Pharmaceutical Management Agency

Annual Review 2009

PHARMAC
Pharmaceutical Management Agency

New Zealand Government

Highlights of 2008/09

During 2008/9 we:

> Hit the budget target of $653 million

> Added eight new medicines to the Pharmaceutical Schedule, and widened access to 55. New medicines include treatments for mental illness, prostate cancer, migraines and skin cancers

> Successfully implemented brand changes for medicines used by approximately 550,000 New Zealanders

> Completed the review of the Pharmacology and Therapeutics Advisory Committee Terms of Reference

> Began reviewing the Terms of Reference of the Consumer Advisory Committee

> Launched the pilot of a new asthma campaign in Taranaki – Space to Breathe He Tapu te Ha

> Sponsored and awarded the first Hiwinui Heke scholarships for Māori pharmacy students

> Continued to support evidence-based prescribing through the PHARMAC Seminar Series and funding BPACNZ.

In this Review

'**Year**' means year ending June 30.
'**This year**' means the year ended June 30 2009;
'**last year**' means the year ended June 30 2008;
'**next year**' means the year ending June 30 2010.

Unless otherwise stated, all values are in New Zealand dollars

Unless otherwise stated, all references to expenditure are unadjusted for any rebates that may be due or paid by suppliers under risk-sharing agreements

Taking up the challenge

PHARMAC is well placed to help the Government meet future challenges in health, writes PHARMAC chairman Richard Waddel

We hear a lot about value for money in the health sector these days, and obtaining the most benefits for patients from our spending. These are messages that resonate strongly at PHARMAC, which has always had a strong focus on getting value for money and the best health outcomes.

PHARMAC has a strong track record in this area, something reflected in the Ministerial Review Group report, which advised the Minister on future changes to the health system. We support any work to improve the way health funding is used, which is the overall thrust of the MRG report. We are willing to assist in any way possible.

PHARMAC's record

For 16 years PHARMAC has brought a disciplined approach to purchasing pharmaceuticals, to ensure newly-funded medicines provide measurable health gains and represent good value for money. Since it was created, PHARMAC has added nearly 200 new medicines to the funded list – including a further eight in the past year.

In the 1980s, spending growth topped 20% per annum; this is now managed in a more controlled fashion – averaging around 3% per annum since 1993. PHARMAC has achieved this without exceeding its budget, agreed with DHBs and approved by the Minister of Health – including in the past year when the budget was managed at $653 million.

Speedbumps ahead

While we have a proud record, we remain open to improving the way we operate and we are focused on the challenges ahead.

To protect and extend our record, we will need to maintain and strengthen the policies and structures that have served PHARMAC and New Zealand well. At our second PHARMAC Forum in October 2009, we received general support for many things PHARMAC had achieved, but it was clear some of our big-ticket policy issues need further discussion. In this Annual Review, we take the opportunity to explain some of our key policies and approaches, including:

> The issues around greater transparency

> The importance of Decision Criteria, and flexibility in their application

> The shortcomings of using a funding threshold, as some suggest, and

> Why PHARMAC uses sole supply and the cost of changing that approach.

"The cost of providing public health and disability services is increasing year-by-year, at a rate far greater than growth in our GDP, and will continue to take an even larger share of our national income unless we change the way these services are provided."

- Ministerial Review Group report

Continued successes

2009 has been a successful year during which, once again, we managed pharmaceutical spending right on budget. As well as adding eight new medicines to the funded list, we widened access to 55. Many of these access widening decisions were a result of our ongoing review of specialist prescriber restrictions; this has been a long term frustration in the system that we are continuing to address.

We continued our important work in promoting the optimal use of medicines. Our campaigns grew with the addition of the Space to Breathe asthma pilot in Taranaki while our established One Heart Many Lives cardiovascular campaign continues to be well supported. And we also committed funding to improve workforce development through the development of the Hiwinui Heke scholarship for Māori pharmacy students (as outlined on P27 of this Annual Review).

The Government also commenced work on a subject in which PHARMAC is very interested – High Cost Medicines. A three-person panel was appointed by the Minister to review and make recommendations on this important subject. We look forward to the panel completing its work.

2009/10 looks to be equally challenging – but exciting too. PHARMAC is well placed to help the sector achieve its goals and to help in any way it can to deliver better health services, including pharmaceuticals, to patients.

"Pharmac is well regarded and has developed widely accepted processes for assessing the relative cost-effectiveness of new pharmaceuticals and making well-informed judgments about priorities for public funding of new and existing pharmaceuticals."

- Ministerial Review Group report

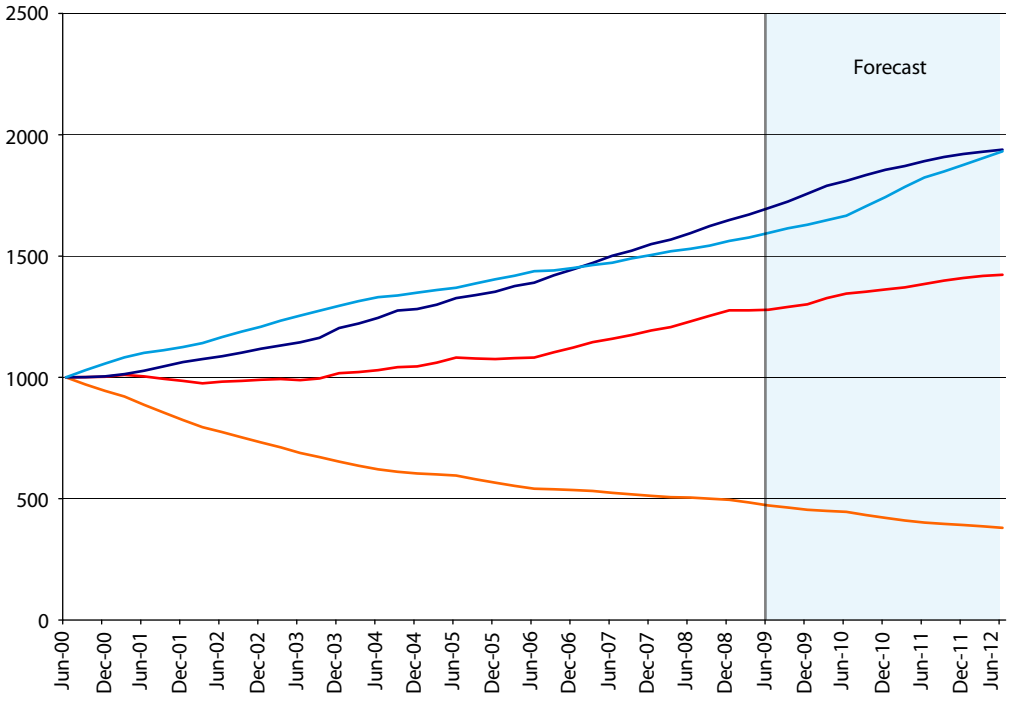
Subsidy, volume, mix and cost indices

Four-quarterly moving averages

Base: four quarters ending June 2000 = 1,000.

Getting more for less:

The subsidy volume and mix indices are like the consumer price index, but for pharmaceuticals. The graph shows that while the amount of pharmaceuticals used, and their cost has been rising, the subsidy index is decreasing.



- **Cost Index** is the drug cost to DHBs ex-manufacturer before GST
- **Subsidy Index** is like the Consumer Price Index but for subsidised pharmaceuticals only
- **Volume Index** is the number of prescriptions multiplied by a standardised measure of the amount prescribed per prescription
- **Mix Index** is the residual from cost index divided by (volume index X subsidy index)

Keeping some information confidential could save your life

PHARMAC is always interested in increasing transparency where it helps get the best health outcomes from available funding – our job, as specified in the relevant statutes. PHARMAC has increased its transparency recently but, in some areas, more transparency could jeopardise the health of New Zealanders, writes Rico Schoeler, manager of analysis & assessment

There are often calls for PHARMAC to be more transparent about its work and decisions; it's important for us to meet these expectations when possible and better explain why when we cannot.

Most of us prefer more information to less, particularly if the information is well-structured and presented, as it gives us the option of finding out something we may find useful. Of course, we now live in a world characterised by more and more information, where 'open government' is an understandable expectation.

Most people also accept there are limits. The police don't openly share sensitive investigation details. The Reserve Bank tightly controls the release of monetary policy information. There are many controls around release of private information. These and other limits exist to avoid jeopardising the results society ultimately wants.

PHARMAC understands that saying something is "commercially sensitive" or "a risk to our negotiations" can be seen as an excuse. These considerations are, however, important, and we need to get better at explaining why we use them.

If you knew that publishing PHARMAC's prioritisation list would cost the lives of New Zealanders, would you still want to see it? The question is deliberatively provocative. It does, however, represent the dilemma PHARMAC faces when deciding what information to publish.

PHARMAC's prioritisation list is the list of medicines we would most like to purchase. It ranks funding options from best to worst, as judged against our Decision Criteria. And, given that our funding system is built on the principle of willing-buyer (PHARMAC) and willing-seller (pharmaceutical companies), if we disclose our

preferences we shift some advantage to the companies. It's a bit like telling a car salesman you've got $5,000 to spend. Could you actually have bought the car you wanted for $4,000?

Every time PHARMAC negotiates lower prices for a medicine (while still getting the health outcomes), it frees up money to buy other pharmaceuticals. In other words, we get more for less by promoting competition between pharmaceutical companies.

Reasons

Some people have asked that we reveal the underlying reasons for our decisions. We have improved the content and quality of the 'notification letters' we send after decisions are made. From our next Annual Report, we will include more extensive information on what we did, and didn't fund, in any year.

Decisions cannot be processed as a formula or tick-box exercise, as the article on P9 explains. The only standard thing between decisions is that the underlying circumstances are always different – such as a different number or type of existing medicines for the same medical issue; a different level of available funding; and/or a different expectation about the medicine's effectiveness in order for it to be funded. The judgments are made carefully, using the same, consistent Decision Criteria and with lots of analysis and clinical advice – but they remain judgments.

There are other considerations. We know pharmaceutical companies would like more certainty about what is required to get a medicine funded. This is an understandable commercial position. But if there were definitive thresholds, our ability to negotiate lower prices would be reduced and, as a result, fewer medicines could be purchased. If more and more detail is explained by PHARMAC, we risk defining thresholds over time – whether actual or perceived – ultimately to the detriment of New Zealand's health outcomes.

Detailed decision write-ups also take more time – time better spent progressing other funding proposals. We're sometimes restricted in what we can say in order to protect companies' commercially sensitive information; a responsibility we take very seriously, and we know this is valued by the companies. Any inappropriate release of information risks our reputation, and our ability to get the right type of information next time.

If you knew that publishing PHARMAC's prioritisation list would cost the lives of New Zealanders, would you still want to see it?

Building trust

Given the limits on transparency, we recognise the importance of building trust in other ways. Trust can be difficult to define, but some core elements are likely to be:

> acceptance of the general approach (making difficult choices between funding options no matter how big the budget);

> understanding important details, such as how advisory committees work, their advice, and how analysis is undertaken;

> being able to have a say, whether on individual decisions, general approaches or policy settings; and

> understanding the decisions that are made, whether at the time, in summary reporting, or through general confidence in the process.

We try to meet these core needs, and keep improving. We have recently put significant effort into improving our communication and relationships – and we continue to put that effort in.

We're publishing more minutes from our clinical advisors and, we think, greatly improving the clarity and accessibility of many publications (such as our Information Sheets and Guide to Cost Utility Analysis). Other improvements are also planned, such as an on-line funding application tracker and potential improvements resulting from consumer participation work on which we're currently consulting.

All changes are carefully considered. It is all too easy to commit government resources to publications or initiatives that cost money yet don't really add value – or even destroy value, if information gives rise to unintended consequences. As increased transparency in some areas can risk reducing health outcomes, it is prudent to err on the side of caution. We believe this care, with New Zealand's health outcomes top-of-mind, is one of our organisational strengths.

We take the issue of transparency very seriously. We understand stakeholder expectations for more and better information, but we are also clear about making better use of existing resources and, above all, getting the best health outcomes from our spending. We want to improve the quality of the information we provide, but only when we're confident it adds to the greater goal of the health of New Zealanders.

Creating a competitive environment

Promoting competition among off-patent medicine suppliers is one of the most effective ways PHARMAC gets good value from pharmaceutical spending, writes Greg Williams, Therapeutic Group Manager

Competition – we've all experienced it. In fact, most of us benefit from it in one way or another, whether from everyday activities like supermarket shopping, or choosing which airline to fly on.

Competition is a powerful force and is used by PHARMAC to manage the pharmaceutical budget, through tendering for sole supply of one brand of medicine – a strategy that provides the maximum incentive to companies to offer low prices.

Pharmaceutical companies have their own version of sole supply: patents, which generally last 20 years during which period no other company can compete.

Once patents expire, generic versions of the medicine become available and PHARMAC generates competition either through tendering or some other kind of competitive process. Once unlocked, savings can be as large as 90%, and the funding that is released can be used to fund newer pharmaceuticals., or growth of medicines prescribing.

PHARMAC promotes competition

Sole supply promotes competition, although largely invisibly to the patient. PHARMAC runs a competitive process, with companies bidding against each other, from which we choose the best bid (taking into account a range of factors). Under our sole supply system, it's the purchasers (the District Health Boards and taxpayers) that reap the benefits of competition: competition between suppliers provides savings that allow reinvestment in medicine. This achieves long-term benefits for New Zealand – more than $400 million of savings since 1997 that have been reinvested in new medicines.

In our experience, sole supply is more effective than multiple supply arrangements in providing incentives to lower prices. In one recent competitive process, the average across all bids was 17% higher for dual supply than for sole supply. If this was the case across all tendered medicines, it would represent $17 million of extra spending, money we then wouldn't have available to invest in new medicines. In tight economic times, such savings are vital.

This is one tangible example. There are also interesting differences when we compare our experience with other countries. The table (opposite) illustrates the prices of five commonly-prescribed sole supply medicines with prices in Australia, Britain and Canada, which don't use sole supply. We estimate our prices are less than half paid in the UK for the same products. The price differentials with Australia and Canada are even greater. This underlines the strength of the competitive processes we harness to achieve low prices compared with other countries.

Companies tend not to market their generic products when there's sole supply; it's very different with dual supply, however. In countries where multiple supply is used, such as Canada, companies build in the price of marketing, then promote their products through

special deals or bonusing to pharmacies. Great for the retailers, but it means higher prices for the funder (the Government). We've seen this practice in New Zealand, when we had multiple suppliers of the gastric ulcer drug omeprazole.

Careful choices

Generics are often deemed to be `bioequivalent', having the same chemical composition and therapeutic effect as the competing brand. Savings are only useful if the product lives up to our expectations so before awarding sole supply status to a generic brand, we take several careful steps. Most importantly, the generic must be registered as safe and effective by Medsafe, the government's regulatory body.

Objective advice is then taken from the Tender Medical Evaluation subcommittee of PTAC (made up of clinicians and pharmacists) on issues such as the taste, shape or colour of the product, pack sizes, packaging, or any other relevant issues. Then we consult with the community about potential changes, and review the supporting information required to help make transition to the new product easier for health professionals and patients.

We're careful about the incentives used to ensure ongoing supply, an important part of the supply equation and one where we've improved dramatically in recent years. Contracts with suppliers include clauses requiring they notify us about any stock level issues. If stocks fall below an acceptable level or problems are anticipated, we can work with the companies to arrange alternative supplies.

The generic brand doesn't work…

Even when medicines have been assessed as bioequivalent, or essentially the same, not everyone responds the same way. This is taken into consideration when we're deciding which medicines to include in a tender.

We contemplated a mechanism called Alternative Brand Allowance (ABA) to enable a small number of people – around 1% for each medicine – to stay on their existing brand if they couldn't take the new brand. Feedback during consultation on the proposal, primarily from pharmaceutical suppliers, indicated such a mechanism would be unworkable: expenditure on generic medicines is sometimes worth less than $50,000 per annum, so giving one supplier 1% of such a market would expose them to significant financial risk for little gain, and the industry told us this would be unworkable.

We've also seen – with a similar system we set up for the ADHD drug Ritalin - how such a system could be used inappropriately – with monitoring and auditing challenges and costs.

As we believe an ABA would be unworkable, we haven't implemented the proposal. But we've certainly considered it, along with many other suggestions.

Overall, we're committed to taking an even more careful approach to choosing which products to tender. This includes thinking about the range of other medicines that are available to treat the same condition, alongside other relevant issues such as size, shape, colour or taste of the new products.

When a brand is switched, we support the change with information for doctors, pharmacists and patients.

Comparative prices of five medicines in Australia, New Zealand, UK and Canada. New Zealand has lower prices for all medicines than all four countries – sometimes up to 90% lower.

Medicine	Price per 30 tablets	NZ Price (subsidised brands)	Australia Price (subsidised brands)	UK Price (subsidised brands)	Canada Price (subsidised brands)
Paracetamol	500 mg	$0.29 (1)	$3.10 (4)	$1.09	$1.07 (7)
Simvastatin	20 mg	$1.00 (1)	$40.78 (16)	$2.21	$52.24 (9)
Omeprazole	20 mg	$3.05 (1)	$37.68 (13)	$4.02	$41.45 (5)
Amoxycillin	500 mg	$1.64 (1)	$19.62 (11)	$4.79	$12.88 (5)
Citalopram	20 mg	$1.35 (1)	$30.20 (13)	$2.96	$32.98 (12)

Notes: 1. All prices are public list prices obtained from the following sources:
***Australia** - Online searchable version of the Schedule of Pharmaceutical Benefits www.pbs.gov.au (accessed 27/10/2009)*
***UK** - BNF 58 (September 2009)*
***Canada** - Alberta Interactive Drug Benefit List https://www.ab.bluecross.ca/dbl/publications.html (accessed 28/10/2009)*
2. Differences in population size and clinical practice have not been considered in this analysis
3. All prices are expressed in New Zealand dollars using the following exchange rates:
Australia = 0.814143 UK = 0.456225 Canada = 0.796052

Computer says no?

PHARMAC's Decision Criteria provide guidance and flexibility for making difficult judgements, writes PHARMAC's Chief Executive Matthew Brougham

If you're anything like me you hate being told what to do. Even worse if a machine was doing the telling – and you had no room to manoeuvre. Comedy series Little Britain has a running gag with a worker tapping away at her computer, then telling the customer: "Computer says no". The joke plays on people's frustration at computerised decisions and worker inflexibility, to great comedic effect.

I'm pleased to say PHARMAC could never be accused of having a `computer says no' mentality. We have a set of Decision Criteria that guide us in our decisions, but ultimately how they are applied is a judgement about the specific circumstances before us. I think most people would prefer it that way – rather than having a mechanistic `tick box' approach to decisions that didn't allow any flexibility.

Decision Criteria

The criteria are necessarily broad and take into account a wide range of factors relevant to making decisions about pharmaceutical funding. These include things like people's health needs, alternative treatments, cost of the treatment, risks and benefits of the treatment, impact on other health resources (does it require more or fewer lab tests or other treatments?), and how it sits with other Government health priorities. In addition, we have discretion to take other factors into account if required.

These are all reasonable things to take into account, and are tested from time to time, through reviews of our Operating Policies and Procedures. At the recent Wyeth Forum on high cost medicines, I asked the large audience what other factors were relevant for our decisions ... … and nothing was identified that cannot already be taken into account under our current criteria. This is comforting.

The main point about the criteria is that they are a guide to help us make judgements about which medicines to fund. There are some very well-developed and scientifically rigorous parts of the process – but ultimately the decisions are made by people taking into account a broad range of factors.

The criteria are used at several levels of our decision-making process. The Pharmacology and Therapeutics Advisory Committee (PTAC) uses the criteria to guide the recommendations it makes on pharmaceutical funding applications. PHARMAC uses them to help rank funding options in order of priority. And our Board uses them when it makes funding decisions.

PHARMAC is sometimes said to be "all about the money" – but a look at our criteria quickly provides a response to that. Clearly funding is an important consideration and can't be ignored, but the criteria make it clear it's not the only thing that matters. Top of our list is patient need, and the health needs of Māori and Pacific People.

PHARMAC's decision criteria.

> The health needs of all eligible people;
> The particular health needs of Māori and Pacific peoples;
> The availability and suitability of existing medicines, therapeutic medical devices and related products and related things;
> |The clinical benefits and risks of pharmaceuticals;
> The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services;
> The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Schedule;
> The direct cost to health service users;
> The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere; and
> Such other criteria as PHARMAC thinks fit.

Another comment we hear is that "the other criteria don't really matter as the focus is always on Cost Utility Analysis." This also isn't true.

Cost Utility Analysis

CUA is certainly a well-developed tool for assessing both the costs and benefits of pharmaceuticals. But it is only that – a tool to help guide and inform our decision-making. Further, CUA allows us to consider better the importance of the other criteria. Because the results of CUA are expressed in a common currency (cost/Quality Adjusted Life Year – QALY), we can look at the gap between two options and ask whether there are any other factors that, when added to the picture, make the gap either wider or narrower. In this way, the importance of other considerations are brought to bear upon, and significantly influence, our decisions.

There are times when one criterion is clearly the defining factor. An example is the brain tumour drug temozolomide, which was funded in 2005 largely because there were few other treatment options available, This meant patient need was highlighted even though, by comparison with some other choices at the time, temozolomide was less cost-effective.

Flexibility

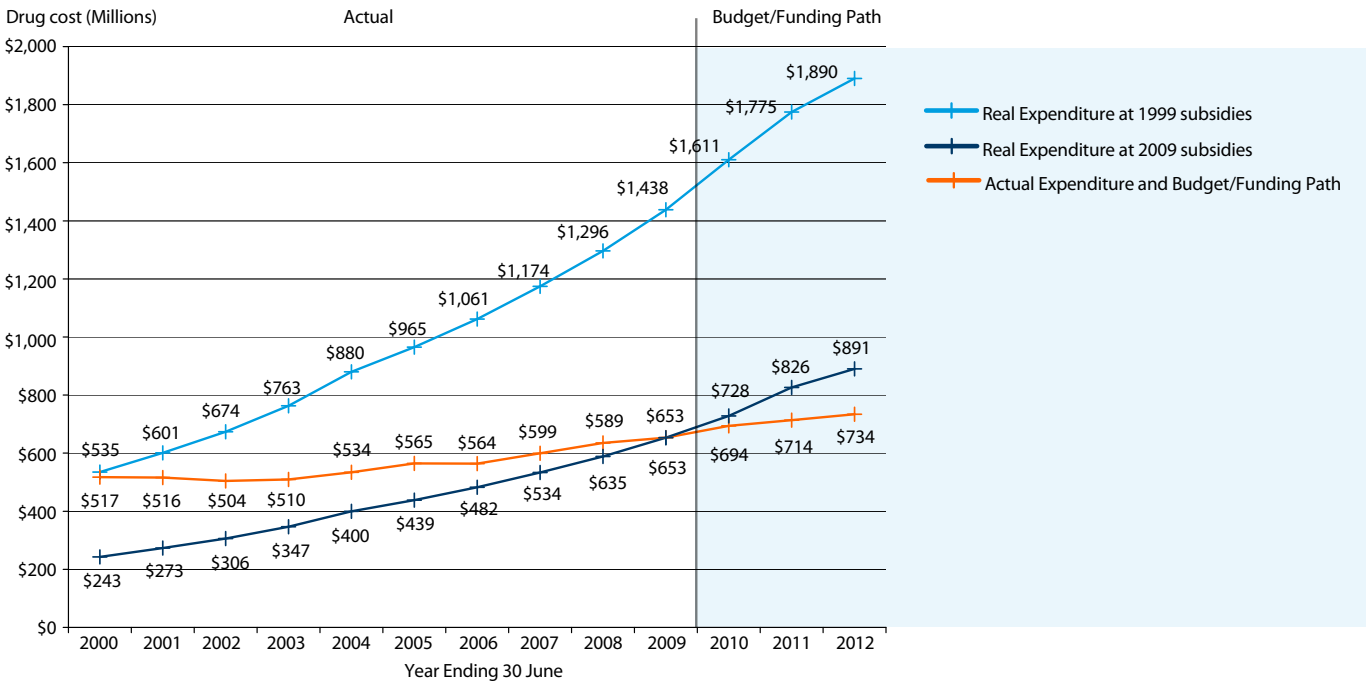
This emphasises another point about the Decision Criteria: allowing flexibility over time. The right decision at one point in time can appear in retrospect to be inconsistent with other decisions. This illustrates the judgements inherent in the criteria. Some people have suggested we should give a weighting to the Decision Criteria, making it explicit when some things outweigh others., It is, however, difficult to comprehend how a particular set of weights could be accurate or optimal for all possible situations and funding options that PHARMAC faces.

There are other problems. Understandably, pharmaceutical suppliers want more specificity and predictability in our Decision Criteria. If, however, they could better predict funding, our ability to secure the best possible price would be reduced (and fewer health outcomes would ultimately be achieved).

There are also limits around how much information we can provide about our use of the Decision Criteria. Money and health aren't always easy bedfellows, but the reality is we operate in a commercial environment so must protect our commercial position. If we compromise it, we will pay too much and, in turn, risk losing health outcomes.

Our Decision Criteria are well established and well tested. They enable us to take into account a wide range of factors that impact on medicine funding, and give scope for making comparative judgements. This isn't something machines do well – this is something far better left to people's informed judgment. Overall, the criteria have enabled PHARMAC to greatly improve health outcomes for New Zealanders while managing the pharmaceutical budget.

Impact of PHARMAC on Drug Expenditure over time



Why PHARMAC doesn't use a funding threshold

Imagine this. You've just bought a new car. It's a great car: fuel efficient, environmentally friendly, and with a 5-star safety rating. A few weeks later, you receive a letter from another car dealer. Another car has come on the market, also with a 5-star safety rating. And because of new government rules, if any car gets a 5-star safety rating you have to buy it. If you don't, the car company can take you to court. That's even though you already have a car just as safe, and you can't afford another car just now. It would be crazy, right?

Yet, this is what some commentators suggest PHARMAC do with medicines. Using a funding threshold, they say, will provide consistent, predictable decisions and aid transparency.

It's certainly a requirement in some countries: once a product meets the funding threshold, national or regional governments are compelled to fund it. It means new money has to be found, or other products or services cut. Although it's a legitimate policy choice, it's not one that has gained traction with successive New Zealand governments and for good reason, in PHARMAC's view.

The threshold suggested is based on Quality Adjusted Life Years (QALYs), the measure used in PHARMAC's economic analysis of medicines; medicines with a cost per QALY of a certain level (perhaps $50,000) would automatically be funded, while those above the threshold would not.

While this might sound feasible, there are many reasons it wouldn't work in our current environment.

Most significantly, automatic funding thresholds don't sit easily alongside managed budgets – irrespective of their size. If there was no funding to purchase the new medicine that had met the threshold test, then it couldn't be bought or other things would have to be chopped.

A threshold approach suggests medicine funding requires simple yes/no, on/off decisions. This would be the case if PHARMAC were a regulator, answering questions over the medicine's clinical efficacy or safety. PHARMAC, though, is interested in relative effectiveness: how much better a medicine is than one already in use. This is clearly not a yes/no answer and is often a judgement, made using all of our Decision Criteria (as outlined in the previous article). Using the threshold approach would remove the ability to make informed judgements, or to take into account whether the medicine is any better than those already in use.

Using a QALY threshold would be making the assumption that economic analysis is an entirely perfect model, always producing a perfect answer. It's not. Cost-utility analysis is a very highly-developed assessment tool – it's the best one we know and is widely used internationally. But it doesn't take into account every consideration, and that's why we use our nine Decision Criteria.

Using CUA isn't about finding the perfect answer; it is about assessing costs and benefits as a way to rank potential funding options. We call this 'relative assessment' – doing enough work to feel confident that one funding option can be ranked ahead, or behind another. Trying to find a 'perfect' answer would mean endless debates and heavy impacts on our resources and, ultimately, slower decisions. There is no perfect answer – even high quality analyses often have wide ranges in their results.

And as our article on transparency on P5 points out, a threshold would also mean no more negotiation. And negotiation is one of PHARMAC's most powerful tools. If a company knew that all it had to do to obtain funding was meet the funding threshold, it would be reluctant to negotiate on price or supply terms once that threshold was reached. This would limit PHARMAC's ability to get the best possible health outcomes from whatever it spends and that, in turn, would restrict New Zealanders' access to the widest and best range of pharmaceuticals possible.

Seeking clinical advice on our communications

PHARMAC is looking for ways to improve further how it communicates with health professionals, writes Medical Director Dr Peter Moodie.

Doctors are busy people and are already inundated with important information. It would be impractical for doctors to take an in-depth interest in all PHARMAC's activities – but at the same time we want doctors to feel well informed and know that we have listened to clinical advice. At the same time, we don't want to provide so much information that it is overloading clinicians. It's a balancing act, and one we are keen to get right.

There are many ways health professionals can provide information to PHARMAC, but three in particular:

> Making funding applications;

> Via our clinical advisory committee PTAC and its advisory committees; and

> Making submissions to our consultations.

Anyone can make a funding application, and clinicians often apply for a particular treatment to be funded on the Pharmaceutical Schedule. We treat all applications equally, taking advice from PTAC and being guided by its recommendations.

PTAC and its sub-committees are the first step for all medicine funding applications. PTAC consists of 10 clinicians, all active practitioners (a list of PTAC and sub-committee members is listed at the back of the Annual Review). Minutes of PTAC meetings are available on our website once the deliberations are completed, although this process can take longer than people expect because PTAC often asks for further information from a subcommittee. PTAC may also seek specific input from particular clinical groups – such as rheumatologists or gastroenterologists, particularly when we are developing a Special Authority for a particular medicine.

As a matter of course, we seek clinical views on our funding proposals through consultation; these can be voluminous and not always of widespread interest but we try to target consultation documents to interested clinicians, so that we are confident we have the right advice.

We also notify people about funding changes and this is, of course, important to health professionals, particularly pharmacists. Our notification letters are sent to anyone who participated in the consultation, and posted on our website. We update the Pharmaceutical Schedule monthly: the front section outlines major changes and flags potential changes. We've also been piloting a newsletter format for PHOs in the Nelson region, and it will be interesting to gauge the response.

Other interactions

PHARMAC maintains close relationships with the major clinical associations and colleges as they are important conduits to health professionals; we try to attend the major health conferences as face-to-face contact is important in developing and maintaining relationships.

Behind the scenes we're doing a lot to help doctors do their jobs better. We fund the Best Practice Advocacy Centre (BPACNZ), run by Professor Murray Tilyard at Otago University, which publishes a monthly magazine and runs services for doctors such as prescribing tools and clinical guidelines. We know from the feedback that these services are highly regarded by doctors.

Professional development is also important for health professionals, so we fund the PHARMAC Seminar Series covering a range of topics such as managing respiratory infections, pharmacology for nurses, and risk factors in cardiovascular disease. The Seminars, usually held in Wellington, are often fully booked, so anyone planning to attend is advised to register early.

Ongoing improvement

In 2007 we began the PHARMAC Forum, providing an opportunity for health professionals and others in the sector to discuss their views with us. PHARMAC is committed to improving its communications, and we're receptive to suggestions on how this can be achieved, without overloading health professionals with too much information. So if you have suggestions on how we can improve how we get information to health professionals, or receive information from them, let us know.

It's all about striking a balance; it's not so much about having all the information put in front of you – it's knowing it's available if needed.

So if you have suggestions on how we can improve how we get information to health professionals, or receive information from them, let us know.

Major funding decisions in 2008-09 – new patients, new spending, better health

Each year, PHARMAC invests millions of new dollars in pharmaceuticals and works to ensure these produce better health for New Zealanders. PHARMAC's major funding decisions in 2008/09 (see table) included adding eight new products to the Pharmaceutical Schedule, and widening access to six pharmaceuticals.

More people treated

As a result of the decisions in 2008/09 an estimated 19,800 new patients were treated with these subsidised medicines. In the first full year of these decisions being implemented, PHARMAC estimates that there would be 30,400 new patients using these medicines – including 9000 new patients using imiquimod and 2900 new users of topiramate. Total expenditure over 12 months for these decisions is estimated to be $11.9 million.

Funding Decision	Month of implementation	Condition treated	Estimated no. new patients by 30 June 2009	Estimated no. new patients by 12 months' implementation	Estimated net extra costs by 12 months' implementation
New listings					
aripiprazole	August 2008	psychosis	969	1,098	$896,092
imiquimod	September 2008	some skin cancers, genital warts	9,073	10,963	$1,894,998
levetiracetam	September 2008	epilepsy	151	175	$195,321
finasteride	October 2008	prostate disorders	1,244	2,532	$192,740
bicalutamide (2)	November 2008	prostate cancer	418	755	$76,675
insulin lispro with insulin lispro protamine	November 2008	diabetes	1,366	2,545	$724,230
amisulpride	December 2008	psychosis	272	670	$188,363
atomoxetine	April 2009	ADHD	223	922	$385,304
Widening access					
methylphenidate ER	September 2008	ADHD	2,392	3,221	$1,146,580
risperidone (1)	September 2008	psychosis			
topiramate	September 2008	epilepsy, migraine	2,948	3,885	$599,476
isotretinoin (1)	March 2009	severe acne			
pegylated interferon alpha-2a, pegylated interferon alpha-2b with ribavirin	April 2009	hepatitis B and C	783	3,641	$5,580,154
Total			**19,839**	**30,408**	**$11,879,932**

Notes :

(1) Insufficent or inconclusive data to provide a reliable estimate;

(2) cancer medicines are funded from the Pharmaceutical Cancer Treatment budget, which is held by DHB hospitals (not PHARMAC)

Top 20 most prescribed medicines

Year ending June 2009

Most commonly prescribed subsidised drugs. Note: This does not include non-subsidised prescriptions (i.e. those paid for by the patient or those where the cost falls under the patient co-payment).

Chemical Name	Prescriptions	Main use
paracetamol	**1,970,000**	*pain relief*
aspirin	**1,320,000**	*prevents heart attack and stroke (cardiovascular risk)*
Simvastatin	**1,240,000**	*impaired cholesterol (cardiovascular risk)*
Omeprazole	**1,070,000**	*heartburn, stomach ulcers*
Amoxycillin	**980,000**	*bacterial infections*
Amoxycillin clavulanate	**870,000**	*bacterial infections*
Metoprolol succinate	**810,000**	*raised blood pressure, heart disease*
Salbutamol	**770,000**	*asthma symptoms*
Diclofenac sodium	**580,000**	*pain/arthritis*
Cilazapril	**540,000**	*raised blood pressure cardiovascular risk)*
Zopiclone	**520,000**	*insomnia*
Prednisone	**500,000**	*steroid treatment for asthma attacks, arthritis etc*
Ibuprofen	**470,000**	*pain relief*
Flucloxacillin sodium	**430,000**	*bacterial infections*
Bendrofluazide	**420,000**	*raised blood pressure (cardiovascular risk)*
Quinapril	**420,000**	*raised blood pressure, heart disease, diabetes*
Fluticasone	**400,000**	*prevents asthma*
Felodipine	**390,000**	*raised blood pressure, heart disease*
Frusemide	**380,000**	*heart failure*
Thyroxine	**380,000**	*underactive thyroid gland*

Health gains from funding decisions

PHARMAC also assesses the health gains obtained through its investments, and measures outcomes in quality adjusted life years (QALYs). QALYs are a standard pharmacoeconomic measure to compare different medicines that do different things.

The funding decisions for the ten pharmaceuticals (indication in brackets) below

> **aripiprazole** (psychosis, second line)

> **atomoxetine** (attention deficit & hyperactivity disorder (ADHD)

> **bicalutamide** (prostate cancer)

> **finasteride** (prostate disorders)

> **imiquimod** (some skin cancers, genital warts)

> **levetiracetam** (epilepsy)

> **methylphenidate ER** (ADHD)

> **pegylated interferon alpha-2a, pegylated interferon alpha-2b with ribavirin** (hepatitis B and C)

> **topiramate** (epilepsy, migraine)

are likely to lead to 27,200 new patients being treated in the first 12 months after listing. These patients are estimated to gain the equivalent of 500 to 1,000 full years of extra life (i.e. QALYs) over their lifetime.

Aripiprazole, bicalutamide, pegylated interferon alpha-2a, pegylated interferon alpha-2b with ribavirin, and topiramate additionally will cause net savings to the health sector through reduced use of other more expensive medicines or reducing the need for hospital use or other costs to the health sector. In addition, some savings to the health sector alongside health gains are expected for finasteride, imiquimod, levetiracetam, atomoxetine, and methylphenidate ER. Amisulpride (pyschosis, first line) will also cause net savings to the health sector through reduced use of other more expensive medicines.

Review of expenditure, 2008/09

Key figures

> **$653 million**
– yearly pharmaceutical expenditure (on budget)

> **$17.6 million**
– increase in spending compared to previous year *(2.8% increase)*

> **35.3 million**
– number of funded prescriptions written *(3.9% increase)*

> **3.1 million**
– number of New Zealanders receiving funded medicines

> **$32.6 million**
– amount of savings achieved

PHARMAC hit the target with its budget management this year. Expenditure came in at $653 million – exactly on budget. This is a $17.6 million increase in pharmaceutical spending compared to the previous year, an increase of 2.8%. At the same time, there was a 3.9% increase in the number of prescriptions written, up to 36.3 million prescriptions.

The rate of prescription volume increase has slowed from the highs of recent years, indicating that the full impact of the Primary Healthcare Strategy has now been felt.

Because the number of prescriptions being written continues to outstrip growth in spending, PHARMAC continues to focus on savings transactions to help meet the budget. In the past year, PHARMAC implemented three large-scale savings decisions that affected a total of 550,000 New Zealanders. These were for:

> **Paracetamol** – used for pain relief

> **Omeprazole** – used for gastrointestinal disorders like stomach ulcers, heartburn and gastric reflux

> **Simvastatin** – used to treat raised cholesterol as part of overall cardiovascular risk reduction.

Brand change can be upsetting for patients and we were well aware that, with such large-scale changes all happening at once, these changes needed to be implemented carefully. We supported the changes with information for health professionals and consumers and kept a watching eye on the patient responses.

While savings transactions were an important feature of the year, we also managed to increase New Zealanders' access to medicines with eight new chemicals funded, and access widened to a further 55. Many of these access widening decisions were a result of our ongoing project to `fix niggles' for health professionals, and included moves such as removing specialist prescriber restrictions and, where appropriate, relaxing or removing Special Authority restrictions on medicines.

The Top 20 Expenditure Groups

Year ending 30 June

$ millions, cost ex manufacturer, excludes rebates and GST

Drug Type	Main Use	2004	2005	2006	2007	2008	2009
Lipid Modifying Agents	Raised cholesterol (cardiovascular risk)	$54.97	$60.82	$68.19	$68.86	$66.06	**$63.47**
Antipsychotics	Mental health (psychoses)	$45.19	$48.59	$53.45	$57.13	$60.58	**$61.58**
Antiulcerants	Heartburn, stomach ulcers	$63.98	$68.64	$73.78	$75.58	$69.91	**$43.42**
Beta Adrenoceptor Blockers	Heart disease	$11.53	$17.58	$21.27	$24.52	$29.29	**$32.01**
Agents Affecting the Renin-Angiotensin System	Raised blood pressure (cardiovascular risk)	$28.44	$29.12	$26.08	$29.10	$29.94	**$31.19**
Diabetes	Diabetes	$19.22	$20.60	$22.51	$26.34	$29.36	**$31.06**
Inhaled Long-acting Beta-adrenoceptor Agonists	Asthma	$14.29	$18.65	$21.65	$19.34	$23.25	**$27.84**
Antiepilepsy Drugs	Epilepsy	$20.72	$21.40	$24.80	$27.85	$24.62	**$25.89**
Chemotherapeutic Agents	Cancer	$10.86	$11.32	$13.65	$16.62	$21.12	**$23.35**
Antidepressants	Mental health (depression)	$27.57	$27.33	$29.71	$30.65	$20.81	**$22.26**
Analgesics	Pain relief	$16.54	$14.52	$15.69	$17.23	$18.86	**$21.18**
Diabetes Management	Blood glucose monitoring	$19.81	$19.51	$16.28	$17.12	$19.03	**$19.79**
Immunosuppressants	Organ transplants, arthritis	$13.08	$13.37	$13.94	$14.50	$15.95	**$17.26**
Antibacterials	Bacterial infections	$13.06	$13.94	$13.88	$14.80	$15.47	**$16.37**
Calcium Homeostasis	Osteoporosis	$8.30	$9.83	$11.84	$13.56	$15.36	**$16.35**
Calcium Channel Blockers	Heart disease	$16.37	$13.02	$13.68	$14.47	$16.02	**$16.31**
Antirheumatoid Agents	Arthritis	$3.01	$3.94	$5.39	$9.14	$11.23	**$15.93**
Antiretrovirals	HIV/AIDS, viral infections	$7.33	$8.88	$10.37	$11.73	$13.82	**$15.71**
Inhaled Corticosteroids	Asthma	$18.68	$17.50	$16.87	$16.20	$15.17	**$14.45**
Endocrine Therapy	Breast cancer	$5.33	$6.47	$8.83	$10.55	$12.21	**$12.81**

Therapeutic group summary

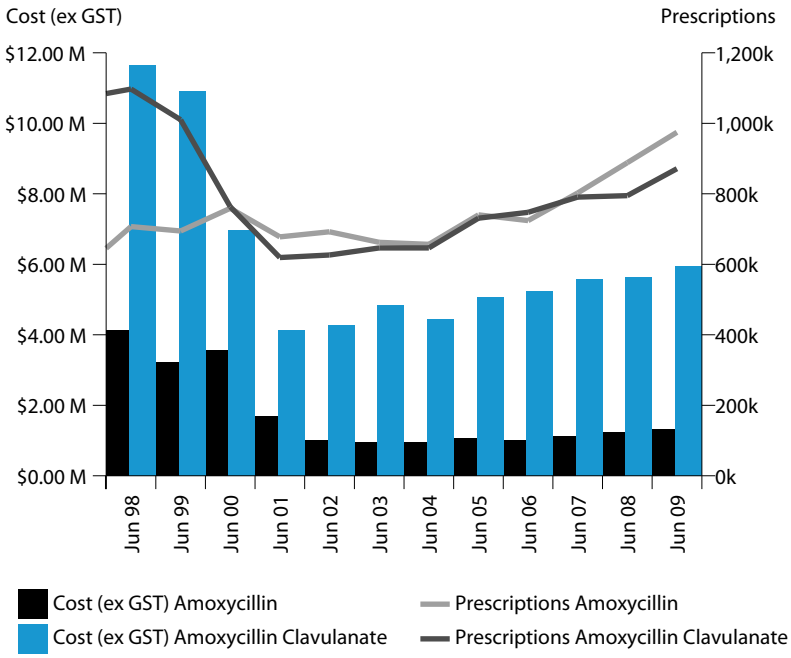
Infections

PHARMAC's longest-running optimal use of medicines campaign, Wise Use of Antibiotics, took a different approach this year. With the campaign's key messages about using antibiotics only to treat bacterial infections appearing to have taken root with health professionals, we decided not to `re-launch' the campaign for the winter cold and flu season. Instead, we developed a new resource for parents and caregivers to give them advice on giving medicine to children. The result, a collaboration with Plunket and the Paediatric Society is a leaflet titled Tips for Giving Medicine to Kids, and has proven popular.

Among medicine funding decisions, the immune modulator drug pegylated interferon alpha was funded for hepatitis B, and given wider access to treat hepatitis C, for which it was already funded. Pegylated interferon was funded for other types (genotypes) of hepatitis C not previously funded, and it also meant the treatment could be used as earlier therapy without the requirement for substantial disease progression. Pegylated interferon can be used on its own, or in combination with another drug, ribavirin.

PHARMAC's estimate is that about 35 people per year would use the treatment for hepatitis B, and a further 40 for hepatitis C. It is available in addition to already-funded treatments such as standard interferon, lamivudine and adefovir.

Antibiotics



Major decisions

> Pegylated interferon – now funded for all Hepatitis C genotypes, and for Hepatitis B.

Asthma/ respiratory

Major decisions

> Development of a new Access and Optimal Use campaign – Space To Breathe - He Tapu Te Ha.

PHARMAC launched a new programme aimed at childhood asthma in April 2009 called Space to Breathe. The programme is focussed on Māori and Pacific children with asthma and their carers.

Developed by PHARMAC, the Space to Breathe programme aims to promote better awareness of asthma and how to manage it. The programme targets health professionals, carers of asthmatic children and children with asthma. By better understanding asthma and how to manage it, families can avoid the need for hospitals, and even death that can result from asthma.

The Space to Breathe (He Tapu te Hā) childhood asthma educated programme was piloted in Taranaki this year. It is aimed at Māori and Pacific children because they are disproportionately affected by asthma compared to other New Zealand children. Each year, around four out of every 1000 children under the age of 19 are hospitalised for asthma. But for Māori, this statistic is higher (6 out of every 1000) compared to NZ European (2 out of every 1000). Māori children are four times more likely to die from asthma than NZ European children.

PHARMAC's data shows that many Māori and Pacific people are being prescribed and using their reliever medicine to treat asthma when they should be using a preventer medicine to prevent asthma symptoms. Rather than using long-acting preventers, people are relying on short-acting relievers (like salbutamol) after symptoms appear.

Space to Breathe was developed by PHARMAC in conjunction with regional health providers (Tui Ora, Tihi and Piki Te Ora) in New Plymouth, and the Best Practice Advocacy Centre BPACNZ. The Paediatric Society and the Asthma and Respiratory Foundation were also strongly involved in the development of the programme. Its aims are to

> increase awareness and knowledge of asthma;

> increase knowledge and understanding about asthma medicines;

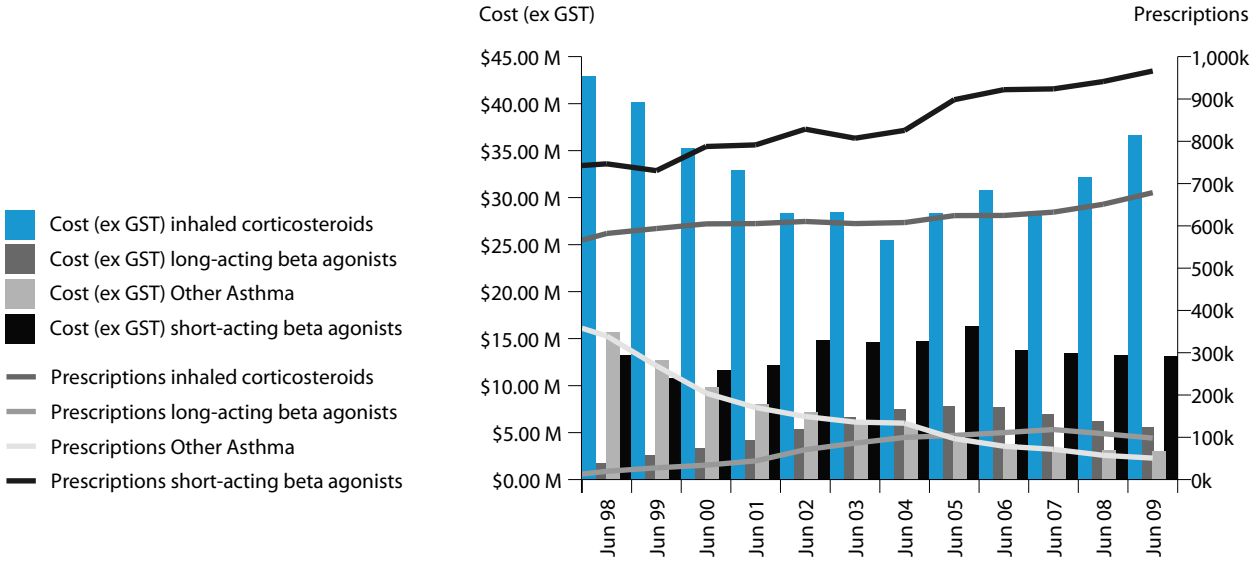
> increase confidence of children with asthma and their families in managing asthma; and

> provide support and resources for carers to support wellness through management of asthma.

The programme targets pre-school children and their families through kohanga reo and early childhood education centres. It also featured a new decision support tool developed by BPACNZ for doctors to use when diagnosing and treating asthma.

SPACE to BREATHE
taking care of asthma

Asthma



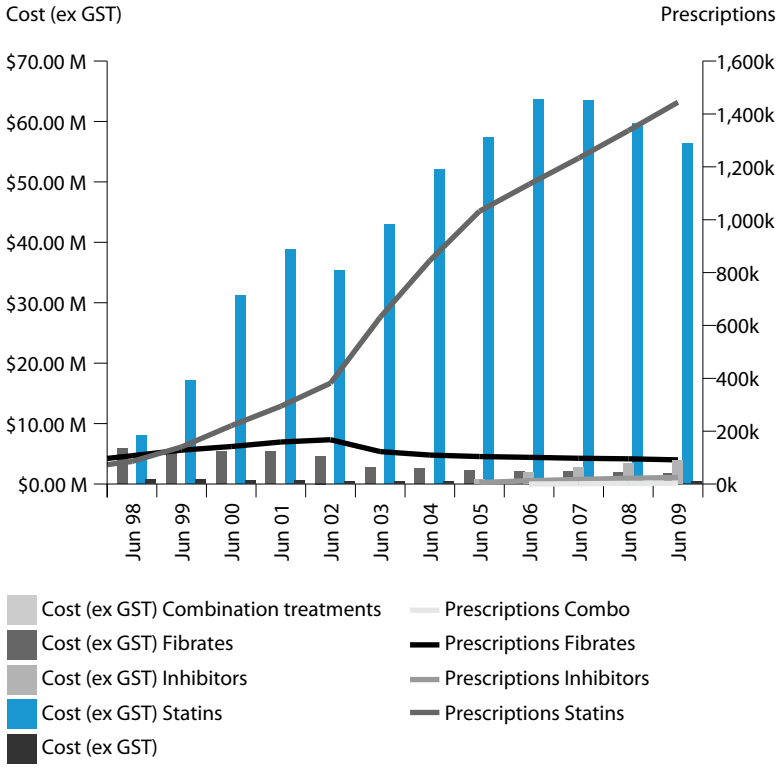
Heart disease

Simvastatin continues to be one of the most commonly-prescribed medicines in the country, now accounting for more than a million prescriptions per year. During the year PHARMAC completed a move to sole supply of simvastatin, with generic supplier Arrow winning with its Arrow-Simva. The transition to the generic – involving more than quarter of a million people, went very smoothly.

Though the use of statins continues to increase (indicated by the graph), there are still indications that some groups with high needs are not getting statins at the same rate as other New Zealanders. So there is a continuing need for campaigns like PHARMAC's One Heart Many Lives, which targets Māori and Pacific men. The messages from the campaign are simple – Māori and Pacific men die up to 14 years earlier than other New Zealand men, often from heart disease. So get your heart checked, take action, and take medicine prescribed for you, including statins.

One Heart Many Lives continues to operate in three DHB regions – Hawke's Bay, Northland and Lakes. In addition, PHARMAC has also taken the campaign to the people at community days such as Te Ra o Te Raukura in Lower Hutt in early 2009.

Cholesterol-lowering treatments



Major decisions

> Statins – simvastatin sole supply awarded to Arrow-Simva

Anti-ulcerants

Major decisions

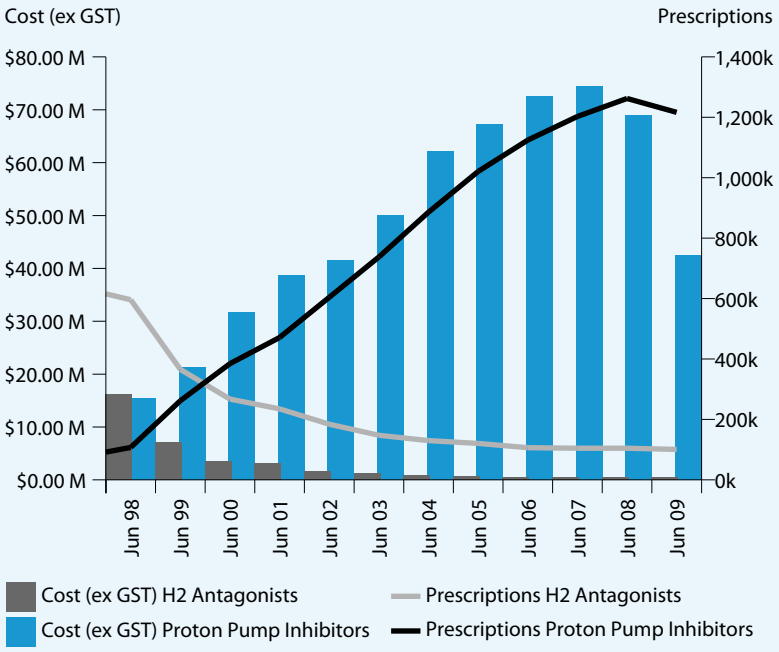
> Omeprazole – Dr Reddys brand goes sole supply

One of the major changes put in place during the year was the shift from the Losec brand of the gastrointestinal drug omeprazole, to the Dr Reddy's brand. The move, estimated to involve net savings of $16 million over five years, began in January 2009 and was completed by May. In that time, about 250,000 people changed to the generic brand.

In terms of patient numbers, this was one of the largest-scale brand changes PHARMAC has implemented. It was supported by information for patients and health professionals, and was closely watched by both PHARMAC and the medicine adverse assessment centre, CARM. CARM received a number of reports to its database, but the nature and number of these did not lead Medsafe to recommend any action be taken. Medsafe commented that most of the reports were for side effects and responses that were common for all brands of omeprazole.

With the move to a generic came the end of sizeable rebate payments to PHARMAC that had been linked with the supply of Losec. This also led to a considerable loss of revenue (through reduced markups) in the pharmacy and pharmacy wholesaler supply chains. Taking into account the impact on pharmacy, PHARMAC and DHBs agreed to reinvest part of the savings into the pharmaceutical supply chain, to maintain the viability of wholesalers and pharmacy.

Anti-ulcerants



Cancers and transplant medicines

Two new treatments were funded for prostate disorders in men. Finasteride (Fintral) was funded for benign prostatic hyperplasia, while bicalutamide (Bicalox) was funded for advanced prostate cancer. Both of the drugs are off-patent and funded at very competitive prices compared with other countries.

Both prostate cancer and BPH are relatively common, particularly in men aged over 50. Prostate cancer is the most commonly diagnosed cancer in New Zealand men and the third most common cause of male cancer deaths. Prostate cancer accounts for 3.8% of all male deaths in New Zealand.

Bicalutamide is funded under Special Authority for advanced prostate cancer. PHARMAC estimates that it could be used by about 160 people in the first year, rising to more than 300 by 2011.

Finasteride is funded under Special Authority for men who are unable to be successfully treated with another group of drugs called alpha blockers. Up to 3000 men could be treated with finasteride each year.

Meanwhile, a new treatment was funded for people with a generally non-malignant form of skin cancer. Imiquimod (Aldara) is a cream that people can apply themselves to treat basal-cell carcinoma. While surgery remains the most effective treatment for skin cancers, imiquimod is useful in treating people for whom surgery might be inappropriate.

Imiquimod (Aldara) is also funded to treat genital warts.

PHARMAC estimates that up to 4500 people with skin cancer will be treated annually with imiquimod by 2013. Together with its other uses, PHARMAC estimates nearly 12,000 people will be treated with imiquimod annually by 2013.

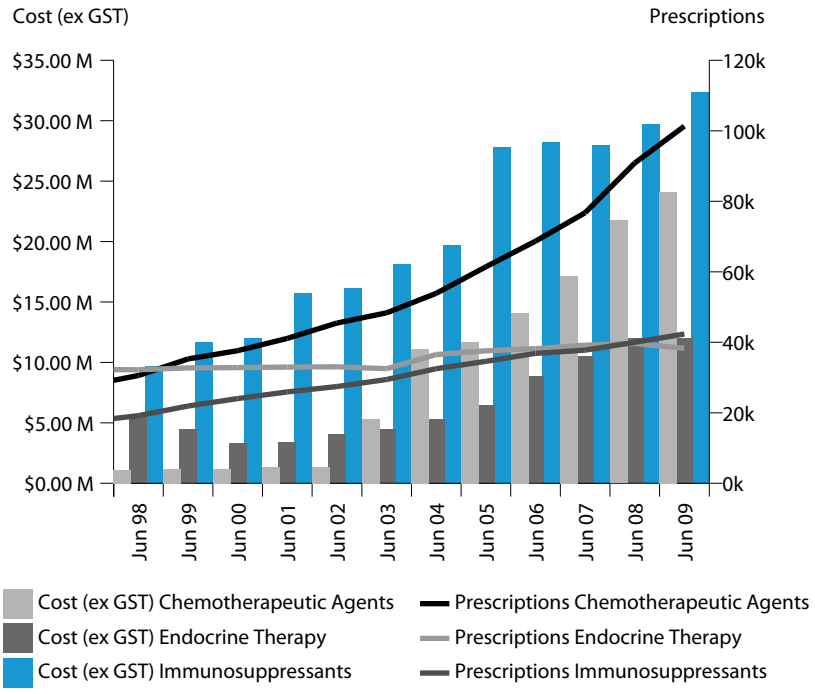
Major decisions

> Imiquimod for some forms of skin cancer, and genital warts

> Finasteride for benign prostatic hyperplasia

> Bicalutamide for prostate cancer

Cancer treatments



Mental Health and Neurology

Major decisions

> Extended release methylphenidate (Concerta) for ADHD

> Atomoxetine (Strattera) for ADHD

> Amisulpride for schizophrenia

> Aripiprazole for schizophrenia

> Topiramate for migraines (and first line for epilepsy)

> Levetiracetam for epilepsy

ADHD

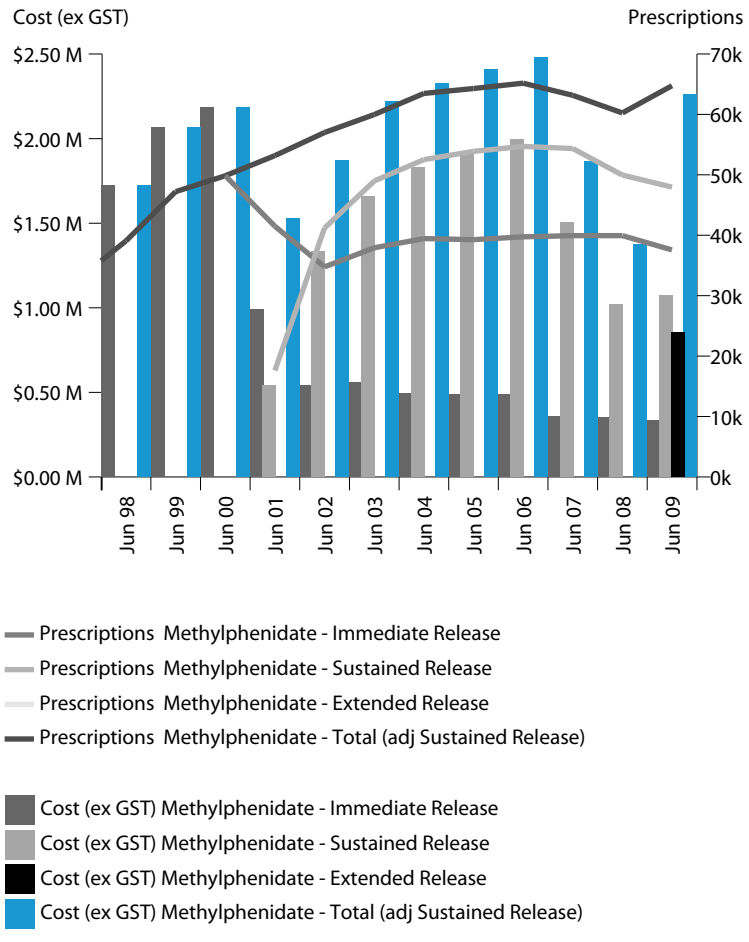
Two new treatments were funded to provide long-acting therapies for the behavioural disorder attention deficit hyperactivity disorder (ADHD).

In September 2008, PHARMAC began funding for extended-release methylphenidate (Concerta). This added to the already-funded immediate release and sustained release formulations of methylphenidate. Having an extended-release formulation on the schedule meant that for the first time a once-a-day treatment was funded.

Then in April 2009, we added a different type of ADHD treatment, atomoxetine (Strattera). Like Concerta, atomoxetine is a once-a-day treatment, but has a different therapeutic action to methylphenidate, and is not a stimulant nor a controlled drug. This means it has benefits for health professionals and patients. It is funded for those people who haven't responded to, or can't take, the stimulant medicines such as methylphenidate or dexamphetamine.

Overall, PHARMAC expects only a small increase in the number of people receiving funded treatment for ADHD to increase, as most patients would already be taking the other funded preparations. About 11,000 people, many of them children, receive funded ADHD medicines.

Attention Deficit Disorder



Schizophrenia and related illness

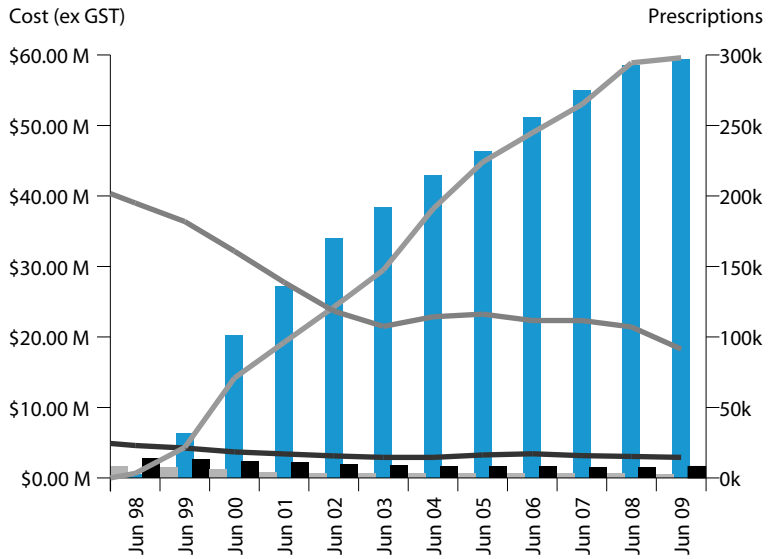
Meanwhile, for patients with schizophrenia and related illnesses PHARMAC funded two new antipsychotic treatments that are associated with less weight gain than some of the existing funded treatments. Amisulpride (Solian) and aripiprazole (Abilify) were both funded during the year and add to a broad range of anti-psychotic medicines that are funded.

Amisulpride is funded without restrictions, so is available as a first-line treatment option for all patients, while aripiprazole is funded under Special Authority as a second-line treatment.

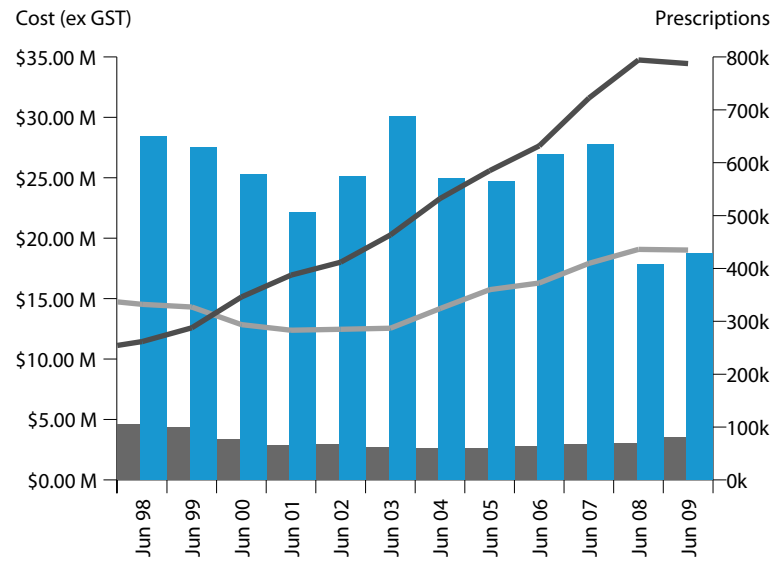
In PHARMAC's view it's important to maintain a range of anti-psychotic treatments, given the difficulties of treating the condition, and the listings this year restore some of the range that has been lost with some older anti-psychotics being withdrawn by suppliers in recent years.

Overall, antipsychotics continue to be one of the highest expenditure groups with total spending of over $60 million annually.

Antipsychotics



Antidepressants



Migraines and epilepsy

People suffering from migraines received access to a further treatment during the year, with a decision to widen access to the epilepsy treatment topiramate (Topamax). Topiramate is a further addition to the range of migraine treatments that also grew in the previous financial year with the listing of rizatriptan wafers.

The widening of access to topiramate also means it is now funded as a first-line treatment for epilepsy.

Another epilepsy decision during the year was the funding for leviteracetam (Keppra), a last-line treatment for the neurological condition. Access to leviteracitam, which is provided to patients who have tried and failed all other available treatments, is provided through a panel of doctors.

Dermatology

Vocationally-registered general practitioners can now provide funded access to the severe acne treatment isotretinoin and psoriasis treatment acetretin. Previously, the treatments were only available from specialist dermatologists

The move should help resolve differences in access for patient groups. An analysis of PHARMAC's data showed that people from wealthier areas were more likely to have funded isotretinoin than those from less well-off areas. This suggests that the cost of seeing a specialist – and access to a specialist – was a barrier to treatment.

Isotretinoin is a potentially dangerous medicine, with a range of side effects including risks for pregnant women, and there is ongoing debate around the evidence of increased risk of suicidal ideation. PHARMAC acknowledged safety issues that were raised during consultation, and responded to them. GPs were always able to prescribe the drug, although the prescriptions would not have been subsidised. In PHARMAC's view, vocationally-registered GPs are well placed to make clinical judgements about the appropriateness of prescribing medicines like isotretinoin.

PHARMAC worked closely with the College of GPs around the decision and its implementation. To support the decision, information was provided to doctors through the Otago University-based Best Practice Advocacy Centre (bpacnz), and through PHARMAC's Seminar Series.

PHARMAC estimates that the access widening will lead to a 5-10% increase in the use of isotretinoin, translating to an increase in spending of $55,000 to $100,000 per year.

PHARMAC in the wider health sector

As well as its work in securing subsidies for medicines used in the community, PHARMAC negotiates national agreements for some medicines used in District Health Board hospitals, and conducts other procurement work on behalf of DHBs or the Ministry of Health. In this way, PHARMAC uses its expertise in combining medical advice with commercial skills to get greater efficiencies in hospital purchasing.

Work in previous years that has continued during 2008/09 includes:

- **Negotiating national agreements for some medicines used in DHB hospitals (as published in Section H of the Pharmaceutical Schedule)**
- **Procurement of the influenza vaccine on behalf of the Ministry of Health**
- **Procurement of bulk intravenous fluids**
- **Procurement of radiological contrast media**
- **Procurement of recombinant factor VIII for haemophilia**

DHB Procurement

PHARMAC continued to manage national agreements for hospital pharmaceuticals and some related products . There were 278 changes to the Hospital Schedule (Section H of the Pharmaceutical Schedule) in 2008/09, made up of:

- **181 new listings**
- **61 price decreases, and**
- **36 price increases.**

As in previous years much of the activity was via the annual multi-product tender, which provided an estimated $3.9 million of savings in the 2008/09 financial year. There were additional savings with price reductions for oxaliplatin and omeprazole, however this was to some extent offset by price increases for recombinant factor VIII. Overall, we estimate changes in 2008/09 achieved additional savings of approximately $5 million per annum for DHBs.

PHARMAC also ran commercial processes in 2008/09 for volatile anaesthetics, bulk intravenous fluids, and radiological contrast media. We estimate savings in excess of $1 million per year can be expected from the anaesthetics process. The other procurement work is ongoing.

In line with the recommendations of the Horn report, we are keen to assist DHBs with procurement in areas where they see that PHARMAC can gain greater efficiencies or add value to DHB work. We continue to talk with DHB CEOs about where PHARMAC may be able to assist.

Influenza vaccine

A world-wide alert over the H1N1 influenza virus ("Swine Flu"), prompted much higher demand for influenza vaccines this year. The Ministry of Health lengthened the subsidised flu season as part of its raised pandemic alert provisions, and this combined with public concern led to nearly a million doses (961,000) of the vaccine being supplied – most of it Government-funded. This was more than 20% higher than 2008, and signficantly more than our stock projections for the year.

With the increased demand PHARMAC sought additional supplies from vaccine companies. We were grateful for the efforts of Sanofi and GlaxoSmithKline to source additional supplies so that the needs of New Zealanders could be met.

(left to right) Kevin Pewhairangi, Hiwinui Heke, Leanne Te Karu (Māori Pharmacists Association) Caroline Blucher and Tess James at the scholarship presentations, Otago University

Workforce development

PHARMAC and Nga Kaitiaki o te Puna Rongoa o Aotearoa (Māori Pharmacists Association or MPA) have combined to sponsor scholarships for young Māori pharmacy students.

The Hiwinui Heke Scholarships are named after Hiwinui Heke (Te Arawa), who was one of the first Māori to graduate from a New Zealand pharmacy school in 1955. Now semi-retired, Mr Heke continues to work in a Rotorua pharmacy part-time.

At a ceremony at the Otago University Pharmacy School, the first awards were presented to Kevin Pewhairangi (Ngati Porou, Ngati Whakaue), Tess James of the School of Pharmacy University of Otago (Ngati Porou) and Caroline Blucher, School of Pharmacy, University of Auckland (Te Aupouri).

Kevin Pewhairangi, 24, was awarded a $5000 scholarship while Tess James, 22, received a $2,500 scholarship – both students are in their last year of study. Caroline Blucher, a 19-year-old first year student, also received a $2500 scholarship.

The awards are aimed at encouraging Māori in the pharmacy profession. A $2,500 scholarship is available at each School of Pharmacy for a third or fourth year Māori student, while a further $5,000 scholarship is awarded for a pharmacy student who has a history working as a Pharmacy Technician/Dispensary Technician or a Dispensary Assistant.

PHARMAC sees the scholarships as a positive initiative to help Māori who have chosen to pursue a career in pharmacy. They align with PHARMAC's Māori Responsiveness Strategy, which aims to improve knowledge about and use of medicines by Māori.

Awards will be presented each year, with a total value of $10,000.

Fixing niggles in the system

We're aware that some of the systems we set up create work for health professionals and this can be frustrating for them. We're committed to reducing paperwork and bureaucracy for health professionals where possible and removing `niggles' from the medicine funding system. We've addressed this in a number of ways in the past year.

Electronic Special Authority

Special Authority is the targeting mechanism PHARMAC uses to ensure medicines go to the patients who most need them. In 2006 PHARMAC worked with the Ministry of Health and software providers to set up an electronic application system, and this has grown in popularity. Under the manual application system, patients sometimes had to wait up to two weeks to receive Special Authority approvals. Now the electronic system means applications can be processed while the patient is still consulting with their doctor.

The speed and convenience of the electronic system has made it popular with doctors and patients. By the end of 2008/09, more than 3000 doctors were using an electronic system, including many hospital doctors. Electronic applications now out-stripping manual ones, where doctors fill out a form and fax it to the Ministry.

The speed and convenience of the electronic system has made it popular with doctors and patients. By the end of 2008/09, about 3200 doctors were using an electronic system, including many hospital doctors. Numbers of electronic applications now out-strip manual ones, where doctors fill out a form and fax it to the Ministry.

Additional payments to pharmacy

During 2008/09 PHARMAC put in place brand changes for a number of medicines, including two that had previously been subject to substantial rebates. Under the rebates mechanism, the pharmaceutical company charged a higher price for their product which was fully subsidised, and a portion of that was then rebated back to PHARMAC (and then passed on to District Health Boards).

With the change to generic forms of omeprazole and simvastatin, the headline price dropped significantly. This had an impact on the pharmacy supply chain, because part of pharmacy reimbursement is based on a percentage margin on the headline price of the medicine. To help compensate pharmacy for the loss of revenue, DHBs agreed to reimburse pharmacy part of the savings that occurred as a result of the brand changes. The payments, were paid twice by PHARMAC during 2008/09 and totalled $2 million.

The net effect of the additional payments was that pharmacy did not lose the income it would have, while DHBs still obtained savings from the reduction in medicine cost.

Special Authority removals/Specialist Restrictions

As outlined above, Special Authority is an important mechanism for ensuring medicines get to the people who most need them. Part of the success of the system is in ensuring it isn't overused, so PHARMAC has an ongoing review in place to ensure the restrictions that are in place are appropriate.

During 2009/10 PHARMAC removed Special Authority requirements, or specialist prescriber restrictions, from 29 medicines. This followed on from the previous financial year when 43 such restrictions were removed.

Exceptional Circumstances

Exceptional Circumstances is the mechanism that gives people access to medicines that aren't otherwise funded through the Pharmaceutical Schedule. PHARMAC administers three Exceptional Circumstances schemes for community (CEC), hospital (HEC), and cancer (CaEC) medicines.

The Community EC scheme provides access to medicines for people with unusual clinical circumstances. Access is subject to approval by a panel of clinicians. The budget for CEC for 2009 was $3 million, which is part of the overall Pharmaceutical budget.

HEC has been running since July 2003. This mechanism enables DHB hospitals to fund medicines in the community where it is more cost-effective for the DHB to do so than continue to treat people in hospital.

Cancer EC was set up in 2005. This mechanism allows DHB hospitals to fund, on application to PHARMAC, cancer medicines that are not funded through the Pharmaceutical Cancer Treatments "basket" – a list of cancer medicines that all DHB hospitals must fund.

As part of Actioning Medicines New Zealand, PHARMAC set about a review of the Exceptional Circumstances Schemes to determine whether they were meeting the needs of patients and functioning well. Subsequent to the Medicines New Zealand work, in early 2009 the new Government announced it would set up a Panel to examine high cost highly specialised medicines, and as part of the review would look at the Exceptional Circumstances schemes.

As a result PHARMAC's own review was put `on hold' pending the outcome of the high cost panel's work.

In the meantime, PHARMAC continued to operate the Exceptional Circumstances schemes. Overall, PHARMAC received 3192 Exceptional Circumstances applications during the year, of which 2460 were approved. This was an increase in both the number of applications and approvals compared to 2008.

A breakdown of applications received and processed during the year is provided in the table below.

Summary of Exceptional Circumstances schemes

		Received	Approved	Declined
Community EC	Initial	365	86	227
	Renewal	174	156	16
Community EC (automatic approvals)	Initial	351	351	
	Renewal	604	604	
Hospital EC	Initial	1059	804	148
	Renewal	414	401	3
Hospital EC (automatic approvals)	Initial	1	1	
	Renewal	1	1	
Cancer EC	Initial	213	187	4
	Renewal	10	10	
Totals		**3192**	**2460**	**398**

Note:

The number of approved plus declined may not equal the total number of applications for a variety of reasons.

> the application may be withdrawn

> the patient may have died

> the application may be approved under other rules (eg as a Special Authority); or

> the application may be transferred from HEC to CEC or vice versa.

External advice from our Advisory Committees

During the year we progressed work to ensure our external advisory committees perform as optimally as possible. We want to ensure we get the best possible advice from these committees and this includes the structures set up to govern the committees are as strong as possible.

Reviews of both our clinical advisory committee (PTAC, the Pharmacology and Therapeutics Advisory Committee) and Consumer Advisory Committee were actions identified for PHARMAC as part of Actioning Medicines New Zealand. From our point of view, it's important these committees function well and give us robust advice, and that their advice has credibility in the eyes of their peers and the wider community.

PTAC Terms of Reference review

By the end of 2008 we had completed the review of the Terms of Reference PTAC, and its sub-committees. PTAC, which consists of nine practicing doctors, has 15 sub-committees with a range of specialist knowledge including cancer treatments, heart disease, endocrinology and mental health. Overall, PTAC and its sub-committees consist of more than 50 practicing doctors and are a major asset for PHARMAC.

The work on reviewing PTAC's Terms of Reference aimed to clarify the role and functions of the committee and its relationship with PHARMAC. We want to avoid the perception that the members of the various committees are `captured' by PHARMAC, so they maintain their clinical independence and the integrity of their advice.

Changes from the review include:

- Publishing more minutes relating to pharmaceutical funding applications on PHARMAC's website, including when PTAC has deferred making a recommendation. PHARMAC is also now publishing minutes from PTAC subcommittee meetings on its website.
- The Committee's operations – its membership, scope of activity and specific functions – have been clarified in a number of ways. For example:
  - membership can now include senior health professionals, such as public health physicians, pharmacists or nurses – not just medical practitioners as in the past. This change reflects that many types of health professionals, not just doctors, have an interest and expertise in prescription medicines; and
  - PTAC can now request that a subcommittee undertake a "rapid review", in order to receive specialised advice from a subcommittee in a more timely way.
- The relationship between PHARMAC and PTAC has also been clarified, like making clear that PTAC can provide PHARMAC with any and all information and views it considers desirable.

These changes are intended to maintain and improve the relationship and continue PTAC's tradition of providing objective advice to PHARMAC. Overall, the changes are aimed at increasing public confidence in the operations of PTAC and its sub-committees.

Consumer participation work

When we thought through the issues around the Consumer Advisory Committee (CAC) , we realised that there was a broader question to ask - `how should PHARMAC ensure consumers are participating in its work?' A review of CAC's Terms of Reference, something PHARMAC had committed to through its Statement of Intent, formed a part of this wider work.

We decided to start by seeking information about how consumers participate in Government health bodies and decision making in other countries. We also sought the views of the community on how the CAC should optimally work. While this was a bit of a `blue skies' question, the intention was to ask people a very broad question to help identify what issues people had with CAC and how these could be addressed.

The information we obtained through these processes was very valuable, and was able to inform a further step in our process. In early October 2009 we released a discussion document on PHARMAC's consumer participation work. This put forward seven options which we sought people's feedback on. We also asked for other suggestions from people as to how consumer participation in PHARMAC's work could be improved.

The seven options broke down into three distinct categories:

>Increasing the amount of information provided to consumers

>Formalising face-to-face meetings with consumer groups

>Changes to PHARMAC's decision-making processes to include consumer views or reviews.

Views are being sought on these options, and any other ideas people want to put forward, by 4 December 2009. We'll then do some further analysis before deciding on next steps and completing the review of the CAC Terms of Reference.

Directory

The PHARMAC Board

Chairman

Richard Waddel BCom, FCA, AFInstD

Deputy Chairman

* Professor Gregor Coster CNZM, MSc (Hons), PhD, MBChB, FRNZCGP

Directors

Kura Denness (Te Atiawa) MBA CA

Dr David W Kerr MBChB, FRNZCGP (Dist), FNZMA

David Moore MCom, Dip Health Econ (Tromso), CA

Adrienne von Tunzelmann MA (Hons), Master of Public Policy (Dist)

** Did not seek reappointment from 1 August 2009. Replaced as deputy chair by Stuart McLauchlan BCom, FCA (PP) , AFInstD*

PHARMAC's Management Team

Chief Executive

Matthew Brougham MSc (Hons), Dip Health Econ (Tromso)

Management Team

Peter Alsop - Manager, Corporate and External Relations

Steffan Crausaz BPharm, MSc, MRPharmS - Manager, Funding & Procurement

Rachel Mackay BA, NZIMR - Manager, Schedule and Contracts

Dr Peter Moodie BSc, MBChB, FRNZCGP - Medical Director

Marama Parore (Ngati Whatua, Ngati Kahu, Nga Puhi) - Manager, Access and Optimal Use & Māori Health Manager

Rico Schoeler - Manager, Analysis & Assessment

PHARMAC's Advisory Committees

Pharmacology and Therapeutics Advisory Committee (PTAC)

Chair

Professor Carl Burgess MBChB, MD, MRCP (UK), FRACP, FRCP, Physician & Clinical Pharmacologist

Deputy Chair

Dr Paul Tomlinson BSc, MBChB, MD, MRCP, FRACP, Paediatrician

Committee Members

Dr Ian Hosford MBChB, FRANZCP, Psychiatrist

Dr Sisira Jayathissa MBBS, MD, MRCP (UK), FRCP (Edin), FRACP, FAFPHM, Dip Clin Epi, Dip OHP, Dip HSM, MBS, Physician

Dr George Laking PhD, MB, B.Med.Sci, MD, FRACP, Oncologist

Dr Jim Lello BHB, MBChB, DCH, FRNZCGP, General Practitioner

Dr Graham Mills MBChB, MTropHlth, MD, FRACP, Infectious Diseases Physician

Dr Peter Pillans MBBCh, MD, FCP, FRACP, Physician & Clinical Pharmacologist

Dr Mark Weatherall BA, MBChB, MApplStats, FRACP, Physician

Dr Howard Wilson BSc, PhD, MB, BS, Dip Obst, FRMZCGP, FRACGP, General Practitioner

PTAC Subcommittees

Analgesic - Dr Howard Wilson (Chair, PTAC, General Practitioner), Dr Ian Hosford (PTAC, Psychiatrist), Dr Rick Acland (Anaesthetist), Dr Jonathan Adler (Palliative Care Specialist), Dr Bruce Foggo (Palliative Care Specialist), Dr Lindsay Haas (Neurologist), Dr Geoff Robinson (Physician), Dr Jane Thomas (Paediatric Anaesthetist).

Anti-infective - Dr Graham Mills (Chair, PTAC, Infectious Diseases Physican), Dr Steve Chambers (infectious disease specialist), Dr Iain Loan (General Practitioner), Dr Howard Wilson (PTAC, General Practitioner).

Cancer Treatments (CaTSoP) - Prof Carl Burgess (Chair, PTAC Chair, Clinical Pharmacologist, Physician), Dr Bernie Fitzharris (Oncologist), Dr Peter Ganly (Haematologist), Dr Vernon Harvey (Oncologist), Dr Tim Hawkins (Haematologist), Dr Scott Babbington (Radiation Oncologist), Dr Anne O'Donnell (Oncologist), Dr Lochie Teague (Paediatric Haematologist & Oncologist), Dr George Laking (PTAC, Oncologist).

Cardiovascular - Dr Sisira Jayathissa (Chair, PTAC, Physician), Dr Peter Pillans (PTAC, Physician/Clinical Pharmacologist), Dr Malcolm Abernathy (Cardiologist), Dr Lannes Johnson (General Practitioner), Dr Stewart Mann (Cardiologist), Dr Richard Medlicott (General Practitioner), Dr Mark Weatherall (PTAC, Geriatrician).

Diabetes – Dr George Laking (Chair, PTAC, Oncologist), Prof. Carl Burgess (PTAC Chair, Clinical Pharmacologist, Physician), Andrea Rooderkerk, (Diabetes Nurse Specialist), Dr Nic Crook (Endocrinologist), Dr Peter Moore (Physician), Dr Bruce Small (General Practitioner), Dr David Hopcroft (General Practitioner), Dr Craig Jefferies (Paediatric Endocrinologist).

Growth Hormone - Prof Carl Burgess (Chair, PTAC Chair, Clinical Pharmacologist, Physician), Dr Paul Tomlinson (PTAC, Paediatrician), Prof. Wayne Cutfield (Paediatric Endocrinologist), Assoc. Prof. Paul Hofman (Paediatric Endocrinologist), Prof. Ian Holdaway (Endocrinologist), Dr Penny Hunt (Endocrinologist), Assoc. Prof. Patrick Manning (Endocrinologist), Dr Esko Wiltshire (Paediatric Endocrinologist).

Hormone and Contraceptive - Dr Howard Wilson (Chair, PTAC, General Practitioner, Clinical Pharmacologist), Prof John Hutton (Gynaecologist), Dr Frances McClure (General Practitioner), Dr Christine Roke (Family Planning), Dr Bruce Small, (General Practitioner), Dr Stella Milsom (Endocrinologist).

Mental Health - Dr Ian Hosford (Chair, PTAC, Psychiatrist), Dr Jim Lello (PTAC, General Practitioner) Dr Crawford Duncan (Psychiatrist), Dr Verity Humberstone (Psychiatrist), Professor Richard Porter (Psychiatrist), Dr Gavin Lobo (General Practitioner), Dr Matthew Eggleston (Paediatric Psychiatrist).

Neurological - Dr Sisira Jayathissa (Chair, PTAC, Physician), Dr Alistair Dunn (General Practitioner), Dr Lindsay Haas (Neurologist), Dr William Wallis (Neurologist), Dr Peter Bergin (Neurologist), Dr Richard Hornabrook (General Practitioner), Dr Mark Weatherall (PTAC, Geriatrician).

Ophthalmology - Prof Carl Burgess (Chair, PTAC Chair, Clinical Pharmacologist, Physician), Dr Neil Aburn (ophthalmologist), Dr Rose Dodd (General Practitioner), Dr Steve Guest (Vitreo Retinal Surgeon), Dr Allan Simpson (Ophthalmologist).

Osteoporosis - Prof Carl Burgess (Chair, PTAC Chair, Clinical Pharmacologist, Physician), Dr Anna Fenton (Endocrinologist), Dr Bev Lawton (General Practitioner), Prof. Ian Reid (Endocrinologist), Dr Liz Spellacy (Geriatrician).

Pulmonary Arterial Hypertension - Dr Howard Wilson (Chair, PTAC, General Practitioner, Clinical Pharmacologist), Dr Paul Tomlinson (PTAC, Paediatrician), Dr Andrew Aitken (Cardiologist), Dr Lutz Beckert (Respiratory Physician), Dr Clare O'Donnell (Paediatric Congenital Cardiologist), Dr Ken White (Respiratory Physician).

Respiratory - Dr Jim Lello (Chair, PTAC, General Practitioner), Prof. Carl Burgess (PTAC Chair, Clinical Pharmacologist, Physician), Dr Ian Shaw (Paediatrician), Dr John McLachlan (Respiratory Physician), Dr Tim Christmas (Respiratory Physician), Dr Henry Doerr (General Practitioner), Dr John Wellingham (General Practitioner).

Special Foods - Dr Jim Lello (Chair, PTAC, General Practitioner), Dr Simon Chin (Paediatric Gastroenterologist), Kerry McIlroy (Dietician), Jo Stewart (Dietician), Moira Styles (Dietician), Dr John Wyeth (Gastroenterologist).

Tender Medical - Dr Jim Lello (Co-Chair, PTAC, General Practitioner), Dr Graham Mills (Co-Chair, PTAC, Infectious Disease Physican), Dr Paul Tomlinson (PTAC, Paediatrician), Ms Sarah Fitt (Pharmacist), Geoff Savell (Pharmacist), Clare Randall (Palliative Care Clinical Pharmacist), John Savory (Pharmacist), Dr David Simpson (Haematologist), Dr John McDougall (Anaesthetist).

Transplant Immunosuppressant – Peter Pillans (Chair, PTAC, Physician/Clinical Pharmacologist), Dr Paul Tomlinson (PTAC, Paediatrician), Dr, Dr Peter Ganly (Haematologist), Dr Peter Ruygrok (Cardiologist), Dr Richard Robson (Nephrologist), Dr Kenneth Whyte (Respiratory Physician), Dr Stephen Munn (Transplant Surgeon).

Consumer Advisory Committee (CAC)

Sandra Coney (chair, women's health advocate, Auckland), Vicki Burnett (mental health consultant, Auckland), Sharron Cole (Patron, Parents' Centres, Wellington), Matiu Dickson (Te Runanga o Kirikiriroa chair, Hamilton), Anne Fitisemanu (Pacific health, Auckland), Dennis Paget (Grey Power, Blenheim), Paul Stanley (general manager, Waipareira Trust), Te Aniwa Tutara (Māori health manager, Waitemata DHB), Heather Thomson (health manager, Te Aroha, eastern Bay of Plenty).

Hospital Pharmaceuticals Advisory Committee (HPAC)

Sarah Fitt (Chief Pharmacist, Auckland DHB - Chair), Paul Barrett (Pharmacy Services Manager, Canterbury DHB), Simon Donlevy (Pharmacy Manager, Southland DHB), Jan Goddard (Manager, Pharmacy Services, Waikato DHB), Neil Aitcheson (Materials Manager, MidCentral DHB), David Ryan (Pharmacy Operations Manager, Waitemata DHB), Chris Morgan (Materials Management, Auckland DHB).

Panels

Exceptional Circumstances (also leviteracetam special access panel)

Dr Howard Wilson (chair, general practitioner, pharmacologist), Dr Mel Brieseman (Medical Officer of Health - retired, Christchurch) Dr Paul Tomlinson (paediatrician, Southland DHB), Dr David Waite (physician, Capital & Coast DHB), Dr Sharon Kletchko (manager funding & planning, Nelson Marlborough DHB), Dr Andrew Herbert (consultant gastroenterologist, MidCentral DHB).

Cystic Fibrosis Advisory

Dr John Kolbe (respiratory physician), Dr Ian Shaw (paediatrician), Dr Richard Laing (respiratory physician), Dr Cass Byrnes (paediatrician).

Gaucher Treatment Advisory

Dr Callum Wilson (metabolic consultant), Dr Ruth Spearing (consultant haematologist), Dr Clinton Pinto (musculoskeletal radiologist).

Multiple Sclerosis Treatment Advisory

Dr Ernie Willoughby (neurologist), Dr David Abernethy (neurologist), Dr Alan Wright (neurologist), Dr Neil Anderson, (neurologist).

Pulmonary Arterial Hypertension

Dr Howard Wilson (Chair, PTAC, General Practitioner, Clinical Pharmacologist), Dr Paul Tomlinson (PTAC, Paediatrician), Dr Andrew Aitken (Cardiologist), Dr Lutz Beckert (Respiratory Physician), Dr Clare O'Donnell (Paediatric Congenital Cardiologist), Dr Ken White (Respiratory Physician).

Growth Hormone

Prof Wayne Cutfield (chair, paediatric endocrinologist), Assoc Prof Paul Hofman (paediatric endocrinologist), Prof Alistair Gunn (paediatrician).

PHARMAC is the Government agency responsible for deciding which medicines are subsidised for New Zealanders.

It manages spending on pharmaceuticals for the District Health Boards, and ensures that a comprehensive list of medicines (the Pharmaceutical Schedule) is subsidised for New Zealanders, and that the list of medicines continues to grow to meet the needs of patients.

Pharmaceutical Management Agency

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