Pharmaceutical Management Agency
Annual Review 2010

New Zealand Government

PHARMAC
Pharmaceutical Management Agency


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2009 /10 Highlights

- Community pharmaceutical spending managed on budget - $693.8 million compared to a budget of $694 million
- 20 new medicines funded and access widened to 25 others
- New investment decisions include medicines for arthritis and auto-immune conditions, pulmonary arterial hypertension, HIV/AIDS, smoking cessation, chronic myeloid leukaemia and various types of cancer
- The largest number of major investments in medicines since 1999 (45)
- Completed a pilot of the Space to Breathe – He Tapu te Hā project in Taranaki
- Continued to grow and promote the One Heart Many Lives cardiovascular campaign nationally
- Hosted the second PHARMAC Forum
- Piloted a campaign in the Bay of Plenty to promote awareness about generic medicines
- Reviewed and updated the Terms of Reference of the Consumer Advisory Committee
- Completed a project to examine the optimal way for consumers to participate in PHARMAC's activities

Learning from the past to meet future challenges

PHARMAC will remain focused on its core functions while responding to the challenges of an expanded role, writes Chair Stuart McLauchlan.

PHARMAC's world is expanding, with greater roles and responsibilities. In response to high-level reviews, the Government has given PHARMAC greater responsibility in the management of hospital pharmaceuticals, and decided it will eventually have responsibility for purchasing medical devices too. This recognises PHARMAC's record in meeting its objectives year after year. The challenge for PHARMAC now is to continue that record while also applying its considerable expertise to these new areas. It is a challenge that PHARMAC is prepared for, and willing to accept.

It's a privilege to be appointed chair of the PHARMAC Board. The staff and board at PHARMAC have created a culture of excellence and a history of achievement in the health sector. It has a considerable head of steam up and has the backing of the Government to take on new roles. It's also being looked to for advice on a range of issues across the health sector. My job, and that of my fellow directors, is to continue to provide the oversight and governance to ensure PHARMAC continues to meet its statutory objectives and Government's expectations.

I come into the Chair's role with PHARMAC having completed another successful year. The range of medicines available to New Zealanders continues to grow, and New Zealanders continue to have access to leading pharmaceutical technology.

The Government's decision to inject $40 million into pharmaceuticals in 2009/10 has played a significant part in this. Without the new funding, it would be difficult for PHARMAC to manage the budget and add new treatments. While PHARMAC is continuing to make savings on older medicines, the new funding gives greater 'headroom' for new funding investments and this has manifested itself in 20 new medicines being added to the Schedule, and 25 others having their access widened in 2009/10. These decisions further enhanced New Zealanders' access to medicines. PHARMAC again managed community pharmaceutical expenditure within budget, $693.8 million compared to a budget of $694 million.

There's more detail on these funding decisions from page 14 onwards.

Expanded role

A focus on its core role has been fundamental to PHARMAC's ongoing success. This was recognised during the year in two major Government reviews – the Ministerial Review Group, and the High Cost Highly Specialised Medicines Review. While both groups had different remits, when it came to looking at getting value for money from health technology, they drew similar conclusions. Both considered PHARMAC, or an organisation using PHARMAC-like methods, should take a greater role in assessing medical technologies. The Government has since acted on this advice, and given PHARMAC responsibility for managing all hospital medicines and, eventually, non-pharmaceutical medical technology (medical devices). PHARMAC Chief Executive Matthew Brougham writes more about this in the next article.

PHARMAC also has other parts of the health sector seeking its input. Last year this led to an increased PHARMAC involvement in community pharmacy contracting. One of the results of this was assisting DHBs to develop a method of paying pharmacists to support medicine brand changes. These recognise the work pharmacists put into counseling patients when a medicine changes brands and will be important to helping ensure patients adjust well when brands change.

Relationships

From what I have seen, PHARMAC is clearly an organisation that learns from past experience – reflecting on the past to work better in the future. PHARMAC now puts considerable energy into engaging with people who will be affected by its decisions, and who can provide input to the decision-making process. This is already the case with PHARMAC's community funding decisions, and policy development work. And it's likely to be a central part of the approach to hospital medicines activity over coming months. This makes good sense, and is welcome.

The second PHARMAC Forum in October 2009 underscored this improved approach to relationships and bringing external views into our decision-making. More than 100 people attended, and acknowledged the efforts PHARMAC has made to take on board external comments and incorporate them into its work. The Forum itself also presents an important opportunity to mix with a range of stakeholders face to face and give them an opportunity to provide their views to PHARMAC. While the format of future Forums may change, they will continue to form a central part of our business and be valued by those with an interest in our work.

The Forum also marked the beginning of a major piece of work that again underlined PHARMAC's commitment to improving stakeholder involvement in its work. This was a discussion paper on improving consumer participation with PHARMAC. Releasing the paper and seeking responses began a process which also included a review of the Terms of Reference for the Consumer Advisory Committee (CAC), and a process to refresh membership of the Committee. This also aligned with recommendations in Actioning Medicines New Zealand. Five new members were appointed to the CAC in July 2010.

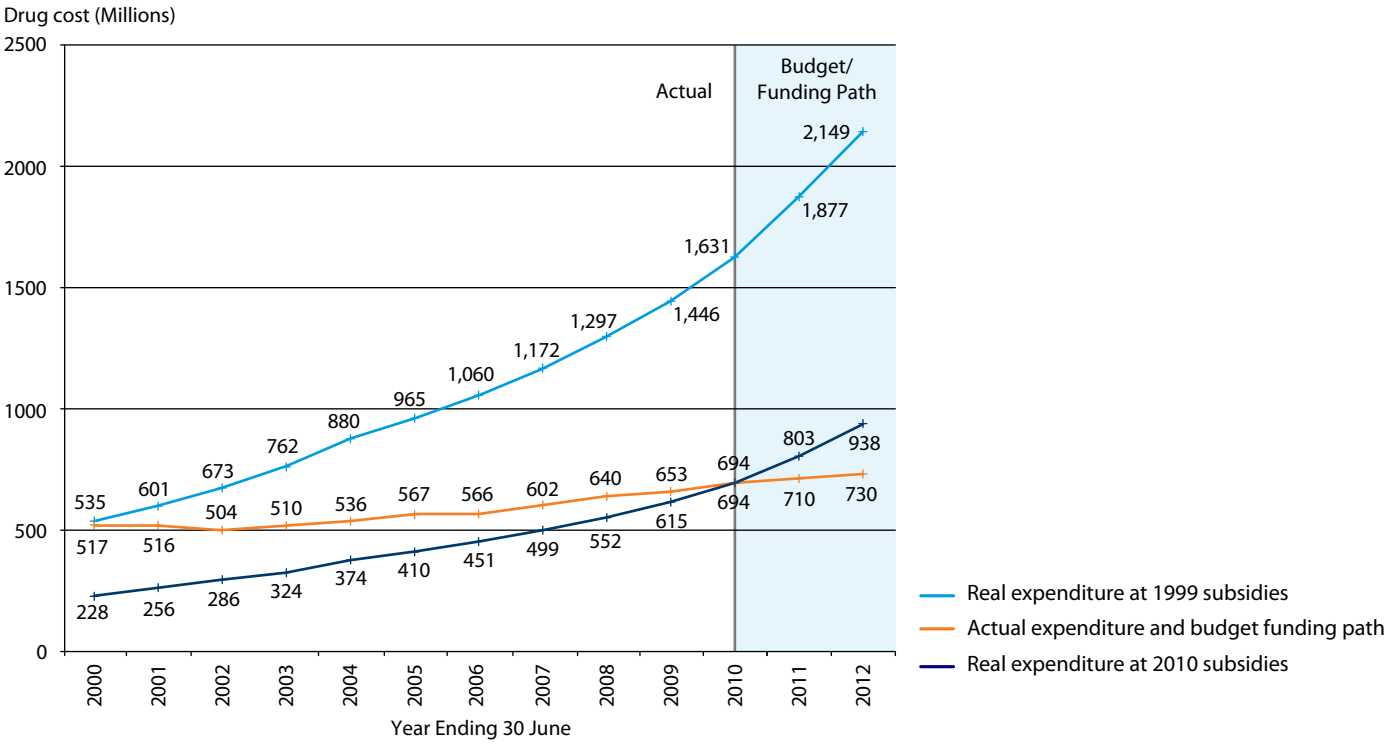
Front-line

Relationships are also a vital part of PHARMAC's Access and Optimal Use work. One of the success stories of the year has been the expansion of the flagship One Heart Many Lives (OHML) cardiovascular programme. OHML is moving from a regional-based programme to a more national footing with PHARMAC providing the foundation to enable this. Such activity puts PHARMAC right in the front-line of bringing people who might otherwise slip through the health system's cracks into doctors' surgeries.

As a relative newcomer to the PHARMAC Board, it has been enlightening to see the organisation in action close up. In succeeding Richard Waddel, I would like to pay tribute to the outgoing Chair's contributions to PHARMAC over the course of a decade. During this time PHARMAC has grown from a small team with a tightly-focussed remit to a somewhat larger (though still comparatively small) organisation with a much larger range of activities to manage. That it has done this successfully is due in no small part to the effective governance of the Board, led by Richard Waddel.

Another long-serving Board member, Adrienne von Tunzelmann, also concluded her term in July 2010. I would like to thank her for her service and contributions and wish her well. The Board has welcomed new members in Professor Jens Mueller of Waikato University, and Auckland paediatric surgeon Anne Kolbe. Their skills and knowledge in management and clinical governance are valuable additions to the Board.

Impact of PHARMAC on drug expenditure over time



Hospital medicines – more of the same… but different

The Government has given PHARMAC greater responsibility for purchasing medicines used in DHB hospitals. Chief Executive Matthew Brougham gives an overview of what PHARMAC will – and won't – be doing with hospital medicines

"We believe that significant increases in allocative efficiency across the health system can be realised by extending the decision-making framework based on methodical clinical and economic assessments, as exemplified by PHARMAC for example, to all health technologies."

Final report of the High Cost, Highly Specialised Medicines Review Panel, April 2010 (p29)

It's been a notable year for PHARMAC, with a succession of high-level reports concluding that PHARMAC's work in managing community medicines has been a success and that this role should be extended. The Government has now responded to the Ministerial Review Group report, and given PHARMAC responsibility for managing all hospital medicines and – ultimately – non-pharmaceutical medical technology (medical devices). A great deal of trust has been invested in PHARMAC.

It's natural to be a little fearful of change, and as we move more into taking responsibility for hospital medicines, I'm hearing about people's fear of how the "PHARMAC Model" will impact on hospital clinicians; how it might limit choice and slow access to new pharmaceutical technologies. But what is the "model" they are talking about? What part of the PHARMAC business is causing this uncertainty and misgiving?

To know how we are likely to approach hospital medicines, it's useful to first give an overview of the approach we take to community medicines. I sometimes hear that PHARMAC is just intent on "tendering everything"; on taking a one-size-fits-all approach to pharmaceutical contracting, but this isn't the case. Our approach in recent years has been more about horses for courses – adapting our approach to suit the situation.

Here are the components that fundamentally make up the PHARMAC model:

- Simple, clear, non-conflicting objective (as outlined in legislation)
- A culture of budget observance, treating the budget as binding
- A clear method to budget management
- Promoting competition
- Dispassionate clinical and economic appraisal of new technology
- Process for dealing with the exceptions

Simple, clear objective

PHARMAC's legislative objective:

*"To secure for eligible people in need of pharmaceuticals the **best health outcomes** that are reasonably achievable from pharmaceutical treatment and from **within the amount of funding** provided"*

NZ Public Health & Disability Act 2000

PHARMAC is equally focussed on managing the budget AND obtaining best health outcomes. In short, it's about minimising opportunity costs.

A binding budget

The budget is a finite amount of money and belongs to District Health Boards. A constrained funding environment disciplines us to make the best choices possible. PHARMAC is proud of its record of never having overspent the allocated pharmaceutical budget.

A clear method

PHARMAC's approach to budget management involves knowing how much funding is available, how much is already allocated (forecasting), then using nine decision criteria to free up funding (same health gains, lower spending) and invest in new technologies (purchasing new health gains).

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

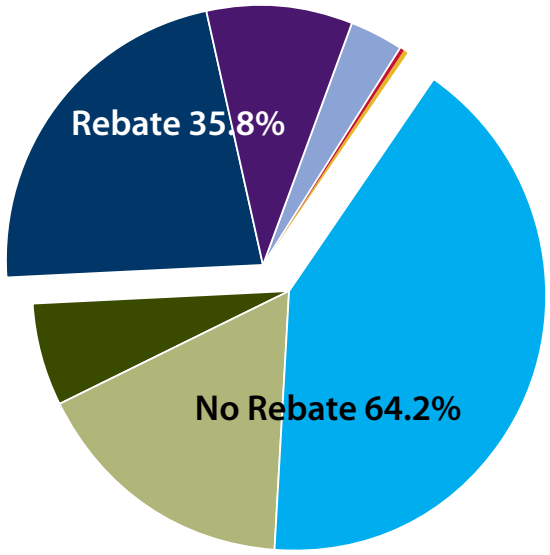
> The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Schedule

> 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.

Pharmaceutical Schedule contracts by value



- No rebate - On contract, 41.3%
- No rebate - On Tender, 16.7%
- No rebate - No Contract, 6.2%
- Rebate - Lower subsidy, 22.5%
- Rebate - Expenditure cap, 9.3%
- Rebate - Average daily cost cap, 3.2%
- Rebate - Exchange rate adjustment, 0.5%
- Rebate - Where treatment unsuccessful, 0.3%

Promoting competition

Put simply, without competition we wouldn't be able to meet our legislative objective. Over the years the number of companies active in New Zealand has grown, particularly those who supply off-patent medicines. Our tender has been central to achieving better competition, and lower prices. In our most recent round, 41 companies won tenders.

When it comes to contracting for pharmaceuticals, we have a range of tools available. Tendering is one of them – but it's not the most-used. In fact by value, tenders source just 17% of all medicines on the Pharmaceutical Schedule.

Tendering is already used extensively in hospitals, to set national prices for off-patent medicines, so its effects are already well-known to hospital clinicians and pharmacists.

We'll be thinking carefully about which of our contracting tools is the right one to use in any situation, and we are already doing this. An example is around how we have treated blood glucose meters and testing strips in the community. Through running various competitive processes since 2005, we have grown the range of meters and test strips from one fully funded meter, to seven meters and six brands of test strips. And while the range has grown savings have also been made.

Dispassionate clinical and economic appraisal

Committees of expert clinicians, led by those on the Pharmacology and Therapeutics Advisory Committee (PTAC), provide the bedrock clinical advice for our decisions. We will be adding a hospital advisory committee to the PTAC subcommittees, to look exclusively at new hospital technologies. For economic evaluation we use cost-utility analysis, the `gold standard' for health technology appraisal.

Dealing with exceptions

We're currently reviewing the Exceptional Circumstances schemes. Many hospitals already have policies to deal with how to access medicines not on the approved formulary. How we deal with this issue will be central to the success of the hospital project.

Adapting our approach to hospitals

Our method for managing community expenditure and history of successful budget management has led the Government to expand our role. But you're only as good as your last decision and we're always looking for ways to improve. While our approach in the community has been successful, things are likely to be done a little differently in hospitals.

The buzzword in the sector is all about engaging with clinicians, and nowhere is this more true than around the hospital project. Without the support of hospital clinicians success of this project will be difficult to attain – so we are treading softly. Our success will depend on good collaboration with clinicians and on how we manage exceptions, and the degree of discretion given to clinicians to do that in the hospital setting.

I don't believe we're going into hospital medicines to make savings. It's likely that over time there will be savings, but that's not the critical issue at the outset. What is most important is making sure the opportunity to access medicines is nationally consistent, and that we get rid of the phenomenon known as postcode prescribing. If we can do that, have the support of clinicians and help better manage national spending on hospital medicines, those will be true measures of success.

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)

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

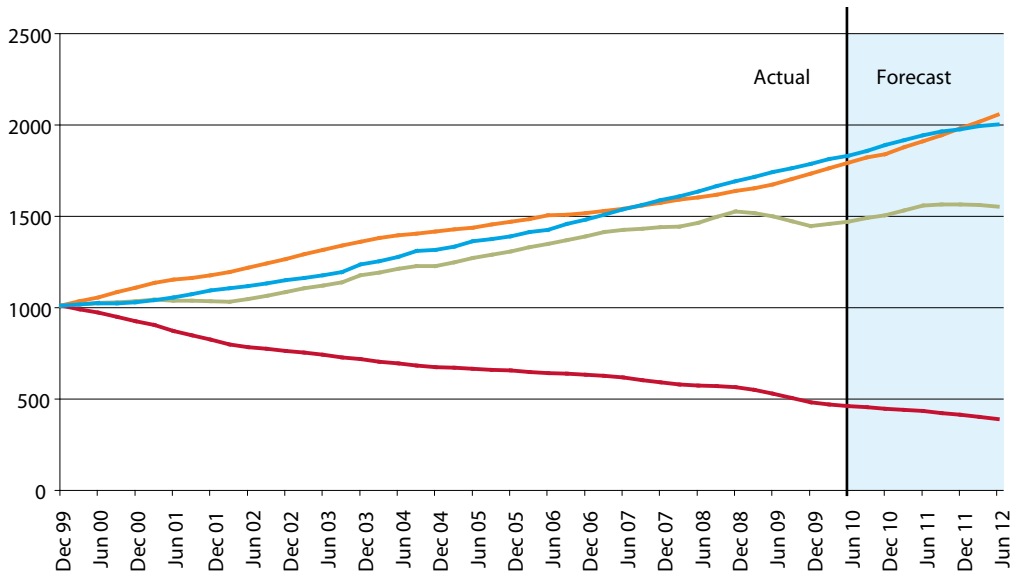
Subsidy, volume, mix and cost indices

Four-quarterly moving averages

Base: four quarters ending Dec 1999 = 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.



View from the front-line

Gaps in Māori access to better health

Dr Lance O'Sullivan MBChB FRNZCGP, Te Rarawa, Ngāti Hau, Ngāti Maru, works in general practice in New Zealand's Far North.

Māori and Pacific peoples' health lags behind the levels other New Zealanders take for granted. Diseases like rheumatic fever are now rare amongst European New Zealanders, but remain a significant problem for Māori and Pacific peoples whose levels of the disease equate to those of European New Zealanders almost a century ago.

I believe the gaps are largely social, which lead to bad health outcomes. The issues are well-canvassed: poverty, lack of jobs, high smoking rates, lack of education, and poor housing; people who don't have a telephone, or a car, or can't afford the $3 prescription fee.

My patients come from two contrasting communities: retired couples living in lovely houses near the beach on the east coast; and then the grinding deprivation in places like Kaitaia. The two communities' needs are disparate, yet both communities get the same health funding.

New Zealand's lower socioeconomic groups are largely Māori and Pacific peoples. I'm not advocating the funding of more medical care; instead the 'big ticket' determinants of health need to be addressed: better education will result in better jobs, homes and economic circumstances. It's relatively easy to explain diabetes to an educated patient on an above average income who can afford the costs associated with managing their condition. This job is much harder when the patient is uneducated, when I need to spend half the consultation filling in WINZ forms.

Designing care to meet needs

Primary care has an important role: culturally unsafe medical institutions and access issues deter Māori patients from visiting the doctor, so they wait until they're really sick, which ultimately costs the health system more. High-risk communities have greater needs, including earlier access to medical advice, interventions and treatment.

I'm in favour of developing culturally acceptable medical establishments, with respect and understanding for Māori and Pacific peoples' languages and values. This would go a long way to bring Māori and Pacific peoples' health statistics in line with other New Zealanders. Māori doctors represent 3.5% of the doctor total, yet Māori are 15% of the whole population; and 25% of the unwell are Māori. I'd like to see more brown faces in the health workforce: physiotherapists, pharmacists, nurses and – of course – GPs. If every New Zealander spoke Māori and had an appreciation for Māori culture it would foster better understanding and ultimately better health outcomes; something as simple as the correct pronunciation of a patient's name makes a lot of difference to the feeling of being in a safe environment.

Targeting

It's not about spending more; it's all about targeting the communities needing extra help. I've been closely involved with One Heart Many Lives, an awesome PHARMAC initiative that's been successful because of its focus on local people delivering culturally appropriate health messages from their own experiences.

It's easy for people to congratulate themselves about all the political initiatives, but the reality is that – despite decades of targeted health programmes and political will – Māori and Pacific people's health is getting worse, not better. Māori have provided some great leaders at local and national level, right back to the early 20th century with leaders of calibre like Sir Maui Pomare and Sir Peter Buck who were both doctors and politicians. There are plenty of examples today, but it's a challenging, hostile and exhausting field in which I work every day.

Genes or environment?

The big health issues for adult Māori are cardiovascular risk, diabetes, and smoking; children's health problems encompass respiratory problems, infectious diseases, rheumatic fever, impetigo, cellulitis and pneumonia. Some of these can be tackled by providing better access to medical care – not just doctors, but also nurses and community workers; some of the work doesn't require a doctor so we could train non-medical people to do specific programmes around cardiovascular screening, education and health promotion.

There's been a lot of debate about Māori and Pacific peoples' vulnerability to disease; what's really significant is these people all share similar situations: poor housing, overcrowding, poverty and lack of education. I also believe there is a certain amount of racism (overt and subtle) in our health system that directly impacts on health outcomes and perpetuates inequalities.

It's just too easy to blame poor gene pools, absolving people from addressing the real causes. Rheumatic fever is an important example where similar circumstances rather than genes contribute to poor health outcomes. In 2006, Māori accounted for 62% of rheumatic heart cases, with 89% of those affecting people under the age of 20. It's unacceptable that our Māori and Pacific youth carry a third world burden of a preventable disease. If medical care was more accessible then the unwell could afford to see their doctors more often; that would make a big difference to the cardiovascular and diabetes statistics. Let's bring some equality to socioeconomic determinants, ensuring people with high needs, known health issues, and higher rates of disease get free access to doctors and medications, moving them higher up the health priority list in addition to helping them become educated so they can get better jobs which, in turn, will give them a more positive outlook on life. It's disgraceful that we need to justify providing more health services to Māori and Pacific peoples; it's not a race-based issue; it's risk-based.

These deprived people just exist, with no hope of escape; jobs need to be created and we need to ensure their children get a decent education. New Zealand can't afford to increase the size of its health spending, so it's time to reallocate it; focusing on those who need more help, so the less fortunate can gain some parity in all aspects of society, leading to a vibrant, healthy and proud country. Then the gaps would close, from both sides.

PHARMAC's contributions to improving Māori health

Māori Responsiveness Strategy Te Whaioranga – the strategy was developed with community input and identifies Māori health priorities for PHARMAC to focus on, and actions for PHARMAC to take to improve the way it thinks about and responds to Māori health needs. Actions have included appointing Māori members to the Board and advisory committees, and making better use of data to analyse Māori health need.

He Rongoa Pai He Oranga Whanau – a programme to improve Māori uptake of medicines, increase awareness of safe and appropriate use of medications, promote medications as part of managing overall healthcare, and includes a component on Rongoā Māori.

One Heart Many Lives – This programme promotes awareness and action in response to high rates of heart disease. Māori men die on average up to 10 years younger than other New Zealand men. Māori men aged 35 and over are among the programme's target audience.

Space to Breathe – He Tapu te Hā – Space to Breathe promotes the optimal use of asthma inhalers by children with asthma. Māori children are more likely to present in hospital with asthma symptoms, or to die from asthma than non-Māori. The pilot of the programme was developed in conjunction with Taranaki Māori health providers, and delivered through kōhanga reo.

Workforce development – PHARMAC and the Otago University school of pharmacy developed the Hiwinui Heke scholarships to promote pharmacy as a career option for Māori.

PHARMAC's decision criteria – Māori health need is taken into account every time PHARMAC makes a pharmaceutical funding decision.

Let's get smarter about pharmacy services

Sharon Kletchko

MD FRCPC FRACP FACEM AFACHSM

Canadian born and trained specialist physician Dr Kletchko has worked in New Zealand's public and private health system for more than 25 years. She is now General Manager, Strategy and Planning at Nelson Marlborough DHB and is well known for her active leadership and involvement at all levels in the New Zealand health system.

Every silver lining has a cloud – New Zealanders' increased access to pharmaceuticals has led to better care, but also to a consequential increase in dispensing costs. These pharmaceutical distribution costs now account for 9% of District Health Boards' (DHBs') services delivery budgets, around $350 million per annum – half as much again as the actual cost of buying pharmaceuticals. The rate of increase in distribution costs exceeds the rate of increase for pharmaceutical costs (as illustrated in the graph [opposite, below]). That's hardly surprising, as the increase in distribution costs is certainly in line with international trends, with more people taking medicines, new technologies, more targeted therapies due to genetic discoveries, and new – often very costly – drugs for conditions formerly considered untreatable; but this progress comes with a big price.

New Zealand is now coming out of the worst global recession seen for decades and PHARMAC has done a brilliant job in widening access to pharmaceuticals, using new money provided by the Government and the savings it achieves on older medicines.. Despite the Government's increased health spending, DHBs have spending constraints; yet are faced with increasing costs as they pay for dispensing more drugs. This increase in patient access is helped by the Government's decision to increase spending on medicines, lower patient co-payments, and the increase in numbers and types of community prescribers (which, in addition to junior and senior doctors and dentists, now includes midwives and nurse practitioners).

PHARMAC's decision criteria remain robust for managing the overall cost of funding pharmaceuticals. However, managing pharmacists' expectations – and the understandably constrained DHB funding levels – remain major concerns of DHBs. This is compounded by the increasing cost resulting from increases in the volume of medicines being dispensed. DHBs pay for this increasing volume through the dispensing fees claimed by community pharmacists.

Many threads

There are many threads in this complex story; some – like the co-payment fee – are governed by statute, others by contract. Pharmacists are paid a fee by DHBs for every prescribed medicine dispensed as part of the contract agreed with DHBs. The mathematics are simple: the more prescriptions pharmacists dispense, the more they earn. It's a concern that the growth in dispensing costs (which covers the pharmacist reading the scripts, organising the medicines, and – ideally – counselling patients) is much greater than the growth in DHB-funding; the taxpayer funds both, and – of course – every dollar spent on dispensing is a dollar not available for other health services.

Some drugs, thanks to PHARMAC, now only cost pennies per tablet but once the distribution costs, consultation fees and dispensing fees are factored in, they actually cost the taxpayer around $45. Of course, in most circumstances, the patient is insulated from this cost and only pays the $3 co-payment for three months' supply of medicines hugely subsidised by the Government, through DHBs.

A focus on value

It's in all our interests – taxpayers and those in the health sector – to get maximum value for taxpayers' dollars by ensuring drugs are prescribed for those who'll gain the most benefit. This precise targeting of benefit, however, does not currently apply for most drugs, which are often used more widely. So to focus on getting better value; more proactive and evidence-based targeting is essential.

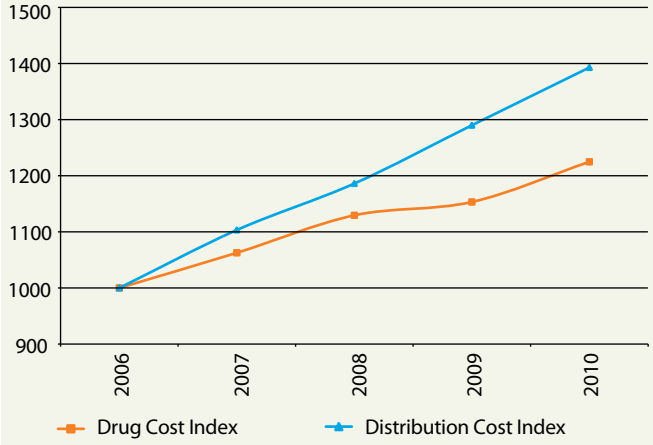
We've also got to get smarter. At present, the funding rules for about 60% of medicines on the Pharmaceutical Schedule allow doctors to prescribe them to almost any person; that's not sustainable and may have to be reviewed, including possible expansion of the use of Special Authorities to restrict the use of some medicines. A lot of money is wasted on drugs that aren't necessarily beneficial; I'd suggest it's time to follow the model used for antibiotics where PHARMAC challenged GPs to provide medical care for colds and 'flu without writing a script. That's been a huge success, limiting the use of antibiotics for times when they're really needed.

Progress

We've made progress. As part of the current Community Pharmacy contract, DHBs are trialing the funding of pharmacists for some 'brand switching'; recognising pharmacists' skills in patient relationships, which should lead to fewer problems over compliance and an increase in the best use of medicines. Pharmacists need

Growth in pharmaceutical and dispensing costs (base = 1000).

The graph illustrates that, over the last five years, the cost of distributing medicines (dispensing fees and markups) has been growing faster than the cost of purchasing medicines (ex-manufacturer drug cost).



better access to prescribers; at present, they can spend an inordinate amount of time trying to contact doctors.

There have been some excellent initiatives, including one in Taranaki where pharmacists took over the management of patients on warfarin – a blood-thinning drug that requires regular monitoring and adjustment of dose; the pharmacists started doing the tests, freeing up the doctors for other work. It's an example of things pharmacists can do just as well, or maybe better than the GPs, because of the issues around doctor availability.

Community pharmacists are the first health access point for many; contributing to patients' health and the well-being of their local communities. Their role is crucial; far wider than simply dispensing medicines. Pharmacists are a safety net: experts in assisting patients' management of medicines, monitoring compliance and adherence issues (pharmacists are the first to know when patients don't collect their scripts) and delivering important preventative messages on issues like smoking.

Changing the incentives?

Pharmacists have a wealth of expert knowledge, often knowing more about the science of drugs and their interactions, the optimal use of medicines, and keeping people safe – especially these days, when patients often have complex, interacting medicine regimens. That's something we haven't, to date, incentivised.

We have to think of different ways of working together, focusing on what makes an effective community pharmacy: safe and efficient work systems, their role in the safe use of medicines, better use of expert clinical human resources, safeguarding communities against harmful medicines (and combinations), and showing leadership as well as dispensing medicines.

Better use of pharmacists will lead to better use of pharmaceuticals, which – in turn – will deliver improvements in the health and well being of New Zealanders. So it's important we maximise community pharmacists' value, by encouraging them to be innovative, embrace new developments and technology; and using their knowledge and skills.

It's not just the cost. Pharmacists can really help ensure the New Zealand health service achieves its goals – better health for everyone. The pharmacists' role needs to be better recognised as a crucial part of primary health care, as the access point to the health system, and become more effective – that's the crux of the mixture of issues around community pharmacy.

The PHARMAC value proposition

Spend a dollar to make a dollar. Or in PHARMAC's case, spend a dollar to save many more.

PHARMAC has proven its worth to the New Zealand health system over the years by regularly producing much more in savings than it costs to operate the agency. The savings PHARMAC makes from its negotiations on pharmaceutical prices far outstrip the amount it costs to run the organisation.

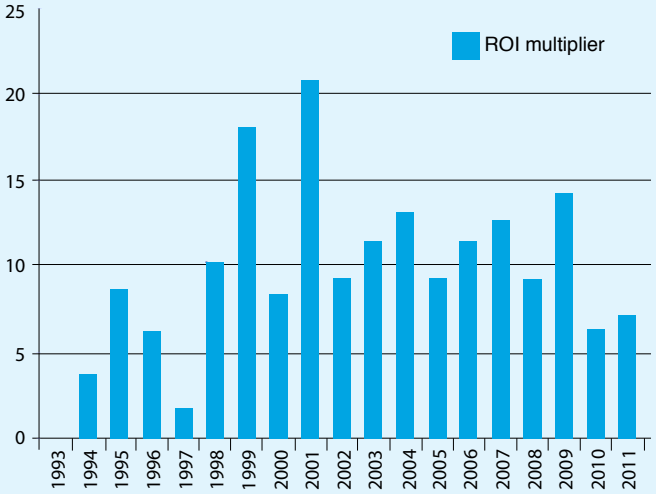
In fact, over the past 10 years, PHARMAC has made annualised savings of up to 20 times the investment in PHARMAC.

We call this ratio of operating budget to savings achieved our `return on investment multiplier'. It is a raw comparison of the cost of keeping PHARMAC operating (our operating expenditure) with the full-year impact of savings transactions from that year. Operating expenditure includes all PHARMAC activities including those not related to pharmaceutical funding (such as our Access and Optimal Use programmes). And the savings figures are only for the first full year (not future years, which the savings continue into). If we were to include these factors, the multiplier would be higher.

The pattern since 1993 is illustrated in the graph. We had a particularly good year in 2001, but since 2000 PHARMAC has regularly achieved savings more than 10 times its operating budget.

The savings PHARMAC achieves in pharmaceutical prices are available to be reinvested into other health services, including new pharmaceuticals. This gives District Health Boards, the fund-holders, spending options they wouldn't otherwise have.

ROI multiplier for return on operating expenditure



Wishes for the future

Reflections on how to improve drug use

Dr Curt D Furberg

Curt D. Furberg, MD, PhD is Professor of Public Health Sciences at Wake Forest University School of Medicine, in North Carolina USA. Dr. Furberg is an internationally recognised cardiovascular epidemiologist with expertise in clinical trials and public health. Dr Furberg joined Wake Forest University School of Medicine in January 1986 where he started the Center for Research and Biometry. He is currently Senior Advisor to the Dean for Health Services Research and Health Policy.

The discovery, development and marketing of a large number of prescription medicines by the pharmaceutical industry have clearly benefited individuals, as well as whole groups of patients. Many of these medicines have improved patient care, and provided effective treatment alternatives for a number of diseases and conditions. Effective pharmacologic treatment can alleviate troubling symptoms, improve quality of life, cure acute conditions, reduce chronic disease complications and even prolong life. Such steady progress, supported by a successful pharmaceutical industry, has been an overall benefit to society.

Unfortunately, these impressive advances are partially offset by two important realities. First, nearly half of all patients do not receive optimal treatment for their condition. Second, all medicines have potential negative or adverse effects, some very serious. It has become clear over the past few decades that the process of informing consumers and prescribers about these undesirable effects needs to be improved. The public has the right to be fully informed about both a medicine's potential benefits and its potential harm.

This report will highlight four areas that could – and should – be addressed and improved. The ultimate beneficiaries will be the recipients of therapeutic drug products around the world.

1. Pay more attention to safety evaluations

There is a striking asymmetry between efficacy and safety in the drug evaluation process. The pre-approval studies documenting beneficial effects for any new medicine are relatively thorough. This information is critical for the regulatory approval process and the subsequent marketing of new drugs.

Experience has shown that regulatory approval of a medicine is no guarantee of its safety. Four types of adverse events are difficult to detect during the approval process: rare, late, or unexpected events, and those similar to disease symptoms or complications. Detection of such adverse events requires large and/or long-term studies, which may not be conducted until well after the medicine has been marketed – or, once a drug is marketed, may not be conducted at all.

One reason why rare adverse events are not detected during the pre-approval process is that required pre-approval studies are too small, as events occurring at a rate of one in 1,000 are seldom detected.

Late events may not be detected because the studies are too short. For many medicines intended for life-long use it may take years before an adverse event manifests itself.

Unexpected adverse events are hard to detect; it is difficult to find something when no one is looking for it.

Adverse events similar to events linked to the disease being treated are obviously difficult to attribute to a medicine.

There are several possible solutions to the problem of not detecting adverse events. Pre-approval studies need to be larger and of longer duration, as a drug's safety profile should be known with high probability at the time of regulatory approval. In addition, proactive assessment of a drug's safety should continue while a drug is on the market. Other countries should follow New Zealand's Intensive Medicines Monitoring Programme (IMMP) model, which monitors the first users of a new drug after marketing. This programme proactively collects safety information from users, in contrast to the systems in the US and other countries that are

passive and voluntary. As a result, there are massive underreporting and serious delays in detecting safety problems, as recently demonstrated by the rosiglitazone (Avandia) tragedy. Avandia, a drug developed to treat diabetes, was withdrawn in some countries during 2010 after its use was linked to an increased risk of heart disease.

2. Leave education about drugs to independent experts

Much of today's postgraduate drug education is controlled by the pharmaceutical industry. This is an obvious conflict-of-interest; manufacturers cannot be expected to offer fair and balanced presentations on drugs from which they will profit.

Medical schools should be responsible for the pharmaceutical education of healthcare professionals who, in turn, should educate patients. Direct-to-Consumer advertising, only allowed in the US and New Zealand, has been shown to influence drug utilisation in an unfavourable way in the US. Governments have a crucial role and responsibility to ensure a level information playing field for both patients and health professionals. Pharmaceutical industry promotional meetings at expensive restaurants and fancy resorts should be disallowed, along with other promotional activities such as free trips to international meetings, excessive consultancy agreements and speakers' tours.

3. Limit prescribers' involvement in marketing efforts

Multifaceted interactions between doctors and the pharmaceutical industry can be productive, and sometimes necessary. Doctors/scientists and medical institutions play an important role in the evaluation of the benefit and safety of new medicines. Independence is critical.

On the other hand, prescriber involvement in marketing programmes represents a major problem area. Doctors work with the industry's sales forces to increase the use of a particular product, in return for often excessive payments. This promotion is typically one-sided – with a major focus on benefits – and may undermine the use of alternative treatments. Additionally, it contributes substantially to the prescription of expensive patented medicines. Patients are rarely told their doctors are paid consultants to the company manufacturing the drugs they are being prescribed. From an ethical and medical perspective, prescribers should sever any financial interests in the drugs that they prescribe.

4 Drug development should focus on new and better prescription medicines

Obviously the pharmaceutical industry needs to make a profit, but this objective has led to an over-development of new drugs offering no benefits over existing medicines. These are referred to as 'me-too' drugs or 'copy cats'. Regrettably, this category applies to most drugs approved today, which offer no advantages for patients or society. Since they are new, they have patent protection and an accompanying high price tag.

There is no doubt society needs new drugs that are more beneficial and/or safer than existing ones. The development of such medicines is a challenge to industry, yet that is how medicine progresses. There is a need to limit the number of drugs within a particular drug class, as we do not need a fifteenth ACE inhibitor… or do we?

Regulatory agencies should limit the number of approved drugs within a drug class. The landmark Kefauver Bill of 1962 strengthened the role of the US Food and Drug Administration in the drug approval process by, for example, requiring new medicines be safe and effective. Interestingly, it also proposed patent protection only be granted to drugs shown to be therapeutically superior to existing agents. Alternatively, the incentive for industry to produce an excessive number of 'me-too' drugs could be limited by instituting some form of strict price control.

If these wishes for the future were to come through, fewer unsafe medicines would make it to the market. The promotion of medicines would be more balanced and evidence-based, which ultimately would improve the quality of patient care. Curtailing prescribers' involvement in marketing would have a similar end result. Finally, a push for more beneficial and/or safer medicines would benefit all parties – patients, doctors, society and eventually the pharmaceutical industry itself.

Review of expenditure 2009/10

Key figures

> **$693.8 million** – community pharmaceutical expenditure *(on budget)*

> **$37.1 million** – number of prescriptions funded *(5.0% increase)*

> **3.2 million** – number of New Zealanders receiving funded medicines

> **$41.5 million** – amount of savings achieved

> **20** – number of new medicines funded

> **25** – number of medicines with access widened

> **149,000** – number of additional patients benefitting from these decisions in a full year

Keeping pharmaceutical spending on budget, funded prescriptions rising to record levels and a big jump in the number of new patients benefiting from funding decisions were the major stories of the year.

The year-end spending figure of $693.8 million was nearly on the budget mark of $694 million. This was a significant achievement given a 5% increase in the number of prescriptions funded. Rising prescription numbers are a major driver of pharmaceutical expenditure. The 5% increase is in line with the pattern seen in past years and was also foreseen in PHARMAC's forecasting model.

The number of New Zealanders receiving funded medicines rose to 3.2 million. Again, this is the highest number recorded by PHARMAC and reflects the increased number of medicines funded in past years, combined with the Government's decision to lift pharmaceutical spending by $40 million this year. New funding, plus the flow-on effect of PHARMAC's saving-related activity from previous years, provided the opportunity to fund 20 new medicines and widen access to 25 others.

The Top 20 Expenditure Groups

Year ending 30 June

$ millions, cost ex manufacturer, excludes rebates and GST

Drug Type	Main Use	2005	2006	2007	2008	2009	2010
Antipsychotics	Mental health (psychoses)	$48.59	$53.45	$57.13	$60.58	$61.61	**$66.07**
Lipid Modifying Agents	Raised cholesterol (cardiovascular risk)	$60.82	$68.19	$68.86	$66.06	$63.48	**$37.85**
Agents Affecting the Renin-Angiotensin System	Raised blood pressure (cardiovascular risk)	$29.12	$26.08	$29.10	$29.94	$31.19	**$34.45**
Inhaled Long-acting Beta-adrenoceptor Agonists	Asthma	$18.65	$21.65	$19.34	$23.25	$27.84	**$31.83**
Diabetes	Diabetes	$20.60	$22.51	$26.34	$29.36	$31.06	**$30.06**
Antirheumatoid Agents	Arthritis	$3.94	$5.39	$9.14	$11.23	$15.94	**$28.36**
Chemotherapeutic Agents	Cancer	$11.32	$13.65	$16.62	$21.12	$23.36	**$26.21**
Antiepilepsy Drugs	Epilepsy	$21.40	$24.80	$27.85	$24.62	$25.90	**$24.93**
Antidepressants	Mental health (depression)	$27.33	$29.71	$30.65	$20.81	$22.26	**$24.19**
Beta Adrenoceptor Blockers	Heart disease	$17.58	$21.27	$24.52	$29.29	$32.01	**$23.31**
Analgesics	Pain relief	$14.52	$15.69	$17.23	$18.86	$21.19	**$23.04**
Diabetes Management	Blood glucose monitoring	$19.51	$16.28	$17.12	$19.03	$19.80	**$21.18**
Immunosuppressants	Organ transplants, arthritis	$13.37	$13.94	$14.50	$15.95	$17.27	**$17.89**
Calcium Homeostasis	Osteoporosis	$9.83	$11.84	$13.56	$15.36	$16.36	**$17.28**
Antibacterials	Bacterial infections	$13.94	$13.88	$14.80	$15.47	$16.38	**$15.59**
Antiretrovirals	HIV/AIDS, viral infections	$8.88	$10.37	$11.59	$12.34	$12.97	**$14.53**
Inhaled Corticosteroids	Asthma	$17.50	$16.87	$16.20	$15.17	$14.46	**$14.21**
Inhaled Anticholinergic Agents	Allergies	$6.60	$8.29	$8.74	$10.47	$12.25	**$13.34**
Calcium Channel Blockers	Heart disease	$13.02	$13.68	$14.47	$16.02	$16.32	**$13.32**
Trophic Hormones	Cancers, inadequate growth	$10.82	$11.71	$10.66	$9.53	$12.23	**$12.31**

Significant decisions during the year included:

> **bosentan, iloprost, sildenafil** – treatments for the respiratory condition pulmonary arterial hypertension

> **bupropion** – a newly funded treatment for people wanting to stop smoking

> **dasatinib** – new treatment for people living with chronic myeloid leukaemia

> **raltegravir** – a new antiviral treatment for people with HIV/AIDS

> **adalimumab** – accessed widened to this biologic drug to treat a range of autoimmune conditions

> **rituximab** – access widened so it can also be used to treat non-Hodgkin's lymphoma

> **gemcitabine** – wider access to this cancer drug so it can also be funded to treat Hodgkin's disease and T cell lymphoma.

These decisions, and others, are discussed in greater detail on the following pages.

Two of PHARMAC's decisions related to products for smoking cessation, which support a Government health priority. Previously nicotine replacement therapy (NRT) was only available through the Quit Card programme run by the Ministry of Health. PHARMAC took on funding for NRT and the prescribing rules were changed to enable doctors to prescribe NRT, in addition to its availability through the Quit Card programme. This made NRT treatment easier for people to get when they want to give up smoking. Further assisting people's efforts to quit smoking, PHARMAC also funded the smoking cessation treatment bupropion (Zyban), helping a further 24,000 people in the first full year of funding. The smoking cessation-related decisions during the year were those that PHARMAC estimates will have the greatest impact on health outcomes in future years.

Another significant decision with implications for greater health outcomes was the widening of access to adalimumab (Humira) for autoimmune conditions.

Details on the estimated health gains from these decisions is published in PHARMAC's Annual Report.

PHARMAC's activity wasn't confined to providing greater access to medicines. Savings-related activity also continued to be important. The year saw PHARMAC complete competitive processes that led to some of the highest savings (in percentage terms) that PHARMAC has achieved. Chief amongst these was a price reduction of over 90% for the diabetes treatment pioglitazone, which enabled access to it to be widened. There were also major savings achieved on the heart drug metoprolol ($65 million saving over five years) and the aromatase inhibitors hormonal treatments for breast cancer ($10.3 million over five years).

Top 20 Medicines by ex Manufacturer cost *(excl GST and rebates)*

		Treats	Year Ending June 2010
1	Olanzapine	Psychosis	$29,440,000
2	Atorvastatin	Raised cholesterol	$24,850,000
3	Adalimumab	Autoimmune disease	$24,240,000
4	Glucose dehydrogenase	Diabetes	$20,440,000
5	Imatinib mesylate	Leukemia	$17,390,000
6	Budesonide with eformoterol	Asthma	$16,160,000
7	Metoprolol succinate	Heart disease	$15,310,000
8	Venlafaxine	Depression	$14,650,000
9	Quetiapine	Psychosis	$14,130,000
10	Risperidone	Psychosis	$14,030,000
11	Candesartan	Heart disease	$11,710,000
12	Pegylated interferon alpha-2a	Hepatitis	$11,480,000
13	Nicotine	Smoking cessation	$11,350,000
14	Fluticasone	Asthma	$11,180,000
15	Fluticasone with salmeterol	Asthma	$10,570,000
16	Alendronate sodium	Osteoporosis	$10,390,000
17	Sodium valproate	Epilepsy	$9,810,000
18	Erythropoietin beta	Anaemia	$9,390,000
19	Omeprazole	Reflux	$9,310,000
20	Tiotropium bromide	COPD	$8,390,000

Top 20 Medicines by Prescription numbers

		Treats	Year Ending June 2010
1	Paracetamol	Pain	2,090,000
2	Aspirin	CV risk	1,370,000
3	Simvastatin	Raised CHD	1,310,000
4	Omeprazole	Reflux	1,020,000
5	Amoxycillin	Bacterial infection	980,000
6	Metoprolol succinate	Heart disease	870,000
7	Amoxycillin clavulanate	Bacterial infection	800,000
8	Salbutamol	Asthma	800,000
9	Diclofenac sodium	Pain	620,000
10	Cilazapril	Heart disease	590,000
11	Zopiclone	Insomnia	560,000
12	Ibuprofen	Pain	540,000
13	Prednisone	Steroid	530,000
14	Flucloxacillin sodium	Bacterial infections	480,000
15	Quinapril	Heart disease	420,000
16	Bendrofluazide	Heart disease	420,000
17	Felodipine	Heart disease	410,000
18	Alendronate sodium	Osteoporosis	410,000
19	Metformin hydrochloride	Diabetes	400,000
20	Fluticasone	Asthma	400,000

Review by Therapeutic Groups 2009/10

Infections

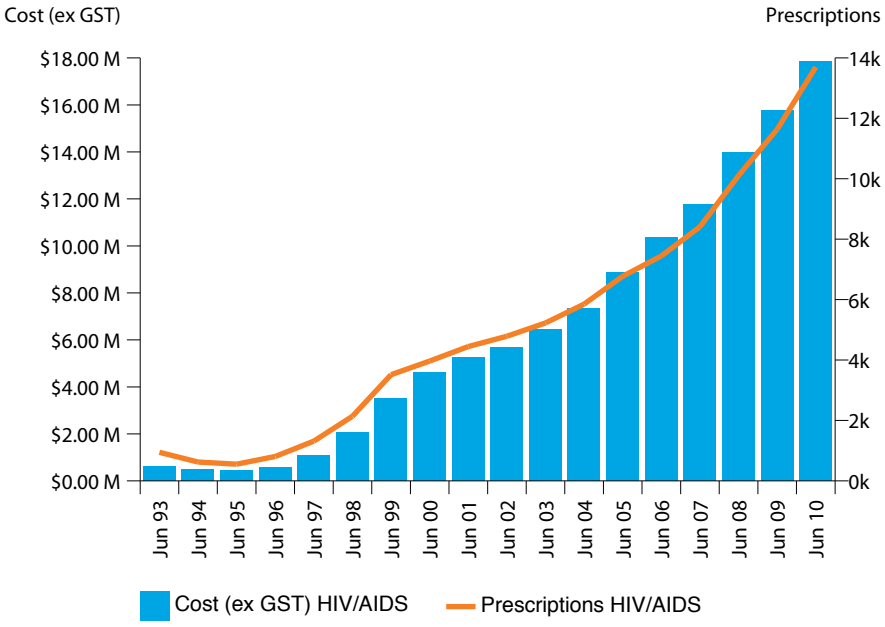
PHARMAC made further decisions this year to fund new treatments and widen access to others for infections such as hepatitis and HIV. This included listing raltegravir (Isentress), the first in a new class of HIV medicines to treat the infection that causes AIDS. Spending on HIV treatments continued to grow, reaching almost $18 million in the financial year, for approximately 1200 patients. Growth in spending and prescription (and patient) numbers reflects the improved treatment of HIV that sees more people with the disease living longer.

PHARMAC estimated up to 240 patients per year with hepatitis B would benefit from a decision to fund entecavir as a first line treatment under Special Authority criteria. Entecavir has lower rates of resistance to hepatitis B than other treatments, even after years of treatment.

PHARMAC also widened access to tenofovir, a treatment for drug resistant chronic hepatitis B and HIV/AIDS. The decision was estimated to save $350,000 due to a reduction in the use of other, more expensive treatments.

Azithromycin is an antibiotic previously funded only for some sexually-transmitted infections. In 2009 PHARMAC widened its access so it could be funded to treat cystic fibrosis, a chronic, congenital condition affecting the lungs. While azithromycin has antibacterial properties, its main role in the treatment of cystic fibrosis is to reduce the inflammation of lungs and airways associated with the disease. PHARMAC estimates $1.6 million will be saved through reduced hospitalisations over the next five years because of this decision.

HIV/AIDS



Major decisions:

> raltegravir – new class of treatment funded for HIV

> entecavir – new listing as first-line treatment for hepatitis B

> tenofovir – widened access to treatment for hepatitis B

> azithromycin – funded for cystic fibrosis

Cardiovascular

Four new medicines are now funded for the treatment of pulmonary arterial hypertension (PAH). PAH is a serious, often fatal disease affecting the heart and lungs. Three medicines that were previously only funded through the PHARMAC-administered Exceptional Circumstances (EC) scheme became fully funded through the Pharmaceutical Schedule. These high-cost treatments will continue to be targeted to the appropriate patients through the use of a specialist panel of clinicians to assess funding applications. PHARMAC later added a fourth treatment – ambrisentan.

Metoprolol is the most used beta blocker medicine in New Zealand. Used for the treatment of raised blood pressure and heart failure, the Betaloc brand of metoprolol had become one of the highest-cost medicines on the Pharmaceutical Schedule. Following the listing of a new brand, significant price reductions on metoprolol were achieved resulting in both the AFT and Betaloc brands being funded and savings of $65 million over five years. The metoprolol reference pricing is, in dollar terms, one of the largest savings achieved on a single medicine in PHARMAC's history. With AstraZeneca reducing its price on Betaloc, these savings were obtained without patients having to change their brand of metoprolol.

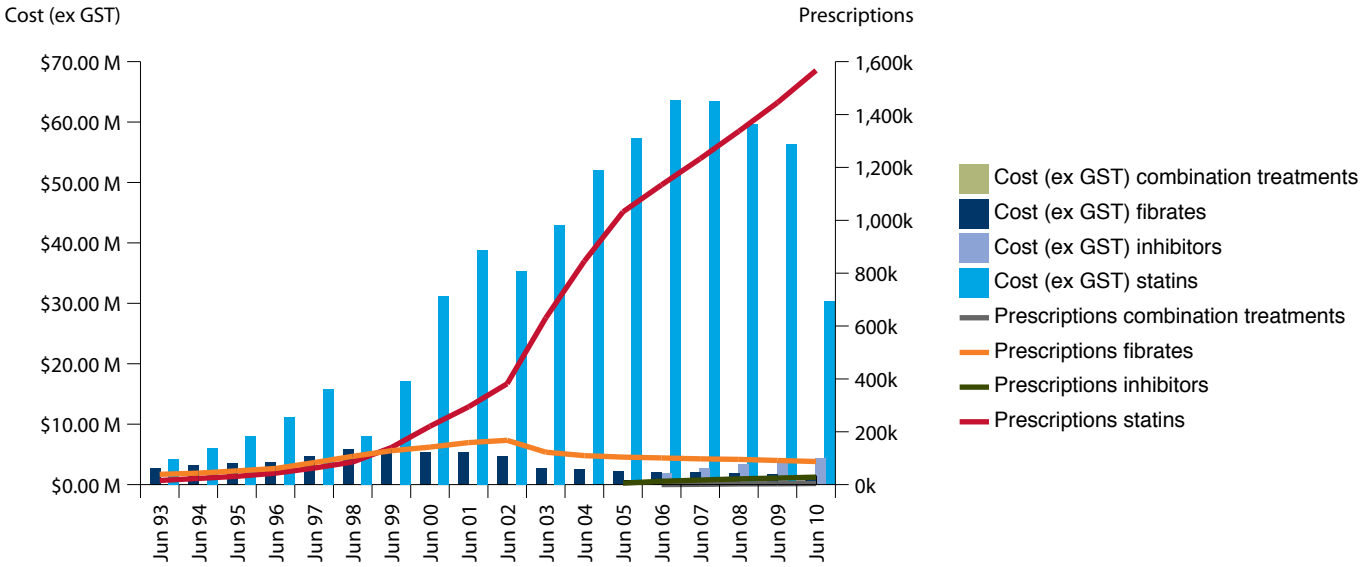
The decision had an immediate effect in the 2009/10 year, leading to spending on beta blockers dropping from $25 million in 2009 (gross) to $15 million in 2010. This is set to reduce further in future years.

The cost of the cholesterol lowering statins continued to decline with a reduction in the price of atorvastatin, which is due to take effect in the 2010/11 financial year, coming on top of the reduction in the price of simvastatin from the previous year. With the lower atorvastatin pricing a decision was made to remove all access restrictions.

One Heart Many Lives continued to be an important part of PHARMAC's response to New Zealand's high rates of heart disease, particularly among Māori and Pacific men. The campaign targets men at high risk of cardiovascular disease.

During the year PHARMAC shifted One Heart Many Lives from a regional to a national focus. One Heart Many Lives' grassroots theme continued with a presence at several community days, including the Pasifika festival in Auckland and the Creekfest festival in Porirua. PHARMAC also hosted 'Boot Camps' for men involved in the programme to gain inspiration and take the messages from the campaign back to their communities. This had several spin-offs with activity in Whanganui, Rotorua and the Far North.

Cholesterol-lowering treatments

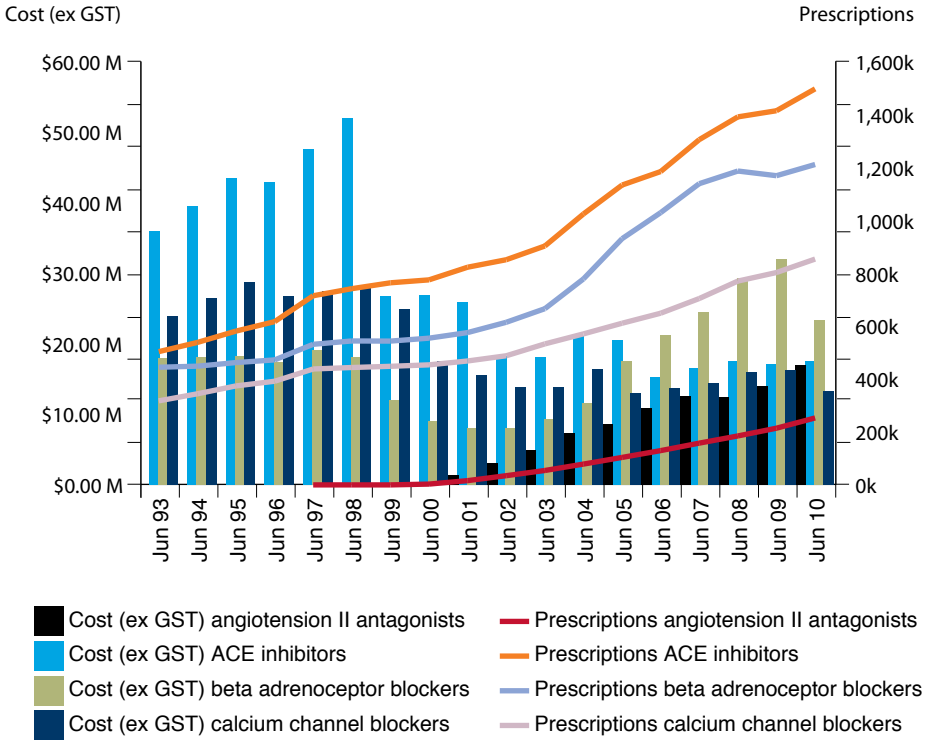


Major decisions:

> Treatments for pulmonary arterial hypertension (sildenafil, bosentan, iloprost) funded on the Pharmaceutical Schedule

> Major subsidy reduction on metoprolol leads to large savings

Blood pressure management



Mental health, neurology and pain relief

Major decisions:

> bupropion for smoking cessation

> mirtazapine for depression

> tramadol for pain relief

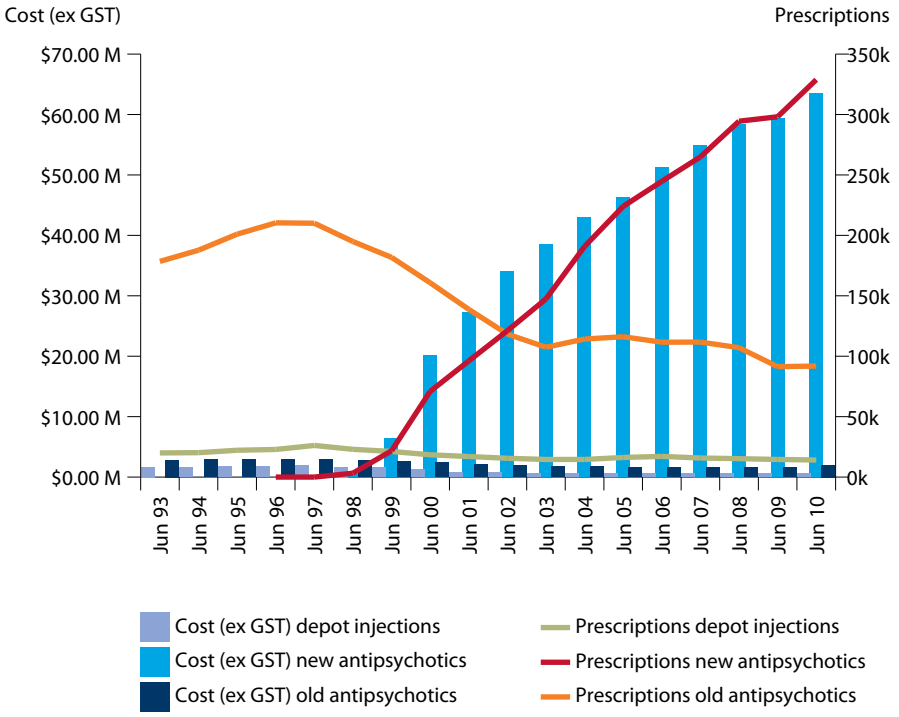
Decisions in this area led to new treatments being funded for depression, pain and to aid people wanting to quit smoking. Mirtazapine is now funded for severe depression for people who have tried and received no benefit from other anti-depressants. Because mirtazapine has a different chemical action to other funded anti-depressants, it may be more effective for some patients. PHARMAC had estimated this decision would help over 2,000 patients in the 2009/10 year (funding began on 1 November 2009).

Tramadol became fully funded to ease patients' pain. Tramadol is shown to have fewer side effects than some other common pain killers. PHARMAC estimated nearly 10,000 patients per year will benefit from this decision. Also for pain relief, PHARMAC funded an injected form of fentanyl, a strong opioid analgesic. Previously, fentanyl had only been available funded as a patch.

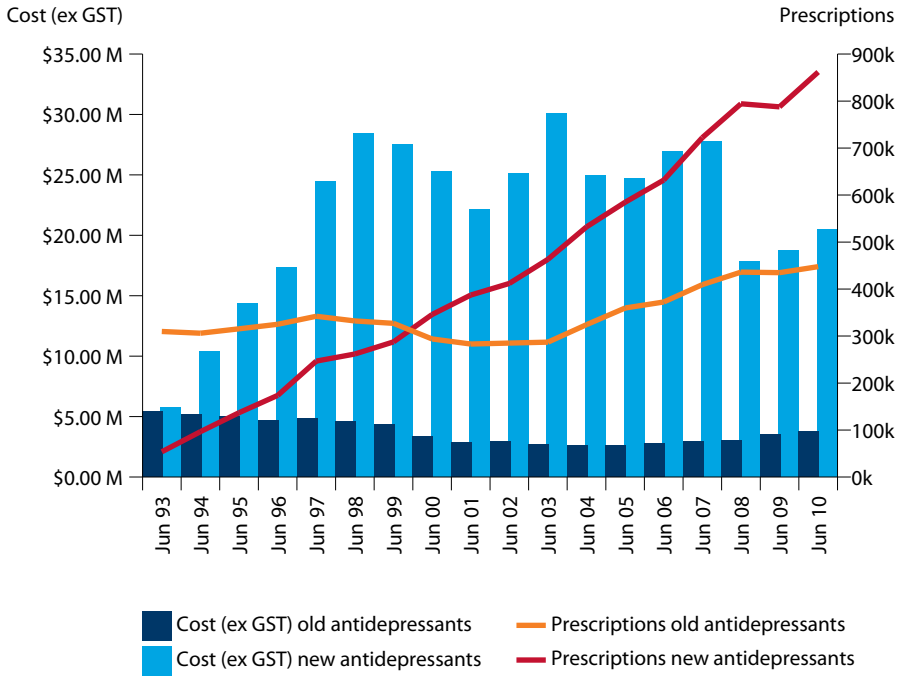
A new brand of gabapentin was funded from 1 August 2009 for the treatment of epilepsy as well as neuropathic pain. This decision is expected to save more than $8.5 million over 3 years.

A decision was also made to fully fund buproprion (Zyban) from 1 July 2009 as a smoking cessation therapy. PHARMAC estimates that this decision has helped over 24,000 New Zealanders since it was funded in their attempts to give up smoking.

Antipsychotics



Antidepressants



Cancers and transplant

PHARMAC continued to provide greater access to treatments for cancer. Decisions included:

> Fully funding dasatinib for the treatment of chronic myelogenous leukaemia

> Fully funding aprepitant to treat more than 1,000 patients with nausea resulting from chemotherapy

> Widening funded access for rituximab to be used as a first line treatment for low grade non-Hodgkin's lymphoma

> Removing the Special Authority restrictions on cyclosporin A to allow funded access to it for steroid-resistant nephrotic syndrome

> Widening access to funded gemcitabine and vinorelbine to treat Hodgkin's disease and T cell lymphoma

Many cancer treatments have now been available so long that they have come off patent, and PHARMAC is able to harness the power of competition to lower their cost to the taxpayer. This occurred with the hormonal breast cancer treatments anastrozole and letrozole.

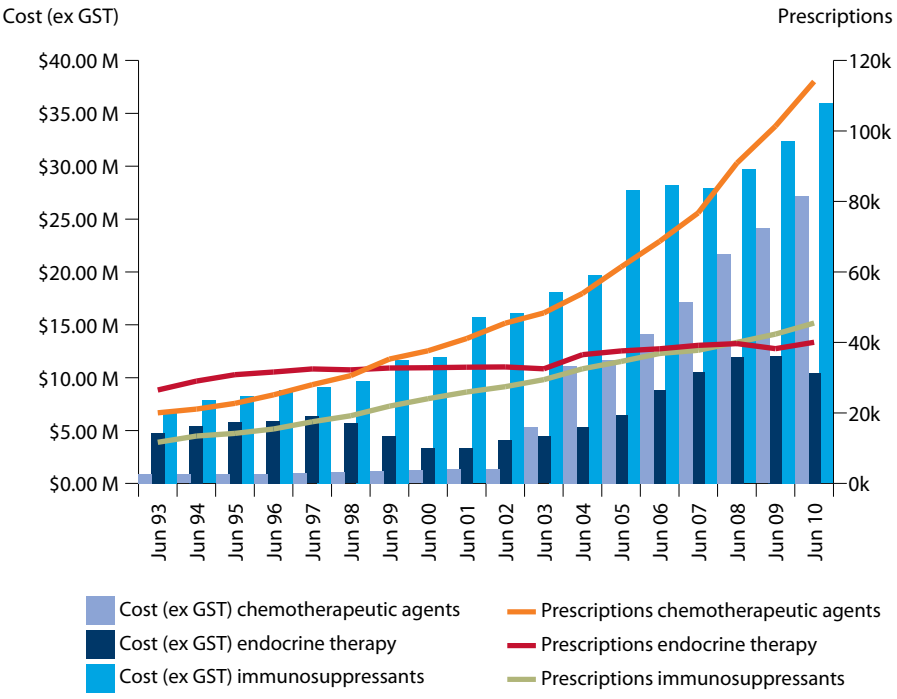
PHARMAC reached an agreement with the respective suppliers that resulted in savings of over $10.3 million over five years. With the supplier of the Arimidex brand of anastrozole choosing to match the new lowered subsidy (an 82% reduction), this also meant patients could continue using the brand they were already familiar with.

Some of the cancer drug decisions related to products used in DHB hospitals. For example, rituximab is a hospital treatment and its use was further widened to include low grade non-Hodgkin's lymphoma. PHARMAC is responsible for managing pharmaceutical cancer treatments, including those used in DHB hospitals, so the decision was a nationally-consistent one in all DHB hospitals.

Dasatanib (Sprycel), became a funded treatment for chronic myeloid leukaemia (CML) subject to Special Authority criteria. It is a similar drug to the already-funded imatinib (Glivec), which was first funded in 2002. Imatinib was a significant step forward for the treatment of CML, turning what had previously been an incurable, fatal disease into a manageable chronic condition. However, some patients do not respond well or cannot tolerate imatinib treatment, so having dasatanib funded would provide another treatment option.

Also, the transplant drug mycophenolate mofetil became available to aid in liver transplants, having previously been funded for use in renal and heart transplants.

Oncology agents and immunosuppressants



Diabetes

PHARMAC added a new type of blood monitoring strips to the Pharmaceutical Schedule this year. Blood ketone testing strips enable people with diabetes to monitor the levels of ketones in their blood and take appropriate action as necessary. This adds to the range of blood glucose testing strips available.

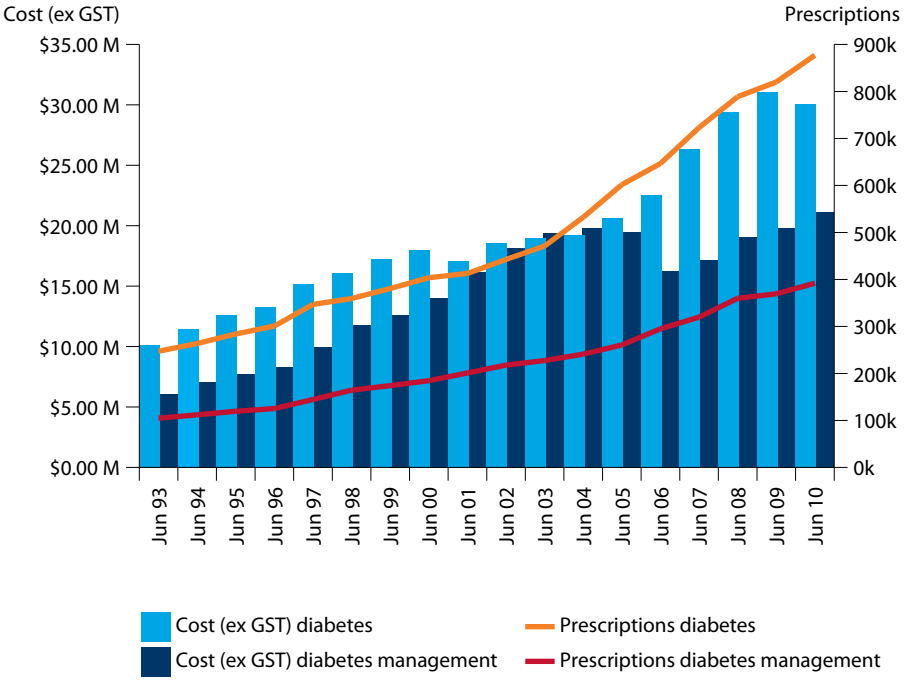
PHARMAC also widened access to pioglitazone for non-insulin dependent diabetes, following a major price reduction. An agreement between PHARMAC and Douglas Pharmaceuticals led to a price reduction of over 90 percent, saving an estimated $13 million over three years. The savings on pioglitazone are, in percentage terms, some of the highest achieved in PHARMAC's history.

Major decisions:

> Blood ketone testing strips funded

> Access widened to pioglitazone for non-insulin dependent diabetes

Diabetes



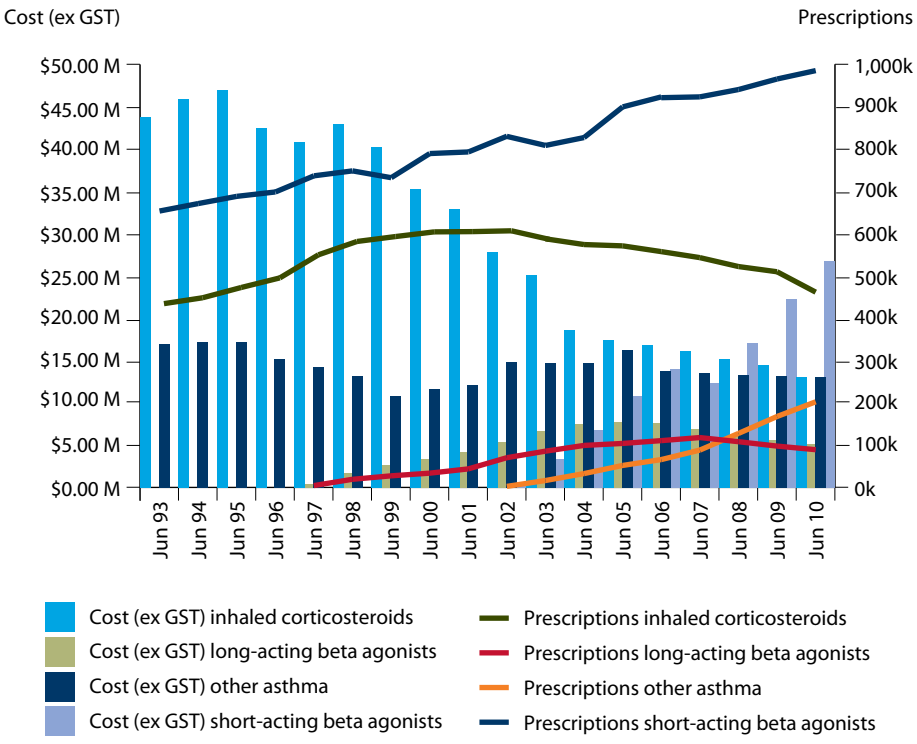
Respiratory

PHARMAC completed a pilot of its asthma campaign Space to Breathe – He Tapu te Hā in Taranaki. The pilot aimed to promote the optimal use of asthma inhalers for children under the age of 5 and raise awareness about childhood asthma. The programme focuses particularly on Māori children due to higher rates of asthma-related hospitalisations observed in this age group (and in this region). PHARMAC teamed with local health provider Tui Ora and Taranaki DHB to deliver education programmes to families and carers of children with asthma through kōhanga reo and early childhood education sessions.

Findings from evaluation of the programme demonstrated success in raising awareness about childhood asthma and promoting some behaviour changes, such as using dehumidifiers to reduce dampness around the home. Currently it is unclear, based on the data, whether the programme improved asthma medication prescribing and medication compliance and adherence. One of the programme's objectives was to improve the use of preventer medications to reduce asthma symptoms and exacerbations over time, as opposed to using reliever medications to treat acute symptoms. Overall, minimal changes in asthma-related hospitalisations in Taranaki were observed over the six-month time frame assessed. However, assessing changes over six months may have been too short to determine any long-term changes that occurred as a result of the programme.

PHARMAC is continuing to develop the programme and will conduct a second pilot to address information gaps from the first evaluation. Pending results of the second pilot, we will seek to develop and implement a national programme to address childhood asthma.

Asthma



SPACE to BREATHE
taking care of asthma

Musculoskeletal

One of the most significant investment decisions of the year involved the widening of access to the TNF-alpha inhibitor adalimumab, one of the 'biologic' class of antirheumatoid treatments. Previously funded only for rheumatoid arthritis, adalimumab became funded as a last-line treatment for a wider range of autoimmune disorders:

> ankylosing spondylitis

> psoriatic arthritis

> chronic plaque psoriasis

> Crohn's disease

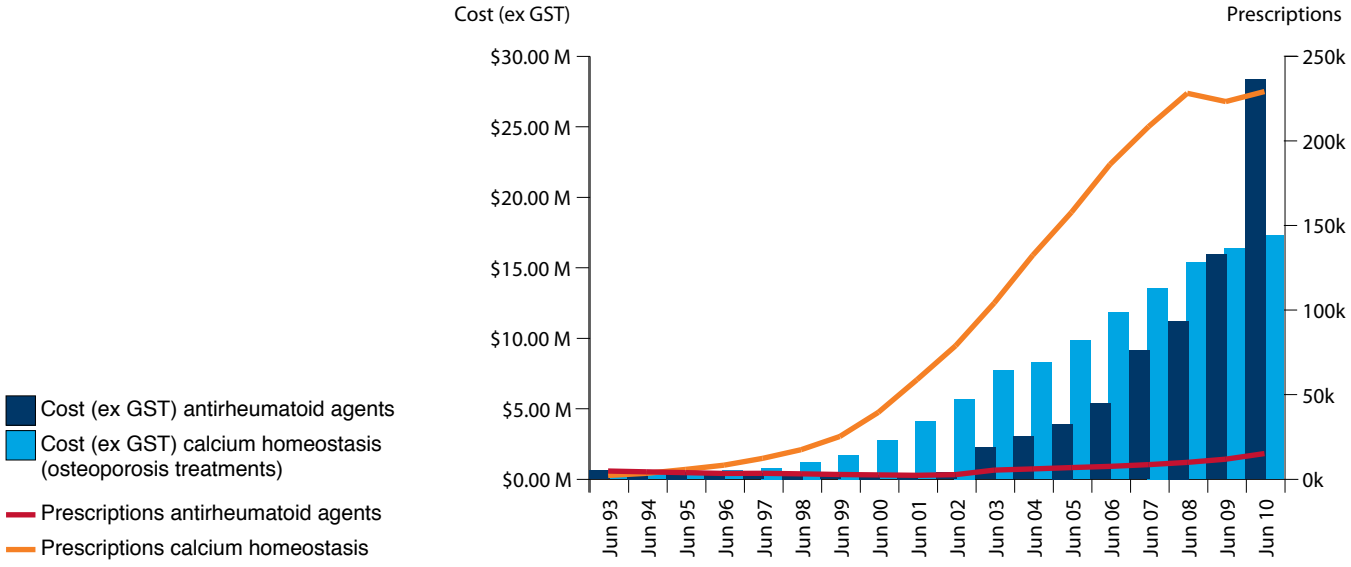
Before this decision, patients with these autoimmune conditions had limited treatment options. Some were able to access TNF-inhibitor treatment through DHB hospitals; however, this was not consistent across New Zealand, which led to criticism of the phenomenon known as `postcode prescribing'. PHARMAC's decision made a funded treatment available for these patients, regardless of where they lived. Adalimumab is an injection that people can give themselves at home, which is more convenient for them than having to visit a hospital for treatment.

Though details of the agreement remain confidential, it required additional community pharmaceutical expenditure. Even taking into account confidential rebates and savings in DHB hospitals, antirheumatoid treatments are now among the highest expenditure items on the Pharmaceutical Schedule. Spending has climbed sharply in the past year with the decision to widen access to adalimumab and, in gross spending terms, this is forecast to continue growing in coming years.

For osteoporosis treatment, a new strength of alendronate with cholicalciferol (Fosamax Plus) became fully funded, and access was widened. This resulted from an agreement PHARMAC reached with Merck Sharp & Dohme for ongoing supply of alendronate, plus the listing of the HIV/AIDS treatment raltegravir (Isentress) and a new anti-nausea treatment (aprepitant – Emend).

Overall, this agreement was forecast to save $5 million over five years to the Pharmaceutical Budget, plus an additional $2.9 million of savings to DHBs.

Musculoskeletal



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.

DHB Procurement

We built on previous years' work in 2009/10, running further competitive processes to obtain volatile anaesthetics, radiological contrast media and bulk intravenous fluids for DHB hospitals. New national contracts resulted in further savings to hospitals of approximately $1 million per annum.

PHARMAC continued to manage national agreements for hospital pharmaceuticals and some related products. There were 493 changes to the Hospital Schedule (Section H of the Pharmaceutical Schedule) in 2009/10, made up of:

>268 new listings

>126 price decreases, and

>99 price increases.

PHARMAC's multi-product tender was the primary source of savings, worth approximately $3 million. Much of the savings were provided from cancer treatments, and an antinausea treatment.

Influenza vaccine

The Government extended the subsidised influenza season in 2009 in response to a world-wide alert over the H1N1 influenza virus ("Swine Flu"). The World Health Organisation ordered the H1N1 strain to be included in the 2010 southern hemisphere flu season vaccine, which PHARMAC continued to procure on behalf of the Ministry of Health.

With memories of the swine flu outbreak still fresh, there was high demand for the seasonal flu vaccine in 2010. An extended season saw more than a million doses supplied – the highest on record. To meet the increased demand, PHARMAC was able to work with suppliers to secure an additional 35,000 doses late in the season.

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.

Actioning Medicines New Zealand, the action plan for the national medicines strategy, required PHARMAC to undertake a review of EC schemes. However, with the Government also conducting reviews of access to high cost highly specialised medicines, PHARMAC decided to delay its review of EC until the High Cost Highly Specialised Medicines Panel report was released.

The Panel's report agreed that the EC schemes should be reviewed and streamlined. In line with this recommendation, PHARMAC issued a discussion paper in August 2010 to begin a review of the EC schemes.

Meanwhile, the three existing schemes continued:

- 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 is $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 to 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 Schedule.

Overall, PHARMAC received 2189 Exceptional Circumstances applications during the year, of which 1702 were approved. There was an overall reduction in the volume of applications from previous years. This is largely because of the Pharmaceutical Schedule funding decisions PHARMAC made during the year, which approved Schedule funding for a number of medicines that were previously subject to high numbers of Exceptional Circumstances applications. These included treatments for pulmonary arterial hypertension (bosentan, iloprost and sildenafil), and human growth hormone (somatropin) for adults with growth hormone deficiency.

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

Summary of Exceptional Circumstances schemes

		Received	Approved	Declined
Community EC	Initial	328	65	220
	Renewal	156	138	12
Community EC (automatic approvals)	Initial	272	272	
	Renewal	166	166	
Hospital EC	Initial	778	600	104
	Renewal	311	304	3
Cancer EC	Initial	162	141	11
	Renewal	16	16	
Totals		**2189**	**1702**	**350**

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.

PHARMAC FORUM

The second PHARMAC Forum was held in October 2009. Hosted in Wellington, the Forum brought together more than 100 representatives from the pharmaceutical industry, consumer groups, doctors, pharmacists and Government to talk about PHARMAC's work and issues related to pharmaceuticals.

PHARMAC provided an update on its work in implementing the workplan from the 2007 Forum. Much of the work PHARMAC committed to at the 2007 event had been undertaken or put in place, and this was seen as significant progress by people attending the Forum. However, while they recognised PHARMAC's efforts to make changes in response to the 2007 Forum, they urged PHARMAC to continue to pursue other projects it had committed to. In particular, they encouraged PHARMAC to complete work to establish an online device to enable people to track the status of pharmaceutical funding applications.

As well as reporting back to people on the progress we have made putting in place the 2007 Forum workplan, we also sought people's feedback on work we are undertaking around generic medicines and consumer participation. We also took the opportunity to use the Forum to prompt debate on our consumer participation discussion paper, which was launched to coincide with the Forum.

PHARMAC also provided an outline of its approach to cost-utility analysis, the primary tool used to undertake economic assessments of pharmaceuticals, and of its work in promoting the optimal use of medicines.

Overall, the day was very constructive and provided useful input to PHARMAC. The workplan from the 2009 Forum has been published on the PHARMAC website, and is being responded to ahead of the next Forum.

Consumer input to PHARMAC

A consultation exercise to examine ways in which consumers could be more engaged with PHARMAC was one of our major pieces of work during the year. Our discussion paper was issued in November 2009. It contained a series of ideas for new or improved ways that consumers could provide input to PHARMAC.

When we looked at the feedback we received, respondents didn't have a consensus view on which ideas would work best. We also had to think about whether any new initiatives would incur costs, and whether it was sensible to take these on in the current constrained economic environment. So our focus will continue to be on improving what we already do, meeting our commitments and continuing to weigh up the potential benefits of new initiatives against their costs.

The consumer participation project helped reinforce that we already interact with the consumer sector in many ways. These include through our website, face to face meetings, our consultation documents, media releases and answering consumer queries. Many of the suggested changes were ongoing refinements to these methods.

Some of the changes we have made, or are planning, include:

- **Changes to the Consumer Advisory Committee** – We reviewed the Terms of Reference for the Committee earlier this year, which is one of the ways we obtain advise on how to gain consumer perspectives on our work. We also refreshed the membership and, under the new Terms of Reference, this will now occur more frequently, which should ensure we regularly get new and fresh perspectives on the committee.
- **Application Tracker** - This is an internet-based tool to enable people to see where medicine funding applications are in the PHARMAC system. Funded medicines are listed on the Pharmaceutical Schedule. The Tracker, and the Schedule, are available on the PHARMAC website www.pharmac.govt.nz.
- **Improvements to the website** - The PHARMAC website is the main way most people interact with PHARMAC, so it needs to work well for them. Ongoing improvements to the way information is displayed and made available will continue to be made.
- **Greater use of 'Plain English'** - We seek to make our public documents as easy to read as possible and avoid jargon. It's a long road but we are already making strides, winning a Plain English award in 2007, and being shortlisted for two awards in 2009.
- **Consider the use of social media** - Facebook, Twitter and chat sites are where many people now meet and share ideas. We are already using some of these communication tools as part of our Access and Optimal Use campaigns and will continue to explore opportunities to use them for broader PHARMAC purposes.

Consumer Advisory Committee membership.

PHARMAC sought applications for new members for the Consumer Advisory Committee, when long-serving members completed their terms of appointment. Members are expected to draw from their own backgrounds and experiences with consumer groups to provide advice to PHARMAC on its engagement with consumers. Members are not appointed to represent the interests of the individual groups they are associated with. However, these consumer connections are noted below to illustrate the range of experience on the current Committee:

- Kate Russell (acting chair, Christchurch) – Chief Executive of Cystic Fibrosis NZ.
- Anne Fitisemanu (acting deputy chair, Auckland) - Programme Manager, Pacific Workforce Development and Pacific Cultural Competency Training, for Counties Manukau DHB.
- Shane Bradbrook (Wellington) – tobacco control advocate with iwi affiliations to Ngāi Tamanuhiri, Rongowhakaata and Ngāti Kahungungu.
- Maurice Gianotti (Taupo) – a former chief executive of the Education Review Office and Assistant State Services Commissioner, Maurice is active in a number of community organisations including as a trustee of Lake Taupo Hospice and through Citizens Advice Bureaux.
- Barbara Greer (Hokitika) – registered psychiatric nurse and life member of the Māori Women's Welfare League.
- Jennie Michel (Auckland) – currently works for Age Concern North Shore.
- Anna Mitchell (Christchurch) - current Chairperson of Canterbury Arthritis Advocates and the Vice-President of the Disabled Persons Assembly for Christchurch and surrounding districts.
- Moana Papa (Auckland) –involved with a number of organisations, including Breast Cancer Aotearoa Coalition (BCAC), the Māori Leadership Group – Northern Cancer Network, BreastScreen Aotearoa in Manukau and Raukura Hauora O Tainui Ki Tamaki.
- Katerina Pihera (Rotorua) - a representative of the Te Arawa Health Board, she provides advice and advocacy to the Lakes DHB through her membership of the Community and Public Health Advisory Committee for Lakes DHB.

Directory

The PHARMAC Board

Chairman

Stuart McLauchlan BCom, FCA(PP), AF InstD

Directors

Kura Denness (Te Atiawa) MBA CA

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

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

Mrs Anne Kolbe ONZM, MBBS (Hons), FRACS, FRCSEng (Hon), FCSHK (Hon), FRCSEd (Hon)

Prof Jens Mueller JurDr LLM MBA MSAM

PHARMAC's Management Team

Chief Executive

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

Medical Director

Dr Peter Moodie BSc, MBChB, FRNZCGP

Management Team

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

Rachel Mackay BA, NZIMR - Manager, Schedule and Contracts

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

Rico Schoeler - Manager, Analysis & Assessment

Jude Urlich MPP(Dist), BA, DipBsStd(PR), APR
- Manager Corporate and External Relations

PHARMAC's Advisory Committees

Pharmacology and Therapeutics Advisory Committee (PTAC)

Chair

Carl Burgess MBchB, MD, MRCP (UK), FRACP, FRCP

Deputy Chair

Howard Wilson BSc, PhD, MB, BS, Dip Obst, FRNZCGP, FRACGP

Committee Members

Stuart Dalziel MBChB, PhD, FRACP

Ian Hosford MBChB, FRANZCP, psychiatrist

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

George Laking MD, PhD, FRACP

Jim Lello BHB, MBChB, DCH, FRNZCGP

Graham Mills MBChB, MTropHlth, MD, FRACP

Peter Pillans MBBCh, MD, FCP, FRACP

Mark Weatherall BA, MBChB, MApplStats, FRACP

PTAC Sub-committees

Analgesic: Dr Howard Wilson (Chair, General Practitioner/ Pharmacologist), Dr Rick Acland (Rehabilitation Specialist), Dr Jonathan Adler (SMO Palliative Medicine), Dr Bruce Foggo (Palliative Medicine Consultant), Dr Lindsay Haas (Neurologist), Dr Ian Hosford (Psychogeriatrician), Dr Geoff Robinson (Chief Medical Officer/ Addiction Medicine), Dr Jane Thomas (Paediatric Anaesthetist).

Anti-Infective: Dr Graham Mills (Chair, Infectious Disease Physician), Prof. Bruce Arroll (General Practitioner), Dr Emma Best Paediatric Infectious Diseases Consultant, Dr Simon Briggs (Infectious Diseases Physician), Dr Steve Chambers (Clinical Director/ Infectious Disease Physician), Dr Iain Loan (General Practitioner), Dr Howard Wilson (General Practitioner/Pharmacologist).

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

Cardiovascular: Dr Sisira Jayathissa (Chair, Physician), Dr Malcolm Abernethy (Cardiologist), Dr Lannes Johnson (PHO Medical Advisor), Dr Stewart Mann (Associate Professor of Cardiovascular Medicine), Dr Richard Medlicott (General Practitioner), Dr Peter Pillans (Director, Clinical Pharmacology/Physician), Assoc. Prof. Mark Weatherall (Geriatrician), Prof. Mark Webster (Consultant Cardiologist).

Diabetes: Dr George Laking (Chair, Oncologist), Prof. Carl Burgess (Physician/Clinical Pharmacologist), Dr Nick Crook (Diabetologist), Dr Craig Jefferies (Paediatric Endocrinologist), Dr Peter Moore (Physician), Miss Andrea Rooderkerk (Diabetes Nurse Specialist), Dr Bruce Small (General Practitioner).

Growth Hormone: Prof. Carl Burgess (Chair, Physician/Clinical Pharmacologist), 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 Paul Tomlinson (Paediatrician), Dr Esko Wiltshire (Paediatric Endocrinologist).

Hormone & Contraceptive: Dr Howard Wilson (Chair, General Practitioner/Pharmacologist), Prof. John Hutton (Gynaecologist), Dr Frances McClure (General Practitioner), Dr Stella Milsom (Endocrinologist), Dr Christine Roke (National Medical Advisor), Dr Bruce Small (General Practitioner).

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

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

Ophthalmology: Prof. Carl Burgess (Chair, Physician/Clinical Pharmacologist), Dr Neil Aburn (Ophthalmologist), Dr Rose Dodd (General Practitioner), Dr Steve Guest (Vitreoretinal Surgeon), Dr Allan Simpson (Ophthalmologist).

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

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

Respiratory: Dr Jim Lello (Chair, General Practitioner), Prof. Carl Burgess (Physician/Clinical Pharmacologist), Dr Tim Christmas (Respiratory Physician), Dr John McLauchlan (Respiratory and Sleep Physician), Dr Ian Shaw (Paediatrician).

Special Foods: Dr Jim Lello (Chair, General Practitioner), Dr Simon Chin (Paediatric Gastroenterologist), Mrs Kim Herbison (Paediatric Dietician), Mrs Kerry McIlroy (Charge Dietician), Ms Jo Stewart (Professional Advisor, Dietetics), Mrs Moira Styles (Community Dietician), Dr John Wyeth (Gastroenterologist).

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

Transplant Immunosuppressant: Dr Peter Pillans (Chair, Director, Clinical Pharmacology/Physician), Dr Peter Ganly (Haematologist), Dr Stephen Munn (Transplant Surgeon), Dr Richard Robson (Nephrologist), Dr Peter Ruygrok (Cardiologist), Dr Paul Tomlinson (Paediatrician), Dr Kenneth White (Respiratory Physician).

Rheumatology: Dr Sisira Jayathissa (Chair, Physician), Dr Andrew Harrison (Rheumatologist), Dr Peter Jones (Rheumatologist), Dr Norah Lynch (Rheumatologist), Dr Sue Rudge (Paediatric Rheumatologist), Assoc. Prof. Lisa Stamp (Rheumatologist), Assoc. Prof. Will Taylor (Rheumatologist).

Panels

Exceptional Circumstances: Dr Howard Wilson (Chair, General Practitioner/Pharmacologist), Dr Andrew Herbert (Consultant Gastroenterologist), Dr Sharon Kletchko (Specialist Physician), Dr George Laking (Oncologist), Dr Paul Tomlinson (Paediatrician), Dr David Waite (Physician).

Cystic Fibrosis: Dr Cass Byrnes (Respiratory Paediatrician), Dr Richard Laing (Respiratory Physician), Dr Ian Shaw (Paediatrician).

Gaucher Treatment Panel: Dr Callum Wilson (Metabolic Consultant), Dr Ruth Spearing (Haematologist), Dr Robert Taylor (Radiologist).

New Zealand Growth Hormone Committee: Prof. Wayne Cutfield (Chair, Paediatric Endocrinologist), Prof Alistair Gunn (Paediatrician), Assoc. Prof. Paul Hofman (Paediatric Endocrinologist).

Pulmonary Arterial Hypertension: Dr Howard Wilson (General Practitioner/Pharmacologist), Dr Andrew Aitken (Cardiologist), Dr Lutz Beckert Respiratory Physician), Dr Clare O'Donnell (Paediatric Congenital Cardiologist), Dr Paul Tomlinson (Paediatrician), Dr Kenneth White (Respiratory Physician).

Multiple Sclerosis Treatment Assessment Committee: Dr Ernest Willoughby (Chair, Neurologist), Dr David Abernethy (Neurologist), Dr Neil Anderson (Neurologist), Dr Alan Wright (Neurologist).

Consumer Advisory Committee (CAC)

Acting Chair

Kate Russell – Chief Executive of Cystic Fibrosis NZ, Christchurch.

Acting deputy chair

Anne Fitisemanu – Programme Manager, Pacific Workforce Development and Pacific Cultural Competency Training, Counties Manukau DHB, Auckland.

Shane Bradbrook – tobacco control advocate, Wellington.

Maurice Gianotti – volunteer worker, Taupo.

Barbara Greer – psychiatric nurse, Hokitika.

Jennie Michel – Age Concern North Shore, Auckland.

Anna Mitchell – Chairperson of Canterbury Arthritis Advocates and Vice-President of the Disabled Persons Assembly for Christchurch and surrounding districts.

Moana Papa – Breast Cancer Aotearoa Coalition, Auckland.

Katerina Pihera – member of the Community and Public Health Advisory Committee for Lakes DHB, Rotorua.

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).

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