

Pharmaceutical Management Agency

Annual Review 2011

New Zealand Government

PHARMAC
Pharmaceutical Management Agency



2010 /11

Highlights

- > Pharmaceutical spending managed on budget - \$706.1 million compared to a budget of \$710 million (budget includes DHB allocation of \$700 million and up to \$10 million from PHARMAC's Discretionary Pharmaceutical Fund)
- > 39 new medicines funded and access widened to 43 others
- > New investment decisions include medicines for various types of cancer, HIV/AIDS, smoking cessation, diabetes, Alzheimer's Disease, long-acting contraception
- > Largest number of new investments since PHARMAC began in 1993
- > Reviewed Exceptional Circumstances schemes and developed Named Patient Pharmaceutical Assessment (NPPA)
- > Appointed five new members to the Consumer Advisory Committee (CAC)
- > One Heart Many Lives provided the anchor for a Whānau Hauora Village concept at the 5-day 2011 Te Matatini festival in Gisborne
- > Minister agreed the Discretionary Pharmaceutical Fund; a significant change in pharmaceutical funding budget parameters
- > Extended role to cover all hospital medicines and medical devices

PHARMAC continues to take a careful approach to spending, despite having additional money to spend in 2010/11, writes Board chairman Stuart McLauchlan



There's little doubt that the Government's increased investment in medicines has enabled PHARMAC to fund more medicines in the past year. The challenge for PHARMAC has been to ensure that spending has remained cost-effective and well targeted.

When you manage a prioritised list of investments, it stands to reason that the further down that list you go the less value for money is being offered. PHARMAC went deep into its priority list in funding 39 new medicines – the largest number of new medicines funded by PHARMAC since its inception; some of these were extremely cost-effective and made possible through medicines coming off-patent. For example, the Alzheimer's Disease treatment donepezil was funded during the year, with competition following patent expiry leading to a price approximately 5% of the original brand's price.

But some other new medicines have been funded at prices that would not have been considered cost-effective just a few years ago. This illustrates the complex interaction between available funding, health need and medicine pricing. Where more funding is available, more expensive funding options can be taken. But care is needed to ensure that this new spending still leads to better health outcomes. The risk is that increasing spending simply spins the wheels, without significant gains being made in terms of improved health for the population.

A more detailed look at our new funding decisions is provided on pages 18 to 26.

Making the best use of new spending

PHARMAC will continue to closely examine its funding options to ensure the decisions it makes represent the best value for the pharmaceutical dollar. However, it doesn't always follow that spending money on pharmaceuticals is the best investment of scarce health dollars.

In line with the recommendations of the Ministerial Review Group (MRG) report, more work needs to be done to look across sectors to find where the best spending opportunities are. This necessity has been further heightened by the current global economic situation, and the challenges to the New Zealand economy brought on by the Canterbury earthquakes and other economic headwinds. If we are to invest more in health, we need to be sure what we are getting for the money being invested.

It is pleasing to see progress in implementing the recommendations of the MRG, with the National Health Committee and Health Benefits Ltd beginning their work programmes. PHARMAC will also have a broader role to play and will be working in conjunction with those agencies to progress projects around medical devices in particular. Medical devices provide a broad and challenging new area of work and are likely to form a significant part of PHARMAC's ongoing work programme.

We're part of the answer

PHARMAC remains committed to achieving improved health outcomes from its funding decisions, however our work is only part of the picture for achieving those outcomes. For example, in the past year PHARMAC contributed to the Government's health target of reducing the impact and incidence of smoking

by funding the smoking cessation drug varenicline (Champix). This is a further tool for clinicians to use in addition to nicotine replacement therapy, bupropion or nortriptyline to help patients quit smoking. But wider policy settings also had an influence – these included moves to make prisons smokefree from 1 July 2011, and increased taxation on cigarettes.

Our value

Overall, PHARMAC continued its record of success in managing spending on pharmaceuticals, enhancing the range of available medicines and providing treatments for more New Zealanders. Prescription numbers rose by 7%, with an additional 214,603 people receiving funded medicines.

Our value to New Zealand was also discussed at length during the year, including during debate over the multi-national Trans Pacific Partnership trade negotiations. This has made us think hard about the value we provide for New Zealand. PHARMAC negotiates medicine subsidies for New Zealand and has a long record of managing within budget. Spending has been managed by lowering prices overall, with prices in New Zealand lower than in other comparable countries, whilst widening access to a greater range of medicines. The graph opposite illustrates that, over the past 10 years, had no price reductions occurred in 2010/11 we would have paid more than \$1 billion more for medicines than we currently do (compared to 2000).

We also undertook work to maintain or improve our funding and distribution systems. We completed our review of Exceptional Circumstances, and the new system, called Named Patient Pharmaceutical Assessment, will come into effect during 2012. We also worked hard in the aftermath of the September and February Canterbury earthquakes to ensure prescribers, pharmacists and patients had uninterrupted supply of medicines. The efforts of our crisis response team were recognised across the sector.

Membership of our Consumer Advisory Committee (CAC) was refreshed during the year, with five new members being appointed. Later in 2011 the Committee co-hosted a community engagement project that will feed into our 2012 PHARMAC Forum. This has strengthened our knowledge and links with the community.

Personnel changes

A major milestone was reached during the year with David Moore's term on the PHARMAC Board finishing in December 2010. David's policy work led to the establishment of PHARMAC in 1993, and he was the agency's first general manager, guiding PHARMAC through its tumultuous early years. He was appointed to the Board in 2001 and made a significant contribution.

The other major personnel change for PHARMAC was the departure of Chief Executive, Matthew Brougham, in August 2011. Matthew was Chief Executive from 2008 and has moved to a new role with the Canadian Agency for Drugs and Technology in Health. We have appointed an Acting Chief Executive, Steffan Crausaz, a long-standing staff member with extensive leadership and pharmaceuticals experience.

I am confident that the strong foundations set by PHARMAC's leaders such as David and Matthew will stand PHARMAC in good stead to continue delivering on its objectives into the future.

Key figures

\$706.1 million – yearly community pharmaceutical expenditure (on budget)

39.7 million – number of funded prescriptions written (7.0% increase)

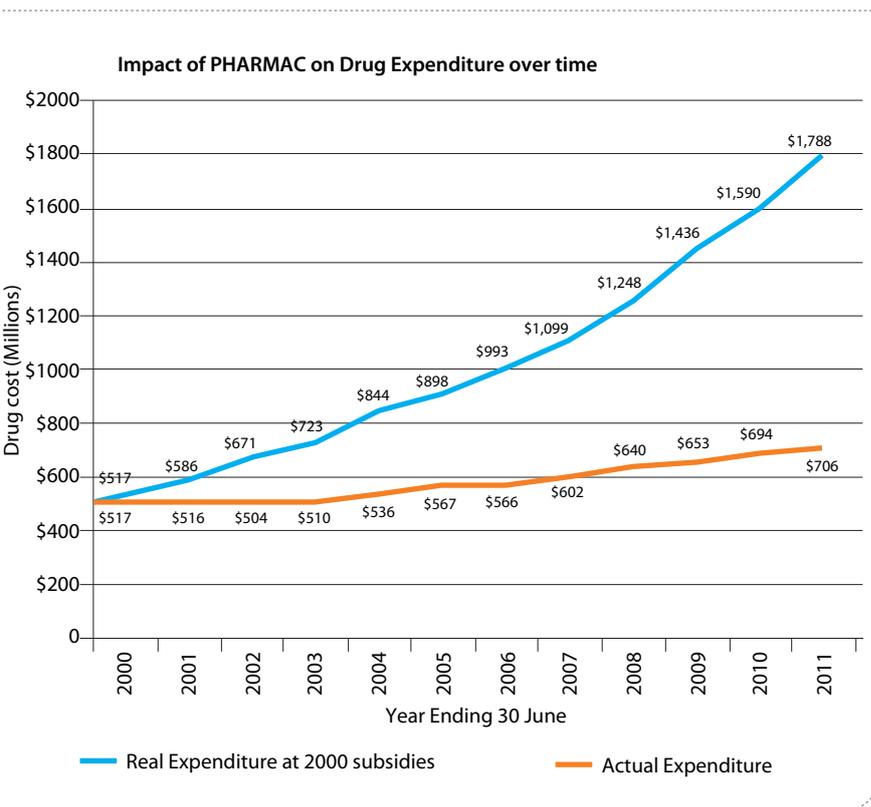
3.3 million – number of New Zealanders receiving funded medicines

\$76.2 million – amount of savings achieved

39 – number of new medicines funded

43 – number of medicines with access widened

264,452 – estimated number of additional patients benefitting from these decisions in a full year



Getting the balance right on new technologies, writes Acting Chief Executive Steffan Crausaz



Funding new medicines has been and continues to be the core of PHARMAC's business, and we have accumulated much experience in that area over the years.

Funding an entirely new medicine class happens less often, although we have seen it with the likes of the leukaemia treatment imatinib (Glivec), TNF-alpha inhibitors like etanercept and adalimumab, or the cholesterol-channel blocker ezetimibe (Vytorin).

We had another opportunity to introduce a new product class in the past year, in the shape of the direct thrombin inhibitor dabigatran (Pradaxa), a new treatment to help prevent clotting. In the process of funding dabigatran, we have learned much about introducing and transitioning patients onto new drug technologies that will be used by large groups of patients.

Dabigatran, and other clot-preventing (anticoagulant) medicines like another drug we recently funded, rivaroxaban, have been developed as replacements for the long-time anticoagulant warfarin. Anticoagulation is important to reduce the risks of strokes and to treat the heart condition atrial fibrillation, and to prevent clots occurring in patients who have had major orthopaedic surgery (hip and knee replacements).

Warfarin has been used for many years and is well known by doctors. While all medicines have risks and benefits, warfarin is particularly challenging because of its interactions with both other medicines, and some foods. Warfarin acts by decreasing the body's Vitamin K, so when patients eat foods containing Vitamin K (green vegetables like broccoli, and some dairy foods), this can affect the warfarin level and clotting.

Careful process

Introducing a new drug needs to be done with care, and this is especially the case with a new class of drugs that large numbers of patients are likely to change to. That is why PHARMAC takes a careful approach and seeks clinical and other advice on its decisions, and consults with the public before they are made.

That's the approach we took with dabigatran. Our clinical advisory committee PTAC, and its cardio-vascular sub-committee, reviewed the evidence for dabigatran. PTAC considered dabigatran to be at least equivalent to warfarin, but without the difficulties of monitoring and management.

Dabigatran's supplier Boehringer-Ingelheim made a commercial offer that included large discounts (including confidential rebates) on the original list price. The net effect was to make dabigatran cost-effective enough for PHARMAC to put together a funding proposal. We sought public feedback on this proposal during April 2011.

We received 34 submissions – a relatively high number compared to many of our proposals to fund medicines. The majority of these submissions were positive; however others highlighted risks around dabigatran including that its risks may not be fully known, and that there is no known antidote for the medicine. Some of those submissions also suggested ways those risks could be managed, such as by formulating guidance for clinicians and providing evidence-based information on the benefits and risks of dabigatran.

Point taken

We took that advice on board and convened an expert group of haematologists to provide advice. This formed the basis for managing bleeding guidance that has been provided to doctors and hospital emergency departments (opposite). This guidance has also been used by Australian authorities for the basis of their bleeding management guidance, so it was clearly a valuable piece of work. The Best Practice Advocacy Centre (bpacnz) also published articles in its Best Practice Journal (sent to GPs and pharmacists throughout the country) about dabigatran and managing bleeding.

Most information was available before our decision came into effect on 1 July, and further resources and tools for doctors have since been made available as part of ongoing medical education.

The complicating factor with dabigatran was that it was new technology replacing old, well-known technology. It was still important to emphasise that the drug had risks and needed to be prescribed with care. Transitioning patients off warfarin and onto dabigatran, and helping them understand the need to self-monitor and report any side-effects, was another part of the process.

Guidelines for testing and perioperative management of dabigatran - for possible inclusion into local management protocols

The following guidelines have been prepared by PHARMAC with the assistance of practicing specialists in response to requests for information. They are provided to assist clinical services to develop their own guidelines in accordance with local procedures and should not be adopted without appropriate review.

Testing for dabigatran anticoagulant effect

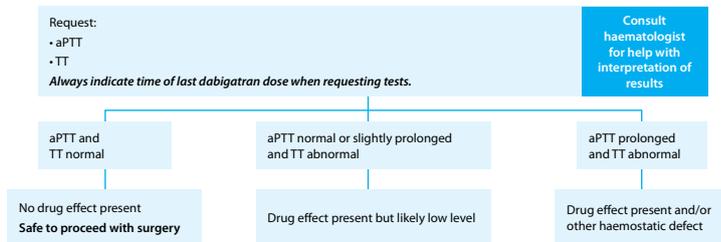
Routine testing is not required during treatment with dabigatran. However, testing may be required in:

- patients with moderate or severe reduction of renal function;
- the perioperative setting; or
- in the event of bleeding.

Tests that can measure the anticoagulant effect of dabigatran exist but are not yet well understood. Note that INR (international normalised ratio) is relatively insensitive to dabigatran with only supra-therapeutic concentrations of dabigatran resulting in an INR of approximately 2.0.² Advice should also be sought from local laboratories on the sensitivity of the coagulation tests used as these may differ and will affect test results.²

The recommended tests for assessing the effect of dabigatran are:²

- **Activated partial thromboplastin time (aPTT)**
 - Moderately sensitive but has reduced responsiveness at higher doses.
 - Result approximately twice baseline value at dabigatran treatment doses of 150 mg bid but varies for different test brands.
 - Result of >80 seconds at trough (when the next dose is due) is associated with a higher bleeding risk.
- **Thrombin time (TT)**
 - Very sensitive with linear dose-response relationship.
 - Significantly raised at therapeutic doses.



Other tests which can be done to guide the treatment of a patient on dabigatran include:

- **Fibrinogen assay**
 - May be useful to monitor for disseminated intravascular coagulation (DIC) and determining whether replacement treatment is required.
 - Note that reagents vary in responsiveness to dabigatran for fibrinogen assays and some brands may give misleading results.³
 - If fibrinogen concentration is below ~1.5 g/L (note this is dependent on assay reagents), a dose of 1 bag of Cryoprecipitate per 30 kg body weight will increase fibrinogen by approximately 1 g/L.
- **Platelet count**
 - Useful to determine whether replacement is required.
 - Transfusion of Platelet Concentrate is indicated where the platelet count is below $70-80 \times 10^9/L$.
 - If the patient has been treated with an anti-platelet agent, a dose of 1 to 2 bags of Platelet Concentrate is appropriate for adults.
- **Ecarin clotting time (ECT) (if available)**
 - Sensitive with a linear dose-response relationship.
 - Result increased 2-4 times at dabigatran doses of 150 mg bid.
- **Haemoclot[®] thrombin inhibitor assay (if available)**
 - Sensitive with a linear dose-response relationship.
 - Clotting time from 30 to 75 seconds at dabigatran dose of 220 mg/day.

Getting the balance right

There is always a tension between being an early adopter, and taking a more patient and sceptical approach to new technologies. PHARMAC is a sceptic when it comes to new drugs, taking a dispassionate approach, seeking evidence and asking the hard questions about what additional health gains they confer and what value they present for the significant investment often involved. The dabigatran experience reaffirms the importance of this approach and we have released substantial information on our website that confirms our evidence-led consideration of dabigatran.

On reflection, I think we got the balance right. Long-term, dabigatran is expected to deliver population health gains greater than warfarin, through a reduction in the incidence of strokes. Medical science is evolving and we are keen to see products that provide greater health gains for the population brought into use. In fact, PHARMAC is often under pressure from clinicians and patient groups to move faster when it comes to new technologies.

We're also aware of the need for clinicians to keep abreast of new developments and to have information about new products becoming available to them. It's not our job to tell doctors how to do their job. But we can provide them with the tools and support they need to make well-informed judgments.

Subsidy, volume, mix and cost indices

Four-quarterly moving averages
Base: four quarters ending Dec 1999 = 1,000.

Getting more for less:

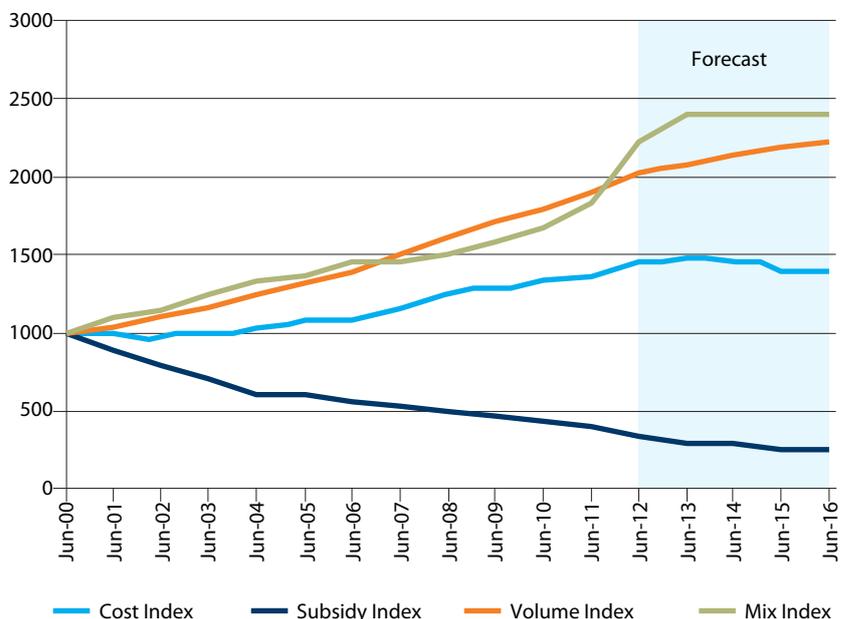
The subsidy volume and mix indices are like the consumer price index, but for pharmaceuticals. The graph shows that while the amount of pharmaceuticals used, and their cost has been rising, the subsidy index is decreasing.

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



Predicting the future is fraught with difficulties, but we know enough to predict that healthcare in future will look quite different to how it does today, writes Dr Robert Hickson

Dr Robert Hickson has a PhD in Genetics from Massey University. After a brief research career in evolutionary biology he joined what was then the Environmental Risk Management Authority (now the Environmental Protection Authority) as a science advisor. He then moved to the emerging technologies team at the Ministry of Research, Science and Technology (now the Ministry of Science and Innovation), where for the past three years he led the Ministry's Futurewatch programme which monitored trends in science and technology. He is now a consultant on strategic foresight.

Five decades ago the contraceptive pill and valium were introduced. Thirty years ago HIV/AIDS was recognised. Ten years ago the first human genome sequences were just being completed and the anti-cancer drug Glivec (imatinib) was approved by the FDA.

What medical developments will occur in the next decade, or by mid-century, and what could they mean for PHARMAC? Will many cancers and neurodegenerative diseases be preventable or curable? Conversely, will we be struggling to develop new medicines? Or, could the health system be overwhelmed by elderly obese patients plagued with chronic diseases?

Predicting the future doesn't have a good track record. However, by looking at current trends and developments we can

anticipate some of the more substantial changes in how we treat medical conditions and consider implications of these.

What is certain is that the model of healthcare that has operated over the preceding decades is changing. A range of trends is affecting healthcare (Table 1). There is a strong desire to reduce costs and improve outcomes. There is also a growing expectation from society that they will be able to have access to the treatments that work best for them. The "artisanal" nature of medical practice (where doctors have considerable discretion in the course of treatment) is being replaced by more data-driven approaches as the rapid pace of research and development provides new tools and information.

Table 1. Some global trends affecting healthcare

Economic	Technological	Social
Rapidly rising costs of healthcare	Convergence of technologies resulting in faster, better, and sometimes cheaper, solutions	Rising life expectancy
Decreasing productivity of drug discovery	Increasing chemical complexity and diversity of new pharmaceuticals	Ageing population
Increasing focus on health outcomes	Increasing focus on electronic medicine	Increasing community and home care
Increasing ability of purchasers to set healthcare prices	Increasing attention toward prediction, prevention and personalisation	Increasing prevalence of chronic diseases
Increasing regulatory requirements and approval times	Rapid growth in diagnostic tools	Increasing prevalence of obesity
New models for innovation in healthcare emerging		Declining health workforce in developed countries

Table 2. Signals of change

Economic	Technological	Social
R&D budgets of big pharmaceutical companies cut in last few years	Clinical trials under way for curing congenital eye diseases using gene therapy	People sharing information about their medical conditions with other patients as well as health researchers on social networking sites such as "PatientsLikeMe"
Open innovation models being adopted by large companies, such as GE's healthymagination programme	Several human organs now simulated by computers. Research under way to create a virtual human brain	In 2011 FDA sought information on how nanotechnologies will impact on the products that the FDA regulates
Venture capitalists now focussing more on devices and eMedicine at expense of drugs	First cancer vaccine (Provenge) approved by the FDA in 2010	Patient groups lobbying for more rapid regulatory approvals
FDA has established the "Innovation Pathway", a programme intended to encourage breakthrough medical devices	Anti-malarial compound artemisinin produced by synthetic biology entered production phase in 2011, with distribution forecast for next year	"Hot spotting" adopted by some health practices to identify patients with greatest treatment costs and work with them to better coordinate healthcare
"PolyPill" being trialled as a preventative for heart disease	First transplant of a lab-grown human organ in 2011 – a trachea grown from the patient's own stem cells	Shortages of a range of medicines, due to lack of profitability, poor quality control, or other factors
"Reverse innovation" occurring, where cheaper healthcare solutions developed for developing countries are now being sold in more affluent countries	Genome sequencing costs now less than US\$10,000 per genome. 30,000 genomes likely to have been sequenced by the end of 2011	Range of health-related smartphone apps approved by the FDA in the last year. More guidance on mobile health devices released in 2012
Germany and the UK medicine purchasers have negotiated payment regimes based on outcomes	First human embryonic stem cell trial commences in Europe this year – treating an eye disease	
Rising number of provisional approvals for medicines, where additional data collected before more widespread use permitted	Over 2,000 da Vinci robotic surgical systems installed worldwide since 1999	

Falling productivity of drug development combined with increased regulatory requirements is prompting the pharmaceutical sector to develop new business models. Both the OECD and PricewaterhouseCoopers have noted that pharmaceutical companies will need to become more collaborative (with other companies, academia and governments) or horizontally integrated (to expand what they do) to improve their success in developing medicines, reducing costs, and remaining viable in a changing healthcare environment.

Large pharmaceutical companies are already changing what they do. This involves focusing more on managing pharmaceutical and healthcare developments rather than developing, distributing and marketing therapeutics on their own. There is an increasing diversity of drugs and markets. A great deal of experimentation (large and small) will occur over the coming years.

For example, Lilly is becoming an integrated pharmaceutical network, collaborating more with other companies and research organisations so that it can tap into a broader range of skills and resources. Other Big Pharma firms are focussing more on partnering with generic manufacturers and/or expanding their markets in countries such as China, India, and other parts of Asia. Meanwhile, a growing proportion of drugs are being developed by smaller companies (See Table 3).

While many lucrative drugs are coming off patent over the next few years (creating what IMS Health has called a US\$98 billion "patent dividend"), other pharmaceuticals will be replacing them. Many of these will be more complex drugs ("biologics") that are likely to require new delivery mechanisms, and so potentially higher costs (Table 3). There is also a shift from treating symptoms to modifying disease outcomes. The most rapidly growing fields for new pharmaceutical products over the next five years are anticipated to be anti-coagulants, followed by oncology, anti-diabetics, vaccines and antivirals.

As healthcare improves a growing number of previously acute medical conditions are becoming chronic conditions requiring long term treatment. In the UK, people with HIV/AIDS now live on average 15 years longer compared with a decade ago. A range of cancers are now regarded as chronic diseases, with an evolving set of treatments to manage disease progression.

Examples of recent developments that are signals to some of the trends are shown in Table 2.

A Changing Pharmaceutical Landscape

Pharmaceutical costs account for only around 15% of total healthcare spending, so the biggest opportunity for savings is in improving how healthcare systems operate. Nonetheless, the price of pharmaceuticals attracts considerable attention because of the high costs of some medicines.

Table 3. Some trends in the pharmaceutical market

Then	Now	Future
Spend on prescription drugs US\$354 billion in 2002	\$711 billion spent on prescription drugs in 2011	Pharmaceutical spend forecast to be \$853 billion by 2016
In 2000, "Big Pharma" produced 40% of drugs	Now Big Pharma produce about 25%	?
	Generics represent 27% of market in 2011	Generics forecast to have 39% of market in 2015
21 blockbuster drugs on market in 1995, representing 16% of pharmaceutical revenue	123 blockbuster drugs on market in 2011, representing 35% of pharmaceutical revenue	48 new blockbusters expected by 2015, but will represent only 30% of revenue
Blockbuster drugs that are biologics represented 10% of revenue in 2000	Blockbuster drugs that are biologics generated 30% of revenue in 2010	?
	Biologics and bioengineered vaccines represented 17% by value of pharmaceutical market in 2009	Share of market may reach 23% in 2016
	Therapeutic vaccines (eg against HIV) represent 0.4% of total vaccines in 2009	Therapeutic vaccines may comprise nearly 10% of vaccine market in 2015

Medical devices currently only constitute up to about 5% of healthcare spending, but this may rise as more devices become available and they are used in initiatives to reduce healthcare costs through greater prevention or early diagnosis. However, medical devices are also coming under greater regulatory scrutiny, so their development times and costs are also anticipated to rise in the coming years.

Technological Trends

Pharmaceuticals are no longer dominated by small chemicals packaged in solid or liquid form. Increasingly complex chemicals, biological compounds, new materials and electronics are being developed and combined. Many will require new methods of delivery, as well as new forms of efficacy and safety assessment.

Regulators are likely to keep struggling to keep up with the pace of technological change. But there is also the potential, like the FDA's "Innovation pathway" programme, for regulators to also be more innovative and work with firms to help find better ways of regulating that doesn't unnecessarily stifle innovation.

Research is leading to more rapid screening of potential drug candidates and drug targets, greater precision and specificity of treatments, and quicker diagnostic testing. In some cases this

will result in cheaper tests, or improved outcomes due to better matching of treatment(s) to individual needs. In some cases, such as robotics, costs will be high in the short to medium term, but will reduce as production processes improve and sales volumes increase.

Increasing technological capabilities to correct or enhance physical and mental well-being are anticipated to further challenge ethical and moral values and what is considered well and sick.

Better healthcare is anticipated to also occur through greater data collection and information mining. This "electronic medicine" is only at an early stage. While the New Zealand health system has very good adoption of electronic medical records, this by itself isn't sufficient.

Benefits from electronic records will come from not just sharing the files between relevant health practitioners, but from researchers being able to mine the records to conduct virtual clinical trials, and to more readily identify healthcare procedures that work particularly well or poorly.

However, more information doesn't necessarily lead to better decisions and outcomes. IBM has noted that for many medical conditions there is already more information than a doctor (or anyone else) can make sense of. As more tools and techniques become available (through gene sequencing, MRI and other scanners,

biomarkers, etc) this information flood will gather strength. A range of analytical and visualisation developments will be needed to help the health practitioner and patient, so that diagnoses and decisions don't become harder. In some cases it will be legitimate to ask "don't we already have enough information to make a decision?"

Other Trends

Social solutions have the potential to have greater impacts on reducing costs and improving outcomes than new medicines and devices.

More "upstream" interventions are being introduced by some healthcare providers. Examples include the use of wireless scales (to monitor patient condition regularly and remotely), free transport for patients to clinics (to encourage attending appointments), frequent monitoring of injuries to patients with diabetes (to ensure small cuts don't become infected).

The use of checklists and greater focus on supporting high needs patients have been shown to significantly improve patient outcomes and reduce costs. The former is cheap and simple to implement, the latter requires more intensive management.

As John Shaw described in the September 2011 issue of Contact (the Pharmacy Guild of New Zealand's newsletter), dispensing of medicines is also likely to change. Pharmacists may become more a service provider to help patients with their medications rather than simply a dispenser of pills.

In addition to purchasers and regulators having greater involvement in pharmaceutical developments, there is also growing patient engagement. More people are seeking information online, and sharing information about their medical conditions with other patients, as well as health researchers on social networking sites.

A challenge will be to ensure that greater health inequalities do not arise due to digital divides where some don't have access to the internet or mobile wireless devices that can facilitate healthcare.

The health effects of a changing climate in New Zealand are uncertain. Warmer temperatures may lead to an increase in the incidence of some infectious diseases (such as dengue fever and water borne

protozoans). On the other hand, it may also reduce the incidence of winter illnesses.

Conclusion

The outlook for healthcare around the world is one of change on many fronts and an increasingly complex environment. There will be a much greater diversity of diagnostic tests, treatments, devices and healthcare practices. Organisations, both public and private, purchaser and provider, will also need to change.

For PHARMAC it seems clear that the nature of discussions it will be having with pharmaceutical suppliers (and local communities) will be quite different from those it has had to date.

Despite a range of initiatives to contain costs, demographic changes and increasing disease complexity seem likely to result in rising healthcare costs. Consequently, pressures on pharmaceutical and device purchasers, such as PHARMAC, seem unlikely to reduce. They may in fact increase due to the greater diversity of treatments making it harder to decide what to buy.

Rather than forecast what percent of GDP will be health-related in 20 or 30 years it is more useful to consider the questions “what is a sustainable and acceptable level of expenditure?” and “how can better health outcomes be achieved through lower costs?” The answer to the first question is: it will depend on how prosperous the society is, and their expectations for healthcare.

International comparisons have shown that rising healthcare costs are not necessarily correlated with better health outcomes (see Fig 1 below), and considerable experimentation is going on to see how costs can be reduced or contained alongside achieving better outcomes. Robert Kaplan and Michael Porter, from Harvard University, have suggested that a greater focus on measuring the costs and outcomes of healthcare is an essential factor for achieving more affordable healthcare.

A growing focus on personalised medicine on the one hand and data-driven healthcare on the other has the potential to add to tensions between what a patient or their doctor think is best and what the health system considers acceptable. We will need to find ways to better manage this.

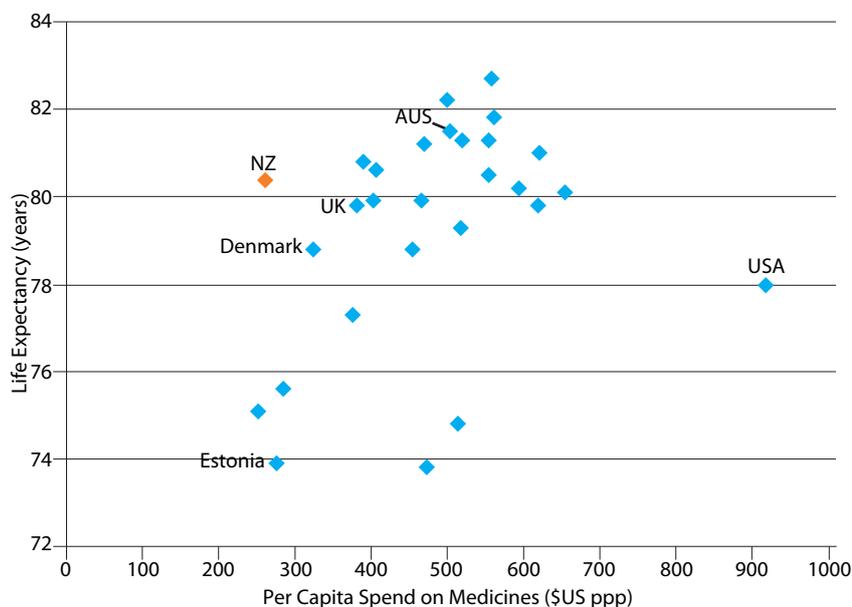


Figure 1. Comparison of national expenditures on medicines (\$US purchasing power parity) with life expectancy. Data for 2009. Source: OECD.

Further information

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New Zealand Population and Health Trends

By 2061 New Zealand’s population may reach 5.75 million (or greater), of which 1.44 million (25%) will be over the age of 65 (twice that in 2002). The proportion of people over 85 years will rise to 5.5% (up from 1.3% in 2002). The Ministry of Health and Treasury projected that by mid-century 63% of health expenditure may go on older people (up from 40% in 2002).

Five hundred million dollars was spent on diagnosing and treating cancers in New Zealand in 2008 (this includes all healthcare associated costs, not just the medicines). An analysis commissioned by the Ministry of Health suggests that this cost may grow by 23% over the next decade, largely due to the growing and ageing population. The prevalence of obesity in adults doubled to 19.9% between 1977 and 2003, with an expectation that the level will be 29% this year. It is predicted that there will be a doubling of the number of people with type 2 diabetes by 2028, to nearly 10 per cent of the adult population. The prevalence of Alzheimer’s and other neurodegenerative diseases will also rise as more people live longer.

In 2009 health expenditure represented 6.9% of New Zealand’s GDP. The annual growth rate in health expenditure over the last decade has averaged out at 7.6% per annum (well above the rate of inflation). The biggest driver of healthcare costs is labour, representing 63% of Vote Health. In contrast, expenditure on medicines is modest; out of the nearly \$14 billion health budget for 2011/12 community and cancer medicines were allocated \$777 million, or about 5.5%.

When looked at in terms of longevity, New Zealand compares well internationally with what it spends on medicines (Figure 1). However, this masks lower life expectancy and poorer health outcomes for Māori and Pacific peoples.

PHARMAC attracts its share of criticism, but the agency has provided long-term benefits, writes David Russell

David Russell is New Zealand's best-known consumer rights advocate, having spent 35 years with Consumer NZ including 17 years as its Chief Executive. He received an honorary doctorate in commerce from Massey University in 2008 in recognition of his championing of consumer rights.

PHARMAC operates on a finite budget, negotiating the prices for subsidised medicines for New Zealand patients. Given this mandate tension is inevitable between consumer expectation and PHARMAC's budgetary constraints. For the majority of patients, it works well but there's a minority whose needs (sometimes real, sometimes perceived) are not met, because PHARMAC does not subsidise their drug of choice.

PHARMAC generally only considers subsidising drugs that have been approved by Medsafe which is responsible for the regulation of medicines in New Zealand, and their safe use; that's something that patients often don't realise, yet it's an important part of the equation. Sometimes Medsafe doesn't consider drugs sufficiently safe or tested; sometimes PHARMAC decides certain drugs are too expensive to fund. And that is the core criticism of PHARMAC.

It's unfortunate the exceptions get the emotional publicity, although I don't want to belittle the opinion of those who may (or may not) benefit from those highly priced medicines for rare conditions. But it needs to be put into perspective: PHARMAC should get more recognition for its excellent work on behalf of all New Zealanders, in negotiating good prices for pharmaceuticals using analytical assessment rather than emotion.

Pressure

PHARMAC operates under enormous pressure from the pharmaceutical industry which use the emotional tugs of case histories to promote their cause to get PHARMAC to fund their drugs; including tactics such as sponsoring time-finite drug trials, and – of course – Direct-to-Consumer advertising (DTC).

Our world is being increasingly medicalised; sex and weight are the two 'biggies' although – in the main – lifestyle

choices are a more effective treatment, rather than pharmaceuticals. New Zealand is one of the few countries that permit DTC, and it dates back to the days before TV in the early 1960s; the legislators of the time had no concept of the eventual power of mass communication, and TV in particular.

DTC is particularly successful with the 'social pharmaceuticals' for erectile dysfunction and weight loss. The DTC advertisements highlight the drugs' benefits, with scant mention of the sometimes decidedly unpleasant side effects. Companies will argue that they disclose side effects and cautionary information in their advertisements, but the text is so small and appears so briefly on TV that it's virtually impossible to read; this may comply with the regulations – but not the needs of consumers.

Prescription pharmaceuticals have an intermediary between the companies and the patients: GPs, with their experience and judgement. The companies like to promote the idea that DTC empowers individuals to challenge their GPs, but I don't believe that GPs are so weak that they need this challenge; with rare exceptions GPs are ethical professionals and experts.

Better information

Of course, patients are entitled – and need – to be well informed, but their sources should be more reliable than the biased promotion by manufacturers. The pharmaceutical companies' main argument is that DTC benefits consumers by providing knowledge, but that's a view I'd dispute; in the main, DTC is used as a promotional tool to manipulate consumers particularly in this age of the internet, smart phones and easily-accessible information.

Patients' information gathering depends on their diligence (they need to pick their

websites carefully) and the intelligibility of their GPs. In my experience, pharmacists are good communicators and often the first point of contact for patients.

PHARMAC doesn't deny consumer choice except, perhaps, at the margins. Instead it focuses on what's really important – the pill's colour, sugar content and advertising is immaterial; drug efficacy is what provides the cure, not the manufacturer's name or branding. After all, people can always pay a premium for the particular drug brand they really want.

High expectations

PHARMAC's collective buying power makes sense from the commercial point of view, and protects consumers. But the emotional tugs of the exceptions inevitably get the publicity; it's important that political decisions about PHARMAC's operations are not based on those expectations. Consumers need to realise that some drugs – especially antipsychotics and antidepressants, according to recent

articles in the US – have only slight benefits, and some have severe side effects.

Alternative medicines certainly need a degree of control, and it's important manufacturers substantiate any claims. One of the basic principles of medicine is 'first, do no harm' so I'm annoyed by some of the charlatans in the field of alternative medicines, where the benefits are often overstated. I accept the products sometimes provide succour and there's certainly evidence that vitamins and mineral supplements can do some good, even if it's just psychological, although I've always rejected the concept of the 'article of faith'! Show me the evidence... and that's what PHARMAC does for prescription pharmaceuticals; it weighs up the evidence and the drugs' efficacy.

Accountability

PHARMAC does a bloody good job, relying on its team of highly skilled and dedicated people, but it's important it doesn't exceed its mandate. I believe that its tight rein on

the criteria for funding pharmaceuticals is essential to the organisation's on-going effectiveness, but as a monopsony (with one buyer and many sellers) it needs close oversight to ensure it continues to perform its function.

PHARMAC is accountable to the Minister of Health and Parliament, but there have been calls to make it more transparent although that needs limits as it could hamper PHARMAC's effectiveness in the commercial world. Perhaps it should have closer links to the National Health Board (chaired by Murray Horn), which has made an excellent start in breaking down the silos in New Zealand's health system. But I'd hate to see PHARMAC's effectiveness diluted by restraints on its activities; it's unfair that PHARMAC attracts so much odium and contempt. Instead, its excellent day-to-day work should be recognised and applauded – it's saved the country billions of dollars.



A key objective of PHARMAC is to fund pharmaceuticals that are cost effective in meeting the health needs of the population, writes Australian health economist Professor Anthony Harris

Understanding and measuring health need is not straightforward, and PHARMAC has been making progress in measuring need to improve its decision making.

Health gains are often measured by improved length of life and improvements in quality of life. The cost effectiveness of a new pharmaceutical is usually measured by these improvements over standard treatment compared to the difference in cost.

But what of the context for those 'health gains'? It may be that we value gains in survival differently depending on the context of the disease and the patient. Many people would argue that we should think of treatment for patients whose disease is imminently life threatening differently from a preventive treatment in someone who is otherwise healthy. Even if the overall expected gain in eventual length of life is similar we would give priority to those who are terminally ill. We might think of this as a difference in "health need".

The implication is that some diseases, like cancer, might get more funding than long-term chronic conditions like asthma, or that we might fund some treatments that offer very little survival gain to patients because we feel that these patients are in "need". The question for PHARMAC arises: should high 'health needs' provide additional weight to decisions to fund some treatments, even where treatment is costly and not significantly effective?

Both ethical theory and public opinion suggest that, in setting priorities for health care including medicines, society wants to include how ill the individuals would be if the intervention did not take place. ¹ The issue has been intensified by increasing life expectancies, innovations in medical

technology, and increasingly sophisticated pharmaceuticals – all with associated costs and patient expectations.

PHARMAC, in seeking to achieve the best health outcomes within the funding provided, has been trying to better define, describe, measure and use concepts of health need in its decisions ². The question for the future is what social value do we place on notions of severity, 'just deserts' and fairness, and how might these modify our concern to get the most health for the population.

Calculating the Benefits

The standard economics approach towards the public subsidy of health technologies, including medicines, has been to evaluate the population's health gains in relation to the cost of the achievement. In other words assessing the value of technology to society (which funds public health care), then finding the cheapest way to fund it. This is a key aim of PHARMAC.

New technology has tended to be valued according to the years of additional life gained for each individual treated and the quality of life in those additional years; the cost is the money devoted to that treatment. This is often called the 'efficiency approach'; the objective is to maximise health, measured by the sum of quality adjusted life years gained (QALYs) per \$ spent. So for example, a new cancer treatment may increase survival by one year for 10 percent of patients treated at a cost of \$5,000 per patient; if their quality of life was high for that year that is a cost per expected life year gained of \$50,000.

However, funding that treatment raises a number of issues:

- Is the survival measurement reliable and can we adequately adjust it for quality of life in those extra months or years provided by treatment?;

- Does totalling the years of survival across patients reflect everything we want to include in the 'social value' of the gains from treatment?; and
- Should we place a higher social value on some groups of patients and, if so, which ones?

In addition to possible health gains and their opportunity costs, society tends to value interventions more highly according to how worse-off the patient would be without the intervention. This 'societal valuation' is often called 'an independent concern for severity'. Severity can be measured in a variety of ways, but one of the main issues is the prognosis without the new treatment. The mixture of years of life and the quality of that life may be another factor we want to consider when comparing treatments, particularly where there is uncertainty about the validity of quality of life measurement.

If we accept that society values some people more than others, we need to adjust the value we place on different health gains. For an equal individual health gain (for example, 10 extra years of life), we might choose to give some priority to those who are closer to death without treatment, or those whose quality of life has been or would be worse without treatment. This might also imply for individuals with the same predicted gain from treatment in terms of years of life some priority be given not only to those with a life threatening illness but also to the elderly (who are expected to be closer to death) or alternatively to those who have experienced long term disadvantage or disability prior to treatment.

International perspective

Many jurisdictions around the world (like PHARMAC), that consider the monetary value of pharmaceuticals prior to public

subsidy, already take into account a range of health-related outcomes (including severity of illness, proximity to death, availability of alternative therapies and extent of the quality life gain). However there seems to be no systematic reporting of factors beyond the total health gain, the total cost, and the cost per health unit gained in these jurisdictions.

In its early attempts to systematise the presentation of these factors within PHARMAC, New Zealand is involved in important innovative work that could improve decision-making. By taking a broader perspective that includes a dimension of "health need", PHARMAC may be able to take account of broader views within the community, while retaining a systematic, coherent and consistent process of deciding which pharmaceuticals to fund.

In those countries that use value for money as a criterion for public subsidy of pharmaceutical and other health technologies and do consider health "needs", the most common approach is to adjust the threshold for an acceptable cost per QALY. For example in England and Wales the National Institute for Health and Clinical Excellence allows the standard acceptable cost per QALY threshold for new technologies (£30,000) to be higher for conditions with life expectancy less than 24 months, where treatment might increase life expectancy by three months or more³.

Australia has 'rule of rescue', allowing some medicines to be accepted when the cost per QALY is less attractive. Canada considers cancer treatments separately, implicitly allowing for a higher threshold cost per QALY in life-threatening therapeutic areas.

Some countries vary the level of subsidy according to patients' income and age; others vary the subsidy according to patient and disease characteristic, even where severity of illness is not a criterion in general subsidy decisions. Ireland, Denmark, Spain, Finland, and Turkey have lower levels of patient payment for chronic long-term conditions – compared with acute conditions – while Korea, Portugal, and Denmark consider the severity of the disease or the essential nature of the therapy. These lower patient payments in a regulated pricing system imply a higher social willingness to pay for patients with certain characteristics (such as the 'level of perceived need').

While the trend internationally has been to have an explicit or implicit cost per QALY criterion to inform decisions on which medicines should be subsidised, this has been generally based on the view that QALYs are a reasonable measure of health gain. As far as I am aware no country has yet tried to include severity of illness in a comprehensive systematic way (or other notions of equity or justice) into their pharmaceutical decision-making processes.

PHARMAC's developing approach

PHARMAC has been considering the use of a range of health status indicators to better capture a notion of 'severity of illness' to inform its funding decisions. Broadly speaking, PHARMAC is starting to quantify health need, having previously considered it in more qualitative ways.

The health need-related metric, with which PHARMAC is experimenting, is:

the gap between the life expectancy (adjusted for the quality of that life) with current standard care for a person of a given age and gender with a particular condition, and the life expectancy of an average, healthy person of the same age and gender.

This approach is consistent with PHARMAC's remit to consider health need, in addition to the clinical benefits and the cost of medicines. This measure of severity is only one possible definition of 'need' but, as an additional quantified criterion in influencing decisions, it should attract considerable international attention.

PHARMAC's embryonic approach suggests one important way in which to value individual QALY gains: the severity of existing illness, as measured by prognosis. In addition, by presenting the decision maker with information on the whole patient life path of quality of life, including the patient's age at treatment, quality of life up until then, and the prognosis with and without treatment, the decision maker can consider severity along with notions of distributive justice – such as 'just deserts' and fairness. For example describing the impact of treatment in this allows us to consider if we think that a young person who has had a debilitating condition since birth is more "in need" or deserving than an older person with a life threatening illness who has otherwise had a healthy life.

It is inevitable that in any resource allocation mechanism, such as public medicines reimbursement decisions, priorities are made about groups of patients. Some patients will gain more

QALYs than others. It may not be enough to continue with the tacit assumption that these QALYs are of equal value no matter who gets them. PHARMAC can make better decisions if it is informed about the QALY gains and costs from a new pharmaceutical, but it can improve on those decisions if it knows who will get the health gains and also has a clearer sense of their health needs.

Note: Professor Anthony Harris is Acting Director of the Centre for Health Economics at Monash University, Melbourne, Australia. He is grateful to Professor Jan Abel Olsen (Universities of Oslo and Tromsø (Norway) and Monash University) for his insights on severity-based measurement in cost effectiveness analysis in health.

References:

¹ Nord E, Daniels N, Kamlet M. QALYs: some challenges. Value Health 2009;12 Suppl 1:S10-5. <http://www.ispor.org/meetings/invitational/QALY/Paper3.pdf>

² New Zealand Public Health and Disability Act 2000 section 47(a)

³ National institute for Health and Clinical Excellence

Appraising life-extending, end of life treatments July 2009 <http://www.nice.org.uk/media/E4A/79/SupplementaryAdviceTACEoL.pdf>

PHARMAC's 86-20 rule

Around 1800 medicines are subsidised through the Pharmaceutical Schedule, and these are taken by more than three million New Zealanders.

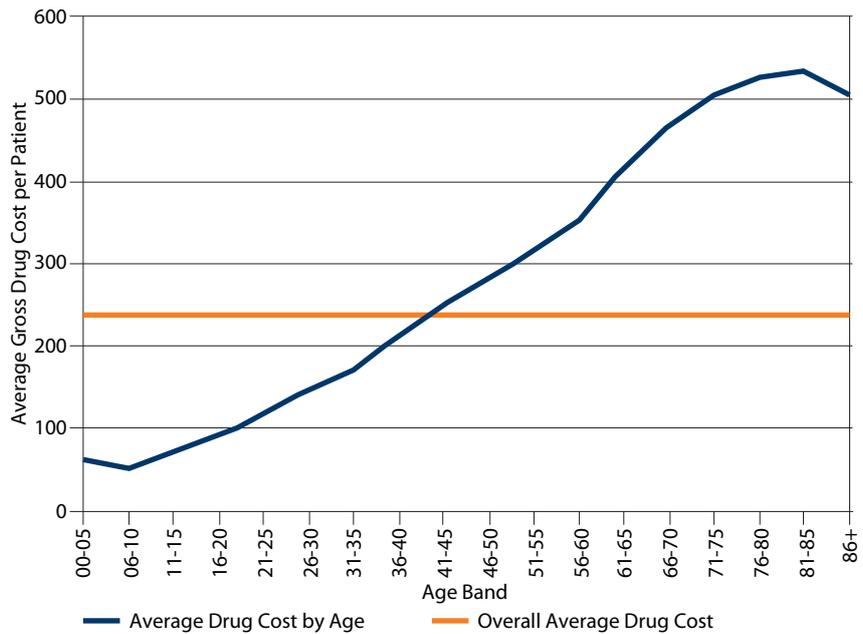
But what's the age profile of this medicine-taking population? Graphs 1 and 2 show that medicine use rises with age. This begins when people are around 30 and rises steadily until they hit their 80s and 90s. Up to about age 50, people may be taking drugs for long-term chronic conditions (such as asthma or diabetes), and adding to that preventive medicines such as statins or low-dose aspirin to reduce cardiovascular risk.

Once people get past 50 the number of medicines they take begins to rise and many people over 50 are on multiple medicines. This means both the numbers of prescriptions and costs of medicines rise with age. As our population lives longer, and an increasing proportion of the population reaches 50+ as the Baby Boomer generation ages, this will be an increasing challenge for PHARMAC and our health system.

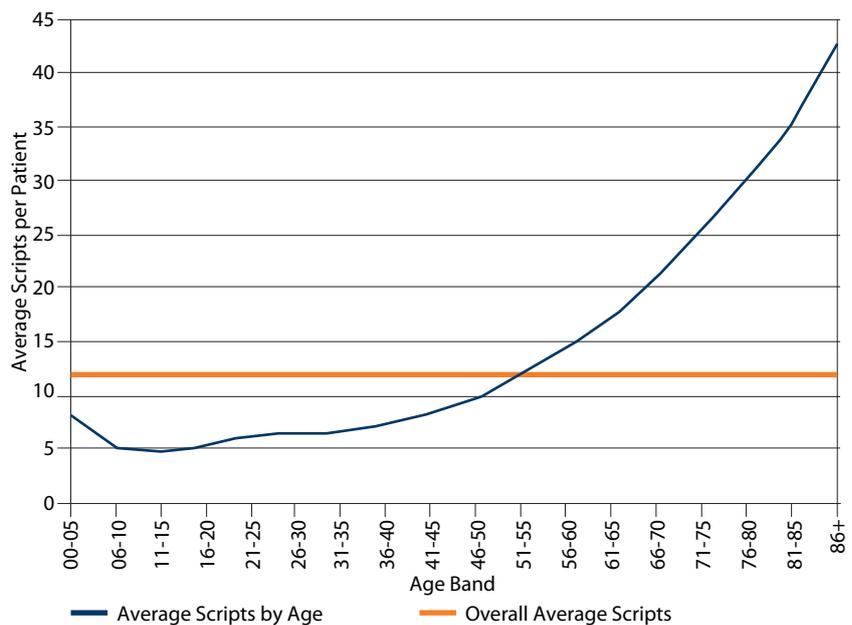
Many of the most widely used medicines are now very inexpensive and this means large numbers of people can be treated for very low cost. But there are small numbers of patients that account for a large proportion of expenditure.

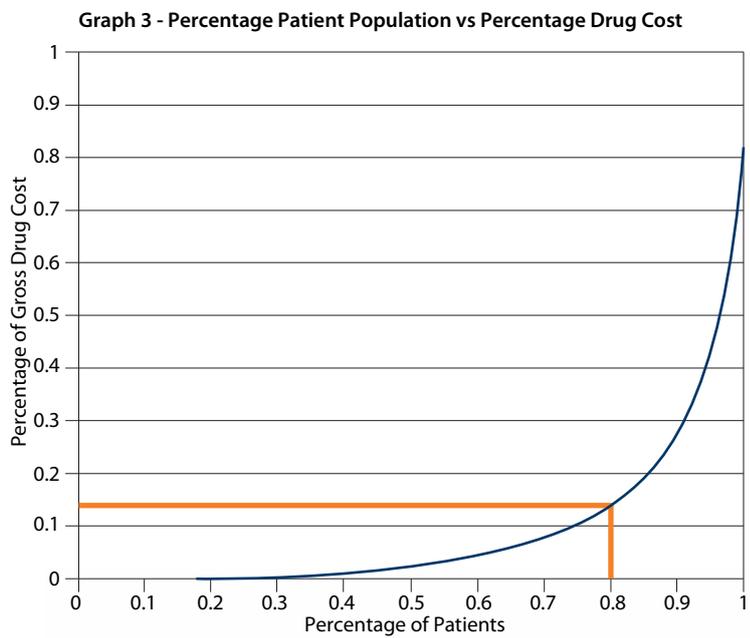
Graph 3 shows that 80% of patients account for just 14% of total expenditure. This means that the top 20% of patients account for 86% of expenditure.

Graph 1 - Drug Cost per Patient By Age



Graph 2 - Prescriptions per Patient By Age





Review of expenditure 2010/11

PHARMAC's heavy investment in medicines in the past year reflects the Government allocating more money to pharmaceuticals. Over the past two years regular increases in the pharmaceutical budget, together with the impact of PHARMAC's long-term savings programmes, has created significant 'headroom' for PHARMAC to invest in new medicines, and to widen access to those already funded.

The result was new or wider access to 82 medicines – including 39 new medicines

added to the Pharmaceutical Schedule – in the past year. When combined with the new or widened access to 45 medicines of the previous year, this is the heaviest and most sustained period of medicine investment in PHARMAC's 18-year history.

Funding medicines isn't a short-term activity, and the decisions made will have long-term repercussions. While we expect them to produce better long-term health outcomes for New Zealanders, the decisions will also have budgetary impacts

into the future that PHARMAC will have to take care in managing. In order to make these new medicines affordable in the future, PHARMAC will need to continue with its savings programmes (including generic substitution of large-volume medicines), and look for increases in the budget where appropriate.

Significant decisions

In terms of patient numbers, the biggest decisions were those involving the anti-

The Top 20 Expenditure Groups

Year ending 30 June

\$ millions, cost ex manufacturer, excludes rebates and GST

Drug Type	Main Use	2006	2007	2008	2009	2010	2011
Antipsychotics	Mental health (psychoses)	\$53.45	\$57.13	\$60.58	\$61.61	\$66.19	\$60.13
Lipid Modifying Agents	Raised cholesterol (cardiovascular risk)	\$68.19	\$68.86	\$66.06	\$63.48	\$37.87	\$53.51
Antirheumatoid Agents	Arthritis	\$5.39	\$9.14	\$11.23	\$15.94	\$28.39	\$42.71
Inhaled Long-acting Beta-adrenoceptor Agonists	Asthma	\$21.65	\$19.34	\$23.25	\$27.84	\$31.84	\$36.53
Agents Affecting the Renin-Angiotensin System	Raised blood pressure (cardiovascular risk)	\$26.08	\$29.10	\$29.94	\$31.19	\$34.47	\$34.54
Chemotherapeutic Agents	Cancer	\$13.65	\$16.62	\$21.12	\$23.36	\$26.23	\$33.88
Diabetes	Diabetes	\$22.51	\$26.34	\$29.36	\$31.06	\$30.07	\$32.80
Treatments for Substance Dependence	Addiction	\$0.33	\$0.41	\$0.51	\$0.56	\$5.90	\$27.02
Antiepilepsy Drugs	Epilepsy	\$24.80	\$27.85	\$24.62	\$25.90	\$24.96	\$26.11
Antidepressants	Mental health (depression)	\$29.71	\$30.65	\$20.81	\$22.26	\$24.20	\$24.70
Analgesics	Pain relief	\$15.69	\$17.23	\$18.86	\$21.19	\$23.05	\$24.67
Diabetes Management	Blood glucose monitoring	\$16.28	\$17.12	\$19.03	\$19.80	\$21.20	\$22.40
Beta Adrenoceptor Blockers	Heart disease	\$21.27	\$24.52	\$29.29	\$32.01	\$23.32	\$18.21
Drugs Affecting Bone Metabolism	Osteoporosis	\$11.84	\$13.56	\$15.36	\$16.36	\$17.30	\$17.49
Antibacterials	Bacterial infections	\$13.88	\$14.80	\$15.47	\$16.38	\$15.60	\$17.48
Antiretrovirals	HIV/AIDS, viral infections	\$10.37	\$11.59	\$12.34	\$12.97	\$14.54	\$16.77
Immunosuppressants	Organ transplants, arthritis	\$13.94	\$14.50	\$15.95	\$17.27	\$17.91	\$15.87
Calcium Channel Blockers	Heart disease	\$13.68	\$14.47	\$16.02	\$16.32	\$13.32	\$14.84
Inhaled Anticholinergic Agents	Allergies	\$8.29	\$8.74	\$10.47	\$12.25	\$13.35	\$14.02
Inhaled Corticosteroids	Asthma	\$16.87	\$16.20	\$15.17	\$14.46	\$14.22	\$13.50

smoking drug varenicline (Champix – 23,000 patients in the year and estimated at 35,000 for a full year); iodine to support pregnant women (33,000); the pain reliever tenoxicam (17,000) and the acne treatment adapalene (11,000).

Overall, PHARMAC estimates over 260,000 new patients will benefit from its decisions in a full year.

PHARMAC listed donepezil, the first treatment funded in New Zealand specifically for the degenerative brain condition Alzheimer's Disease.

Also significant, but without the large patient numbers, were decisions to continue trends in cancer and HIV treatment. PHARMAC listed two new-generation cancer treatments (erlotinib and sunitinib) that, in addition to being targeted to specific types of cancer, are pills that patients can take at home. This continues the trend of cancer treatments moving out of hospitals and into treatment in the community. And new HIV treatments provide further tools to help patients live with what is becoming a manageable chronic condition.

Budget management

Through all this activity, PHARMAC maintained DHB pharmaceutical spending within the target range set by the Minister. Originally set at \$710 million for the year, the Minister agreed to give PHARMAC a \$10 million Discretionary Pharmaceutical Fund to manage, which will enable PHARMAC to carry forward some funding from one year to another. The fund will also help PHARMAC 'smooth out' the impact on DHBs of funding decisions across financial years. In all, spending on pharmaceuticals was \$706.12 million, which means PHARMAC has \$3.88 million to carry forward into the next financial year.

A total of 39.7 million prescriptions were written – a 7% increase on the previous year and a record high – for about 3.3 million New Zealanders.

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

		Treats	Year Ending Jun 11
1	Atorvastatin	Raised cholesterol	\$40,110,000
2	Adalimumab	Autoimmune disease	\$36,640,000
3	Olanzapine	Psychosis	\$30,150,000
4	Blood glucose diagnostic test strip	Diabetes	\$21,560,000
5	Imatinib mesylate	Leukemia	\$18,820,000
6	Budesonide with eformoterol	Asthma	\$18,790,000
7	Venlafaxine	Depression	\$16,490,000
8	Risperidone	Psychosis	\$14,280,000
9	Candesartan	Heart disease	\$13,370,000
10	Fluticasone with salmeterol	Asthma	\$13,200,000
11	Nicotine	Smoking cessation	\$12,920,000
12	Alendronate sodium	Osteoporosis	\$11,550,000
13	Fluticasone	Asthma	\$10,810,000
14	Sodium valproate	Epilepsy	\$10,050,000
15	Metoprolol succinate	Heart disease	\$9,950,000
16	Omeprazole	Reflux	\$9,840,000
17	Tiotropium bromide	COPD	\$9,830,000
18	Erythropoietin beta	Anaemia	\$9,310,000
19	Pegylated interferon alpha-2a	Hepatitis	\$8,950,000
20	Bupropion hydrochloride	Smoking cessation	\$7,480,000

Top 20 Medicines by Prescription numbers

		Treats	Year Ending Jun 11
1	Paracetamol	Pain	2,260,000
2	Aspirin	CV risk	1,380,000
3	Simvastatin	Raised cholesterol	1,280,000
4	Omeprazole	Reflux	1,080,000
5	Amoxicillin	Bacterial infection	1,040,000
6	Metoprolol succinate	Heart disease	920,000
7	Salbutamol	Asthma	840,000
8	Amoxicillin clavulanate	Bacterial infection	820,000
9	Ibuprofen	Pain	630,000
10	Cilazapril	Heart disease	620,000
11	Diclofenac sodium	Pain	600,000
12	Prednisone	Steroid	560,000
13	Zopiclone	Insomnia	550,000
14	Flucloxacillin sodium	Bacterial infections	530,000
15	Cholecalciferol	Osteoporosis	520,000
16	Metformin hydrochloride	Diabetes	440,000
17	Levothyroxine	Thyroid gland deficiency	430,000
18	Felodipine	Heart disease	430,000
19	Quinapril	Heart disease	430,000
20	Bendrofluazide	Heart disease	410,000

Therapeutic Group summary 2010/11

Infections

Key decisions

- Funding for darunavir – a new medicine for HIV
- Funding for etravirine – a new medicine for HIV
- Funding rule changes to allow antiviral medicines to be used to prevent HIV infection

PHARMAC funded two new medicines for HIV and made changes to how HIV medicines can be used.

PHARMAC funded darunavir (Prezista) and etravirine (Intelence) to help add to the treatments available for HIV, as the disease becomes resistant to other forms of antiviral treatment.

Etravirine is most effective when used in combination with darunavir. And darunavir can also be effective when combined with another recently-funded treatment, raltegravir, in patients who have already undergone extensive treatment.

The prophylaxis decision means that people who know they have been exposed to potential HIV infection through sexual activity can receive funded treatment to prevent them becoming infected. This could be used in situations where, for example, a sexual partner's condom has failed and there is a risk of infection.

Funding is expected to cost an additional \$2.2 million over five years.

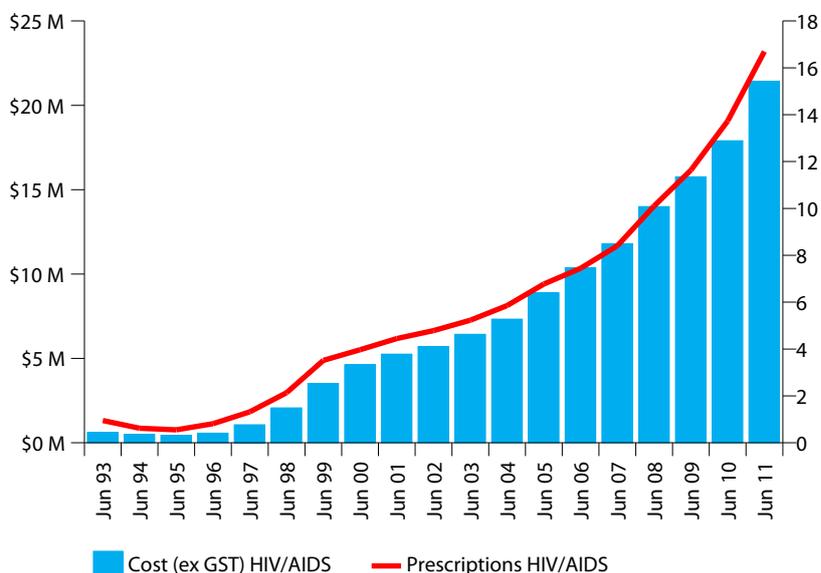
PHARMAC has listed 17 HIV treatments (including combination products) in five drug categories. In the year to June 2011, spending on HIV treatments was \$21.4 million.



HIV/AIDS

Cost (ex GST)

Prescriptions (000)



Diabetes

Key decisions

- Widening access to the long-acting insulin glargine (Lantus)
- Funding a new rapid-acting insulin glulisine (Apidra)
- Widening access to blood ketones testing strips (Optium)
- Widening access to the diabetes treatment acarbose (Glucobay).

Decisions on diabetes treatments will impact on people with both Type 1 and Type 2 diabetes.

Insulin glargine, a long-acting form of insulin first funded in 2006 for Type 1 diabetes patients, had its Special Authority restriction removed, meaning it can now be prescribed and funded for anyone with diabetes. Insulin glargine usually only needs to be injected once a day by people requiring regular injections of insulin, so is more convenient.

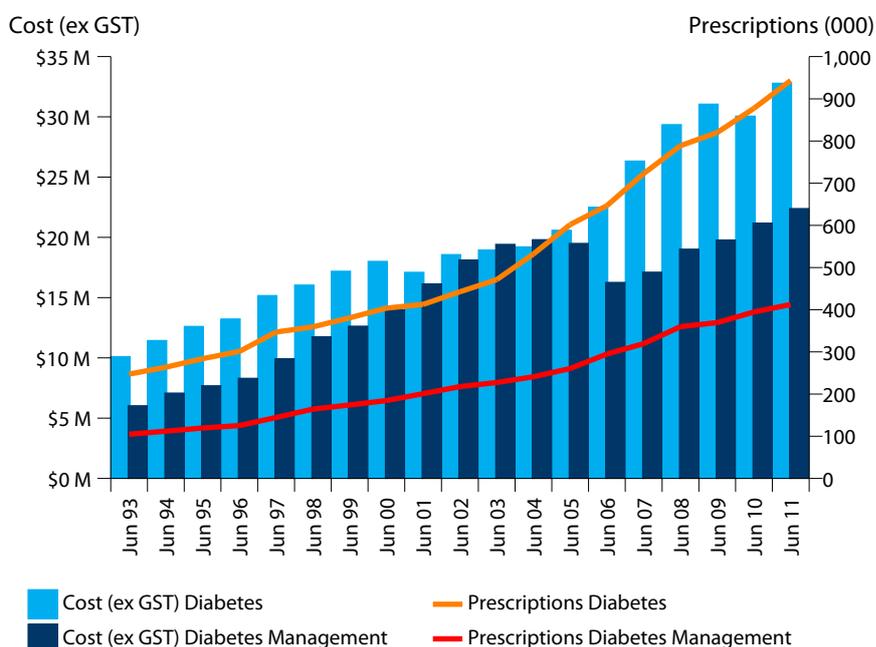
In addition, a new rapid-acting insulin, insulin glulisine (Apidra), was funded without access restrictions, meaning it can be used by anyone requiring short acting insulin injections.

PHARMAC estimates that nearly 10,000 people will be using insulin glargine within three years, with a further 2,500 on insulin glulisine.

PHARMAC also lifted restrictions on blood ketone test strips. Both blood and urine testing strips are funded, however the advantage of blood ketone strips is that they can detect diabetic ketoacidosis (DKA) earlier. DKA is a potentially life-threatening complication in patients with diabetes mellitus, resulting from an absolute shortage of insulin. Urine testing strips continue to be funded.

Removing access restrictions for the oral hypoglycaemic agent acarbose gives greater treatment options, particularly in Type 2 diabetes patients who are intolerant of metformin.

Diabetes



Heart disease

Key decisions

- Rivaroxaban, an anti-clotting drug, funded
- Open access to atorvastatin
- Open access to clopidogrel
- Widened access to ezetimibe

Cholesterol treatments

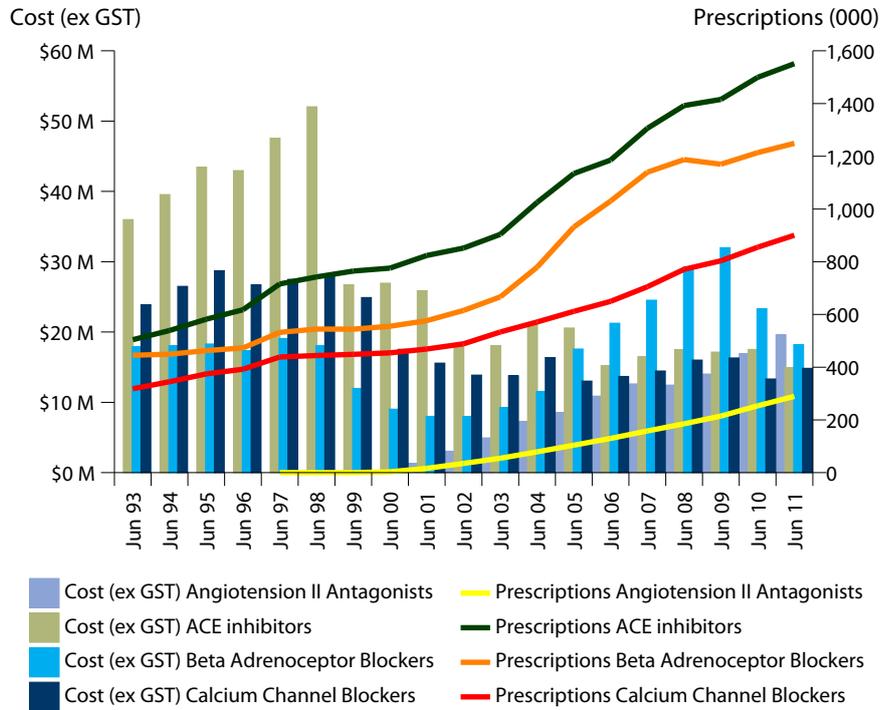
An agreement with the supplier incorporating confidential rebates enabled PHARMAC to provide open access to the cholesterol-lowering drug atorvastatin. The decision means GPs and cardiologists can prescribe either simvastatin or atorvastatin for any of their patients, taking into account the New Zealand Cardiovascular Guidelines.

Statins are used to reduce cholesterol levels and lower the risk of heart attack or stroke, and are currently taken by more than 300,000 New Zealanders. The price reduction means that, even while providing open access, PHARMAC expects to make savings.

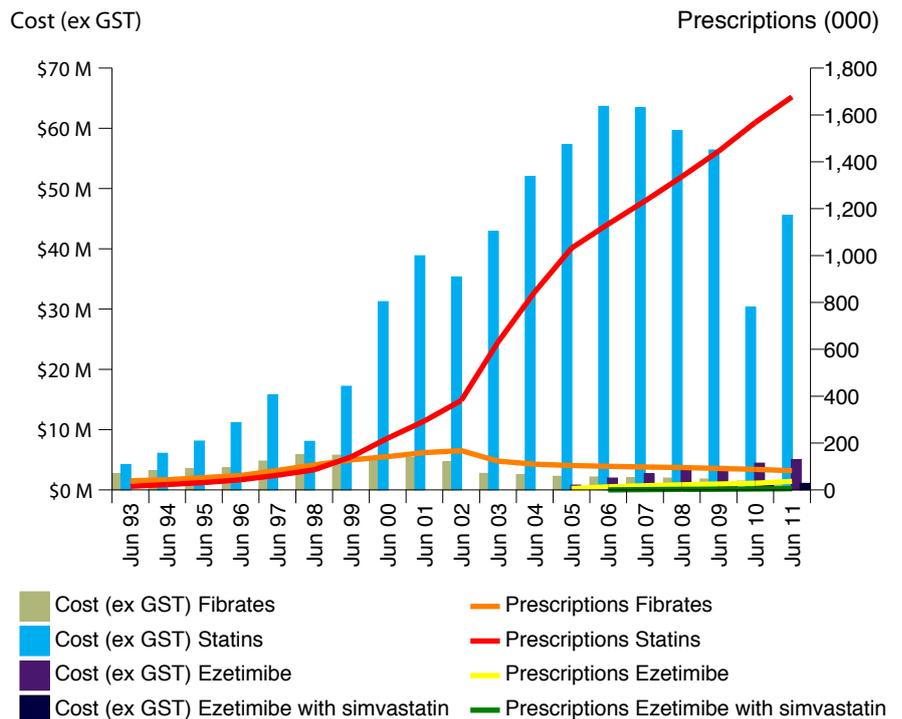
PHARMAC also amended the funding rules for the cholesterol absorption inhibitor ezetimibe (Ezetrol), plus the ezetimibe/simvastatin combination product (Vytorin).

The changes give general practitioners the ability to prescribe ezetimibe, and also widen the group of people who would be eligible for treatment. Ezetimibe continues to be restricted to people whose cholesterol levels haven't reduced sufficiently using statin drugs alone. PHARMAC estimates about 18,000 people will be using ezetimibe within three years.

Blood Pressure Management



Lipid Modifying Agents



Rivaroxaban

Rivaroxaban, a new-generation anti-clotting drug, is funded for people who have had major orthopaedic surgery (knee and hip replacements) to reduce the risk of blood clotting.

Rivaroxaban, an oral treatment, has advantages over existing treatments such as enoxaparin, warfarin or low-dose aspirin.

Clopidogrel

Price reductions on the blood-thinner clopidogrel, obtained through the tender process enabled the access restrictions to be removed.

Clopidogrel is an important treatment for people who have had, or are at risk of, heart attack and stroke. Clopidogrel was previously funded only for people with acute coronary syndrome, those who had stents inserted to open blocked arteries and for people allergic to aspirin. The access widening means doctors can now prescribe it for any patient they think is appropriate.

Originally funded at a cost of \$168 for a month's treatment, clopidogrel now costs taxpayers \$5.50 a month per patient – a reduction of more than 95%.

PHARMAC predicts the number of people taking clopidogrel will double to around 50,000 within three years, and for spending to rise by nearly \$6 million over the next five years.



Neurology

Key decisions

- First funded treatment for Alzheimer's Disease – donepezil
- New treatment funded for epilepsy – lacosamide (Vimpat)
- Modafanil funded for the sleep disorder narcolepsy

Epilepsy

PHARMAC funded lacosamide for people whose epilepsy symptoms haven't been adequately controlled by currently-funded treatments – and for those people who have unacceptable side-effects from other treatments.

PHARMAC estimates funding lacosamide will cost \$4.8 million over five years (including pharmacy markups and dispensing fees).

First Alzheimer's treatment funded

The first listed treatment for people with the degenerative brain condition Alzheimer's Disease became available in late 2010, when PHARMAC funded donepezil.

Donepezil is one of the acetylcholinesterase inhibitor group of medicines, specifically used to treat Alzheimer's Disease and related types of dementia. The funding decision followed the patent expiry on the branded donepezil, and a significant price reduction brought on by competition that made the treatment cost-effective.

Donepezil is funded without restrictions, so can be prescribed and funded for anyone with Alzheimer's Disease or other types of dementia.

PHARMAC estimates that donepezil will be used by about 15,000 people after three years, at a cost of approximately \$680,000 per year.

Modafanil

Modafanil is the first treatment funded by PHARMAC specifically to treat the sleep disorder narcolepsy – a condition that causes people to be excessively drowsy during the day, or to fall asleep when they don't expect to.

Narcolepsy is typically treated with stimulant drugs. For people with particularly severe symptoms, this can include treatments such as methylphenidate and dexamphetamine, which are also used to treat ADHD. Modafanil, which can only be used as a treatment for narcolepsy, is only funded for patients who have already tried using other stimulants.

The five-year cost of funding modafanil is estimated to be approximately \$950,000.

Hormones

Key decisions

- Levonorgestrel implants (Jadelle) funded

Removable, long-term contraceptive implants for women were funded during 2010, and there was a high demand for these devices.

The Jadelle implants (levonorgestrel 75mg) are small rods, inserted just below the skin in the arm, and can provide contraception for up to five years.

When they became funded, PHARMAC saw a spike in demand that exceeded predictions. This led to a brief period when they were unavailable, although demand has now reduced to earlier anticipated levels. Despite the increased demand, PHARMAC expects the funding decision to be cost-saving overall to the health sector (largely through long-term reduction in doctor visits and dispensing fees).

As part of the agreement with Bayer, doctors and other health providers received training in how to implant and remove the devices.

Mental health

Key decisions

- Introducing generic versions of the antipsychotic quetiapine leads to savings
- Sertraline funded for depression
- Escitalopram funded for depression
- Access widened to mianserin for depression
- Varenicline (Champix) funded for smoking cessation

Antipsychotics funding

PHARMAC predicts that savings totalling \$26 million over five years will flow from its decision to fund an additional brand of the antipsychotic quetiapine and introduce reference pricing.

Funding the Dr Reddy's brand of quetiapine added a third option to the existing two brands. Reference pricing – paying the same price for medicines that do the same or similar things – would then lead to savings. About 35,000 people a year take quetiapine.

Antidepressants

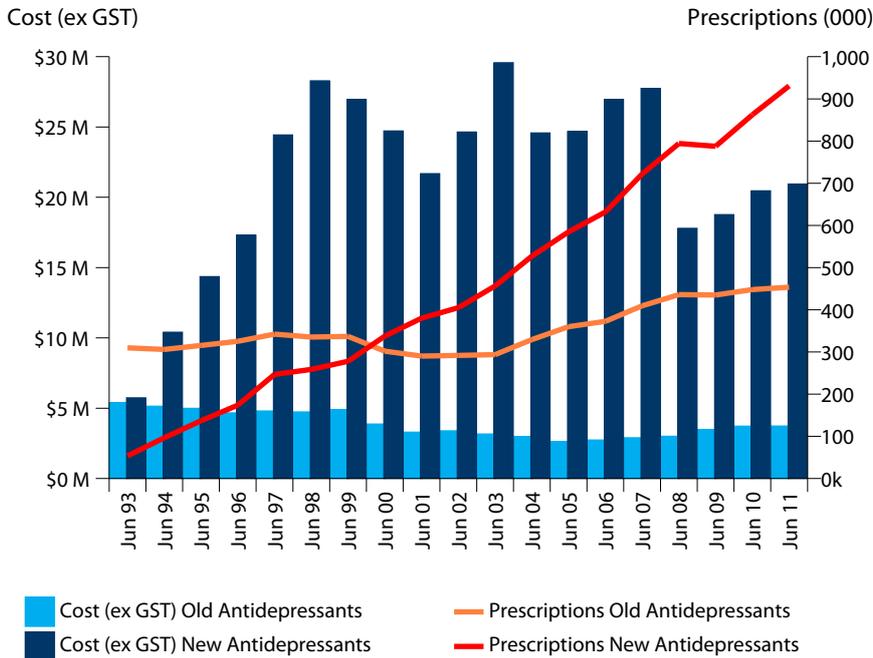
Two new antidepressant treatments were added to the Pharmaceutical Schedule during the year.

Sertraline and escitalopram were both funded without restriction for patients with depression. Both are selective serotonin reuptake inhibitors (SSRIs), of which three were previously funded.

PHARMAC doesn't expect that funding the new antidepressants will significantly grow the number of people prescribed antidepressants; however, it will still require additional funding of about \$700,000 over the next two and a half years.

PHARMAC also widened access to mianserin so it is available for people who haven't responded to other antidepressants.

Antidepressants



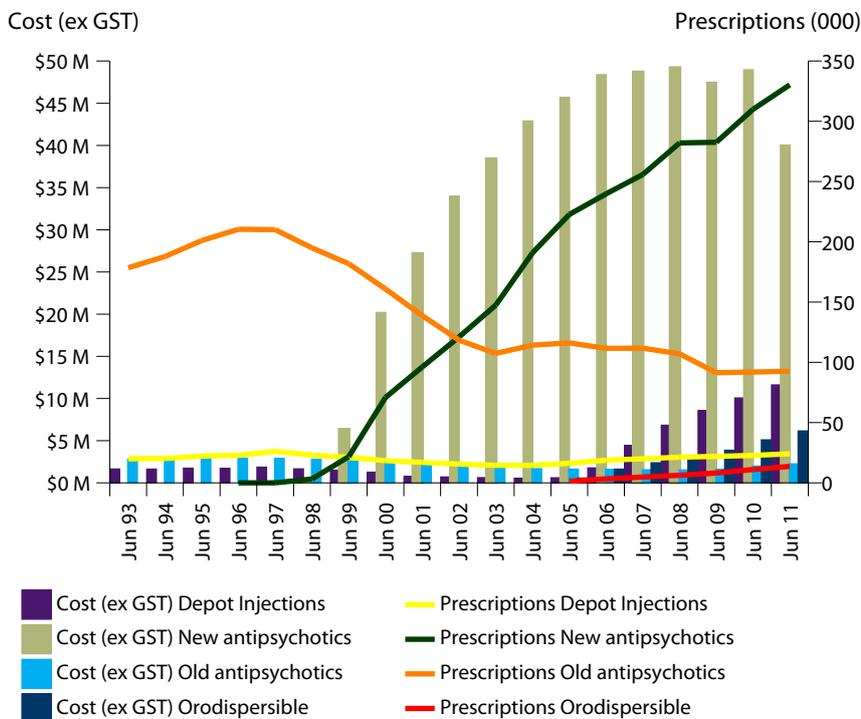
Treatments for addiction

The smoking cessation treatment varenicline (Champix) provides another option for people seeking help to stop smoking, adding to the available funded treatments nicotine replacement therapy (NRT), bupropion (Zyban) and nortriptyline.

PHARMAC has targeted varenicline's use through funding rules that require people to try at least one other funded product first, and to use varenicline only as part of a comprehensive smoking cessation programme.

Reducing rates of smoking and smoking-related harm is a key Government health target that PHARMAC has contributed to by providing a further tool for clinicians to help people quit smoking. This is expected to lead to long-term health gains through reductions in smoking-related heart attacks and strokes, and cancers. From its funding on 1 November 2010 to the end of June 2011, approximately 23,000 people were prescribed funded varenicline.

Antipsychotics



Cancer

Key decisions

- Bortezomib funded for multiple myeloma
- Erlotinib funded for lung cancer
- Sunitinib funded for kidney cancer
- Access widened to multiple myeloma treatment thalidomide
- Access widened to the brain cancer treatment temozolomide
- Access widened to rituximab for lymphoma
- Access widened to capecitabine – a colon cancer treatment
- Access widened to gemcitabine for pancreatic and biliary cancers

As cancer treatments advance, more therapies are being developed that can be taken as pills at home. Many cancers are now treated without the patients having to visit hospitals for costly and time-consuming injections or infusions. PHARMAC helped continue this trend by listing the lung cancer drug erlotinib (Tarceva), the kidney cancer treatment sunitinib (Sutent) and by widening access to capecitabine (Xeloda) for more patients with colon cancer.

Sunitinib and erlotinib are examples of new targeted therapies for cancer. These type of treatments are specifically designed to target cancerous cells reducing side effects compared with traditional chemotherapy treatment approaches which damage both cancerous and healthy cells. Both sunitinib and erlotinib are used to treat cancers for which there was previously a lack of targeted therapies.

By funding more oral therapies PHARMAC has not only made treatment more convenient for patients, but enabled hospital infusion resources to be freed up so they can be used to treat more cancer patients overall. This leads to reduced waiting times for cancer treatment – a key Government health target.

In another key decision, PHARMAC funded bortezomib (Velcade). Bortezomib is a hospital infusion that is funded for first or second line treatment of patients with multiple myeloma or amyloidosis, both of which are incurable blood disorders with few treatment options.

While individually each of these treatments is used for comparatively small numbers of patients (less than 1000 per year in each case), they provide enhanced treatment options and will lead to better health outcomes for patients with cancer.

Other changes in cancer drug funding included:

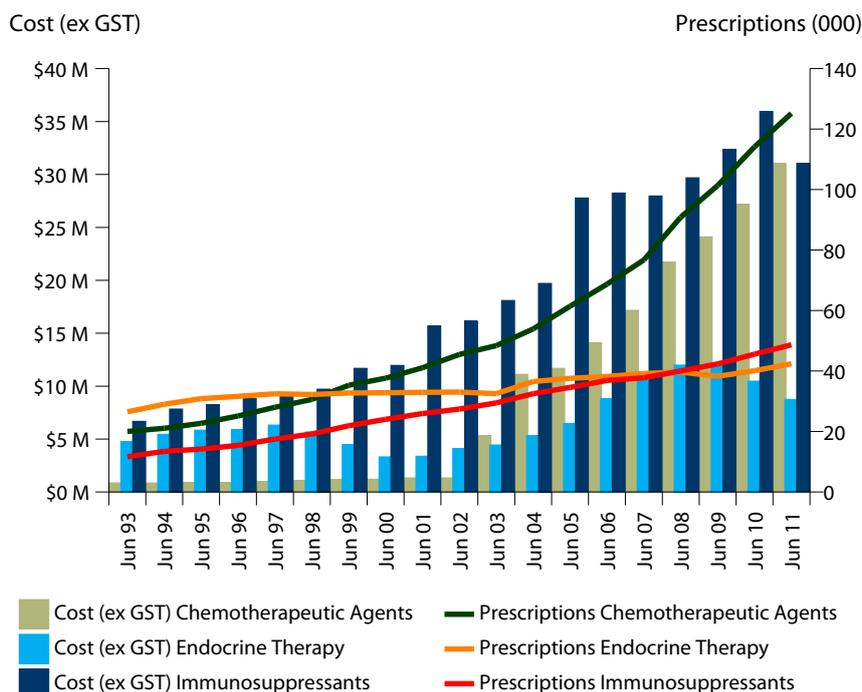
- Rituximab (Mabthera) – Wider access for this in-hospital cancer drug, so that it is funded for more patients with relapsed/ refractory aggressive CD20-positive Non-Hodgkins lymphoma (NHL), and the duration of funded treatment for patients with relapsed indolent NHL was increased.
- Capecitabine (Xeloda) – Wider access to this oral cancer drug so that it is funded to treat patients with stage II (Duke's B) colorectal cancer following surgery, and patients with locally advanced rectal cancer when given with radiation prior to surgery. Current funding also includes stage III (Duke's C) colorectal cancer, advanced gastrointestinal malignancy, and metastatic breast cancer.

- Thalidomide (Thalomid) – Wider access for this oral cancer drug so that it is funded when used at any stage in the disease for patients with either multiple myeloma or amyloidosis.

- Temozolomide (Temodal) – Wider access for this oral cancer drug so that it is funded for people with brain cancers known as anaplastic astrocytomas. Temozolomide is also funded for a more advanced form of brain cancer, called glioblastoma multiforme.

- Gemcitabine (Gemcitabine Ebewe) - Wider access for this in-hospital cancer treatment so that it is funded for people with pancreatic cancer after surgery and patients with locally advanced biliary cancers.

Oncology Agents and Immunosuppressants



Musculoskeletal

Key decisions

- Access widened to etanercept (Enbrel) for the last-line treatment of rheumatoid arthritis and other inflammatory diseases
- Zoledronic acid (Aclasta) funded for osteoporosis and Paget's disease

Arthritis

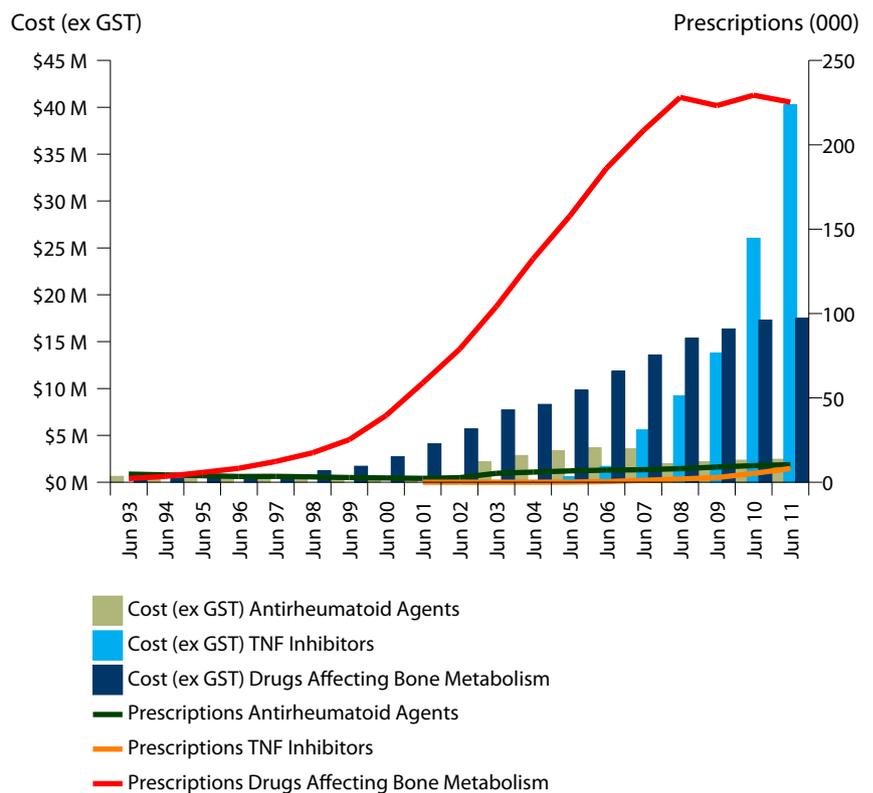
Etanercept (Enbrel) has been funded for juvenile arthritis since 2004. Funding has now been extended to cover diseases such as rheumatoid arthritis, psoriasis, ankylosing spondylitis and psoriatic arthritis. Etanercept is the second of the TNF-alpha inhibitor biologic class of drugs to be funded in New Zealand for this group of diseases. It is an alternative to adalimumab (Humira), which was funded for rheumatoid arthritis in 2006 and the other conditions in 2009.

Osteoporosis

Zoledronic acid, a once-a-year treatment for people with the bone disorders osteoporosis and Paget's disease, was funded in 2010.

Zoledronic acid (Aclasta) is from the bisphosphonate group of drugs that includes the currently funded treatments alendronate and etidronate. Zoledronic acid is an infusion delivered once a year – while the other funded treatments are tablets that are taken more regularly.

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 purchasing.

DHB Procurement

PHARMAC procures a number of products used in DHB hospitals including bulk intravenous fluids, volatile anaesthetics and radiological contrast media. In the past year, PHARMAC ran a request for proposals for haemophilia products, and also for the influenza vaccine. In addition to renewing an agreement for the blood-clotting agent Factor VIII, PHARMAC negotiated an agreement for another clotting agent Factor IX.

For influenza vaccine we entered contracts for two suppliers for three more flu seasons. We estimate the savings from these activities to be approximately \$1 million a year.

PHARMAC continued to manage national agreements for hospital pharmaceuticals and some related products.

There were 506 changes to the Hospital Schedule (Section H of the Pharmaceutical Schedule) in 2010/11, made up of:

- > **253** new listings
- > **92** price decreases
- > **66** price increases
- > **95** products de-listed.

Supporting Workforce Development

PHARMAC and Ngā 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 Otakau Marae in August, the awards were presented to Mark Nicholls (Ngāti Awa), Danielle Maulder (Ngāti Kahungunu) of the School of Pharmacy University of Otago and Cassie Butler (Whakatohea/Ngāti Kahungunu) School of Pharmacy, University of Auckland.

Mark Nicholls, 33, was awarded a \$5000 scholarship, with Danielle Maulder, 22, and Cassie Butler, 21, receiving a \$2500 scholarship each.

The awards are aimed at encouraging Māori in the pharmacy profession. A \$2500

scholarship is available at each School of Pharmacy for a third or fourth year Māori student, while a further \$5000 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. These scholarships align well with PHARMAC's Māori Responsiveness Strategy (Te Whāioranga), which aims to improve knowledge about, and use of, medicines by Māori.

Awards are presented each year, with a total value of \$10,000.

Hiwinui Heke Māori Pharmacy Student Scholarship



Exceptional Circumstances

EC Review completed

The PHARMAC Board approved changes to the schemes that assess individual patients' applications for medicines that aren't otherwise funded. PHARMAC currently assesses more than 2000 applications a year for the three Exceptional Circumstances schemes (Community, Cancer, and Hospital). The changes flow from a recommendation in the Medicines New Zealand strategy and follow a two-stage consultation process that began in 2010. The revised scheme, called Named Patient Pharmaceutical Assessment (NPPA), will take effect from March 2012.

The revised exceptions scheme abandons the need for patients to have rare conditions to be considered for funding. Greater urgency will also occur for patients whose condition would significantly deteriorate or who would miss the opportunity for significant improvement during the usual time taken to assess a Pharmaceutical Schedule application.

PHARMAC expects the revised scheme to be more permissive and to more clearly describe PHARMAC's discretion to consider funding applications not meeting the letter of the scheme.

It's likely that one of the results of the change will be that more conditions experienced by small groups of patients will be considered for funding. Rather than rarity, which is the focus of the current Community Exceptional Circumstances scheme, the focus of the new scheme will be on patients with unusual clinical circumstances, or those whose conditions are urgent and serious.

Other features of the NPPA include:

- PHARMAC will be able to approve funding some medicines through NPPA while they are under consideration for Schedule listing (unlike previously)
- Cancer and community treatments will be considered under the same scheme – likely to lead to more nationally consistent decisions
- Greater clarity and enhanced transparency for clinicians of what might be funded, because PHARMAC will publish the outcome of funding applications
- Applications costing less than \$500 for Hospital Pharmaceuticals can be approved by eligible DHBs.

Funding for NPPA will continue to be drawn from the overall pharmaceutical budget.

Exceptional Circumstances assessments in 2010/11

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. These schemes will continue to operate until succeeded by NPPA in March 2012, although funding for CaEC is from within the Combined Pharmaceutical Budget from 1 July 2011.

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 was \$3 million from within the overall Community 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 allowed DHB hospitals to fund, on application to PHARMAC, cancer medicines that were not funded through the Pharmaceutical Cancer Treatments "basket" – a list of cancer medicines that all DHB hospitals must fund. From 1 July 2011, all pharmaceutical cancer treatments are funded through the Combined Pharmaceutical Budget and DHB funding approval is not required.

Overall, PHARMAC received 1821 Exceptional Circumstances applications during the year, of which 1478 were approved. There was an overall reduction in the volume of applications from previous years. This is largely because of the number of 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 cancers, including bortezomib, temozolomide, thalidomide, sunitinib and gemcitabine; medications for depression (sertraline and escitalopram) and a number of liquid medications (caffeine citrate, potassium citrate, sodium chloride) and Ora liquid base products used for preparing oral liquid formulations of solid funded medications.

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

Summary of Exceptional Circumstances schemes 2010/11				
		Received	Approved	Declined
Community EC	Initial	248	72	147
	Renewal	116	114	4
Community EC (automatic approvals)	Initial	264	264	
	Renewal	163	163	
Hospital EC	Initial	613	488	99
	Renewal	234	220	7
Cancer EC	Initial	167	141	18
	Renewal	16	16	
Totals		1821	1478	275

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.
- the application may be pending the provision of more information which may not have been supplied by the end of the reporting period.

Consumer Engagement

Our Consumer Advisory Committee (CAC) continues to play a significant role in helping us engage with consumers. Membership of the Committee was refreshed during the year - the Board approved five new members, as all the foundation members of the Committee ended their terms. The refreshed membership followed a review of the Committee's Terms of Reference, and brings the committee to nine members. The Board appointed Kate Russell (CEO, Cystic Fibrosis NZ) as Chair of CAC. Anne Fitisemanu (Pacific Cultural Competency Training, Counties Manukau DHB) was appointed the Deputy Chair. CAC continue to work with PHARMAC to provide advice on avenues for consumer engagement with medicines issues.

During 2011 we worked alongside the Committee to hold, for the first time, a series of Regional Forums throughout the country, six in total. These events will contribute to the planning for, and discussion at, our national Forum, which will be held in Wellington in February 2012.

The Regional Forums provided consumers and their supporters a chance to engage

with PHARMAC on a more personal level; to ask questions and have discussions about the issues that matter to them. Key topics discussed at these events included our review of Te Whaioranga (the Māori Responsiveness Strategy), our Pacific Responsiveness Strategy and how we can better communicate with health users, for example through our website. We sought feedback from people attending the Regional Forums on our current websites and obtained comments on how to improve this. This information will be valuable as part of our review of PHARMAC's online presence.

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.



**ONE HEART
MANY LIVES**



The One Heart Many Lives kaupapa promotes better heart health for men. The programme has a simple message: Get Your Heart Checked. In the recent years the programme has gone national with high-level exposure at the Pasifika Festival in Auckland, the Te Matatini national kapa haka festival in Gisborne, and as part of the Ironmaori half-ironman in Napier.



Heart campaign a success

Manawatu Standard 20 June 2011



Boot camp concept proves a winner

Mana Magazine 1 July 2011



Pharmac village popular with Maori

'Easy to use' services key to success

NZ Doctor 1 June 2011



Comments from Heart Check participants:

"Thanks for the insight into my future health"

"Its fantastic to have a kaupapa to tautoko our tane to be healthy"

"Enjoyed it very much it was a shock to see my statistics but also good for me. Thank you very much Kia Ora!!"

"Outstanding information by all ladies that I was with"

"I think you are all TUMEKE"

"Well worth while good wake up call"



Our survival is being challenged by heart disease.
Get your heart checked, and pass the message on...

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Directory

The PHARMAC Board

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Directors

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

David Moore MCom, Dip Health Econ (Tromso), CA (until Dec 2010)

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

Prof Jens Mueller JurDr LL.M MBA MSAM

PHARMAC's Management Team

Chief Executive

Matthew Brougham MSc (Hons), Dip Health Econ (Tromso)
(resigned June 2011)

Medical Director

Dr Peter Moodie BSc, MBChB, FRNZCGP

Management Team

Steffan Crausaz BPharm, MSc, MRPharmS
Manager, Funding & Procurement
(Acting Chief Executive from 1 September 2011)

Rachel Mackay BA, NZIMR
Manager, Schedule and Contracts

Dr Peter Moodie BSc, MBChB, FRNZCGP - Medical Director

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

Rico Schoeler - Manager, Analysis & Assessment

Jude Ulrich 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

Graham Mills MBChB, MTropHlth, MD, FRACP

Mark Weatherall BA, MBChB, MAppStats, FRACP

Christina Cameron MBChB, FRACP

Melissa Copland PhD, BPharm(Hons), FNZCP, MCAPA, MPS,
PharmReg

Dee Mangin MBChB, DPH, MRNZCGP

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 Ian Hosford (Psychogeriatrician), Dr Geoff Robinson (Chief Medical Officer/Addiction Medicine), Dr Jane Thomas (Paediatric Anaesthetist), Dr Kieran Davis (Anaesthetist), Dr Christopher Jephcott (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), Assoc. Prof. Ed Gane (Hepatologist), Dr Nigel Patton (Haematologist), Dr Jane Morgan (Sexual Health Physician), Dr Tim Matthews (General Physician), Dr James Chisnal (General Practitioner).

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), Assoc. Prof. Mark Weatherall (Geriatrician), Prof. Mark Webster (Consultant Cardiologist), Dr John Elliott (Cardiologist), Assoc. Prof. Dee Mangin (General Practitioner, Clinical Researcher), Dr Martin Stiles (Cardiologist).

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

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).

Hospital Pharmaceuticals: Prof. Carl Burgess (Chair, Clinical Pharmacologist), Assoc. Prof. Mark Weatherall (Physician), Dr

Matthew Dawes (Clinical Pharmacologist), Dr Andrew Stanley (Respiratory Physician), Dr Andrew Herbert (Gastroenterologist), Prof. Murray Barclay (Gastroenterologist/Clinical Pharmacologist), Dr Paul Tomlinson (Deputy Chair, Paediatrician), Sarah Fitt (Pharmacist), Marilyn Crawley (Pharmacist), Jan Goddard (Pharmacist), Billy Allan (Pharmacist), Chris Jay (Pharmacist).

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), Assoc. Prof. Dee Mangin (General Practitioner, Clinical Researcher).

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

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), 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), Dr Stuart Dalziel (Paediatrician), Dr Tim Christmas (Respiratory Physician), Dr John McLauchlan (Respiratory and Sleep Physician), Dr Ian Shaw (Paediatrician).

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).

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), Dr Stuart Dalziel (Paediatrician).

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), Dr Melissa Copland (Pharmacist).

Transplant Immunosuppressant: Dr Howard Wilson (Chair, General Practitioner, Pharmacologist), 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).

Special Access 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), Dr Mark O'Carroll (Respiratory Physician).

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)

Chair

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

Deputy Chair

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

Committee Members

Shane Bradbrook – tobacco control advocate, Wellington.

Maurice Gianotti – retired, 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.

ISSN 1179-3775 (Print)
ISSN 1179-3783 (Online)

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