How New Zealand has contained expenditure on drugs

The approach of New Zealand's Pharmaceutical Management Agency (PHARMAC) has much to commend it, say **Jacqueline Cumming and colleagues**

The recent economic crisis has forced Western countries to examine how they contain health spending and improve value for money. Spending on drugs averages around 15% of total health spending for countries in the Organisation for Economic Cooperation and Development (OECD).[1] Improved management of spending on drugs can therefore make an important contribution to containing health budgets.

In recent years, increases in drug costs in New Zealand have been below those experienced in other countries while public coverage has improved. We discuss the Pharmaceutical Management Agency's (PHARMAC) role in achieving this, its processes for setting priorities, criticisms about its work, and implications for other healthcare systems.

History and role

New Zealand's healthcare system is predominantly publicly financed from general taxation and provides all drugs free of charge for people in hospital and a comprehensive set of subsidised drugs for people receiving services outside hospital.

For many years, the rise in expenditure on community drug treatment was a major problem. During the 1980s, for example, government expenditure on non-hospital drugs grew at almost 15% a year, faster than any other component of healthcare spending.[2]

PHARMAC was established in June 1993 with the objective of securing the best health outcomes from community drug treatment, within the amount of funding available.[3] PHARMAC's role has now expanded, and it not only manages the community drug budget but also works to ensure the optimal use of medicines; negotiates prices and supply terms for some hospital medicines; manages the basket of essential cancer drugs that must be made available to New Zealanders; and manages exceptional circumstances schemes that supply drug funding for people with rare conditions.[3] PHARMAC is governed by a government appointed but independent board accountable to the minister of health and acts on behalf of New Zealand's 20 geographically based district health boards, which plan, purchase, and provide health services.

Box 1 | PHARMAC's criteria for deciding funding[4]

- Health needs of all the eligible population
- Particular health needs of Maori and Pacific peoples (both groups have lower health status than other New Zealanders)
- Availability and sustainability of existing medicines, treatment devices, and related products
- Clinical benefits and risks
- Cost effectiveness of meeting health needs by funding the drug rather than using other publicly funded health and disability support services
- Budgetary impact of any changes to the schedule
- Direct cost to health service users
- Government's priorities for health funding
- Such other criteria as PHARMAC thinks fit (after appropriate consultation)

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Health needs of Maori and Pacific peoples are one of PHARMAC's criteria for funding

How PHARMAC works

Once a drug is approved for sale in New Zealand, drug companies can apply to PHARMAC for it to be government funded. PHARMAC's key roles are to decide whether a medicine will be subsidised, the price the government is prepared to pay, and conditions of access. In community settings, only drugs on PHARMAC's pharmaceutical schedule receive government funding; New Zealanders must pay for other registered medicines themselves. Patients generally make a co-payment (NZ$3 (£1.40; €1.70; US$2.20) per item) for each medicine listed in the schedule, but they may also have to pay an additional fee if the subsidy level PHARMAC has set is less than the price charged by the drug company.

The schedule currently contains about 2000 items. PHARMAC uses a rigorous and well documented[4 5] process to determine which drugs are added to the national schedule, to try to ensure the best outcomes for the funding available.

When a company applies to PHARMAC for government funding for a new drug it submits information on the costs and benefits. This information is assessed by PHARMAC's pharmacology and therapeutics advisory committee, which advises whether the medicine should be subsidised, although PHARMAC is not bound to accept the committee's recommendations.

The decision whether to fund is based on nine criteria (box 1).[4] The weight given to each criterion varies as PHARMAC considers appropriate. However, one of the key criteria is cost effectiveness. PHARMAC calculates incremental costs and benefits (using quality adjusted life years or QALYs) associated with new medicines compared with current and expected clinical practice, including any averted health sector costs.[6] It then prioritises new drugs against other potential expenditures, such as other new drugs or expanding access to drugs that are already funded.

Because cost effectiveness is only one of PHARMAC's decision making criteria and because the agency must work to a variable annual budget, there is no one cost per QALY value that determines whether a medicine is subsidised. Rather the data are used to create a relative ranking of medicines that could be funded. Medicines are funded according to their place on the list along with information on the other decision criteria. Between 1998 and 2005, new investments cost on average $6900 per QALY gained, although the patient weighted annual average cost per QALY gained ranged from $2991 in 2001-2 to $15 768 in 2003-4.[5]

PHARMAC then uses several processes to manage the prices of medicines on the schedule. Drug companies negotiate with PHARMAC over the price and other conditions of access, encouraging competition between suppliers.[7] PHARMAC uses reference pricing to set government subsidies at the same level for medicines with the same or similar effects (that is, within

a therapeutic subgroup), forcing suppliers to either match the lowest price for a group of medicines or risk patients and general practitioners choosing a different medicine since patients pay the additional cost if the actual price of a drug is higher than the government subsidy.

PHARMAC encourages development of generics by running competitive tenders for the right of exclusive supply, for a limited period, once a drug's patent expires. PHARMAC also enters into risk sharing, multiproduct deals with drug companies and arrangements which set expenditure caps or rebates, sharing risk with the drug companies over the likely uptake of a particular medicine.[7] Substantial savings have been made for several medicines as a result of these policies,[7] with statins now around half the cost that they are in Australia[8] and the price of fluoxetine having fallen from $1.92 per 20 mg capsule in 1993 to $0.05 per capsule in 2004.[7] A recent analysis by the Canadian government shows that the price of generic drugs in New Zealand is less than a quarter of the price in Canada and that patented drugs are 20% cheaper.[9]

Effect on drug expenditure and access

Complete data are not readily available on measures relating to spending and access. However, PHARMAC has made substantial savings, and growth in expenditure has slowed, since it was established in 1993. At the end of PHARMAC's first year, it announced a first year saving of $3.1m against the previous trend and had halved the growth in drug expenditure to around 5% a year.[10] PHARMAC's estimated cumulative savings for the year ending June 2006 were $1032m, predicted to rise to $1250m for the year ending June 2008 (fig 1).[11] New Zealand's Treasury reports that between 1994 and 2008, the community drug budget increased at an average annual rate of 2% compared with 15% in the 1980s. This compares with an overall rise in public health spending over the same period of 7.2% a year.[12]

OECD data (fig 2) show that New Zealand's

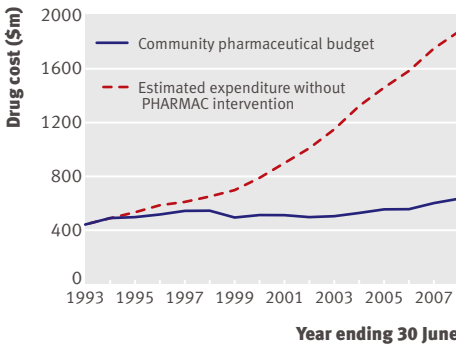

Fig 1 | Estimated effect of PHARMAC on drug costs, 1993-2008 (figures for 2007 and 2008 are 2006 predictions)[11]

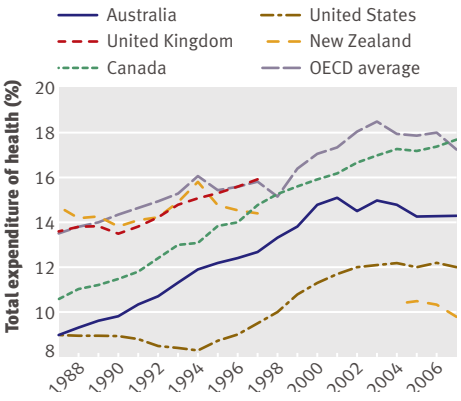

Fig 2 | Expenditure on drugs and other medical nondurables as a proportion of total health spending in selected OECD countries, 1987-2007 (data are incomplete for some countries)[1]

pharmaceutical expenditure as a percentage of total expenditure on health services (public and private) fell after PHARMAC was established in 1993, while such spending rose elsewhere. By 2007, drug spending as a proportion of health spending was much lower than that of other OECD countries.

Despite the low rise in drug spending, the number of medicines on the pharmaceutical schedule increased by 188 items between June 1993 and 2007.[13] The number of prescriptions has also increased from around 18 million in 1993 to almost 32 million in 2007,[13] although a reduction in copayments over the past seven years explains some of this increase. The average cost per prescription in 1993 in New Zealand was $24.30, but by 2007, this had fallen, in nominal terms, to $19.00.[14]

Criticisms

PHARMAC has been criticised for using anticompetitive strategies to reduce the overall cost of drugs and for the fact that PHARMAC's decisions and contracts relating to subsidised drugs are exempt from New Zealand's Commerce Act (which aims to promote market competition). Examples cited include grouping patented medicines with generics within therapeutic subgroups, thereby eroding intellectual property; tendering for sole supply rights; refusing to list a new drug for subsidy unless it undercuts the price of the existing reference drug; and refusing to include a new drug on the schedule if PHARMAC deems the market sufficiently provided for.[15] Such policies, however, could be viewed as essential for managing the drugs market in the face of well known, serious imperfections.[16 17] In 1997 and 1998, decisions of the High Court, Court of Appeal, and the Privy Council upheld the legality of PHARMAC's procedures in managing drug expenditure and its exemption from the Commerce Act.[10]

A second concern is access to clinically effective medicines. PHARMAC's decisions not to fund particular drugs have often been controversial.[18-21] For example, restrictions meant statins were initially available only for secondary prevention in people at higher risk (on application by a specialist). These restrictions continued into the mid-1990s despite international studies that had begun to show greater effectiveness for patients with lower cholesterol levels.[22]

Critics also focused on a later decision to fully fund only fluvastatin, which some commentators said was less effective than other statins.[22 23] Concern was also expressed about repeated changes in the reference priced statin, resulting in patients having to switch medicines, some several times, as simvastatin eventually became available more cheaply after a deal with the manufacturer.[22 23] Begg and colleagues argue that the statins saga shows that PHARMAC has focused more on financial imperatives than evidence based medicine and good patient care, and that such switching between drugs is not good for patients.[23]

PHARMAC responded to the criticisms by focusing on the high initial costs of statins, stating that wider availability could have cost almost $200m a year—40% of the community drug budget.[24] This would have prevented expenditure on drugs for other conditions, including, at that time, atypical antipsychotics for treatment resistant schizophrenia; cyclosporine A and tacrolimus for treatment resistant epilepsy; and treatments for refractory glaucoma.[24 25] PHARMAC noted that although fluvastatin might have been less effective in lowering lipids than simvastatin, its lower price made the potential to fund treatment for many more patients "compelling."[24]

More broadly, critics focus on whether New Zealanders are missing out on effective medicines that are available in other countries, thus harming their health. In 2007, the Pharmaceutical Industry Taskforce identified several drugs available elsewhere that were restricted in New Zealand (box 2).[26] A more recent report has argued that New Zealand has 84 fewer innovative medicines funded than Australia,[27] although PHARMAC says that of the 42 which it has been asked to make a decision on, seven have been funded, 11 have been declined, and the remainder seem to offer little or no benefit over drugs already funded.[28]

Several criticisms have also been made about quality of care resulting from PHARMAC decisions. There have been medical concerns about switching patients not only to different brands of medicines but to different chemicals within the same sub-groups. We have noted the concerns over switching between statins. Another

example is the substitution of quinapril, and to a lesser extent cilazapril, for other angiotensin converting enzyme inhibitors in 2002. A retrospective study of 345 patients showed that 30% did not sustain the initial switch and 11% of those patients with previously stable blood pressure remained uncontrolled six months after the switch,[29] although a second study found no change in mean blood pressure.[30]

Sole supply has also caused problems. For example, there were complaints about the poor quality of supplies of slow release morphine and that the generic paracetamol was difficult for some people to swallow because it had no covering film.[31] The flu vaccine chosen for sole supply in 2005 was under-strength in one of the three component flu strains, and another company had to step in to supply the vaccine.[31] PHARMAC now works with two suppliers for vaccines but notes that sole supply is the norm with all patented medicines.[32] Sole supply has similarly been blamed for drug supply problems towards the end of the contract period.[31]

Government intervention

Despite these criticisms, PHARMAC has survived major health system reforms by different governments over the past 16 years, and only twice has government over-ruled its decisions.

The first case was interferon beta for multiple sclerosis. Although the drug was available for private purchase, PHARMAC said it was not cost effective for most patients at $20 000 per patient a year. After a pledge by the Labour party to fund the drug as part of its successful 1999 general election campaign, the minister of health directed PHARMAC to make it available to a limited number of people judged suitable by a panel of neurologists (this cap was removed in 2002). This action raised questions of both the independence of PHARMAC and the problems of balancing a budget while providing adequate health care.[33]

In 2006, PHARMAC decided against funding a 12 month trastuzumab (Herceptin) programme for women with the aggressive HER2 positive form of breast cancer, which would have cost an estimated $25m-$30m year.[34] Instead, PHARMAC agreed to fund a nine week course, at an estimated cost of $5m, with a further $3.2m to participate in an international trial of a short versus long course of concurrent treatment.

PHARMAC was taken to court by patients but did not change its decision after reconsultation. In 2008 the newly elected National party government announced that it would subsidise the 12 month course directly through the ministry of health, bypassing PHARMAC altogether.

What can other countries learn?

The main lesson from PHARMAC for other systems is that it is possible to manage drug spending within a public budget while improving access to subsidised medicines. However, other countries need to consider several factors if they are to learn from PHARMAC's experience.

Firstly, New Zealand has limited its own drug development and manufacturing (and what there is focuses on generics). The government is not as concerned with the economic performance of its drug industry as with the efficiency with which its health budget is used. In other countries, decisions would need to balance economic and health system objectives.

Secondly, PHARMAC is legally bound to keep within a community drug budget, set each year by the minister of health with advice from PHARMAC and the district health boards. Thus it has to take account of the opportunity costs of its decisions (at least with respect to other drugs), rather than merely providing advice or requiring others to implement its decisions as, for example, the National Institute for Health and Clinical Excellence (NICE) does in England. As a result, PHARMAC has strong incentives to limit prices and obtain better value for money, and the budget setting process enables general consideration of the opportunity cost of spending more on drugs against spending on other services every year.[7]

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Box 2 | Examples of drugs restricted in New Zealand in 2007 but available elsewhere[26]

Unfunded

- Risedronate for osteoporosis and Paget's disease
- Methylphenidate and atomoxetine for attention deficit hyperactivity disorder
- Galantamine for Alzheimer' disease
- Montelukast for asthma

Long delays in access

- Mycophenolate mofetil for renal transplant patients
- Glatiramer acetate for multiple sclerosis

Restrictions on access

- Candersartan for congestive heart failure (now subsidised)
- Insulin glargine for diabetes

A third feature is PHARMAC's strong focus on trying to achieve the best outcomes within its funding. There is some evidence that cost effectiveness analysis has more of an effect on drug funding decisions in New Zealand than in the United Kingdom and Australia. For example, of the 10 drugs deemed least cost effective by NICE between 1996 and 2005, all were approved for funding in the UK, six were approved in Australia, and just five in New Zealand.[35]

Finally, PHARMAC has had an important role in debates on the need to set priorities in health care in New Zealand and has shown how this can be done using rigorous processes. The fact that PHARMAC has only twice been over-ruled by government shows that a focus on explicit priority setting within a budget can work well and that hard decisions can gain support if well justified.

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A longer version of this article is available on bmj.com.

1 Organisation for Economic Cooperation and Development. OECD health data 2009—selected data. http://stats.oecd.org/Index.aspx?DatasetCode=HEALTH
2 Ministry of Health. Health expenditure trends in New Zealand, 1980-2000. Wellington: Ministry of Health, 2002:1-75.
3 PHARMAC. Introduction to PHARMAC. www.pharmac.govt.nz/2008/12/16/01_PHARM_Infsheet_INTRO.pdf.
4 PHARMAC. Operatingpolicies and procedures of the pharmaceutical management agency ("PHARMAC"). 2006. http://www.pharmac.govt.nz/2005/12/22/231205.pdf
5 PHARMAC. *Prescription for pharmacoeconomic analysis: methods for cost-utility analysis*. 2007. www.pharmac.govt.nz/2007/06/19/PFPAFinal.pdf
6 Metcalfe S, Dougherty S, Brougham M, Moodie P. PHARMAC measures savings elsewhere to the health sector. *NZ Med J* 2003;116:U362.

7 Grocott R. Applying programme budgeting marginal analysis in the health sector: 12 years of experience. *Expert Rev Pharmacoecon Outcomes Res* 2009;9:181-7.
8 PHARMAC. Medicines Strategy. 2007. www.pharmac.govt.nz/2009/07/10/Submission%20on%20the%20development%20of%20the%20Medicines%20Strategy.pdf.
9 Patented Medicine Prices Review Board. *Non-patented prescription drug prices report: Canadian and foreign price trends.* 2006. www.pmprb-cepmb.gc.ca/CMFiles/nppdp-2e38IJV-1162006-9192.pdf.
10 PHARMAC. About PHARMAC: Important events in PHARMAC's history, 2008. www.pharmac.govt.nz/dhbs/AboutPHARMAC/history.
11 PHARMAC. Annual review 2006. 2006:32. www.pharmac.govt.nz/2006/11/24/ARev06.pdf.
12 Treasury. Historical vote health information. 2009. www.treasury.govt.nz/budget/votehistory/health.
13 PHARMAC. Annual review 2007. 2007:32. www.pharmac.govt.nz/2007/11/21/PHARMAC_AR_2007.pdf.
14 World Health Organization. World health report 2008. WHO, 2008:1-143.
15 Pharmaceutical Research and Manufacturers of America. New Zealand: market access for pharmaceuticals.www.cptech.org/ip/health/phrma/nte-98/nzealand.html.
16 Scherer FM. The pharmaceutical industry—prices and progress. *N Engl J Med* 2004;351:927-32.
17 Docteur E, Paris V. Ensuring efficiency in pharmaceutical expenditures. In: *Achieving better value for money in health care*. OECD, 2009:101-28.
18 Grainger R, Harrison A. TNF inhibitors for inflammatory arthritis in New Zealand. *N Z Med J* 2005;118:U1706.
19 Gillies J, Brown J, Byrnes C, Farrell A, Graham D. PHARMAC and Ventolin in New Zealand. *N Z Med J* 2005;118.U1616.
20 Grocott R, Metcalfe S. Going against the flow: the impact of PHARMAC not funding COX-2 inhibitors for chronic arthritis. *N Z Med J* 2005;118:U1690.
21 Metcalfe S, Moodie P, Davies A, McNee W, Dougherty S. PHARMAC responds on salbutamol. *N Z Med J* 2005;118:U1644.
22 Ellis C, White H. PHARMAC and the statin debacle. *N Z Med J* 2006;119:U2033.
23 Begg E, Sidwell A, Gardiner S, Nicholls G, Scott R. The sorry saga of the statins in New Zealand—pharmacopolitics versus patient care. *N Z Med J* 2003;116:U360.
24 Moodie P, Metcalfe S, McNee W. Response from PHARMAC: difficult choices. *N Z Med J* 2003;116(1170):U361.
25 Moodie P, Dougherty S, Metcalfe S. PHARMAC and statins—getting the best population health gains. *N Z Med J* 2006;119:U2092.
26 New Zealand Pharmaceutical Industry Taskforce. Submission on the *Towards a New Zealand Medicines Strategy* Consultation Document. 2007. www.rmianz.co.nz/downloads/NZPITsub.pdf.
27 Researched Medicines Industry. The Trans-Tasman Gap Widens. *RMI Newsletter* 2009;24. www.rmianz.co.nz/ezines/Vol24.htm.
28 McCormack P, Quigley J, Hansen P. Review of access to high-cost, highly specialised medicines in New Zealand. Wellington: Ministry of Health, 2009.
29 Maling T. Finding a better balance between pharmaceutical supply and demand – a medicinal issue. *N Z Fam Physician* 2002;29:3.
30 Perkins E, Dovey S, Tilyard M, Boyle K, Penrose, A. A change management strategy to modify ACE-inhibitor prescribing. RNZCGP Research Unit, 1999.
31 MacKay P. Is PHARMAC's sole-supply tendering policy harming the health of New Zealanders? *N Z Med J* 2005;118:U1433.
32 McNee W, Moodie P, Schmitt S, Dick A. PHARMAC's response to Tim Blackmore on the sole supply of influenza vaccine. *N Z Med J* 2005;118:U1601.
33 McNaughton H, Kayes N, McPherson K. Interferon beta, PHARMAC, and political directives: in the best interests of people with multiple sclerosis? *N Z Med J* 2006;119:U1939.
34 Metcalfe S, Evans J. PHARMAC responds on Herceptin assumptions and decisions. *N Z Med J* 2007;120:U2692.
35 Raftery JP. Paying for costly pharmaceuticals: regulation of new drugs in Australia, England and New Zealand. *Med J Austr* 2008;188:26-8.

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β blockers in COPD

Journal club is a new forum on doc2doc, BMJ Group's global clinical online community. This week's discussion is fuelled by a study reported in *Archives of Internal Medicine*, which suggests that β blockers may reduce mortality and risk of exacerbations in patients with chronic obstructive pulmonary disease (COPD).

yoram chaiter: "As far as I know β blockers were never a drug of choice in obstructive lung disease of any kind. On the contrary, there were contraindications. I find it intriguing that an opposite effect was shown in this study, but for me one study is not quite enough to be convinced."

DundeeChest: "Respiratory physicians have long held the belief that β blockers are beneficial in COPD. I have little hesitation in starting or continuing treatment with, or increasing the dosage of, β blockers in COPD patients with ischaemic heart disease or tachyarrhythmias—the incidence of β blocker induced bronchoconstriction is surprisingly rare in COPD. I think we need to take a more holistic view of prescribing β blockers in COPD—when cardiac risk exceeds respiratory risk we need to make sensible decisions. I think we'll be seeing a shift in prescribing practices over the next few years."

csm@csm: "The overall conclusion is that β blockers may be administered in COPD associated with cardiac comorbidity, but this administration requires utmost care."

tnolan: "What sort of COPD patients are taking β blockers? Perhaps only those who are given the diagnosis after being put on β blockers for some other indication? Or those with 'COPD,' but without it causing a significant morbidity (that is, they take an inhaler from time to time)?"

maha: "More evidence from larger numbers of patients with different degrees of disease severity is needed before we follow each new piece of research."


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Asclepius: "I use β blockers in patients with COPD when indicated—for example, in ischaemic heart disease and heart failure. It seems perverse to deny them the benefits of these drugs when by definition their airways are pretty non-reactive. I have seen β blocker induced bronchospasm in patients with asthma, so I personally do not prescribe them for such patients.

What do you make of these research findings? Would you change your practise? Have your say on doc2doc, BMJ Group's global online clinical community, at http://bit.ly/a2k4oV

FROM BMJ.COM

NICE: the beginning of the end or a new beginning?

Health economist James Raftery contemplates the future of the National Institute for Health and Clinical Excellence (NICE) under the new coalition government in the United Kingdom. The government has recently announced its intention to establish a new cancer drug fund, reform NICE, and move to a system of value based pricing, as well as give patients a stronger voice locally through their primary care trusts (PCTs).

"The new UK coalition government's first test of new thinking was likely to relate to the next controversial technology appraisal from the National Institute for Health and Clinical Excellence (NICE) recommending against NHS use of some new high cost drug with poor clinical and cost effectiveness," says Professor Raftery. "This turned out to be guidance on 26 May recommending against the use of Bayer's sorafenib (Nexavar) for hepatocellular carcinoma for patients in whom surgery or locoregional therapies have failed or are not suitable. NICE rejected this drug on the basis of its poor clinical and cost effectiveness . . ."

On the same day, a spokesperson from the Department of Health said: "We respect the expert independence of NICE and believe that it must be allowed to continue to issue guidance free from political interference. However, we believe there are fundamental failings within the wider system for drug pricing and access. We are determined to address this and are clear that NICE plays a vital advisory role . . . in the meantime PCTs should continue to consider carefully whether there are particular local or individual circumstances that would make it appropriate to fund Nexavar or drugs NICE has been unable to recommend for routine use."

Professor Raftery concludes: "A tension exists between the continuance of NICE as source of national guidance on one hand and the freedom for PCTs to represent local voices and differences. This is the postcode prescribing debate under another name. That debate seems due another chapter."

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