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New Zealand Pharmaceutical Policies

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New Zealand Pharmaceutical Policies

Time to Take a Fresh Look

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Table of Contents

Tables

Figures

1 Summary

New Zealand's funding of pharmaceuticals is unusual:

Two elements make New Zealand's policy for funding pharmaceuticals prescribed to patients not in hospital[1] fundamentally different from policies adopted in other countries:

we subsidise only one drug for a relatively wide range of conditions, and

- First, where possible, New Zealand uses sole source tenders to bid down the price of prescription medicines. Under this policy, only one or a limited number of products are procured for each indication. The expectation is that the winning bidder would agree to a lower price in return for the opportunity to supply the entire New Zealand market demand for that medicine. In some cases, this is widened to preferential or sole supply access for a therapeutic group/sub-group. And the danger here is that patients react differently (benefits as well as side effects) to different medicines, hence the need to have multiple medicines in each therapeutic category.

access to drugs is varied during the year to keep to a budget.

- Second, the budget for the funding of pharmaceuticals (in other words, PHARMAC's budget) is strictly capped. In some jurisdictions, the entitlement (in terms of drug availability and the level of co-payment) tends to be determined first, and then the budget is adjusted to deliver the necessary funding to support the agreed level of entitlement. In New Zealand, it is the entitlement that gets adjusted through the year in order to remain within the set budget. New drugs tend to be approved only if savings are made on older drugs. Further, there is strict control over the discretionary approvals for drugs that are made available under "special authority criteria". The ability to grant "special authority" is limited by the budget cap, rather than by clinical considerations.

In addition to these explicit restrictions on customer access, there are concerns about the transparency of the process for getting new medicines listed. In particular, we have encountered growing concern that the Pharmacology and Therapeutics Advisory Committee (PTAC), whose job it is to review the effectiveness of new medicines, is being influenced in their judgements by fiscal imperatives rather than by the relevant clinical considerations. While fiscal issues must be taken into account, there are risks to the

[1] This includes medicines funded by PHARMAC in New Zealand and PBS in Australia, and excludes procurement of medicines for use within hospitals, even through that function is now being taken over by PHARMAC.

integrity of the system and the quality of decisions if fiscal restraint is exercised implicitly under the guise of concerns about effectiveness or safety.

Finally, New Zealand, like a number of other countries, also uses reference pricing to beat down prices of patented pharmaceuticals. Under reference pricing, the purchasing agency sets the price for a whole class of drugs by reference to the cheapest drug in the class, even if the class is so broad that the drugs within it are not substitutable for each other for clinical purposes. In a sense, this is a tool for using the government's monopsony power. In New Zealand, reference pricing has a particularly strong impact because the price of the winning medicine is applied to the entire therapeutic group without differentiation for therapeutic effect. This lack of differentiation means that more effective, but more expensive, medicines within a therapeutic group tend to attract high co-payments in New Zealand. For practical purposes, this may deny access to more effective medicines to some patients, who are likely to be those least likely to afford the additional cost.

We do not address the general effects of reference pricing in this report because it is not unique to New Zealand. However, since we focus on those aspects of New Zealand policy which separate us from other developed countries, and which shift outcome risks and costs to the population, we do address the absence of differentiation for therapeutic effect in the application of reference pricing.

As a result, our drug use has declined relative to other OECD countries…

This policy has been consistently implemented since 1997. As a result, in the last eight years, New Zealand's pattern of expenditure on pharmaceuticals has diverged dramatically from other OECD countries. New Zealand's pharmaceutical expenditure – both as a proportion of total health expenditure and of GDP – fell sharply during a period when, elsewhere in the OECD, these proportions have grown in response to innovative treatments and increased reliance on pharmaceutical rather than surgical interventions.

… but at a cost of reduced access and choice.

In essence, New Zealand set out to achieve the lowest possible prices for pharmaceutical products but in the process, has restricted the range and quantity of medicines available to prescribing medical professionals and their patients.

This does not appear to be minimising <u>total</u> costs:

This restraint can be considered good policy if and only if:

- the restrictions on the availability of medicines do not result in adverse health and social outcomes and do not impose additional costs by leading to more costly surgical and other interventions, and

- the restrictions are the only way to achieve reasonable prices for pharmaceuticals.

Our analysis suggests that there are good reasons to believe the above conditions do not hold:

restrictions may be worsening disability rates…

- First, there is indicative evidence to suggest that restrictions on pharmaceuticals have had a negative impact on New Zealand's disability burden and health outcomes. Our high level of welfare dependency, at a time of nearly full employment, has recently become a focus of political attention and has been attributed, in part, to a culture of dependency. However, our analysis suggests that New Zealanders may indeed be more disabled than comparable populations, in part due to poor management of conditions arising out of restrictions on pharmaceuticals.

…and increasing the need for more costly and intrusive treatments…

- Second, there also appears to be evidence that restrictions on pharmaceuticals are shifting costs to other more invasive, costlier treatments.

…while achieving prices not much better than in Australia.

- Finally, while the Pharmaceutical Management Agency (PHARMAC) was successful in reducing New Zealand pharmaceutical prices at a more rapid rate than other OECD countries during the early years of the policy, New Zealand prices now appear to have settled at a constant ratio to the level in Australia, with the gap between the two countries likely to narrow.

Both countries are enjoying on-going reductions in the prices of medicines due to a mix of purchasing techniques (such as reference pricing) and the on-going substitution of brand products by generics as patents come off. While New Zealand prices are, on average, somewhat lower than those in Australia, our analysis suggests that these differences can not be attributed to the severe restrictions on access imposed on New Zealand consumers.

These possibilities are serious enough to warrant a thorough review of pharmaceutical funding.

Since so many factors affect health outcomes, heroic assumptions would be required to isolate the impact of restrictions on pharmaceuticals from everything else that is going on to a standard of scientific proof. We do not pretend to be able to do that. However, we believe there is sufficient information to suggest that very serious questions should be asked about the effects of the current pharmaceutical benefits scheme on the well-being of New Zealanders.

Suspicion of pharmaceutical

Strong suspicions of pharmaceutical companies' motives and business tactics, combined with the successes achieved in the late 1990s in shifting New Zealand from a high pharmaceuticals price country to a low price one, have cemented in many peoples' minds

companies should not be allowed to prevent a careful check of whether drug cost containment is increasing costs elsewhere…

the idea that the policy works, and that complaints about the system are no more than self-interested lobbying.

However, in our view, it is risky to allow prejudices against the "big pharma" to obscure the costs that restrictions on access to pharmaceuticals are imposing on the New Zealand society. Even in the narrow fiscal sense, it is likely that the spectacular "achievement" of keeping spending on the funding of outpatient pharmaceuticals virtually unchanged for many years, simply masks higher costs and inefficiencies in other parts of the health and welfare budgets.

…that is, whether we have the right cost <u>mix</u>.

A common mantra in defence of the current pharmaceutical funding policy is that New Zealand is a poor country, and while we would like to spend more, we can not afford it. However, this begs the question, confusing restraint on expenditure on pharmaceuticals with the overall fiscal constraint on health and welfare spending.

The real question going forward is whether it is possible to

- achieve better health and social outcomes by re-allocating resources from other areas of health expenditure to pharmaceuticals while remaining within the overall budget envelope.

It should be possible to do better by rebalancing overall spending between drugs and other treatments…

Our analysis suggests that the answer to this question is "yes". It is certainly timely to examine alternatives. In preparing this report, we have not sought to design a detailed proposal for an alternative model. However, our analysis suggests there are strong indications that the costs of the current funding model are likely to exceed its benefits. The available evidence certainly raises sufficient concerns to recommend a wide-ranging inquiry into the policy.

…consistent with sound fiscal management…

…and increasing patient choice.

In our view, the key challenge will be to design a funding regime which improves access to a broad range of pharmaceuticals and provides sufficient incentive to the pharmaceutical companies to market and trial their products in New Zealand, without undermining sound fiscal management and without creating conditions for unjustified price increases in New Zealand.

2 Introduction

Public policy with respect to the funding of pharmaceuticals needs to balance cost containment objectives with optimization of health outcomes. Most countries employ a range of price and expenditure containment techniques. New Zealand is unique, however, in using the capping of the pharmaceutical budget and tendering for exclusive supply to reduce prices as the corner-stone of its approach. Some policy-makers have lauded our experience as a major success. To view our current approach as a success, it must be true that restrictive access policies and the nearly fixed budget for PHARMAC are necessary for New Zealand to secure best prices for pharmaceutical products, and that we are able to do this with no detriment to health outcomes and no other unintended costs. This report reviews the available evidence to consider whether the pharmaceutical policies adopted in New Zealand have indeed been a success.

In many policy areas, New Zealand defines itself by reference to patterns observed in the rest of the OECD. For example, the pattern of public expenditure in New Zealand typically reflects the levels and allocation of funds observed in other developed countries. This is not surprising, as advanced market democracies tend to use broadly similar tools to address similar issues. Given this, any significant deviation from the typical pattern deserves careful review.

One of the most striking deviations from the prevailing pattern is in New Zealand's spending on pharmaceuticals and the availability of pharmaceuticals. Up to 1997 New Zealand's spending on pharmaceuticals as a proportion of the total health budget was generally in line with the OECD average. Given its relatively low *per capita* GDP, New Zealand's spending in *per capita* terms was also in line with the OECD trends. Since 1997, New Zealand has moved dramatically out of line with the OECD. New Zealand's public spending on pharmaceuticals, as a proportion of our total public expenditure on health, is now less than half of the OECD average, while our total health spending as a proportion of GDP has remained in line with the OECD trends. [2]

This kind of deviation suggests that we have either got the policy dramatically right, and that other OECD countries should shortly follow our example, or that we have taken a wrong turn. This is the key question addressed in this report. In order to answer this question, we need to consider whether the restrictions on the availability of pharmaceutical products, while delivering savings to the specific pharmaceutical budget, have resulted in increased costs elsewhere in the health system, as well as in costs to society and the economy overall due to lower health outcomes resulting from limited access to pharmaceuticals. We are conscious that – certainly within the scope of this report – such questions cannot be answered with absolute certainty. Health outcomes and the patterns of health care expenditure are determined by so

[2] This discussion draws on Ministry of Health, Health Expenditure Trends in New Zealand 1990-2002 , Published April 2004, Ministry of Health, Wellington New Zealand, as viewed at http://www.moh.govt.nz on 10 February 2005 and Productivity Commission 2001, International Pharmaceutical Price Differences, Research Report, AusInfo, Canberra.

many factors, that it would take a brave analyst to try to isolate the influence of a single policy, such as the policy on the funding of pharmaceuticals.

However, these questions clearly have to be faced up to. While it may be impossible to achieve a scientific standard of proof, we believe that much can be learned from a careful comparison of experience with comparator countries, such as Australia.

To anticipate our conclusions, we find that a positive view of the New Zealand model is difficult to support, and that the available evidence strongly points to the view that current policies – while initially successful in cutting prices – are no longer achieving the desired outcomes.

3 Australia and New Zealand

As discussed, the nature of health care makes it difficult to isolate the influence of a single policy, such as the policy on the funding of pharmaceuticals. Ideally, to understand the effects of the unique aspects of the New Zealand pharmaceuticals funding policy, we would look at long-term health outcomes in two populations with similar relevant characteristics and subject to similar policies, except for the funding policy. Clearly, this ideal is not possible within the limits of this report, if at all.

Instead, for the purposes of our analysis we focus on comparison between Australia and New Zealand. Australia and New Zealand are as close as two countries can be, sharing many common factors:

- Open labour markets, and long history of close association, have resulted in an inter-mingling of the populations. While New Zealand faces a number of special health care issues associated with the Maori and Pacific Island communities, Australia too has a number of ethnic communities with particular health needs, in particular its indigenous population. Overall, similar life-styles, attitudes to health and cultural backgrounds make the two populations as nearly comparable as any two societies can be
- Close links between the medical professions in the two countries would, all other things being equal, tend to lead to common approaches to treatment and to the prescribing of pharmaceuticals
- Both countries have strong public health systems, and both have been focused on the need to contain health care costs. Australia and New Zealand spend approximately the same proportion of GDP on their health systems
- Despite widespread perception to the contrary, both countries have similar sickness and disability welfare arrangements, with eligibility rules and levels of payment sufficiently close that one could expect comparable incentives.

While far from perfect, comparison of Australian and New Zealand policies and outcomes provides us with probably the only practical means to try to focus on the effects of the pharmaceuticals funding policies.

In this context, before we commence our analysis, it is useful to outline the formal processes which exist in both countries before a pharmaceutical becomes available on the market.

From 1 July 2006 there will be a single body responsible for evaluating new medications for safety, quality and efficacy for both Australia and New Zealand called the Joint Therapeutic Products Agency (JTPA). This will replace New Zealand's existing MedSafe and Australia's existing Therapeutic Goods Administration (TGA). Once drugs are registered by the JTPA, the next stage will be for each country's pharmaceutical reimbursement agencies to decide which drug products their respective governments will subsidise.

It is at this point that the key differences between the two systems emerge. Unlike New Zealand, Australia does not link a decision to put a medicine on the subsidy list with an overall budget cap. Nor, in Australia, is such a decision determined by a tendering process for the cheapest amongst similar but not identical drugs.

In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Pharmaceutical Benefits Pricing Authority (PBPA) and the government on the suitability of a drug for reimbursement on the Pharmaceutical Benefits Scheme (PBS). The PBAC requires that pharmaceutical companies submit economic evaluations with applications for listing new pharmaceuticals, for applications to increase the price, or for widening the clinical use of pharmaceuticals already listed. In deciding what pharmaceuticals to subsidise, PBAC considers efficacy, costs, cost effectiveness, safety and the clinical place of the new product in relation to other products on the market.

In New Zealand, the role of PBAC is performed by PTAC (Pharmacology and Therapeutics Advisory Committee). The key difference, however, is that the PTAC process is relatively more informal and less transparent, without an opportunity to seek review of PTAC's compliance with the principles and objectives set for it. This has created growing concern that, in effect, PTAC has simply become part of price bargaining, while in Australia, the ability to seek review of PBAC recommendations through the courts may have kept it more focused on an evaluation rather than price setting or cost control. The PBS process has recently also incorporated a formal review arrangement through the free trade agreement between Australia and the US, which, while yet to be tested, is likely to further enhance the process's independence from price bargaining. Industry participants, in particular, have pointed to numerous PTAC reports citing safety issues despite the products already being cleared by Medsafe as evidence of PTAC seeking to engage in access bargaining.

Like New Zealand, Australia has implemented a reference pricing system. Australia has three levels of reference pricing:

- Reference pricing policy for different brands of the same molecule. PBS sets reimbursement at the price of the cheapest available brand, with all brands receiving this level of reimbursement. Pharmaceutical companies with more expensive brands are allowed to charge a "brand premium" from clients who are willing to pay extra to get their preferred brand, although this is virtually never allowed for new products, but can be applied to an existing product when another existing product, or a new product in the reference group comes in at a lower price
- Reference pricing within a therapeutic group for products considered to be interchangeable on the population basis. Again, reimbursement is generally set at the price of the cheapest medicine within the group. Where a more expensive product within the group is proven to have greater effectiveness, it would receive greater reimbursement to allow for the beneficial difference. If customers wish to purchase a more expensive product of their choice, where the higher price is not reflected in greater effectiveness, they are again able to pay a premium for their preferred product
- Reference pricing between non-interchangeable products, where no premium can be charged, and where reference points are negotiated.

The differences therefore are that in New Zealand

- PHARMAC tends to sole tender a single brand of the same molecule. In other words, customers have no option to pay a premium for their preferred brand; their only choice is to pay full, unsubsidized price for their preferred brand
- Where different brands are reimbursed within a therapeutic group, PHARMAC typically does not increase reimbursement for those products that have demonstrated greater effectiveness.

Hence, co-payments tend to be much higher than in Australia.

For example, in 2003-04, the total cost of PBS drugs was A$5.94 billion, of which the Government subsidized A$5 billion, or 84 percent of the total. "Brand premiums" and other co-payments accounted for 16 percent of spending. This approach allows greater access for a larger proportion of the population to more treatment options than is available in New Zealand. In essence, the Australian subsidy system allows for gradual substitution between various brands. By contrast, sole tendering and the absence of a link between therapeutic effectiveness and the level of reimbursement, leave New Zealand customers with a much starker choice between a free listed drug and a much more expensive product of their choice.

4 Health Spending

According to the Treasury, total health spending in New Zealand increased by over 35% between 1996 and 2004. However, public expenditure on pharmaceuticals remained almost unchanged during this period. Thus, spending on pharmaceutical therapies as a proportion of the New Zealand health budget has plummeted over the last decade. This is at odds with the rest of the OECD.

In the rest of the OECD countries, spending on pharmaceuticals either maintained, or in many cases increased, its share of health spending. In 1996, the average expenditure on pharmaceuticals in OECD countries was about 15% of total health expenditure. At that time, New Zealand was very close to that average, with 14.5% of the health budget going on pharmaceuticals. By contrast, Australia was below average, spending just above 10 percent of its total health costs on medicines.[3]

Figure 4-1 Per Capita Expenditure on Pharmaceuticals, New Zealand & Australia

Source: *PHARMAC, Statistics NZ, RMIANZ*

By 2002 (the latest year for which internationally comparable statistics exist), the OECD average increased to over 16 percent. However, the patterns in Australia and New Zealand reversed. The Australian share rose to 14 percent, or 80 percent of the OECD average, while New Zealand's share fell to below 10 percent. This change-over is also reflected in per capita expenditure, presented in Figure 1.

By 2005, public sector pharmaceutical expenditure (including hospital drug budgets) fell to 8 percent of public health spending, while in Australia the corresponding share has continued to increase slightly in recent years.

[3] The discussion throughout this section draws on the OECD Health Database, and well as on New Zealand Ministry of Health reports

According to the OECD, while levels of pharmaceutical prices differ between different markets, most countries experienced reductions in average pharmaceutical prices over the past 10 or so years. This has come about from the greater role played by generic drugs, more competitive market environment, and the adoption by all jurisdictions of increasingly tough procurement rules. Hence, international increases in the share of health spending taken by pharmaceuticals have come through greater availability of medicines, and through substitution of pharmaceutical therapies for more invasive and costly surgical treatments. The focus on early and better diagnosis and on preventative treatment has also resulted in greater demand for medicines.

By contrast, New Zealand has clearly acquired a culture of extreme fiscal restraint when it comes to pharmaceuticals. Not only has the overall public sector pharmaceuticals budget been capped, PHARMAC has persistently generated surpluses within that cap. Although PHARMAC has no specific mission statement to run at a surplus, it has consistently achieved a surplus over the last few years. In the year ending June 2002 its community pharmaceutical expenditure was $23.4 million under budget. In the year ending June 2003 it was $3.3 million under budget and in the year ending June 2004 PHARMAC ran a surplus of $7.27 million.[4] At the end of the financial year, this surplus is fed back to the District Health Boards (DHB). Despite this ongoing surplus, the net number of pharmaceuticals available with subsidy has actually declined. The persistence of surpluses in the face of clear indications of unmet need strongly suggests that PHARMAC is highly risk averse with respect to breaching the funding cap, and clearly less risk averse with respect to patient needs. This institutional focus can be contrasted with the overall behaviour of DHBs, where persistent (albeit declining) deficits indicate that the balance of risks runs the other way.

Overall, three reasons can be advanced for New Zealand to be so out of step with the pattern of expenditure observed in other OECD countries:

- New Zealand has been able to secure significantly more rapid reductions in the prices of pharmaceuticals than those enjoyed in other countries
- New Zealand has not had access to the same degree of improvement in the health status and quality of life as has been enjoyed in other countries, and
- New Zealand has not been able to achieve the same degree of substitution from more invasive and costly interventions to pharmaceutical-based treatments.

Clearly, the first explanation would be benign, while the latter two reasons – if they were more significant explanations – would expose weaknesses in the New Zealand model.

[4] Reports of the Pharmaceutical Management Agency for the years ending 30th June 2002, 2003, 2004 as viewed at www.pharmac.govt.nz on 10 February 2005.

5 Prices of Pharmaceuticals

There is strong evidence that prior to the creation of PHARMAC in 1993 and the full implementation of the current policies in 1997, New Zealand was a country with relatively high prices of pharmaceuticals. Significant reductions in prices have been achieved since then, making New Zealand a relatively low price country. There is no doubt that some policy steps needed to be taken in order to achieve this transformation. However, it is not obvious that the extreme form of restrictiveness applied in New Zealand was indeed necessary to gain the price benefits.

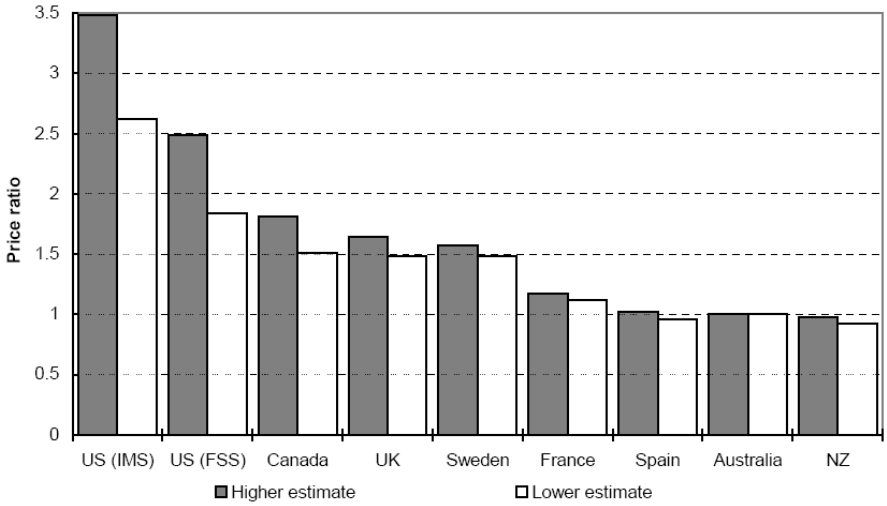
In this respect, it is instructive to compare Australia and New Zealand. Cross-country pharmaceutical price comparisons are extremely complex, having to account for different forms and preparations used in different countries, as well as for complex rebate structures, which affect the average price of the product. We are aware of two detailed studies attempting like-with-like comparison of pharmaceutical prices in different countries, including Australia and New Zealand. The first is a research report prepared by the Australian Productivity Commission in 2001. The second is a study by the Canadian Patented Medicines Price Review Board (PMPRB) in 2003.[5]

The Productivity Commission report (using 1999 and 2000 data) found that by then, New Zealand, along with Australia, was already enjoying lower pharmaceutical prices than many OECD countries. Our interviews with pharmaceutical companies suggest that the price differential is likely to have remained largely unchanged in the last 3 to 4 years, although we have been quoted examples of New Zealand getting some very good deals on specific drugs.

The Productivity Commission cautioned against cross-country comparisons because in most countries, purchasing authorities enter into secret rebate agreements with the pharmaceutical companies. In essence, under such arrangements, sellers of medicines are able to offer discounts without lowering their published prices, and thus without creating price expectations which can affect other purchasers. This is a common marketing tactic used for a wide range of consumer and industrial products. The comparison undertaken by the Productivity Commission did not take rebates into account.

[5] Productivity Commission 2001, International Pharmaceutical Price Differences, Research Report, AusInfo, Canberra and PMPRB *A Study of the Prices of the Top Selling Multiple Source Medicine in Canada,* 2003

Figure 5-1 Price differences – all categories of pharmaceuticals



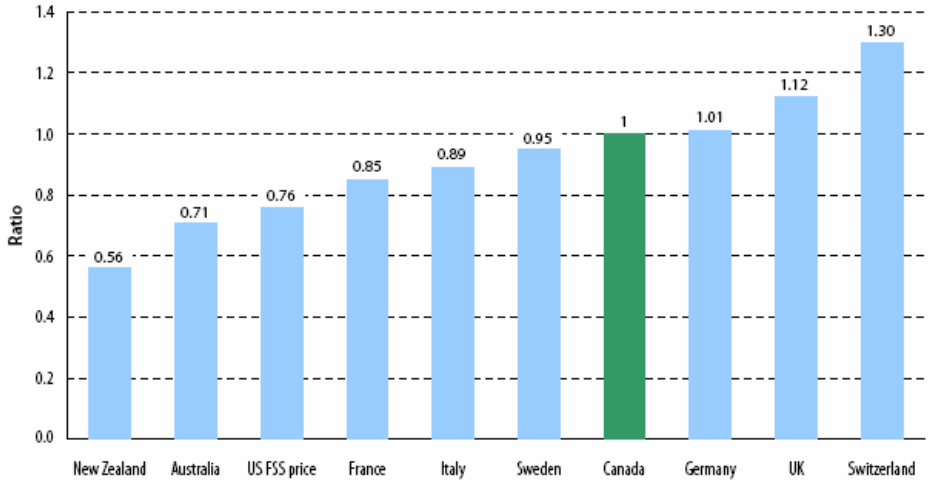
Source: *International Pharmaceutical Price Differences Research Report, Australian Productivity Commission*

In New Zealand, PHARAMC reports the total amount of rebates it receives from all its purchase agreements. In the year ending June 2004, New Zealand received $86.28 million in rebates against the total PHARMAC budget of $533.73 million net of rebates. This represents an average discount of 14% on reported prices. (6) As we understand, there were few rebates in Australia[6]. This would indicate that New Zealand's average prices would be 14 percent to 20 percent lower than Australia's for like products, depending on whether we use the Productivity Commission's higher or lower estimate. If risk-sharing and price-volume arrangements in Australia are counted as a form of rebate, the differential is less.

The PMPRB review, which looked at multiple source medicine prices (both branded and generic) in Canada and in a number of other countries, including New Zealand (see figures below) comes out with slightly different conclusions.

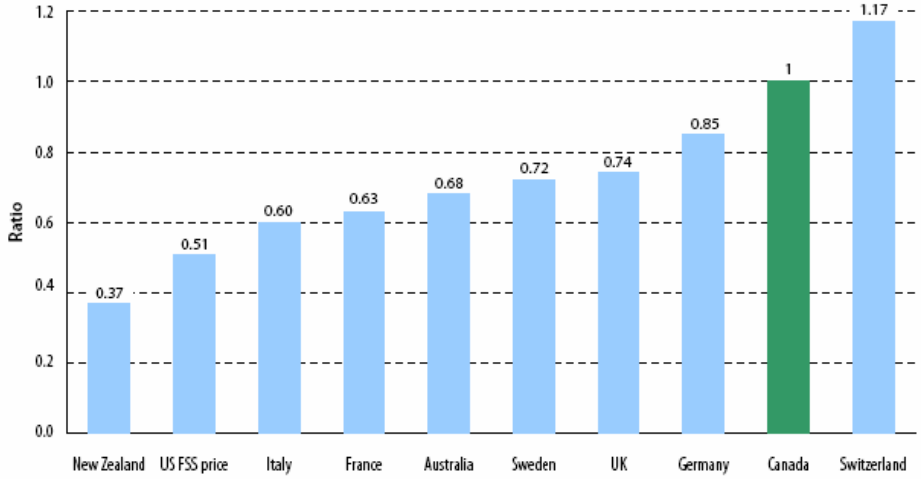
[6] Although some companies offer indirect rebates through risk sharing and price-volume agreements.

Figure 5-2 Ratio of Median Multiple Source Medicines Prices to Canadian Prices



Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*: p. 48, table 12, Bilateral Comparison—The Average Foreign to Canadian Price Ratio.

Figure 5-3 Ratio of Median Generic Prices to Canadian Prices



Source: Patented Medicines Price Review Board (PMPRB) (2003). *A Study of the Prices of the Top Selling Multiple Source Medicines in Canada*: p. 48, table 12, Bilateral Comparison—The Average Foreign to Canadian Price Ratio.

This research indicates that, for all multiple source products, New Zealand's prices in 2003 were 21 percent below prices in Australia. Interestingly, the PMPRB data also shows that generics were 45 percent cheaper in New Zealand than in Australia[7]. This would suggest that the difference for the multiple source branded medicines was less than the difference for all multiple source medicines, in other words, less than 21 percent.

[7] Interestingly, the Productivity Commission found little difference between generic prices in Australia and New Zealand.

The discrepancies between these two pieces of research suggest that neither is perfect. However, at a high level, the two reports point at a similar picture: that, on average, New Zealand's pharmaceutical prices are likely to be around 20 percent lower than prices in Australia. In our view, much of this differential can be explained by factors which have nothing to do with the restrictions placed on access to pharmaceuticals by the New Zealand public. These include:

- New Zealand's lower per capita GDP. Like many other products, pharmaceuticals tend to be priced to market. Hence, lower income countries can expect to pay less than higher income countries[8]
- Australia's industry policy. Australia has an explicit policy of supporting the domestic pharmaceutical manufacturing industry, which mainly produces generics. Hence, the Australian government is likely to be less focused on achieving the lowest possible prices for generics than its New Zealand counterpart
- The relative isolation of the New Zealand market. Overall, pharmaceutical companies need to recover the costs of research investment while a drug is under patent. However, in some isolated markets, they may have an incentive to sell single-source patented medicines at less than the full cost recovery price rather than not sell at all, as long as the price is greater than the actual marketing and production costs. In other words, paradoxically, the government reimbursement agencies in small and distant markets, such as New Zealand have greater bargaining power than the agencies in bigger countries. The key consideration is that pricing in such markets must not affect the company's ability to secure full cost recovery prices in the major markets. As markets become less differentiated, this ability by small, countries to secure better prices declines. For example, traditionally isolated European markets, such as Portugal, are now being integrated into a common European pharmaceutical market, and hence Portugal's pharmaceutical prices are rising.

This analysis suggests three important conclusions:

- First, since both Australia and New Zealand enjoy some of the lowest pharmaceutical prices in the world, the low level of prices in both countries most likely results from the factors that are common to the two funding systems
- Second, where New Zealand is able to achieve lower prices than Australia, this ability is more likely to be derived from the relative isolation of the New Zealand market and the conscious decision made in New Zealand not to support a domestic pharmaceutical industry. The specific New Zealand practices – such as sole tendering of supply and other restrictions

[8] Low income is not sufficient by itself to guarantee low prices. Prior to 1990, New Zealand paid relatively high prices for pharmaceuticals despite its low income. Clearly, if procurement arrangements are divorced from income limitations, producers will have no incentive to price to market. However, given similar competitive procurement arrangements, a country with a lower income can expect to pay less than a country with a higher income.

on access by New Zealand consumers – appear to contribute relatively little to the price level achieved in New Zealand. As we will discuss later, a small contribution to the differential would not appear to justify the costs of the arrangement

- Third, the price benefits of the current policies appear to have been fully captured in the early years of its implementation. In other words, on-going reductions in the share of pharmaceuticals in total health spending over the past 3 to 4 years are more likely to be explained by restrictions on access and by slower substitution towards less invasive treatments.

6 Access to medicines

The previous section suggested strongly that New Zealand's pattern of expenditure on pharmaceuticals – that is our apparent ability to achieve heroic fiscal restraint in this area – is explained by the restriction on access, rather than by our ability to secure particularly low prices. This is borne out by the data on the relative rate of new pharmaceutical listings in Australia and New Zealand presented in Table 1. Three types of listings are important. New chemical entities (NCEs) are the "holy grail" of the pharmaceutical industry, representing research breakthroughs which provide new ways of treating medical conditions. New products and brands include significant adaptations of known chemical entities that advance treatment options and increase effectiveness of treatments. New forms and preparations are essentially minor adaptations which provide additional convenience, and may increase compliance with treatment regimes.

With respect to NCEs, the gap between Australia and New Zealand is particularly significant in 2002 and 2003 June years. In the year to June 2003, New Zealand listed 3 NCEs, compared to 15 in Australia.

Table 1 Comparison of New Listings in Australia and New Zealand from June 1999 to June 2004

	New Zealand (PHARMAC)	Australia (PBS)	New Zealand new availability relative to Australia
New chemical entities reimbursed	63	109	58%
New products (brands)	203	778	26%
New items (forms and strengths)	105	593	25%

Source: PHARMAC Annual Reports, Department of Health and Ageing Annual Reports

It is interesting to note that the disparity appears to be greater with respect to more minor adaptations and new products. In other words, the New Zealand system appears to place less value on individual patient's needs and convenience.

In addition to the number of medicines listed, the delay between registration with the appropriate safety authorities (Medsafe in New Zealand, TGA in Australia) and listing with the public funding agency is also an important dimension of access. One New Zealand review undertaken in 2002 put the average time for products to be listed following registration at 33.6 months.[9] Australian estimates for such delays

[9] Section three: New Zealand Pharmaceutical Expenditure, Researched Medicines Industry as viewed at http://www.rmianz.co.nz/pdfs/hfacts%2001-02/section3_0102.pdf on 10th February 2005

range from 6 to 18 months. In other words, even if New Zealand listed the same number of NCEs as Australia every year, New Zealanders would still have to wait for up to 2 years more than Australians to access treatment improvements.

In the remainder of the report we consider whether relatively severe restrictions on access in New Zealand compared to Australia may themselves be imposing costs. Such costs may come from a number of sources:

- Sole tendering and other restrictions on the range of pharmaceuticals available to the New Zealand public disrupt established clinical routines and limit clinical choice. Periodic changes in the product being procured by PHARMAC may lead to health costs being higher than necessary due to such disruptions. In one recently reported example, when PHARMAC forced the switch from Cipramil (a form of citalopram, an SSRI antidepressant) to a cheaper preparation Celapram, there were 25 reports of reduced therapeutic effect, including three reports of suicidal ideation.[10] Another example of the move to Fluvastatin mandated in the 1990s is described later in the report. The fiscal saving in switching brands is obvious, but the impact that it has on patients' health is difficult to measure and often hidden. In patients who are well controlled on a particular brand, substitution could lead to increased health care costs.

  Sole tendering restricts the range of options available to consumers. Different brands tend to have slightly different preparations, which may lead to different side effects in patients. Hence, sole tendering reduces opportunities for minimizing side effects. This could have two consequences. First, it may lead to increased levels of disability, as patients suffer from debilitating side effects. The costs of such side effects, for example, may come through longer periods on sickness and other disability benefits. Second, it may lead to patients not complying with treatment requirements, and hence suffering disability.

  An almost farcical example of the effects of sole tendering has been the case of paracetamol, one of the most commonly used pain killers and the most commonly prescribed pharmaceutical in New Zealand[11]. It can come in different forms: there is a round tablet, a soluble tablet, and a capsule. The cheapest variant is a generic preparation called Pacimol, a large square tablet with no coating and hard edges. From 2002, New Zealand only subsidised this option. By June 2003, there were 43 reports

[10] Information for Health Professionals, Adverse Reaction Reporting and IMMP, Minutes of the 114th Medicines Adverse Reactions Committee Meeting, 26 June 2003, as viewed at www.medsafe.govt.nz/Profs/adverse/Minutes114.htm on 17 February 2005.

[11] PHARMAC Media Release, Paracetamol most prescribed, 10 November 2004, as viewed at www.pharmac.govt.nz on 10 February 2005.

describing choking, vomiting and difficulty in swallowing the tablets.[12] If patients with swallowing difficulties, such as the terminally ill or the elderly, wanted to acquire a form of paracetamol that they could actually use, they had to pay full price. A proportion of these 43 reports of choking may have presented to an emergency department, GP or hospital. The costs of this do not appear to be measured in calculation of savings from sole tendering. Following much ridicule and concern, PHARMAC has announced that it would procure capsules from 1 July 2005. However, this illustrates the approach in its extreme form.

- Delays in the introduction of innovative medicines compared to other countries, such as Australia, could lead to poorer health outcomes and greater expenditures on other forms of care
- Lack of access to cutting edge pharmaceutical therapies may affect the career and professional development opportunities of the New Zealand medical profession which will ultimately impact on standards of care.

We will examine these areas of cost in the remainder of this report. At this point, it is worth noting, however, that PHARMAC itself, in its 2002 Briefing to the Incoming Minister indicated that its funding was not sufficient to procure all the medicines which it believed would be of benefit to the New Zealand public.

[12] Information for Health Professionals, Adverse Reaction Reporting and IMMP, Minutes of the 114th Medicines Adverse Reactions Committee Meeting, 26 June 2003, as viewed at www.medsafe.govt.nz/Profs/adverse/Minutes114.htm on 17 February 2005.

7 Health Care Outcomes

Pharmaceutical therapies have played a major role in reducing both morbidity, disability and mortality throughout the world. For example, antipsychotic medications have enabled the closure of psychiatric wards and allowed many patients to live in the community. Changing attitudes towards mental illness have contributed to this but these changes in attitude have come about as a result of psychiatric conditions becoming treatable conditions. Medications that manage cardiac disease risk factors, such as cholesterol lowering drugs and antihypertensive medications have reduced the damage from cardiovascular disease and strokes.

Health care is also evolving towards greater reliance on pharmaceutical therapies and towards individualized drug therapy. Responses to, and side effects of, any given medication vary from one patient to another. This variability is partly due to genetics. Differences between ethnic groups in drug responses have been documented since the early 1900s due to differences in receptor subtypes. (12) There are also racial variations in the ability to metabolize substances. (13) A well known illustration is the difference in the ability to metabolize alcohol: fifty percent of Japanese and Chinese people do not have the active form of the enzyme aldehyde dehydrogenase. In people who lack the enzyme, consumption of alcohol results in an accumulation of acetaldehyde. This leads to the appearance of unpleasant symptoms including facial flushing, palpitations and tachycardia. (13) Although reactions to alcohol may not be such an important medical issue, there are racial differences in responses to many essential pharmaceuticals including those used to treat cardiovascular disease (12), mental illness (14) and HIV (15). A growing area in medicine is the development of individually tailored pharmacological treatments, a field called pharmacogenetics. (16)

Individual preferences for safety and side effects also vary. Greater access to a wide range of pharmaceuticals increases the chance of successful treatment. For example, some antipsychotics are more likely to cause sedation while others are more likely to cause sexual side effects. Although having to choose between being sedated or being impotent is not particularly desirable, individuals place different values on these potential side effects. Having a larger choice of medications available reduces the risk of unacceptable side effects and allows individuals to have greater control over their treatment. In New Zealand, unlike Australia, the antipsychotic medications aripiprazole and amisulpride are not available (33,36). Of the newer atypical antipsychotics, these are the least sedating medications. In New Zealand the option of a non sedating atypical antipsychotic medication does not exist.

Reducing the side effects of pharmaceuticals leads to improved adherence to treatment with obvious subsequent effects on health. Studies show that compliance varies between drugs of different classes. (17) Poor compliance with treatment guidelines has been shown to increase fracture rates in people with osteoporosis. (18) More convenient preparations help improve adherence. (19) With New Zealand's current pharmaceutical policy, choice is difficult to offer because the policy does not subsidise the use of more convenient preparations if they are not the cheapest available.

The future of pharmacological medical treatment thus involves catering for tolerability and response variations. New Zealand's policy, by contrast, appears to

run against this trend. The policy restricts the exercise of clinical judgement and shifts the risks associated with unusual drug response to the patients. This appears to be fundamentally at odds with the philosophy underpinning the public health system: that resources would be allocated on the basis of need. When it comes to pharmaceuticals, people who find themselves at the tail ends of drug response and tolerability distribution – and hence are most in need – are least looked after.

7.1 Country comparisons

New Zealand has a worse health profile than Australia, as well as many other OECD countries (9). For example, our death rate from cardiovascular disease is 233 per 100,000, compared to Australia's 198 and Canada's 191. Similarly, New Zealand's death rate from cancer is 180 per 100,000, compared to Australia's 162 and Canada's 176. Does this have anything to do with our particular approach to subsidising pharmaceuticals, and to the low level of spending on medicines?

As we have already emphasized, in comparing health data between countries it is important to be aware of the many factors contributing to health outcomes. Environmental, lifestyle, cultural and genetic factors all contribute to health, as do the health services available. Direct causation is difficult to prove. We are substantially limited by the low availability, poor quality and variability of both national and international data. Health statistics in different countries are given in different units, with different classifications and often incomplete data sets. Strong caveats must be placed on any international comparisons. We have found only a limited number of medical studies looking at the effects of drug availability in New Zealand, and even fewer that have attempted international comparisons.

In addition, changes in policy will tend to have a delayed effect on population health outcomes. New Zealand's recent deviation from the OECD trend in access to pharmaceuticals may not have been in place for a long enough time for the associated changes in population health outcomes to have fully emerged.

While it is impossible to find overall population health measures of the effects of New Zealand's pharmaceutical policy compared to the policies in Australia, case studies of psychiatric illness and cardiovascular disease give a strong indication of the problems which are beginning to emerge. These two cases are interesting because these diseases have particularly benefited from advances in pharmaceutical treatments.

With all the caveats mentioned above, we believe the evidence suggests that New Zealand's policies are imposing social and economic costs through poorer health outcomes and slower uptake of less interventionist treatments. We also note that the number of people on sickness benefits in New Zealand during a period of record low unemployment has recently received much political publicity. The tendency to be on disability benefit has been identified as a symptom of welfare dependency. It may also be a symptom of relatively higher levels of actual disability in New Zealand, arising in part from poorer access to pharmaceutical treatments (38).

Chronic illnesses such as cardiovascular disease and mental illness impose a heavy burden on the country. Failure to prevent or ameliorate impairment leads to chronic incapacity and disability. New Zealand spends more on disability benefits as a

percentage of GDP than Australia, even through the levels of benefit relative to the average wage are comparable.

Improving treatment of chronic disorders would lead to a reduction in disability and may lead to an increased rate of return to work in affected people. Due to the limitations on pharmaceuticals, many chronic disorders such as psychiatric illness and cardiovascular disease appear to be sub-optimally treated in New Zealand.

7.2 Mental health

In general, the folklore in New Zealand ascribes poorer health outcomes and lower access to health services in New Zealand than in Australia to our lower levels of income. In per capita terms, one would expect New Zealand to spend less on all interventions, with the consequent effect on outcomes. We approached this analysis with the same mindset, and were surprised to discover that Mental Health Services is an area where New Zealand spends twice as much per capita as Australia (22). What makes this particularly interesting is that this higher spending is due to non-pharmaceutical treatments, such as provision of psychological services. There are fewer antidepressant and antipsychotic medications available in New Zealand, and the clinical culture in New Zealand is less conducive to pharmaceutical intervention in this area. In particular, New Zealand has fewer antidepressants and antipsychotics available for treatment than in Australia. Of the newer antidepressants available in Australia, New Zealand does not subsidise sertraline, fluvoxamine, reboxetine or mirtazapine. Paroxetine receives a subsidy of $NZ1.90 on the supplier price of $NZ35.02. (33) (36). Venlafaxine, an antidepressant that has been shown to be more effective than selective serotonin reuptake inhibitors (37), only became available in New Zealand in 2004 (34) whereas it has been available in Australia since 1996 (35). Of the newer antipsychotic medications available in Australia, New Zealand does not subsidise amisulpride or aripiprazole. (33) (36). A disparity in access to pharmaceuticals for the treatment of mental illness between Australia and New Zealand is evident.

Despite significantly higher spending, New Zealand mental health outcomes are comparable to those in Australia (20, 21) when measured in terms of disability adjusted life years.

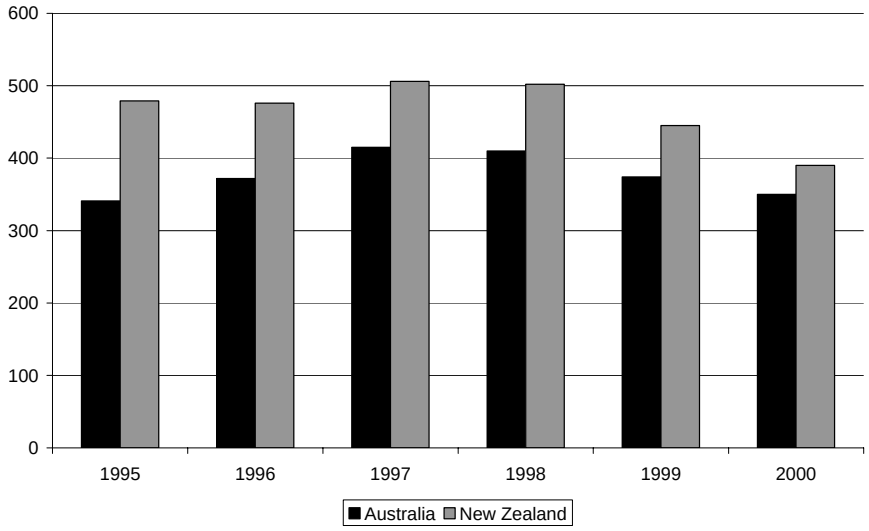
New Zealand has a higher suicide rate than Australia (9). While suicide is a very emotive topic, and the reasons for different suicide rates in different countries are poorly understood, there is strong evidence suggesting that pharmaceuticals, i.e. antidepressants, are associated with a reduction in suicide. Four epidemiological studies in four different countries have shown that there is an association between increased antidepressant prescribing and a reduction in suicide rates. (24, 25, 26, 41) The latest of these studies showed an association between greater prescribing of newer antidepressant (i.e. non tricyclic antidepressant) and lower suicide rates (41).

Recently, there has been some concern that SSRI antidepressants increase suicide and self harm behaviour in vulnerable individuals receiving them. This association has been found in randomised placebo controlled trials of people being treated for depression. This has lead to an FDA directive to the manufacturers of all antidepressants to add a warning about increased risk of suicidal behaviour in children and adolescents who take antidepressants (43).

The risk of increased suicide in adults taking antidepressants remains unclear. In February, 2005 the British Medical Journal published a meta-analysis of randomised placebo controlled trials of SSRIs in adults (42). This report analysed 477 placebo controlled trials of SSRIs, including 52,503 subjects. This data included 16 suicides, 172 episodes of non fatal self harm and 177 episodes of reported suicidal ideation. The results were inconclusive with very wide confidence intervals for the risk estimates due to the small number of suicides. The authors concluded that "Because of the low incidence of suicide, it is not possible to rule out either a threefold increase or a decrease in its occurrence among people treated with SSRIs." (42)

Overall, it is likely that antidepressants have contributed to reducing the rate of suicide by decreasing the population health burden of depression. This is not inconsistent with the possibility of an increase in suicidal behaviour in susceptible individuals during the early phases of treatment. It is clinically recognised that during the early phase of treatment with SSRIs, some people experience side effects of insomnia and agitation. Further, during the early phases of treatment for depression, some people experience an improvement in their energy levels before an improvement in their mood. These factors combined may lead to an increase in suicidal behaviour in vulnerable individuals. However, it is generally recognised that the appropriate response from health providers is a combination of informing patients and better monitoring during the early phase of treatment, rather than a failure to treat.

Figure 7-1 Potential Years of Life Lost from Intentional Self -Harm (- <70 year, /100,000 pop.)



NOTE: Assumes average lifespan of 70 years

Source: *OECD Health Data, 2004*

Given the mental health outcomes, it is reasonable to question the mix of health services being purchased in New Zealand's mental health service, given that it spends more on mental health than Australia. It appears plausible that greater reliance on pharmaceutical therapies would have enabled New Zealand to achieve the same mental health outcomes at less fiscal cost, or may have led to better outcomes.

7.3 Cardiovascular disorders

Disorders of the circulatory system which include cardiovascular disorders, cerebrovascular disorders (strokes) and renal complications are partially preventable through reduction of risk factors. Prevention is both possible and cost effective (27). Pharmacotherapy has a large role to play in prevention of these diseases. This involves the pharmacological management of hypertension, diabetes and blood lipid profiles. Poor management of these risk factors results in more expensive end-stage treatments, increased disability and increased mortality rates. (20, 21)

Unfortunately, there are no studies directly comparing cardiovascular disease burden in Australia and New Zealand. However, it is useful to use studies carried out in the two countries in the late 1990s (20, 21) as starting points for analysis. While these studies covered different periods and used different methodologies, they expressed disease burden in "common currency": Years of Life Lost (YLL), which measures the disease burden of fatal disease and injury; Years Lost to Disability (YLD), which estimates the burden of non-fatal outcomes; and Disability Adjusted Life Year (DALY) which combines both the fatal and non-fatal burden.

In the late 1990s, prior to the systematic implementation of the current pharmaceutical subsidy policy, New Zealand already appeared to have a higher cardiovascular disease burden to Australia (see Table 2).

Table 2 Cardiovasclar disease outcomes in New Zealand and Australia in 1990s

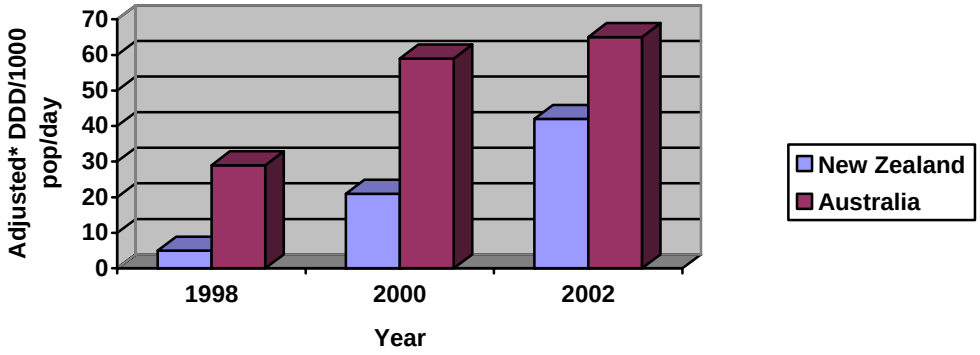
	New Zealand (1999)	Australia (1996)
Years of Life Lost	34.7	33.1
Years Lost to Disability	10.8	8.8
Disability Adjusted Life Years	24.0	21.9

Source: OECD

The more recent data from the OECD (9) indicates that this divergence has grown. New Zealand has seen an increase in deaths from diseases of the circulatory system, ischemic heart disease, myocardial infarcts and cerebrovascular disease when compared to Australia since 1997. New Zealand death rate from circulatory system diseases is now approximately 15 percent higher than the rate in Australia (232 per 100,000 in New Zealand vs. 198 per 100,000 in Australia).

The causes of the higher mortality rates in New Zealand are complex and it is difficult to isolate individual factors. However, the restrictive pharmaceutical policy appears to be directly contributing. The rate of pharmaceutical use for cardiovascular disease remains modest in New Zealand when compared to other OECD countries. (27). While statin consumption in New Zealand has increased in recent years, it still remain significantly below Australia's level (27A).

Figure 7-2 New Zealand and Australia Statin Consumption



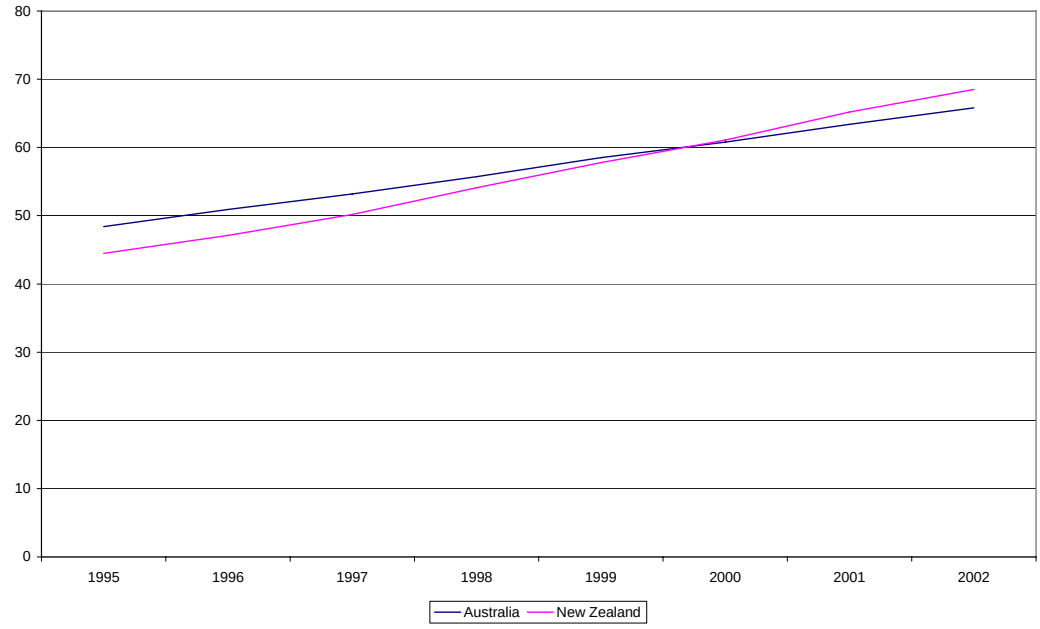
Source: *BMJ Rapid Response*

One well documented example of the direct adverse impact of New Zealand's pharmaceutical policy on cardiovascular disease has been the switching of subsidisation from one cholesterol lowering agent to another. In the past 10 years, PHARMAC has repeatedly changed the subsidised statin (a class of cholesterol lowering agents) as pharmaceutical companies competed by making deals offering the cheapest agent available. In December 1996 many patients were forced to switch from simvastatin or pravastatin to a less potent but cheaper cholesterol lowering agent, fluvastatin that now became PHARMAC's subsidised statin. At that time the available medical evidence was for simvastatin or pravastatin. There was no evidence showing that fluvastatin's had any impact on morbidity or mortality. (31) Overall simvastatin and pravastatin had the greatest evidence base and were shown to be cheaper per percentage reduction in cholesterol than fluvastatin (31). However, despite this to make short term savings PHARMAC chose to subsidise the cheapest statin at the time i.e. fluvastatin.

There was immediate evidence of the adverse impact of this. An audit in the Otago region of 262 patients that had switched medication, found that following the forced switch there was a significant increase in total cholesterol (29) and in strokes and heart attacks (30). Eventually PHARMAC acknowledged the deficiencies of fluvastatin and switched subsidisation to another statin, atorvastatin. However, like the previous statin chosen by PHARMAC the reason for choosing atorvastatin was not based on evidence of its effect on mortality or morbidity but on a cross subsidisation deal that PHARMAC could make with the company distributing it. In 2002, with the expiry of the simvastatin patent, the reference price for statins fell even further, with simvastatin now being the favoured statin. This resulted inevitably in patients on statins yet again switching to the cheapest statin. Many patients have had to change their statin medication three times over the last 10 years. It appears that such enforced changes have become routine in many therapeutic groups. The present New Zealand system does not provide for any accountability for government agencies for imposing detrimental effects of this kind on the population.

End stage complications in circulatory disease have increased in New Zealand, with an increase in expensive end stage treatments. New Zealand's rate of end stage renal failure has increased faster than Australia's and the absolute level has been higher since 2000 (see Figure 4-1). (9) This may reflect early evidence of a worsening treatment of risk factors, such as management of elevated cholesterol or hypertension, in New Zealand since the divergence in pharmaceutical practice in the late 1990s. As a result, New Zealand has higher rates of expensive and disabling dialysis (9) than Australia.

Figure 7-3 End Stage Renal Failure



Source: OECD Health Data

This cross over between New Zealand and Australia in the rates of renal failure and dialysis has occurred since 1997 and it seems plausible that it may be linked to the change in pharmaceutical policy.

7.4 Lack of substitution to less interventionist treatments

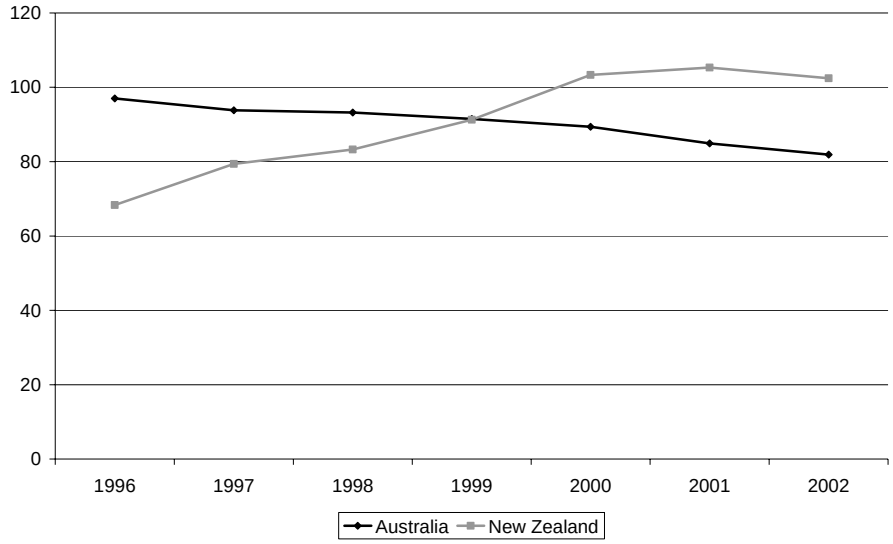
While New Zealand's relative health outcomes with respect to cardiovascular disease have worsened since the late 1990s, this has not been for lack of cardiac interventions. In fact, New Zealand has experienced the fastest growth in cardiac interventions in the OECD since 1996.

New Zealand has markedly higher rates of cardiac bypass surgery than Australia. Unlike the other countries where bypass rates have either declined or stabilized, New Zealand's bypass rate has increased by over 30% since 1997. (9) World-wide the trend has been to move away from bypass surgery to less invasive procedures. By contrast, New Zealand has lower rates of cardiac stenting and other percutaneous cardiac interventions than Australia New Zealand's rate of percutaneous coronary

interventions remains at 65 percent of the rate in Australia, while the rate of coronary stenting is about half of Australia's. (9).

Overall, since 1996 the rate of cardiac intervention surgery in New Zealand increased by 80%, while in both Australia and Canada, intervention rates grew by 46%. The U.S. rate only grew by 6%. (9) A large proportion of this movement has been New Zealand catching up with international levels. However, a contributor to the growth may be the poor early pharmacological treatment of risk factors, and a more liberal approach to setting surgical budgets compared to pharmaceutical benefits.

Figure 7-4 Coronary Bypass Operations (per 100,000)



Source: *OECD Health Data, 2004*

The key observation from these statistics is that while New Zealand places strict budgetary controls on pharmaceutical purchasing, in other areas, it does not place such budgetary restrictions. When it comes to expenditure on expensive end stage procedures New Zealand has comparable rates to Australia, but the spending on pharmaceutical management of conditions is considerably less (9). Remarkably, when it comes to the most extreme and expensive intervention – heart transplant – New Zealand has a higher rate than Australia, with 0.6 procedures per 100,000, compared to Australia's 0.4 procedures per 100,000.

8 Culture of Health Care Provision

Even within a small country like New Zealand, the health care provided in each District Health Board (DHB) varies. This variation is due to differences in populations serviced, differences in funding, but also due to differences in the institutional cultures. Institutional culture is a very important and under-recognized influence. No health care event occurs in isolation and all service provision is interconnected. More generally, New Zealand – compared with countries such as Australia – appears to have a culture where fiscal restrictions have translated into habits and patterns of behaviour which profoundly affect the quality of health care provided. While in the first instance, pharmaceutical restrictions appear to harm drug companies, the impact on the companies feeds back and reverberates through the medical profession, ultimately affecting patient care.

The pharmaceutical industry is responsible for a large proportion of the continuing medical education of health professionals. The strict limitations on pharmaceuticals have reduced the incentive for pharmaceutical companies to market products in New Zealand. In other words, the companies do not spend time and effort promoting new or alternate treatments to doctors. Traditionally, the pharmaceutical industry has familiarised doctors with new medications and has often provided free samples to trial, like a computer company educating its clients and allowing free initial use of its software. With reduced effort in this area, New Zealand is slow to take up new pharmaceuticals, despite scientific evidence as to their efficacy. Some people would argue that the pharmaceutical industry should not be allowed to alter doctors prescribing habits by offering new drugs just to line their corporate pockets. However, international research shows that the main determinants of doctors' prescribing practices are habit and the age of the doctor. (28) PHARMAC itself has been quoted stating that it is "not their responsibility to educate doctors potentially unfamiliar with newer agents." (32) This was PHARMAC's response when it was found that following its forced switch from simvastatin to fluvastatin, there was substantial under dosing with the new agent that resulted in adverse health effects. (29)

In the absence of information usually provided within the overall marketing strategy through educational meetings sponsored by pharmaceutical companies, doctors' prescribing lags advances in treatments, even when medicines become listed. In other words, New Zealand's restrictive policies pack a double whammy: first, they delay the introduction of new drugs, then they delay the uptake. Ironically, in New Zealand, unlike Australia, the pharmaceutical industry is allowed to market directly to patients.

The pharmaceutical industry is obviously also responsible for the major proportion of research and development into new drug treatments. New Zealand's policies have led to the pharmaceutical industry withdrawing research funding from New Zealand. This has many potential implications. Firstly, it reduces the likelihood of research into the pharmacological requirements of New Zealand minority populations; secondly, it threatens the viability of pharmaceutical research companies in New Zealand; and thirdly, it limits the careers of our doctors. Participation in drug trials is an important part of career development for specialists allowing them to be

involved and become internationally known for their research, alongside their practice.

It is also important to emphasise that, from the patient point of view, participation in clinical trials provides a unique opportunity both to gain access to new medicines earlier than would have been otherwise possible and to receive a wide range of medical services at pharmaceutical company expense. For example, in order to maintain research standards, participants in such trials receive a greater level of diagnostic attention than is typically available within the public health system. From the government point view, clinical trials reduce the burden of some of the most expensive patients on the public system, since most of their treatment within the trial is covered by the pharmaceutical companies.

Although both New Zealand and Australia have a shortage of both general practitioners and specialists, it is a substantially greater problem in New Zealand(9). It is difficult to attract and keep doctors in New Zealand. There are many contributing factors, including the size of the country and medical incomes but reducing the opportunities for professional development cannot help.

Table 3 Doctors in New Zealand and Australia in 2001 (number/1,000 pop.)

	New Zealand	Australia
Practicing Specialists	0.7	1.2
General Practitioners	0.8	1.4

The influences of institutional culture are often initially subtle, but insidiously cumulative and far-reaching in their effects. Prescribing does not occur independently, but is part of an overall health package.

9 Social and Economic Impacts

Our review indicates that the social and economic costs of the existing restrictions on the availability of pharmaceuticals in New Zealand are likely to be substantial:[13]

- Non-pharmaceutical treatments and interventions are likely to be costing New Zealand more than the equivalent medicines-based treatments would have cost. For example, reductions in end-stage renal dialysis which could be achieved with more emphasis on earlier pharmaceutical interventions, may alone generate tens of millions of dollars of net savings
- The lower quality of life available to sick people in New Zealand relative to Australia is likely to impose further economic costs in reduced productivity and the additional support required by such people. Such costs are likely to run into hundreds of millions of dollars, particularly during the period of labour shortages
- High levels of disability associated with poor management of psychiatric conditions are also likely to result in social costs. Reduction of New Zealand medical practitioners' professional development opportunities and domestic experience with pharmacological treatments. The inability to participate in research because of restrictions on pharmaceuticals is likely to increase the costs of recruiting and retaining world class specialists in New Zealand.

We believe that a detailed investigation is warranted to develop a clearer picture of the costs associated with the current policies. However, even without such an investigation, the available evidence points to a likely ball-park figure for these costs in the hundreds millions of dollars a year.

We believe it is therefore easy to reach the conclusion that the costs of the current policy are likely to strongly outweigh its benefits, because the benefits are known to be relatively small. The only social and economic benefit of the current policy is its ability to achieve pharmaceutical prices in New Zealand below the levels that would have prevailed otherwise. It appears likely that removal of restrictions on access to pharmaceuticals would, at most, result in prices rising to the level prevailing in Australia. As we discussed before, such a rise would, on current expenditure and given other factors explaining price differentials, amount to much less than the current 20 percent or so price gap. By way of an example, a 10 percent price rise resulting from less stringent restrictions on choice and access, would cost in the region of $55 million per annum on current spending. Our ability to avoid this small additional expense is the total value of the benefit resulting from the current restrictive approach to the funding of pharmaceuticals. Clearly, it is likely that the social and economic costs would be as much as an order of magnitude greater.

[13] In this context, it is important to emphasize that the reduction of expenditure resulting from denying consumers access to some drugs can not, in itself, be considered a benefit of the current policy. However, to avoid double counting, we need to consider social and economic costs after subtracting the direct costs of funding pharmaceuticals.

10 The Way Forward

Our analysis suggests there are strong indications that the costs of the current funding model are likely to exceed its benefits. The available evidence certainly raises sufficient concerns to recommend a wide-ranging inquiry into the policy. In this section, we would like to consider the main issues that such an enquiry may need to address.

In our view, the key challenge will be to design a funding regime which improves access to a broad range of pharmaceuticals and provides sufficient incentive to the pharmaceutical companies to market and trial their products in New Zealand, without undermining sound fiscal management and without creating conditions for unjustified price increases in New Zealand.

Clearly, this will not be as simple as just increasing PHARMAC's budget. This challenge will need to be addressed at three levels:

- First, institutional arrangements for the setting of the health budget will need to be re-examined to allow for rational consideration of trade-offs between pharmaceutical and other forms of treatment. The current approach to health budgeting relies on capping specific expenditure categories. For example, there are separate caps on pharmaceuticals, stenting procedures, mental health and so on. Each of these budgets tends to be considered separately. In other words, it is theoretically possible for PHARMAC to argue that increasing its budget in order to list more drugs would lead to cost reductions in other areas of health and welfare spending. In practice, however, there is no institutional mechanism for the Government to claim these savings from other areas of spending, and to use them to fund the pharmaceuticals budget.

  Various studies undertaken by Treasury and the Office of the Auditor General have highlighted the difficulty of achieving re-allocations of resources within New Zealand's public finances. As a result, while the decision-makers may in theory agree that spending more in one area and less in others would be a good idea, they are intensely aware that the institutional arrangements under which they operate make it very difficult to secure such offsets. Hence, they tend to consider each expenditure area in isolation, with pressure to keep each individual budget under control.

  Since the pharmaceutical funding model has led to such a significant distortion of New Zealand's spending patterns, it is likely that any shift to a more demand-driven model would result in a sharp rise in New Zealand's pharmaceutical spending. If New Zealand was to return to the OECD average share of pharmaceutical spending in its total health budget, PHARMAC's budget would need to about double. Clearly, this would not be fiscally sustainable if the resulting social and economic savings also do not translate into direct fiscal savings in other areas of expenditure. Hence, mechanisms would need to be put in place to claw back the spending from other areas in a way that does not interfere with

the quality of policy programs. In essence, it will be essential to break down the silos into which health care spending has been straight-jacketed.

- Second, if New Zealand is to move from the current budget cap, it will be important to ensure that the funding arrangement does not create incentives for over-consumption or inefficient consumption. For example, if subsidies were to fully cover both generic and branded products, it will be important to re-think New Zealand's current approach to co-payment by consumers. As we mentioned before, one of the key differences between Australia's and New Zealand's approach to the funding of pharmaceuticals is that the Australian model leverages considerably more private spending by consumers. While this is seen as a major benefit in many countries, the folklore in New Zealand tends to consider co-payments as inequitable. Our analysis indicates that, in fact, it is the current model which is highly inequitable, as it allows the very well-off full access to branded products, but excludes most of the population from this choice.
- Third, New Zealand authorities should continue to focus on getting the best value for New Zealand. Clearly, continued use of a wide range of tools will be important to achieve this result. However, it would be useful to investigate other techniques which provide wider access and a more rational distribution of healthcare spending. We would be concerned that the current staff of PHARMAC have heavily invested in developing skills of extracting low prices in the context of budget caps and sole tendering. They may not be fully aware of other experiences, and may be inclined to defend the current regime because they believe that in the absence of the existing restrictions, they may not be able to hold the line on prices.
- The arrangement for establishing prices will need to avoid the currently blurred lines between cost control and review of clinical effectiveness. It will be important to put in place transparent and reviewable criteria for making medicines available to the New Zealand public, and the agencies responsible will need to be clearly accountable for their performance under these criteria.

11 Conclusion

Good health is multifactorial in nature. Although it is difficult to prove direct or single factor causation in health outcomes, the evidence is strongly suggestive that the restriction on pharmaceutical prescribing in New Zealand is impacting adversely; it is costing the country both financially and in health outcomes. There appears to be cost shifting to more expensive end-stage interventions and potentially to more welfare payments. This is in fact probably an under-estimation of health costs as there will be a time delay in the true impact of this divergence in pharmaceutical policy. There are also many health costs that are difficult to measure in monetary terms. The limited number of pharmaceuticals subsidised, the often strict eligibility criteria enforced on subsidies, the delays in new pharmaceuticals being listed and the destabilization caused by delisting of medications are all factors contributing to New Zealand's poor health profile.

Health provision occurs within a culture. The provision of pharmaceuticals both determines the culture and is influenced by it. New Zealand's pharmaceutical policies have caused a divergence in the health culture of New Zealand away from the rest of the world. This divergence has negatively impacted on health outcomes, patient autonomy, patient choice and the ability to maintain a medical workforce.

The current New Zealand funding model has succeeded in keeping down the cost of pharmaceuticals. However, the prices are only marginally cheaper than what is being paid in Australia. The apparent fiscal restraint in New Zealand has been achieved by shifting risks to the general public and to other areas of spending.

Although PHARMAC uses some elements of an evidence based approach to subsidy decisions, it ignores two essential features of evidence based medicine: clinical experience and patient choice. As the future lies in more individual tailoring of treatment, New Zealand will fall further behind.

The weight of evidence suggests that the costs of the current policy outweigh its benefits, and that the cost to benefits ratio will continue increasing as pharmaceutical innovation brings more medicines targeted to individual tailoring to the use of medicines for patients. The current approach is not sustainable in the medium term. We believe the time is ripe to undertake a far-reaching review of New Zealand's pharmaceutical policy.

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