Background notes

Produced for Medicines New Zealand

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PHARMAC economic analysis and "savings" claims

PHARMAC frequently claims that it achieves savings through its negotiations practices and approvals process for new medicines.

In the 2017 financial year, PHARMAC claims to have achieved $52 million in savings for New Zealand.[1] PHARMAC further claims that between 2005 and 2016, it saved the District Health Boards nearly $6 billion.[2]

This note provides an explanation and critique of these claims, and a summary of the economic analysis, negotiating strategies, and decision criteria used by PHARMAC as well as the consequences of PHARMAC's approach. It also includes examples that illustrate the trade-offs that are less visible in funding decisions.

What do PHARMAC's "savings" represent?

PHARMAC negotiates with suppliers using a range of strategies that have been highly successful in driving prices down. PHARMAC's savings claims are based entirely on these reductions in the *purchase prices* of funded medicines.

In other words, PHARMAC is arguing that if New Zealand obtained the *same set* of medicines without PHARMAC's negotiating power, that set of medicines would cost New Zealand significantly more.

It is true that as a result of the purchase price of medicines being low, more funds are available to spend in other ways.

However, this way of reporting savings provides no insight into the *value* of the set of funded medicines. Indeed, "savings" of the kind reported by PHARMAC can be achieved by negotiating down the prices of *any* medicines, regardless of how effective they are.

What New Zealanders *want to know* is whether the set of medicines funded by PHARMAC generate financial savings for the health system in the form of reduced hospitalisations for example, and value for consumers, in the form of improved quality of life, *as well as* being able to obtain these benefits at the lowest possible cost.

Meaningful savings

A major reason for funding medicines is the reduction in health service utilisation that is expected as a result of reduced pain, better symptom control, cured disease, slowed or prevented progression of disease, reduced infection rates, reduced adverse effects, and faster recovery. Medicines help people get well and stay well, and well people are less costly to the health system than sick people.

If funded medicines result in reductions in health service costs that exceed the cost of purchasing and dispensing the medicines, then it is fair to say that the decision to fund those medicines has resulted in savings. Reductions in the purchase price help such savings to be realised, but what's important is the *total* possible savings.

This definition of savings is important not only to the wider health system, but also to PHARMAC. In fact, PHARMAC's decision to fund medicines is based on economic analysis which consists primarily of cost-utility analysis. Cost-utility analysis demonstrates what the impact of medicines will be on:

- Health service utilisation costs (costs of GP visits, laboratory tests, medicines, inpatient and outpatient services, etc.)
- Costs to patients (co-payments, homecare, etc.)
- Quality and length of life, generally measured in quality-adjusted life years (QALYs).

Because PHARMAC requires this information as part of every funding application, it can estimate the net savings to the health system associated with any possible funding decision and with the total set of funded medicines.

A statement of the health system savings that are estimated to occur as a result of access to funded medicines is also more meaningful and more consistent with other approaches to public funding. And yet,

[1] PHARMAC. 2017 year highlights. Accessed 15 June 2018 from: https://www.pharmac.govt.nz/about/2017/highlights-of-2017/

[2] PHARMAC. Introduction to PHARMAC. Accessed 15 June 2018 from: https://www.pharmac.govt.nz/about/your-guide-to-pharmac/factsheet-01-introduction-to-pharmac/

PHARMAC reports only financial savings related to purchase price.

The focus of medicines funding should be on the best decisions for the health system rather than on the decisions that result in bigger "savings" claims for PHARMAC.

Fiscal savings versus health "savings"

Given that PHARMAC has available to it all of the information necessary to provide an estimate of health system savings associated with funded medicines, why does it choose to report only fiscal savings achieved on the purchase price of medicines?

One reason for this might be that PHARMAC's failure to fund many cost-effective medicines may represent a significant lost opportunity to generate much greater health system savings.

Using a more meaningful definition of health savings may lead to questions about why more medicines are not funded, since the savings to the health system could be even greater if more cost-effective medicines were funded. And this will inevitably lead to questions about the current medicines funding model.

And because PHARMAC also includes the QALY gains associated with medicines in its economic analysis, PHARMAC would be able to report the *total value* realised by funded medicines, not just savings to the health system.

So a meaningful question that could be addressed is: What proportion of *potential value* is actually being realised by medicines funding decisions?

Missed opportunities to realise savings as well as value

While cost-effectiveness is a major consideration in PHARMAC's decision-making process, it also includes other considerations, with the most concerning being the constrained budget under which PHARMAC operates. This constraint introduces an element of opportunity cost that impedes PHARMAC's ability to generate greater savings to the health system.

The constrained budget is largely responsible for the lack of a decision-relevant threshold for cost-effectiveness. It creates three undesirable effects that are more pronounced in New Zealand than in jurisdictions with more flexible budgets:

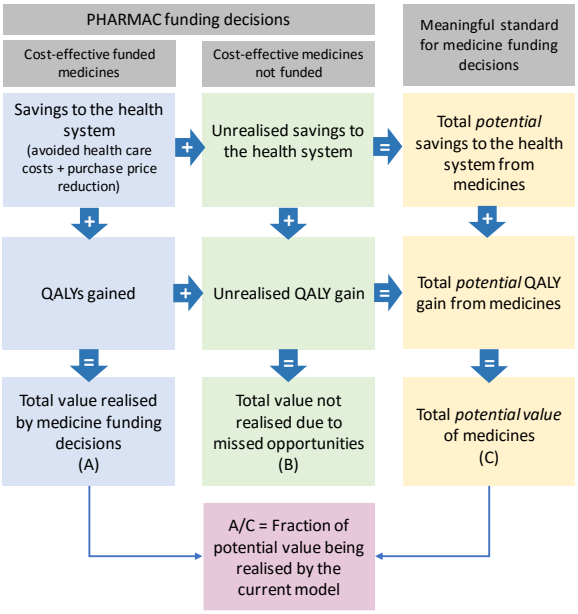
- The cost-effectiveness of medicines approved for funding, and their ability to generate value for New Zealanders, varies wildly from year to year[3]
- Medicines that generate significant savings or value resulting in funding in other jurisdictions may not always be funded here, resulting in missed opportunities
- Funding of medicines in New Zealand is time-inconsistent, meaning a medicine may not be funded one year and then be approved for funding in a later year with no change in clinical evidence or cost-effectiveness, resulting in further missed opportunities to generate savings.

Failing to fund cost-effective medicines results in health system costs such as hospitalisations, as well as higher mortality, more productivity loss, and greater loss of quality of life.

Missed opportunities to fund cost-effective available medicines represent costs to the system. These have a direct bearing on the value of PHARMAC funding decisions (see Figure 1) and on the proportion of value being realised.

[3] According to PHARMAC, between the 1998 and 2015, new investments made by PHARMAC varied between $40,000 per QALY 25 and over $200,000 per QALY. Source: PHARMAC. Health Economic Analysis at PHARMAC. Accessed 15 June 2018 from: https://www.pharmac.govt.nz/medicines/how-medicines-are-funded/economic-analysis/pfpa/2-health-economic-analysis-at-pharmac/

Figure 1 Meaningful value of PHARMAC funding decisions



Source: NZIER

The cost of PHARMAC's pursuit of purchase price "savings"

The pursuit of lower prices within a constrained budget model is itself not costless.

The pursuit of generics, which are generally priced 60 percent lower than brand name medicines, is encouraged by health authorities around the world as a means of delivering similar outcomes at a lower cost. However, it can be years before generic medicines become available.

If PHARMAC is delaying funding decisions in anticipation of generic medicine availability, there is a cost in the form of unnecessary suffering and health service utilisation which would not occur if a funded brand name medicine were available. PHARMAC provides no evidence that the price reductions achieved by delaying access make up for the costs of delays.

It is also important to note that generic medicines are not equivalent to the brand name medicine or even across generics for all people.

For this reason, the pursuit of "savings" is perhaps most questionable when PHARMAC switches to and between generic medicines to obtain the lowest price. This practice is associated with anxiety, confusion, loss of effectiveness, increased adverse effects and reduced adherence, particularly in long-term users, resulting in a higher total cost of care.[4] Recent experiences with statins and anti-depressants illustrate the reality of these risks.[5]

Another feature of the New Zealand model, sole supply contracts — one of PHARMAC's key negotiating strategies — result in dependence on a single supplier of important medicines. This practice has been associated with shortages toward the end of contract periods as well as a greater impact of lower quality medicines than would be the case in a multi-supplier scenario.[6]

Are we going wrong?

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.

However, 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.

Numerous studies based on the experiences of 20 OECD countries have shown that innovator medicines with high prices have led to important gains in survival as well as generating savings to the health system (mainly reduced hospitalisation costs) that far exceed the price of the medicines.[7]

From 2010 to 2015, New Zealand ranked lowest in the OECD for the proportion of new medicines that are subsidised – 12%, compared with 48% for Australia, and 58% on average across the OECD (Figure 2).[8] This fact suggests that an investigation into possible missed opportunities is well-warranted.

[4] Generics are typically tested only on healthy adults, not on the specific populations for whom they are prescribed. (https://www.pharmac.govt.nz/assets/bpjse-generics-2009.pdf)

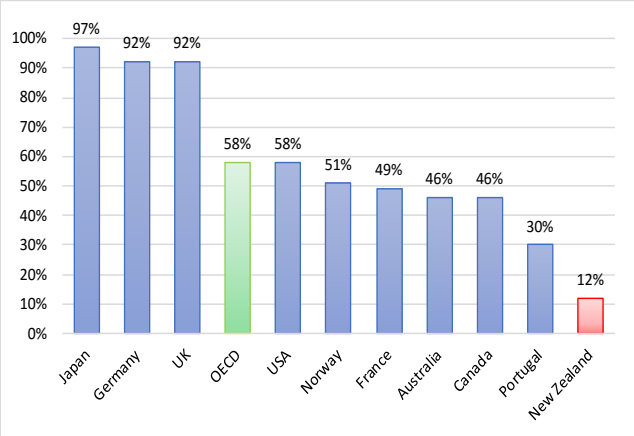
[5] Henry, D.(2018). Patients say generic Pharmac-funded version of antidepressant venlafaxine left them depressed, anxious. The New Zealand Herald. 28 February 2018. Accessed online 10 June 2018 from: https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12002918.

[6] MacKay P. Is PHARMAC's sole supply tendering policy harming the health of New Zealanders? NZMJ; 118: U1433.

[7] Lichtenberg FR. (2008). Have Newer Cardiovascular Drugs Reduced Hospitalization? Evidence From Longitudinal Country-Level Data on 20 OECD Countries, 1995-2003. NBER Working Paper No. 14008, May 2008: JEL No. I12,O33,O51,O52,O56.

[8] Medicines Australia (2016). Comparison of Access and Reimbursement Environments. A report benchmarking Australia's access to new medicines. Compare. Edition 2, 2016.

Figure 2 Access to new medicines, New Zealand versus selected OECD countries and OECD average, 2010-2015



Source: NZIER, based on Medicines Australia (2016). Comparison of Access and Reimbursement Environments. A report benchmarking Australia's access to new medicines. Compare. Edition 2, 2016

As much as missed opportunities from lack of funding represent costs to the health system, delayed access has the same result. For whatever reason – protracted negotiations, yearly budget-setting, or waiting for generics to become available, PHARMAC's process is very slow.

PHARMAC is particularly slow to act on PTAC's recommendations[9] to fund new medicines with an average time from recommendation to reimbursement of 2.8 years – with some medicines waiting up to 5 years longer.

In summary

PHARMAC's savings claims refer to reductions in prices achieved as a result of its negotiating strategies, not to reductions in health system costs as might be expected.

PHARMAC's negotiating strategies and decision-making process are also associated with costs that are not offset against the stated savings.

Savings are also possible even when prices of medicines are high. These can occur when the medicines are highly-cost-effective, as many innovative new medicines have proven to be. A failure to fund all medicines that can produce total health system savings imposes an invisible cost on the system.

Studies have shown that new medicines have greatly increased survival and generated savings to health systems in recent years. Waiting for generics to become available is associated with higher than necessary health system costs as well as reduced quality of life (and sometimes loss of life) in the meantime.

The slow speed of decisions and limited access to medicines in New Zealand warrants and in-depth evaluation to determine whether PHARMAC's approach to cost-containment is in fact resulting in optimal funding decisions.

Examples

Savings from investing in higher cost medicines – innovator medicines examples

In Canada between 1995 and 2012, the number of cancer patient hospital days declined by 23% despite the number of new cancer cases increasing by 46%. Cancer sites that experienced more pharmaceutical innovation showed larger declines in hospital days. If no new drugs had been registered during the 1980-1997 period, there would have been 1.72 million additional cancer patient hospital days in 2012, costing C$4.7 billion in hospital expenditure, whereas total spending on cancer drugs (old and new) in 2012 was an estimated C$3.8 billion. Pharmaceutical innovations in cancer care are therefore associated with substantial health system cost savings.[10]

[9] PTAC – the Pharmacology and Therapeutics Advisory Committee – is PHARMAC's primary clinical advisory committee. Made up of senior health practitioners from a range of specialties, it makes recommendations to PHARMAC based on clinical evidence and PHARMAC's other considerations.

[10] Lichtenberg, FR (2016). The Benefits of Pharmaceutical Innovation: Health, Longevity, and Savings. Montreal Economic Institute, June 2016.

In addition to reduced hospital days, a study of innovator drug use in the US found that the mean number of work days lost, the mean number of school days lost, and the number of hospital admissions declined more rapidly among medical conditions with larger increases in the mean number of innovator drugs consumed. The total value of the reductions in work days lost and hospital admissions attributable to pharmaceutical innovation was estimated to be three times the cost of the innovator drugs consumed, suggesting that innovator drugs result in savings when all costs are considered.[11]

Innovator drugs are also associated with additional life years. A study of medical expenditure in France using data for the period of 2000 to 2009 found that pharmaceutical innovation was responsible for one fifth of the total increase in longevity. These innovations increased the per capita cost of pharmaceuticals by $125 in 2009 but 87% of this was offset by reduced hospital costs alone. The mean extension of life gained as a result of pharmaceutical innovation (3.43 months) was worth $8100, indicating that the social value gained far exceeded the cost.[12]

Based on the experiences of 20 OECD countries with 1100 cardiovascular medicines between 1995 and 2003, it has been estimated that if newer drugs had not been adopted, hospitalisation and mortality would have been higher. For the $24 of additional per capita expenditure on medicines, $89 per capita was saved on hospital costs alone.[13]

Costs from delayed access to high cost medicines – Hepatitis C example

One cause of delays in making new medicines available is likely to be the constrained budget under which PHARMAC operates. This means that decisions to fund highly cost-effective but expensive treatment would preclude many other cost-effective treatments unless PHARMAC can secure additional funding. Such investments will often be delayed until additional funding is provided.

In 2016 PHARMAC obtained an increase in funding based partly on the case made for a new treatment for Hepatitis C. The new treatment had a cure rate of 55 percent. Despite being a very high cost treatment with an eventual price of $16,500 after negotiations with suppliers.[14] Access to the medicine was widened the following year after a further increase in PHARMAC's budget.

Delays in access to medicines like this one are more likely in systems with fixed budgets where funding highly cost-effective, high cost medicines would preclude the funding of many low-cost medicines that are not necessarily more cost-effective. Waiting until PHARMAC can obtain more funding to allow for such investments has a high cost for the health system and for individuals affected.

The result of delays or lack of funding is the continued significant health system costs associated with the disease. The total lifetime health system cost associated with Hepatitis C was estimated by PHARMAC at $78,000 per person infected.[15] These costs are not offset against the savings claimed by PHARMAC while it continues to favour low-cost medicines that may not offer the same potential savings to the wider health system.

There are also significant personal and social costs from reduced quality of life and mortality. At least 50,000 New Zealanders are estimated to have chronic Hepatitis C. About 200 people die each year from it.[16]

11 Lichtenberg, FR (2014) The Impact of Pharmaceutical Innovation on Disability Days and the Use of Medical Services in the United States, 1997-2010. Journal of Human Capital; 8 (4): 432-480.

12 Lichtenberg, FR. (2013). The impact of pharmaceutical innovation on longevity and medical expenditure in France, 2000–2009. Economics and human biology; 13(1):DOI:10.1016/j.ehb.2013.04.002

13 Lichtenberg FR. (2008). Have Newer Cardiovascular Drugs Reduced Hospitalization? Evidence from Longitudinal Country-Level Data on 20 OECD Countries, 1995-2003. NBER Working Paper No. 14008, May 2008: JEL No. I12,O33,O51,O52,O56.

14 https://www.pharmac.govt.nz/news/notification-2016-06-10-hepatitis-c-treatments/

15 Publicly available information on budget initiatives, Treasury website.

16 https://www.stuff.co.nz/national/health/101319893/thousands-of-hepatitis-c-sufferers-unaware-a-cure-is-within-reach

Costs associated with excessive focus on continued price reductions – statins example

In the late 90s and early noughties, PHARMAC repeatedly changed the subsidised statin to take advantage of intense price competition between drug companies. Savings in expenditure on statins were said to be allowing increased expenditure on other medicines.

The Pharmacology and Therapeutics Advisory Committee (PTAC) subcommittee had made recommendations for funding based on simvastatin and pravastatin having the greatest evidence base, and lowest cost per percentage reduction in cholesterol than fluvastatin. PHARMAC, however, opted to subsidise fluvastatin.

The switch to fluvastatin which affected 12,000 New Zealanders[17] resulted in reduced effectiveness and a significant increase in the frequency of thrombotic vascular events compared to the previous six months on simvastatin.[18]

The decision to switch to fluvastatin did not take into account the increased costs associated with thrombotic vascular events or the cost of additional GP time involved in switching patients and monitoring their progress on the new medicine. Risk of death or major cardiovascular events was significantly associated with patients switching statin therapy so such switching should be carefully monitored and the costs of this factored into decisions to implement a switch.[19]

Such costs were once again ignored when PHARMAC switched again to atorvastatin following a cross-subsidisation deal between PHARMAC and the supplier.

Soon after, simvastatin, which had a superior evidence base to either fluvastatin or atorvastatin, came off patent, enabling PHARMAC to negotiate a lower price which finally resulted in access to this previously heavily restricted medicine being widened.

Although a higher price per patient would have been paid for simvastatin if it had been subsidised earlier, and the total cost could have reached nearly $200 million per year,[20] much of this may been offset by the lower health system costs associated with simvastatin's higher effectiveness.

Costs of switching funded medicines for long-term users – the case of antidepressants

Approximately 150,000 New Zealanders use the anti-depressant venlafaxine. PHARMAC recently switched from funding Effexor XR and Arrow-Venlafaxine, two brand name formulations of venlafaxine, and to fund instead a cheaper generic, Enlafax XR.[21]

According to PHARMAC, the savings generated from moving from the brand name venlafaxine to the generic version amount to $5 million per year which will enable more medicines to be funded for more people.

Medsafe also reports that between April 2017 and April 2018, it received 142 reports of adverse side effects to the generic venlafaxine. Medsafe's estimate that approximately 1 percent of patients will experience problems with a brand switch suggests that adverse side effects from the switch may be more widespread than reported.

The health system or societal costs associated with these problems need only surpass the $5 million per year in expected savings to make PHARMAC's decision a mistake. This is a real possibility, given that the problems reported to Medsafe include reduced effectiveness, headaches, anxiety, suicidal ideation and one suicide attempt.

17 Cumming J, Mays N, and Daube J. (2010). How New Zealand has contained expenditure on drugs. BMJ; 340: 1224-1227.
18 Thomas M, Mann J. (1998). Increased thrombotic vascular events after change of statin. Lancet 1998;352:1830–1831.
19 Phillips B, Aziz F, O'Regan CP, Roberts C, Rudolph AE, Morant S. (2007). Switching statins: the impact on patient outcomes.
20 Cumming J, Mays N, and Daube J. (2010). How New Zealand has contained expenditure on drugs. BMJ; 340: 1224-1227.
21 Henry, D. (2018). Patients say generic PHARMAC-funded version of antidepressant venlafaxine left them depressed, anxious. The New Zealand Herald. 28 February 2018. Accessed online 10 June 2018 from: https://www.nzherald.co.nz/nz/news/article.cfm?c_id=1&objectid=12002918.

The Ministry of Health commissioned a report in 2005 which found that the cost to New Zealand of a suicide was $2,931,250 in 2004 dollars, which amounts to $5,613,206 in 2018 dollars.[22]

This implies that a single suicide in the 1,500 individuals likely to be negatively affected by the change in their anti-depressant medicine, would more than negate the savings claimed to be associated with this decision.

Hundreds of GP visits and emergency department visits followed by hospital stays or stays in mental health facilities as a result of headaches and suicide attempts, can equally negate much of the savings from lower prices. Additional costs in the form of productivity losses for those whose depressive symptoms were previously under control further erode any possible savings.

Many other cases of increased health system costs and mortality associated with a switch to generic medicines have been recorded, such as schizophrenia medicines, hypertension medicines, antiepileptics, antiarrhythmics, thyroid medicines, and anticoagulants.[23]

The decision to switch long-term users to generics should take into account the total cost of care and potential indirect costs of switching.

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[22] Inflated using the New Zealand Treasury cost-benefit tool (CBAx) impact values database.

[23] Straka RJ, Keohane DJ, Liu LZ. (2017). Potential Clinical and Economic Impact of Switching Branded Medications to Generics. American Journal of Therapeutics; 24 (3): 278–289. doi:10.1097/MJT.0000000000000282.