expenditure on Drugs," *British Medical Journal* 340 (2010).

58 Jacqueline Cumming, et al. "How New Zealand Has Contained Expenditure on Drugs," Ibid. 1225. See also Stephen Duckett, et al. "Australia's Bad Drug Deal: High Pharmaceutical Prices," op. cit.; Eric Schneider, et al. "Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care" (New York: The [US] Commonwealth Fund, 2017); and Linda Cobiac, "Pharmac Looks Great Value for Money – An Australian Perspective," *The New Zealand Medical Journal* 125:1358 (2012).

59 Robin Gauld, "Ahead of its Time: Reflecting on New Zealand's Pharmac Following its 20th Anniversary," op. cit. section 5.

60 Donna Chisholm, "Cancer cost: The great disparity between treatment for rich and poor," *North & South* (6 February 2018).

61 Vaccines, hospital medicines, and practitioner supply orders can be dispensed without a prescription.

62 The units per prescription index is chain-linked and weighted similarly to the subsidy index.

63 Pharmac, "A 25-year History (1993–2018)," op. cit. 51.

64 For an explanation of how government regulations can induce this outcome, see Patricia Danzon, *Pharmaceutical Price Regulation*, op. cit.

65 "Clearly, a significant slice of the money we spend on drugs is wasted, a good deal of it in the way doctors prescribe." Pharmac, "Annual Review 1996" (Wellington: New Zealand Government, 1996), 12.

66 Donald Light and Joel Lexchin, "Pharmaceutical R&D: What do we get for all that money?" *British Medical Journal* 345 (2012), 23.

67 "Why, for example, is the per capita cost of new-style antidepressants in Southern RHA more than two and a half times greater than in Northern RHA (see graph three, page 13); and why is the per capita cost of acne drugs in Northern RHA nearly double that of Midland RHA …, with no evidence of different health outcomes." Pharmac, "Annual Review 1996," op. cit. 12.

68 Jacqueline Cumming, et al. "How New Zealand Has Contained Expenditure on Drugs," op. cit. 1226.

69 Robin Gauld, "Ahead of its Time: Reflecting on New Zealand's Pharmac Following its 20th Anniversary," op. cit. section 2.

70 Ibid. Section 5 states that these roles are separated in most other health systems. Other OECD member countries commonly separate these roles and may have more open-ended budgets.

71 Two cases where government overrode Pharmac have been documented in Jacqueline Cumming, et al. "How New Zealand Has Contained Expenditure on Drugs," op. cit. They involved Interferon beta for Multiple Sclerosis and Herceptin for breast cancer. Such interventions risk politicising subsidy decisions

by encouraging pharmaceutical companies and other self-interested groups to lobby politicians directly. The pressure on Pharmac to subsidise Keytruda for melanoma illustrates the dynamic.

72 Robin Gauld, "Ahead of its Time: Reflecting on New Zealand's Pharmac Following its 20th Anniversary," op. cit. section 4.

73 Its role in carrying public debate analytically is also mentioned in Jacqueline Cumming, et al. "How New Zealand Has Contained Expenditure on Drugs," op. cit.

74 Sarah Hogan, "Pharmac economic analysis and 'savings' claims," op. cit. 3.

75 An NZIER report points to declining real CPB spending on pharmaceutical medicines once inflation and other categories of CPB spending are taken into account. Prince Siddharth, "Community Pharmaceuticals: Expenditure Trends," op. cit.

76 Several of these, most commonly from aggrieved users, really relate to the setting of Pharmac's budget. Users needing an unsubsidised medicine seldom tell Pharmac what it should stop subsidising; they just want the government to increase the subsidy budget (the CPB). Politicians set its budget.

77 Pippa MacKay, "Is Pharmac's Sole-Supply Tendering Policy Harming the Health of New Zealanders?" *The New Zealand Medical Journal* 118:1214 (2005).

78 In turn, Pharmac's history of its first 25 years makes it clear that it thought the industry's legal actions at its expense were confrontational.

79 The dramatic disruption to global supply chains caused by Covid-19 is a test of supplier flexibility and New Zealand's degree of vulnerability. Pharmac has inevitably faced some supply issues, but it remains to be seen whether sole supply arrangements were a material cause.

80 Sophie Bateman, "New Zealand ranks last in OECD for medicine access," Newshub (12 August, 2019).

81 If suppliers were locally owned, the gain to consuming New Zealanders would be offset by the losses to investing New Zealanders. Any national income gains would depend on second round effects.

82 The Ministry of Health's Briefing to the Incoming Minister in 2017 commented that the rate of health quality loss in New Zealand had declined more in the last 25 years than in other high-income countries and life expectancy at birth was 13th longest in the OECD. OECD statistics put health spending per capita in New Zealand at $US3,590 in 2016. Eighteen of 36 member countries were spending more per capita.

83 Jackie Evans, et al. "Mind the Gap: An Analysis of Foregone Health Gains from Unfunded Cancer Medicines in New Zealand," *Seminars in Oncology* 43:6 (2016), 265, Abstract.

84 An implicit assumption in this approach is that if a medicine is not subsidised, it will not be consumed. See Chapter 3 in this report.

85 Donna Chisholm, "Cancer cost: The great disparity between treatment for rich and poor," op. cit.

86 In 2016, 79% of pharmaceuticals used in New Zealand by volume was for generic medicines, but by value it was only 31%. Of 31 OECD member countries, only the United Kingdom, Chile and Germany had a higher share by volume. The volume share in Switzerland was only 22.5%. OECD, "Pharmaceutical Innovation and Access to Medicines," op. cit. Figure 1.6.

87 Pharmac, "Decision to fund a new hepatitis C treatment (Maviret) and to widen access to adalimumab (Humira) for psoriasis" (17 December, 2018), Website.

88 Richard Milne and Michael Wonder, "Access to New Medicines in New Zealand Compared to Australia," *The New Zealand Medical Journal* 124:1346 (2011). Note that the Ministry of Health determines registration for distribution in New Zealand. An earlier decision is likely if the pharmaceutical has already been registered in overseas benchmark countries.

89 Richard Milne and Michael Wonder, "Response to Pharmac on Access to New Medicines in New Zealand Compared to Australia," *The New Zealand Medical Journal* 124:1347 (2011).

90 IQVIA, "International Comparisons of Modern Medicines (ICOMM)," Report 2019, commissioned by Medicines New Zealand (2019), 6.

91 Robin Gauld, "Ahead of its Time: Reflecting on New Zealand's Pharmac Following its 20th Anniversary," op. cit. section 5.

92 Communication from Pharmac's chief executive.

93 KPMG, "Kiwi Health: Improving Health Outcomes" (2017), 4.

94 It appears to have been small in 2006/07. Specifically, out-of-pocket spending on "pharmaceutical and other medical non-durables" was $589.5 million in 2006/07 compared to the $33.3 million spending by private health insurers. Department of Health, "Health Expenditure Trends in 1997–2007" (Wellington: Ministry of Health, 2010), Table 7.5, 48.

95 But note that private insurers commonly reinsure ongoing members annually even if they develop conditions that pre-exist the year of renewal.

96 Yet another frustration has been the absence of any published official data on the proportion of unsubsidised prescription medicines, its rate of growth, if any, or corresponding statistics on the growth in private insurance for unsubsidised prescription medicines.

97 This question is raised in Richard Milne and Michael Wonder, "Response to Pharmac on Access to New Medicines in New Zealand Compared to Australia," op. cit.

98 District Health Boards New Zealand and Pharmac, "Approval of 2017/17 Pharmaceutical Budget Bid" (1 December, 2015), 2.

99 "'Treatment for cancer isn't all about medicines, it's about screening, it's about diagnosis. The most effective things to manage cancer are screening, diagnosis, radiotherapy, and surgery. Medicines are about eight to ten percent of cancer control,' Pharmac's chief executive Sarah Fitt told Guyon Espiner." Colin Peacock, "Cancer campaign coverage put heat on Pharmac," Radio New Zealand (7 July, 2019).

100 Scott Metcalfe and Rachel Grocott, "Comments on 'Simoens, S. Health Economic Assessment: A Methodological Primer. *Int. J. Environ. Res. Public Health* 2009, 6, 2950–2966' – New Zealand in Fact Has No Cost-Effectiveness Threshold," *International Journal of Environmental Research and Public Health* 7:4 (2010), 1831–1834.

101 Lack of information may be a valid concern; undue paternalism would not be.

102 Pharmac, "Estimating health benefits," op. cit.

103 Scott Metcalfe and Rachel Grocott, "Comments on 'Simoens, S. Health Economic Assessment," op. cit. See also Pharmac, "Factors for Consideration," Website.

104 Pharmac, "Factors for Consideration," Ibid.

105 See for example, Pharmac, "Annual Review 1996," op. cit. 8.

106 See Pharmac, "Prescription for pharmacoeconomic analysis – Methods for cost-utility analysis," op. cit. section 7.8.

107 Alan Woodfield, John Fountain and Pim Borren, "Money and Medicines: An Economic Analysis of Reference Pricing and Related Public-Sector Cost-Containment Systems for Pharmaceuticals with Special Reference to New Zealand" (Merck, Sharp and Dohme (New Zealand) Ltd. (1997)), 1–269, 11.

108 Victoria University of Wellington research recently estimated the marginal welfare cost of raising an extra dollar from personal income tax revenue to be 12 cents, albeit with large variations across household compositions. The implication is that New Zealanders could afford to buy 12% more pharmaceutical medicines were they not taxpayer funded. The 12 cents is an average. Their estimated marginal welfare costs range from only about 5 cents per dollar raised for most single men to over $6 for low-income single parents. John Creedy and Penny Mok, "The Marginal Welfare Cost of Personal Income Taxation in New Zealand," *New Zealand Economic Papers* 52:3 (2018), 323–338.

See also the empirical evidence that cutting unnecessary public subsidies tends to increase economic growth. Jean-Marc Fournier and Asa Johansson, "The Effect of the Size and Mix of Public Spending on Growth and Inequality," OECD, Website, 68.

109 Public policy agitation to tax sugar and cigarette smoking and introduce compulsory savings plans are frequently justified in part by the need to reduce future fiscal costs from hospitalisation or reliance on welfare. For an explanation of why the fiscal case for additional layers of restrictive regulation is dubious, see Edgar Browning, "The Myth of Fiscal Externalities," *Public Finance Review* 27 (1999), 3–18.

110 Work and Income, "Health and disability related benefits," Website.

111 In a normal year, the average uninsured household would spend a lot less. On Pharmac's figures, 20% of those using prescription medicines account for 91% of CPB spending. Pharmac, "A 25-year History (1993–2018)," op. cit. 39.

112 It is less than this to the degree that some of this amount funds hospital medicines, medical devices, etc.

113 For specialist prescriptions, from DHBs it is $5 per item. "Everyone who is eligible for publicly funded health and disability services should in most circumstances pay only $5 for subsidised medicines." Ministry of Health, "Pharmaceutical co-payments," Website. From private specialists, it is $15 per item. Only the first 20 prescriptions filled in a year are chargeable for families. In contrast, Australians pay up to $A40.30 for most PBS prescriptions. Note that some pharmacists in New Zealand are waiving or discounting the $5 charge. Anuja Nadkarni, "Free prescriptions, competition shakes up pharmacy industry," *Stuff* (19 July, 2018).

114 Love Food Hate Waste New Zealand, "9 ways to save money on your food bill," Website, and The New Zealand Press Association (NZPA), "Food prices for average family over $230 per week," *The New Zealand Herald* (8 September, 2003).

115 Find a Rest Home, "Residential care subsidy means test," Website.

116 Find a Rest Home, "Private paying," Website.

117 See Shuyun Li, Solmaz Moslehi and Siew Yew, "Public-Private Mix of Health Expenditure: A Political Economy Approach and a Quantitative Exercise," *Canadian Journal of Economics* 49:2 (2016).

118 Unfortunately, there are no official statistics for New Zealand for pharmaceutical spending alone.

119 Pharmac, "A 25-year History (1993–2018)," op. cit. 55.

120 Reducing the average subsidy per prescription should be an option.

121 Pharmac, "Annual Review 2019" (Wellington: New Zealand Government, 2019), 10.

122 Ibid. 11.

123 Pharmac, *Achieving Medicine Access in Equity in Aotearoa New Zealand: Towards a Theory of Change* (Wellington: New Zealand Government, 2019), 18. (A footnote reference in the original has been deleted from this quote.)

124 Of course, it is cheaper per unit to purchase in bulk, but a state agency is not needed to do that.

125 To be fair, lay members of the public could not be expected to know.

126 Pharmac, "Annual Review 2019," op. cit. 23.

127 Pharmac's 2017 Annual Review and some of its predecessors included lone sentences reporting related but different statistics.

128 Pharmac, "New funding applications," op. cit.

129 Alan Woodfield, et al. "Money and Medicines," op. cit. 43.

130 MBIE, "Funding information and opportunities," Website.

131 See, for example, the Health Research Council, "Annual Report 2018" (Wellington: New Zealand Government, 2019), 48. Confirmed by personal communication from the acting chief executive of the HRC on 29 November, 2019. However, that communication raised a question about the materiality of this limit.

132 See, for example, MBIE, "Callaghan innovation," Website, and MBIE, "Marsden Fund: Innovation and Employment: Assessment of Strategy and Management: Report to the Minister of Science and Innovation" (2017), Figure 3, 15.

133 In effect, the supplier of Logem was giving a discount for the bulk demand expected to arise from sole subsidised supply status. Logem's cost to the CPB dropped from $56.19 to $4.40.

134 Pharmac, "Memorandum for Board Meeting 29 March 2019," A1244700, 98 in the combined the files Pharmac released relating to this decision.

135 Rebates weaken this statement, depending on their structure and magnitude. Pharmac has advised that there were rebates on Arrow-Lamotrigine, but not Logem or Lamictal.

136 Neil Quigley and Lewis Evans, "Money and Medicines: An Economic Analysis of Reference Pricing and Related Public-sector Cost-containment Systems for Pharmaceuticals with Special Reference to New Zealand, by Alan Woodfield, John Fountain and Pim Borren (A Review)," Working Paper Series 3941 (Victoria University of Wellington, 1998).

137 This research has encountered the argument that the CPB subsidy for paracetamol, a very cheap non-prescription medicine can be justified on the grounds that otherwise people might buy a less effective product.

138 John Stuart Mill, *On Liberty* (1859).

139 Cases of inferior goods being an exception. (The rich may spend nothing on bus fares.)

140 Issues of parallel importing and agreed patent life are relevant, but beyond the scope of this report.

141 Third-degree market segmentation is said to exist when different prices for the same product exist in different segments of a market.

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Taxes are not collected to help everyone pay their grocery bills, so why is the government subsidising prescription medicines? Doing so puts endless pressure on the government to increase the subsidy.

If the government were to subsidise the average Kiwi's groceries, it would also have to decide which groceries to subsidise. That would be contentious, to say the least. However, this is precisely what is happening with prescription medicines subsidies.

New Zealand's Pharmaceutical Management Agency (Pharmac) bears the brunt of such criticisms because it administers this subsidy system.

Pharmac has commendably achieved many eye-watering price reductions for prescription medicines, while keeping within a tight budget. The agency is now funding many more filled prescriptions per capita than its equivalent in Australia – and for a much lower fiscal cost.

But those achievements do not mean the subsidy system is improving Kiwi health and wellbeing.

Those not in financial need do not necessarily benefit from subsidy-distorted choices and those in financial need might prefer cash assistance. Customers are empowered when allowed to spend their own money directly. Private insurance helps pool risks of large expenses. Price discounts can be achieved in other ways, but perhaps not to the same degree.

The deep problem with current arrangements is inadequate accountability due to lack of clarity about what the subsidy is intended to achieve. Exactly what is the public policy problem for which subsidies for those not in financial need is the remedy?

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ISBN
978-0-9951208-8-4 (print)
978-0-9951208-9-1 (online)

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Wellington 6143