Pharmaceutical Management Agency

Annual *Review* 2012

New Zealand Government

PHARMAC
Pharmaceutical Management Agency

2011/12

Highlights

Pharmaceutical funding

- Community and cancer pharmaceutical funding managed on budget - $777.4 million
- 24 new investments in medicine – including 14 new medicines and 10 widened access
- New investments include medicines for various types of cancer, preventing blood clotting, osteoporosis, pain relief, infections and mental health
- First agreement reached to list a medicine on the national hospital preferred medicines list

Improving our engagement with stakeholders

- We heard from about 120 stakeholders from patient groups, medical and pharmacy groups, pharmaceutical industry and government sector at the third national PHARMAC Forum. The Forum provided input to some key workstreams, including hospital medicines and medical devices, and the beginning of our review of our Operating Policies and Procedures
- We heard from community groups and consumers at six regional forums in 2011
- We consulted on a proposal to fund three blood glucose testing meters and their testing strips, and insulin pumps for people with diabetes. This included public meetings and led to a high level of submissions from consumers

Supporting the health sector and policy work

- Government confirmed further expansion in PHARMAC's responsibilities to incorporate vaccines, in addition to community medicines, hospital medicines and medical devices
- PHARMAC supported the new Community Pharmacy Services Agreement by making changes to Pharmaceutical Schedule rules, enabling the agreement to be smoothly implemented
- An increase in applications, and the rate of approvals, followed the implementation of the Named Patient Pharmaceutical Assessment policy, which gives people the ability to seek funded medicines that are not listed on the Pharmaceutical Schedule
- PHARMAC began a review of its Operating Policies and Procedures.

Chair's report

Out of the starting blocks

Sound preparation will be essential to PHARMAC's future success in its expanded role, writes PHARMAC Board chairman Stuart McLauchlan

Last year New Zealand hosted the largest sporting event in its history – the 2011 Rugby World Cup. The tournament was a month-long celebration full of spectacle, drama and high achievement – and of course, the end result that all New Zealand wanted, an All Blacks triumph.

What's often forgotten, and certainly not seen, is that events like the Rugby World Cup involve enormous amounts of planning, preparation and groundwork going back many years. Preparations are largely invisible, and aren't usually appreciated nor seen until the event itself gets underway. In the case of the World Cup, years of preparation went into an event that lasted four weeks.

It's felt a little like that at PHARMAC this year, too. Back in 2010 PHARMAC was given the task of taking over full management of hospital medicines and medical devices. PHARMAC has been busy since then putting in place the planning, groundwork and systems we will need to manage these workstreams effectively. Much of this work has involved gathering information from the sector – through meetings with hospital clinicians, pharmacists and managers – so that we have a clear picture of how hospital systems operate, and so that DHB staff are engaged in the process involving products they use. We aren't alone in this work – in particular our devices work forms part of DHB-wide national procurement programmes being run by Health Benefits Ltd (HBL). PHARMAC and HBL will be working closely around the national procurement programmes.

For those outside PHARMAC, it would be understandable to see this as a long process without much visible happening. But – to continue the sporting analogy – we're now starting to see some runs on the board. In the past year, PHARMAC began seeking the sector's view on draft lists of hospital medicines to be included in the national hospital preferred medicines list (PML). This will be the nationally-consistent list of medicines that all DHB hospitals will fund, and will be published as an initial full list in July 2013. In addition, we reached a milestone with our first supply agreement for a medicine to be listed on the hospital PML. Importantly – and as a demonstration of what PHARMAC can achieve with a deeper involvement in hospital medicines – the agreement included a price reduction that will lead to savings in hospital budgets.

These are important steps. As PHARMAC moves into new areas of business – including vaccines - it is vital that we have the confidence of the sector, are inclusive and listen to the feedback we hear about the best way forward. PHARMAC's record in managing community medicine spending has given confidence that it can effectively take on a wider role involving vaccines, hospital medicines and medical devices. PHARMAC's Board is determined to show that that confidence is not misplaced.

Record continues

Just to prove the point, PHARMAC's management record in community medicines continued in the year just finished. Combined pharmaceutical spending – for community medicines and hospital cancer medicines – was on budget at $777.4 million.

PHARMAC made 24 new investments during the year, enhancing the range of funded medicines for New Zealanders. Of these, 14 were newly-funded medicines or new formulations that represent a significant shift in treatment options. We expect an additional 56,840 patients to benefit from these decisions in a full year – over and above those patients already receiving funded medicines. During the year, 3.3 million New Zealanders received funded medicines, the highest number yet.

A detailed look at new investments and medicine trends in New Zealand is available on pages 17 to 30.

Listening to the community

Hearing the community's views has always been a central part of PHARMAC's decision-making and this was again illustrated during the year. We held our third national Forum and a series of community engagement Forums to enable better input from consumers. Feedback from previous

Forums was that consumers and front line health professionals don't find it convenient to attend a one-day conference at a centralised location – so we decided to take the Forum to the regions. This provided themes to feed into the national Forum, which was attended by approximately 120 delegates from a range of stakeholder groups. The Forum gave us input to our current workstreams including the hospital medicines and medical devices work, and kicked off our review of the Operating Policies and Procedures.

Our proposals to fund blood glucose testing meters and strips, and insulin pumps drew a large response from the public. While there was considerable public debate on aspects of the diabetes management equipment proposals, from the Board's point of view the debate and its outcomes demonstrate how PHARMAC builds feedback into its processes and adapts to incorporate community views into decisions. PHARMAC changed its proposals following feedback, including giving some people the option of remaining on their previous meters, and introduced a further, higher-spec meter than originally proposed. Decisions were made and implementation began in the second half of 2012.

It was clear to the Board that PHARMAC staff listened to the feedback received. As the final decision-maker, it is important for the Board to see that the organisation followed a thorough and well-considered process and addressed any community concerns around its proposals, before a decision is made. I can confidently say that the decision we ultimately made incorporated community views, responded to concerns, provided choice for clinicians and consumers and preserved the $10 million annual savings that were originally estimated. This was a very positive outcome for all concerned and I believe will have long-term benefits to the health sector.

Policy change

Another area of change during the year was the completion of the Exceptional Circumstances review and the beginning of its successor policy, Named Patient Pharmaceutical Assessment (NPPA).

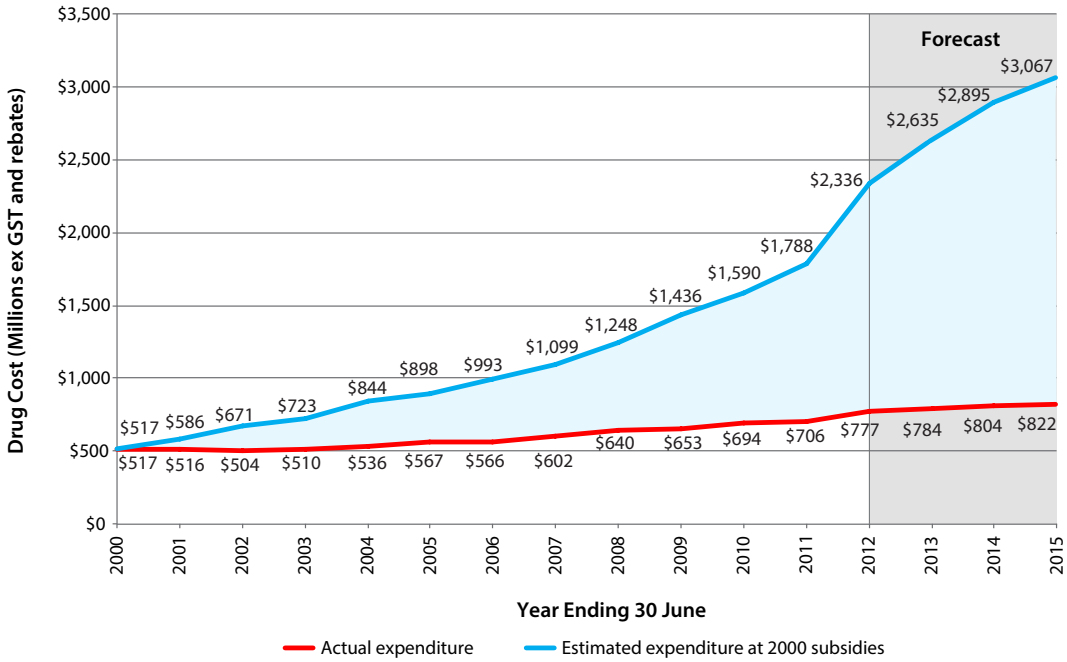
In its first few months, NPPA saw a higher rate of applications than the previous schemes, and had a higher ratio of approvals than the preceding community Exceptional Circumstances policy. Later in 2012, we also began to see how NPPA would link more closely with Pharmaceutical Schedule decisions, with several medicines the subject of multiple NPPA applications being processed for funding through the Schedule. Such a move frees up clinician time from making individual funding applications and illustrates one of the planned benefits of the new policy.

Changing faces

Another milestone was reached during the year, when the Board decided to appoint Steffan Crausaz as Chief Executive. Steffan joined PHARMAC in 2003 and had been in a senior leadership role as manager of the funding and procurement team – the team that manages pharmaceutical funding applications and negotiates with pharmaceutical companies.

The Board has every confidence in Steffan's ability to lead PHARMAC through this challenging period and into its future, backed by the PHARMAC team.

Impact of PHARMAC on drug expenditure over time (actual and predicted 2000 to 2015)



Chief Executive's report

Innovative approaches and adaptability will feature strongly in PHARMAC's future, writes Chief Executive Steffan Crausaz

By health sector standards, PHARMAC is now a mature institution. In 2012/13 PHARMAC marks its 20th year of operations. Quite an achievement through a period of change throughout the health sector.

PHARMAC's longevity is built on its successful record – managing the allocated pharmaceutical budget each year while also growing access. But to survive, organisations need to do more than just meet their objectives. They also have to adapt to their changing environment and continue to meet the expectations placed on them.

Part of PHARMAC's culture is that we are continually looking to past experience as we move into our next area of work. We learn from the past, use and adapt the strategies that have worked well, change or shun those that don't. We honour those who have gone before us, who have contributed to the organisation and its impact on the New Zealand health sector. It's why we've named our meeting rooms after significant figures in PHARMAC's past.

PHARMAC will be changing over the coming years as it moves to incorporate its expanded roles. But one thing I expect to see continue is the work culture that has developed and runs strongly through the organisation. It is one of the strengths of PHARMAC that it listens to the feedback it receives, adapts its work practices and responds to the changing environment around it. This approach will never be more important than now, as PHARMAC is set to go through a considerable growth and change in its structure, primarily in relation to management of medical devices.

A learning organisation

In the past year the Government has confirmed PHARMAC's expanded role in relation to medical devices. This is a considerable expansion of our business. While there are about 2000 products listed on the community Pharmaceutical Schedule, with medical devices (depending on how you define devices), the number is somewhere between 50,000 and 250,000. As we heard at our national Forum this year, it's a complex area with a more rapid pace of change than pharmaceuticals, and we will need to adapt our approach to suit the difference in technologies. We're very aware that in terms of procurement strategies, `one size fits all' just won't work.

We already use a range of tools, demonstrating our adaptability through such processes as the national influenza vaccine procurement (which uses a dual-supply model), and the process we completed this year to select national providers of insulin pumps (also dual supply).

On the other hand, we've chosen a different strategy in relation to blood glucose testing strips and meters – selecting one supplier with three different models, through a flexible contract that provides the option of new technology being introduced as it becomes available. These are examples of the different approaches PHARMAC has available and which can be used to suit the circumstances.

As the devices work unfolds, it's likely even more innovative contracting techniques will be required. The inter-relationship between devices, technology and the clinician training required to use some devices makes it a more complex area than pharmaceuticals. This will have to be something we bear in mind, and take advice on, as we progress.

Technology change

Most medicines follow a common lifespan of having patent protection and then undergoing price reductions as generic competition becomes available. This is now a familiar pattern to New Zealanders who are well used to the brand changes that sometimes result from our tender of off-patent medicines.

The pattern will look a little different in the future, with the advent of biosimilars. These are copies of biologic drugs – molecules that are made from living tissue and which can't be precisely copied

in the same way as small molecule chemicals. We've seen a proliferation of biologics in recent years for the treatment of many types of cancer, auto-immune disorders and other conditions. Drugs like adalimumab for arthritis, rituximab for some types of cancer, and trastuzumab for breast cancer. As the patents on these drugs expire, we anticipate that biosimilars will become available, and this will provide the opportunity for savings on these expensive therapies.

We anticipate that as biosimilars begin to enter the market, there will be considerable debate about their merits relative to the products they are competing with, regulatory issues and relative effectiveness. In New Zealand, the first biosimilar (filgrastim) was funded in 2012.

A future PHARMAC

There's no doubt PHARMAC will need to adapt and be agile to adjust to the expanded landscape it will be operating in. There have always been high expectations on PHARMAC's ability to deliver, and these expectations will be even higher in future.

The organisation will grow, and we will have to make sure our internal systems and structures are well suited to the work ahead of us, and that they enable us to keep meeting our objectives.

One thing is certain – how PHARMAC looks and acts in five years is likely to be quite different to how it looks and acts today. But we stand on our record, welcome the confidence in our ability to do the job we have been assigned, and are determined to do the job expected of us.

In the Annual Review we look at some of PHARMAC's past achievements and how these have helped shape, or might help shape, future strategies for our organisation. PHARMAC wants to continue evolving, shaping itself to meet the demands of its expanded role and the expectations that come with it.

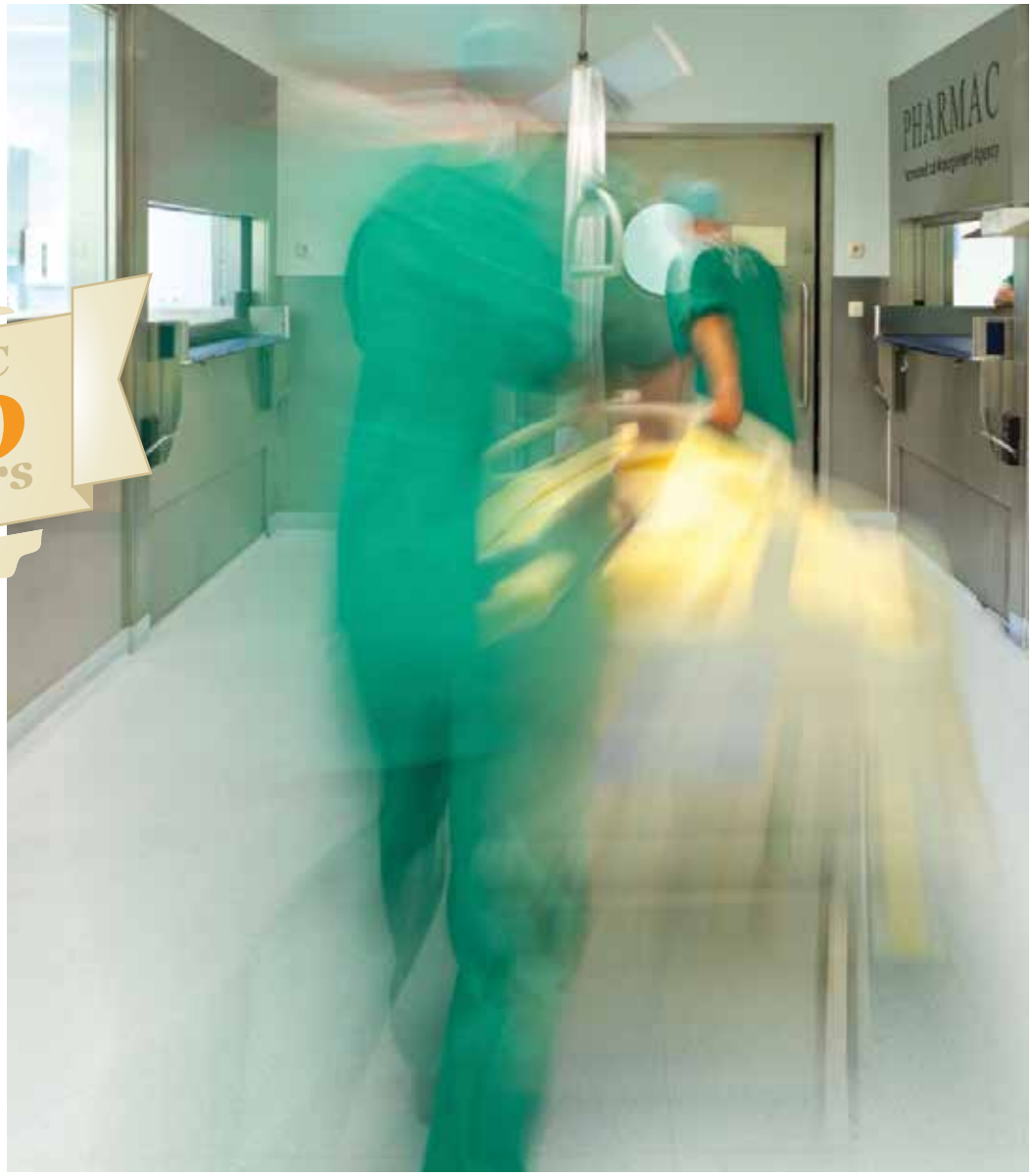
Top 20 Medicines by Prescription numbers

		Treats	Year Ending Jun 12
1	Paracetamol	Pain	**2,430,000**
2	Aspirin	CV risk	**1,380,000**
3	Omeprazole	Reflux	**1,140,000**
4	Simvastatin	Raised cholesterol	**1,110,000**
5	Amoxycillin	Bacterial infection	**1,100,000**
6	Metoprolol succinate	Heart disease	**970,000**
7	Salbutamol	Asthma	**860,000**
8	Amoxycillin clavulanate	Bacterial infection	**820,000**
9	Ibuprofen	Pain	**740,000**
10	Cilazapril	Heart disease	**650,000**
11	Atorvastatin	Raised cholesterol	**640,000**
12	Diclofenac sodium	Pain	**590,000**
13	Prednisone	Steroid	**590,000**
14	Cholecalciferol	Osteoporosis	**580,000**
15	Zopiclone	Insomnia	**520,000**
16	Flucloxacillin sodium	Bacterial infections	**510,000**
17	Metformin hydrochloride	Diabetes	**480,000**
18	Levothyroxine	Thyroid gland dificiency	**450,000**
19	Loratadine	Allergies	**450,000**
20	Felodipine	Heart disease	**440,000**
		Total:	**16,450,000**

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

		Treats	Year Ending Jun 12
1	Atorvastatin	Raised cholesterol	**$64,530,000**
2	Adalimumab	Autoimmune disease	**$44,860,000**
3	Trastuzumab	Breast cancer	**$28,080,000**
4	Blood glucose diagnostic test strip	Diabetes	**$22,900,000**
5	Imatinib mesylate	Leukemia	**$18,790,000**
6	Budesonide with eformoterol	Asthma	**$18,770,000**
7	Venlafaxine	Depression	**$18,330,000**
8	Fluticasone with salmeterol	Asthma	**$17,230,000**
9	Rituximab	Cancer	**$15,310,000**
10	Dabigatran	Blood clotting	**$15,070,000**
11	Candesartan	Heart disease	**$14,950,000**
12	Risperidone	Psychosis	**$14,800,000**
13	Varenicline tartrate	Smoking cessation	**$11,840,000**
14	Tiotropium bromide	COPD	**$10,940,000**
15	Fluticasone	Asthma	**$10,620,000**
16	Sodium valproate	Epilepsy	**$10,070,000**
17	Etanercept	Auto immune disease	**$9,750,000**
18	Metoprolol succinate	Heart disease	**$9,740,000**
19	Erythropoietin beta	Low blood cell count	**$9,580,000**
20	Bortezomib	Cancer	**$9,270,000**
		Total:	**$375,430,000**

PHARMAC goes to hospital



PHARMAC - the first 20 years

PHARMAC's growing role

PHARMAC has grown to take on new or expanded roles since its creation in 1993. Here are some of the milestones in PHARMAC's growth.

- **1993** – PHARMAC is formed to create and manage the Pharmaceutical Schedule – the list of pharmaceuticals funded for all eligible New Zealanders.

In fact PHARMAC has been involved in hospital purchasing since 2002 – in addition to its role in managing community pharmaceutical spending on behalf of DHBs.

We're going to have greater involvement in hospitals in future – with our work expanding into all hospital medicines and medical devices. This will require us to work closely with hospital managers, hospital clincians, pharmacists and other health professionals to ensure the work we do is bringing in the right advice from the right people.

Hospital medicines have been an issue because not all DHBs were offering the same medicines to all patients. We can fix that. We're aiming to have a nationally-consistent list of hospital medicines in place by 1 July 2013. After that we will be managing funding and making decisions on which medicines to add to the national list – just as we do with the community Schedule.

With medical devices it's longer-term. PHARMAC will be taking on national management from 2015, with budget management scheduled to begin in 2017. We will be working closely with others in the sector – particularly Health Benefits Ltd – to make sure the processes and technologies are in place to enable our management of devices to proceed smoothly.

In the meantime we will be working to involve clinical staff and hospital managers in our work, to create a framework for obtaining clinical input to decisions on devices, and picking up some individual funding projects along the way. We have much to learn, and much to gain.

Evolving our purchasing strategies

PHARMAC's early reliance on reference pricing and therapeutic group reviews to manage costs has given way to a more considered approach about when to use each cost management tool available.

The PHARMAC tender, which began in 1996, is now widely accepted with more than 400 line items tendered annually and medicines used by hundreds of thousands of people routinely undergoing managed brand changes. Savings from the tender are used by PHARMAC to make other medicines available.

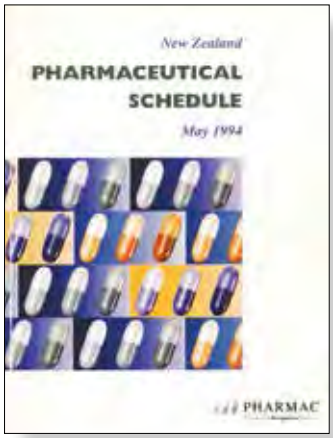
We've learned that in some cases, patients need additional support to adjust to brand changes. District Health Boards, provide Brand Switch payments to pharmacists to help patients adjust to large-scale or potentially troublesome changes.

One size fits all?

While the tender now accounts for about half the products listed on the schedule, it's just one of the approaches we use to buying drugs. PHARMAC's "model" is about more than just tendering. Now, and into the future, our approach will be about smart contracting, finding the solution that best fits with the option in front of us, and taking advice from clinicians and other stakeholders on the appropriateness of the approach to be used.

Over the years we have learned to adapt our approach depending on the products involved - particularly for those with a narrow therapeutic index, lack of available alternatives in the event of a stock shortage, or other factors. That's why the seasonal influenza vaccine has a dual supply process, and also why we have recently chosen to have two suppliers of insulin pumps.

- **1994** – Pharmaceutical Schedule published for the first time.



Top 20 expenditure groups, 1993

($millions ex GST and rebates)

Rounded to the nearest 10,000 dollars.

Drug Type	Main Use	1993 Ranking	Current Ranking	Jun 93	Jun 12
Corticosteroids	Asthma	1	22	$43.78	$13.03
Agents Affecting the Renin-Angiotensin System	Raised blood pressure (cardiovascular risk)	2	8	$35.99	$31.65
Antibacterials	Bacterial infections	3	17	$27.41	$17.48
Antiulcerants	Reflux/heartburn	4	35	$26.64	$7.70
Calcium Channel Blockers	Heart disease	5	21	$23.06	$13.47
Beta-Adrenoceptor Agonists	Asthma	6	28	$21.24	$9.03
Non-steroidal Anti-inflammatory Drugs (NSAIDs)	Pain relief	7	37	$17.54	$7.14
Beta Adrenoceptor Blockers	Heart disease	8	15	$16.59	$18.53
Antidepressants	Mental health (depression)	9	10	$10.99	$26.62
Diabetes	Diabetes	10	6	$10.12	$35.85
Analgesics	Pain relief	11	13	$9.94	$24.67
Contraceptives - Hormonal	Contraception	12	32	$9.63	$8.05
Lipid Modifying Agents	Raised cholesterol (cardiovascular risk)	13	1	$7.70	$76.51
Nitrates	Heart disease	14	63	$7.62	$1.47
Agents for Parkinsonism and Related Disorders	Parkinsons disease	15	39	$7.11	$5.82
Nasal Preparations	Allergies	16	38	$6.61	$5.98
Corticosteroids Topical	Skin disorders	17	36	$6.51	$7.42
Antiepilepsy Drugs	Epilepsy	18	9	$6.21	$27.75
Diabetes Management	Blood glucose monitoring	19	14	$5.90	$23.84
Immunosuppressants	Organ transplants, arthritis	20	3	$5.50	$59.30

The future

Many of the large-volume blockbuster drugs have now come off-patent and been replaced by generics, but that doesn't mean that the opportunity for large-scale savings through generics is past. Each time a new on-patent medicine is listed, that is another potential candidate for generic competition in the future. Certainly, PHARMAC has not yet seen the end of large-scale savings emerging from tendering or any other cost-management tool.

Our learnings about which of our procurement methods to use will be important as we head into greater involvement in hospital medicines and medical devices. The devices area is quite different to medicines, with a faster rate of technology change, and often co-dependent technologies that are updated or replaced more frequently than pharmaceuticals. Our approaches will need to be smart enough to account for technology upgrades, while also protecting the savings taxpayers expect from PHARMAC's involvement and ensuring ongoing supply.

We've already shown what we can achieve through our contracting for diabetes management devices in 2012. The contracts for these products enable new technology to be introduced during the life of the contract, giving consumers the opportunity to have more up to date devices while also preserving the savings achieved in the initial agreement.

• **1999** – PHARMAC begins funding and managing the Wise Use of Antibiotics campaign, its first foray into demand side management.

Involving the public

In PHARMAC's early years the focus was on getting clinician buy-in to our decisions. PHARMAC's interactions with consumers was not widely recognised, something picked up in the Government-commissioned Caygill-Lexchin report of 2000, which resulted in a recommendation for PHARMAC to form a Consumer Advisory Committee.

The Committee, which first met in 2002 with women's health advocate Sandra Coney as chair, was given a broad scope with the ability to provide advice from a consumer perspective across a wide range of PHARMAC's activities. The CAC, as it became known, encouraged PHARMAC to be more inclusive of consumers and better respond to consumer concerns. Primarily the committee has a particular interest in the way PHARMAC engages the public around its operations.

CAC's existence is not a proxy for consumer engagement, but it is a committee that ensures PHARMAC thought harder about involving consumers in its processes. A further innovation came in 2007 with the first PHARMAC Forum. The Forum is a national conference bringing together a range of PHARMAC stakeholders to discuss issues around pharmaceuticals and PHARMAC's work. To bring a stronger community and consumer voice into the Forum, in 2011 PHARMAC created a series of regional consumer forums at six locations around the country.

Public interest in our decisions has grown, with patients and consumers very much to the fore. As an example, the 2012 consultation on diabetes management products (blood glucose meters and insulin pumps) received nearly 3000 submissions, mostly from patients.

Bigger role, more tools?

With an increasing range of products coming under PHARMAC's control in coming years, the resources and tools used for consultation will have to change and evolve. The emergence of social media, a heightened public expectation of involvement in Government decisions and of increased transparency, means that PHARMAC will need to examine using further avenues for obtaining the public's views.

Changing technologies such as smart phones have further increased the pace of information sharing, and there is an expectation of immediacy in online discussions – which would have an impact on PHARMAC's resourcing.

With social media options, instant feedback can be obtained on policy questions or consultations, with open feedback. Any moves in these directions would need to be balanced against PHARMAC's need to maintain confidentiality within its commercial negotiations, and the resources required to ensure they work well.

International *comparisons*

New Zealanders love to compare themselves and their institutions with those in other countries. PHARMAC is no different, and has long been the subject of debate about how its performance compares with similar funding institutions in other countries.

PHARMAC was set up in 1993 to obtain the greatest health gains with a fixed budget, and in its 20 year existence this is still the feature that sets it apart from pharmaceutical reimbursement schemes internationally. New Zealand is still the only nation that has a national pharmaceutical budget with economic and clinical analysis, commercial negotiation and budget management wrapped up in one agency.

Here's how PHARMAC measures up against some of the common themes comparing New Zealand's pharmaceutical funding with other countries.

Price comparisons – a Commonwealth Fund (US) survey published in 2012 showed New Zealand has the lowest prices of both on-patent and generic drugs of the nine countries surveyed (see table). This means for each dollar spent, PHARMAC is able to purchase more medicines for New Zealanders than other countries can. This explains why New Zealand's spending can be lower than other countries, for an equivalent basket of medicines.

Number of funded brands – PHARMAC's tender selects one brand of a particular medicine and uses a competitive process to achieve low prices. For example, there may be 10 brands of paracetamol in the market, but PHARMAC chooses just one to subsidise. This means there are fewer medicine brands on the New Zealand Pharmaceutical Schedule than there are in other countries (for example in Australia, where multiple brands of medicines are funded).

**Fewer `me-too' drugs** – Many medicines said to be `innovative' are simply minor adjustments of other drugs in the same class. For example, internationally there are nine drugs in the cholesterol-lowering class known as statins. New Zealand funds three of these (simvastatin, atorvastatin and pravastatin). Clinically speaking, there would be little to gain from funding further statins for the population, although PHARMAC can consider funding others for specific named patients through the NPPA policy.

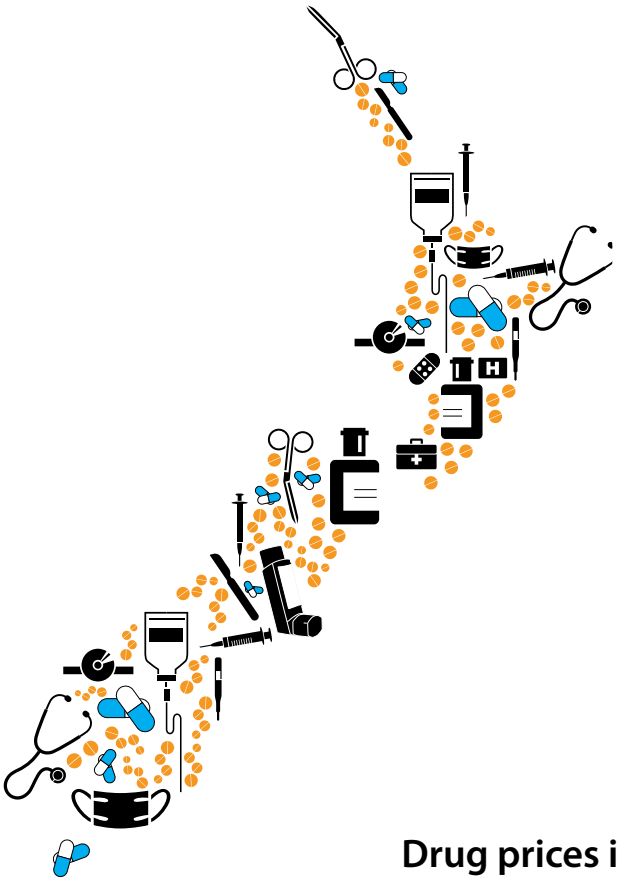
Comparable (and in some cases better) health outcomes to similar countries – New Zealanders continued to enjoy good health outcomes, comparable to those in many other developed countries. Data from the OECD shows that, in 2009, New Zealanders' life expectancy continues to be above the OECD average.1

Speed of approvals - PHARMAC is always interested in relative efficacy and improving health outcomes and value for money. This means

- **2002** – PHARMAC takes on the management of hospital pharmaceutical purchasing – publishes Section H of the Pharmaceutical Schedule for the first time. Section H includes the national cancer medicines `basket', the list of cancer medicines all DHBs must fund. PHARMAC is responsible for making all changes to the cancer treatments basket.

[1] *http://www.oecd.org/els/healthpoliciesanddata/49105858.pdf*

• **2004** – Purchasing the national seasonal influenza vaccine is transferred to PHARMAC.



moving swiftly to fund new medicines where they can demonstrate advances over existing products. However, in an environment where funding is limited, not everything can or will be funded. Newer medicines aren't necessarily better, and need to stand up to critical scrutiny. If we're going to spend more on a new medicine, we need to be convinced it does the job better than the medicine that is already funded.

The main benefits of PHARMAC's process are that it doesn't accept claims about medicines at face value and, before a decision is made, there is a clear picture of the value the new treatment represents. Where it sees value in an innovative new medicine, PHARMAC can lead the world in being the first to fund. For example, in 2011 PHARMAC funded the new generation anti-coagulant medicine dabigatran, making New Zealand one of the first countries of the world to provided funded access to the treatment.

Because PHARMAC manages a budget effectively, and can demonstrate what is bought in terms of health outcomes, it's been cited as a model that ought to be more widely used in New Zealand.

The 2010 Ministerial Review Group, led by Murray Horn, commented that a more PHARMAC-like approach was required in other parts of the health sector.

Drug prices in select OECD countries

	Prices for 30 most commonly prescribed drugs, 2006-07 (U.S. set 1.00)[a]		
	Brand name	**Generic**	**Overall**
Australia	0.40	2.57	0.49
Canada	0.64	1.78	0.77
France	0.32	2.85	0.44
Germany	0.43	3.99	0.76
Netherlands	0.39	1.96	0.45
New Zealand	0.33	0.90	0.34
Switzerland	0.51	3.11	0.63
United Kingdom	0.46	1.75	0.51
United States	1.00	1.00	1.00
Median *(countries shown)*	**0.43**	**1.96**	**0.51**

[a] *Source: Analysis by G. Anderson of IMS Health data.*

It's all about competition

It's common sense to most people – competition leads to lower prices. It's no different for PHARMAC. Promoting competition means PHARMAC is able to deliver the same health outcomes from medicines for patients, while reducing costs.

There has always been a tension between this desire to promote competition, and the use of patents by pharmaceutical suppliers to prolong their market monopoly. Patents are a legitimate way for companies to protect the intellectual property they have invested in pharmaceuticals and their development. However, patents can also be used as a barrier to competition.

Patents

PHARMAC has been involved in a number of court battles relating to patent disputes between pharmaceuticle suppliers. Evidence or undertakings PHARMAC has given have often been influential in the ultimate decision.

More recently, PHARMAC has taken a more proactive stance, researching when patents expire and considering challenging those patents it thinks might be invalid. PHARMAC has a dedicated fund to pursue these actions – a justifiable step since the cost of a court case could lead to much greater savings in pharmaceutical spending (sometimes in the tens of millions of dollars).

Patent expiry is an essential first step before PHARMAC can reap the benefits of generic competition. Generic medicines have been, and will continue to be, an important part of the PHARMAC story. The first tender was run for one product in 1996, and the tender now runs to over 400 line items each year. Funding generics in place of `innovator' products is relatively straightforward. Because generics need to prove `bioequivalence' – proving to the Government regulator Medsafe that they contain the same amount of medicine and are used in the body in the same way as the original product – the process for getting a licence to sell is relatively simple and cost effective.

Once there are several brands of the same medicines available, PHARMAC can run tenders or other commercial processes to get the best price possible.

Biologics and future challenges

The landscape looks a little different heading into the future. The emergence of biologic drugs – those made from living systems rather than produced as small-molecule chemicals – raises many questions about the future of product lifecycles and the ability to promote competition.

In New Zealand, and internationally, biologic drugs have become firmly established, with products like adalimumab (Humira), rituximab (Mabthera), trastuzumab (Herceptin) and etanercept (Enbrel). The top five biologic products make up about $100 million in annual spending.

Without some kind of competition, growth in spending on biologics will become unmanageable. The answer to this problem lies in effective competition from biosimilars – competitor products for biologics. These are now becoming available with the first such product, biosimilar filgrastim, being funded in New Zealand in 2012.

International debate on the development, assessment and use of biosimilars is continuing. Whilst they offer significant health and economic benefits care needs to be taken when introducing biosimilars and PHARMAC is watching international developments in this area with interest.

- **2005** – PHARMAC begins procuring some further hospital products under national contracts (radiological contrast media and bulk intravenous fluids), as well as managing the national contract for the blood anti-clotting product Factor VIII.

Making best use of medicines

- **2010** - PHARMAC's role expands to include managing all hospital medicines, and to begin investigating medical devices.

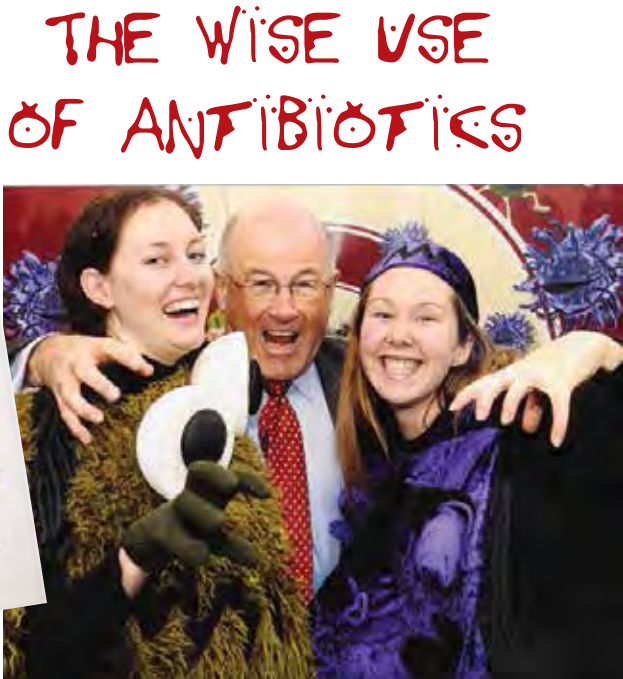
Funding pharmaceuticals is only part of the equation for helping patients to improve their health. How well medicines are prescribed and used are just as important

The New Zealand Public Health and Disability Act 2000 cemented PHARMAC's role in promoting the responsible use of medicines, but PHARMAC had already begun heading down that path with the Wise Use of Antibiotics campaign, that kicked off in 1997.

Subsequent public campaigns included Gut Reaction (for dyspepsia), One Heart Many Lives (for heart disease), Antipsychotics in Dementia, and Space to Breathe (for asthma). Most of these large-scale campaigns include messages for the public, guidance for clinicians or a mixture of both. In addition, PHARMAC contracts with the best practice advocacy centre (bpacnz), to provide evidence-based prescribing advice and prescribing audits to doctors.

PHARMAC has largely defined the `responsible use of medicines' role as one developing and implementing its own campaigns. But the landscape is changing.

PHARMAC's future involvement in responsible use of medicines is likely to change with it. Rather than developing and delivering large-scale campaigns, PHARMAC could become a knowledge shop, developing the ideas for programmes and providing the intellectual grunt, desired outcomes, messages and design concepts, then passing the package to other organisations to run. This would make the most of PHARMAC's skills – creating new knowledge and translating it into new actions.



Responding to *Māori health need*

Māori health need has long been part of PHARMAC's decision-making, with a specific strategy to embed Māori health into PHARMAC's culture being developed in 2001. A series of hui led to the publication of the Māori Responsiveness Strategy in 2002. This strategy set PHARMAC on a pathway toward improving Māori health outcomes, Māori health priorities and activities to help Māori improve health through better use of medicines.

Data on Māori health need was used to inform development of the cardiovascular campaign One Heart Many Lives. Data showed Māori men were some of those most at risk of suffering heart attack or stroke. Subsequent programmes with a Māori focus included information about gout, and the Space to Breathe He Tapu te Ha programme.

In 2006 PHARMAC created the He Rongoā Pai He Oranga Whānau programme, to improve use of medicines by Māori. The programme includes seminars for Māori health provider community health workers and community nurses, to show them how to use the Pharmaceutical Schedule and help their patients understand what medicines are available.

2009 saw PHARMAC join forces with the Māori Pharmacists Association (Nga Kaitiaki o te Puna Rongoa o Aotearoa) to create Hiwinui Heke Scholarships for young Māori pharmacy students. The scholarships commemorate Hiwinui Heke (Te Arawa), who, in 1955, was one of the first Māori to graduate from a New Zealand pharmacy school. The scholarships are for students at Otago University Pharmacy School, worth a total of $10,000 and aimed at encouraging Māori in the pharmacy profession.

PHARMAC's lead in the 2011 Whānau Hauora Village at the Te Matatini o Te Rā national kapa haka festival further demonstrated its leadership role in responding to Māori health need.

Key features of the PHARMAC strategy include:

- Better recognising Māori health priorities (as defined through consultation in the strategy)
- Improving Māori representation on PHARMAC bodies such as PTAC, the Consumer Advisory Committee and the PHARMAC Board
- Improving PHARMAC's consideration of Māori health in its analyses
- Creating programmes specifically designed to respond to Māori health need.

The changing face of pharmaceutical treatments

Medical care has changed significantly in the 20 years since PHARMAC began. The pharmaceutical world has seen whole new drug classes developed, evolve to be international blockbuster best-sellers, then enter mainstream and be replaced by cheaper generic versions and (in some cases) over the counter treatments.

The coming pages outline 20-year trends in medicine use for some of the major therapeutic groups, together with commentary on developments in the past year. Here is a summary of major changes in the past two decades, with reference to the chart illustrating the trends.

In **mental health** (page 23), the story has been one of new technology overtaking old, both in relation to the treatment of depression and psychoses. Depression treatment has seen the rise of the selective serotonin reuptake inhibitors (SSRIs) and related drugs, while in the treatment of schizophrenia and related psychoses the atypical antipsychotics have emerged as the treatment of choice.

In the early and mid-1990s, **HIV/AIDS treatment** (page 25) was in its infancy, with few effective agents funded. More than a decade of international research and investment later, PHARMAC funds more than a dozen HIV/AIDS therapies which can be used individually or in combination to tailor treatment to individual patients. Treatment means that for many patients the disease is now a manageable long-term chronic disease.

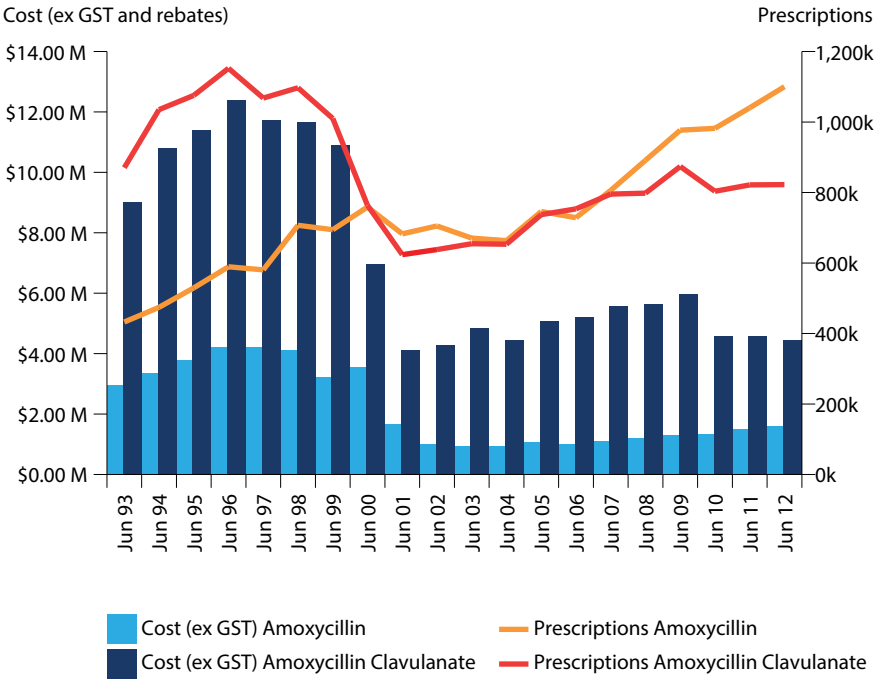
The rise in the use of **statins** (page 20) has been a major international pharmaceutical story. Statins have replaced fibrates as the drug class of choice for raised cholesterol, and become more-or-less standard treatment for people with elevated cholesterol levels and risk of heart disease. In New Zealand their use took off from 2002 when PHARMAC opened access to simvastatin. Growth in expenditure has been managed through the introduction of generics (simvastatin 2002, atorvastatin 2010).

PHARMAC - the first 20 years

- **2012** – Scope of PHARMAC's role in hospital medical devices is confirmed. PHARMAC to take on management of most devices by 2015. Management of national immunisation schedule (vaccines) transfers to PHARMAC.

Antibiotics were a major source of debate over the past two decades. International clinical debate focussed on overuse of antibiotics to treat infections, causing bacterial resistance and reduced efficacy of the available drugs. In New Zealand, the response was the PHARMAC-funded Wise Use of Antibiotics campaign, which began in 1997 and led to a significant reduction in the use of antibiotics, a trend that has since been maintained by New Zealand prescribers. International debate is now focused on the lack of new antibacterial agents becoming available, despite the rise of multi-drug resistant `superbugs'.

Antibacterials



Top 20 expenditure groups, 2012

($millions ex GST and rebates)

Rounded to the nearest 10,000 dollars.

Drug Type	Main Use	Current Ranking	Ranking Last FYr	Jun 07	Jun 08	Jun 09	Jun 10	Jun 11	Jun 12
Lipid Modifying Agents	Raised cholesterol (cardiovascular risk)	1	2	$68.86	$66.06	$63.48	$37.87	$53.53	**$76.51**
Chemotherapeutic Agents	Cancer	2	6	$16.62	$21.12	$23.36	$26.23	$33.88	**$61.33**
Immunosuppressants	Organ transplants, arthritis	3	17	$14.50	$15.95	$17.27	$17.91	$15.88	**$59.30**
Antirheumatoid Agents	Arthritis	4	3	$9.14	$11.23	$15.94	$28.39	$42.72	**$57.25**
Inhaled Long-acting Beta-adrenoceptor Agonists	Asthma	5	4	$19.34	$23.25	$27.84	$31.84	$36.54	**$39.86**
Diabetes	Diabetes	6	7	$26.34	$29.36	$31.06	$30.07	$32.80	**$35.85**
Antipsychotics	Mental health (psychoses)	7	1	$57.13	$60.58	$61.61	$66.19	$60.17	**$32.82**
Agents Affecting the Renin-Angiotensin System	Raised blood pressure (cardiovascular risk)	8	5	$29.10	$29.94	$31.19	$34.47	$34.55	**$31.65**
Antiepilepsy Drugs	Epilepsy	9	9	$27.85	$24.62	$25.90	$24.96	$26.11	**$27.75**
Antidepressants	Mental health (depression)	10	10	$30.65	$20.81	$22.26	$24.20	$24.70	**$26.62**
Antithrombotic Agents	Stopping blood clots	11	23	$9.94	$10.33	$9.45	$11.10	$11.04	**$26.55**
Treatments for Substance Dependence	Addiction	12	8	$0.41	$0.51	$0.56	$5.90	$27.03	**$24.92**
Analgesics	Pain relief	13	11	$17.23	$18.86	$21.19	$23.05	$24.67	**$24.67**
Diabetes Management	Blood glucose monitoring	14	12	$17.12	$19.03	$19.80	$21.20	$22.41	**$23.84**
Beta Adrenoceptor Blockers	Heart disease	15	13	$24.52	$29.29	$32.01	$23.32	$18.22	**$18.53**
Antiretrovirals	HIV/AIDS, viral infections	16	16	$11.59	$12.34	$12.97	$14.54	$16.77	**$17.76**
Antibacterials	Bacterial infections	17	15	$14.80	$15.47	$16.38	$15.60	$17.49	**$17.48**
Antivirals	Viral infections	18	21	$3.55	$5.86	$7.79	$10.01	$12.72	**$15.17**
Anticholinergic Agents	Allergies	19	19	$8.74	$10.47	$12.25	$13.35	$14.02	**$14.76**
Drugs Affecting Bone Metabolism	Osteoporosis	20	14	$13.56	$15.36	$16.36	$17.30	$17.49	**$14.17**

Cancer treatment has come a long way since the early 1990s. Few cancer therapies were available outside of hospitals, and most of those used in hospitals were blunt instruments with side effects that were dreaded nearly as much as the disease itself. But since the turn of the 21st century two major trends have emerged. Firstly has come the rise of the targeted cancer treatment, one developed specifically to treat a defined form of cancer. Many of these treatments, such as rituximab for certain types of lymphoma or imatinib for leukaemia, had superior side effect profiles and better long-term outcomes for patients than previous treatments.

The other significant trend in cancer treatment has been the development of oral treatments (tablets and capsules) that patients can take at home. This frees up resources at hospitals which means more patients can be treated, reducing waiting times. PHARMAC has helped speed this process in recent years, extending funding to treatments such as bortezomib (for multiple myeloma), erlotinib and gefitinib (for lung cancer), and sunitinib (for kidney cancer).

Overall the impact of these trends has led to

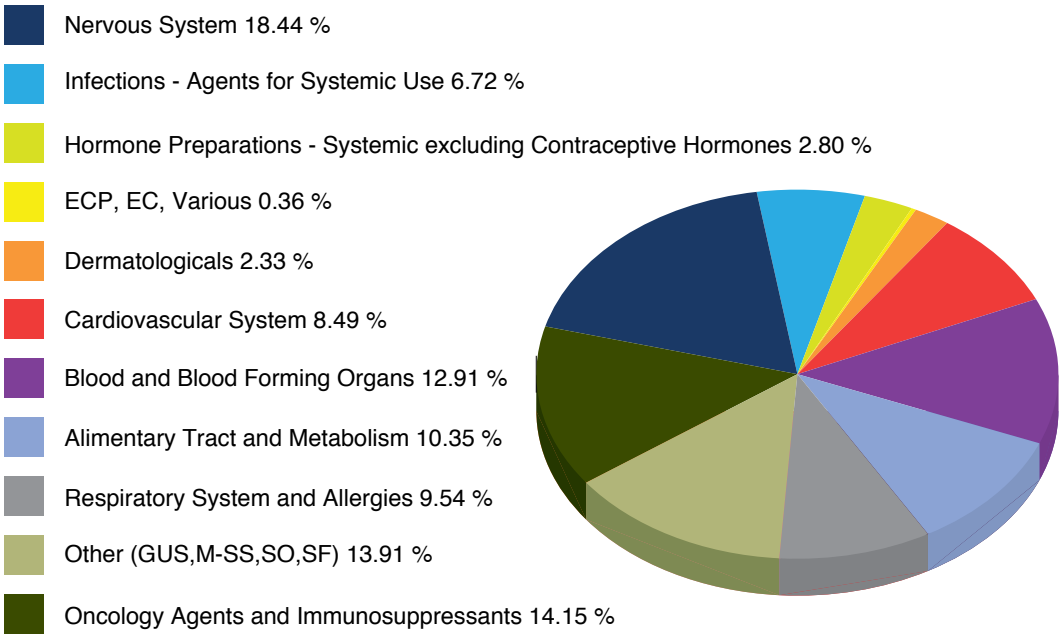
- Better long-term health outcomes (patients living longer and having better quality of life)
- More convenient treatment for patients
- Reduced demand on District Health Boards to treat patients in-hospital.

Asthma treatments were a source of debate and concern through the 1990s with high levels of expenditure and debate over the relative merits of combination inhalers vs their individual components. Today the impact of generic competition and the introduction of combination inhalers along with the individual component parts has seen that debate largely disappear.

Cost of individual treatments has risen significantly in the last 20 years. In the 1990s, it was rare to see a medicine come on the market with a price tag of $20,000 per patient per year or more. That barrier has been broken many times in recent years, with the development of biologic drugs and targeted enzyme replacement drugs that can cost upwards of $500,000 per patient per year.

An ageing population raises questions about the sustainability of pharmaceutical funding and the phenomenon known as polypharmacy – multiple medicines used to treat symptoms, some of which are caused by pharmaceuticals themselves. In 2011 PHARMAC published data illustrating the rise in the number of prescriptions, and cost of treatments, as patients age. This will be a challenge to PHARMAC, and the New Zealand health system, in the future as people live longer and a greater proportion of the population is aged over 50. Most medicine – and the greatest cost of treatment – is prescribed for people aged 50 or over.

Investment by Therapeutic Groups 2012



Therapeutic group summaries

The anticoagulant medicine dabigatran was PHARMAC's highest-value investment for the year, accounting for more than $16 million of spending in its first year of listing. Used by 8800 patients during the year, dabigatran has been funded as an alternative to warfarin for people with heart conditions who need anti-clotting treatment (to prevent strokes). See page 20 for more details.

Funding of cancer medicines was another theme for the year, with two new treatments added and access widened to others. A key decision was the widening of access to rituximab to also include chronic lymphocytic leukaemia. In terms of funding, this was another significant decision with the widening of access to rituximab accounting for $2.25 million of spending for the year.

Overall we estimate the funding decisions made during the year will benefit 56,800 patients in a full year (2012/13).

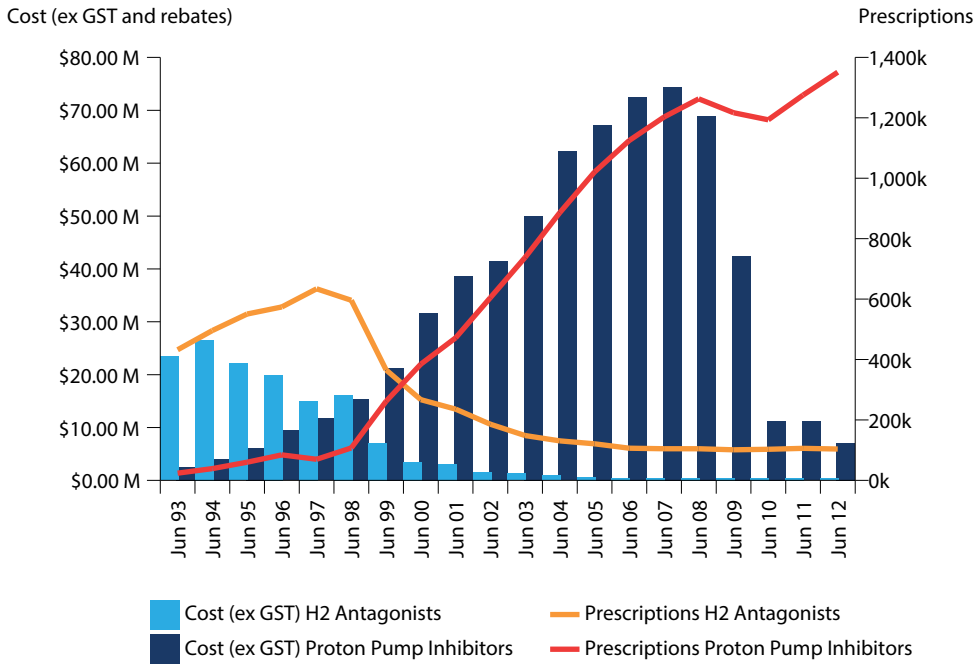
PHARMAC's management of the Pharmaceutical Schedule includes spending new money on medicines (such as those outlined above), and also extracting greater value from pharmaceutical spending by seeking price reductions on funded medicines.

In terms of savings on existing medicines, 2011/12 was a good year with full-year savings estimated at $70.1 million – nearly 10% of the total pharmaceutical spend. Major savings transactions occurred with cardiovascular drugs that rank among the most-prescribed drugs in New Zealand - in particular the cholesterol-lowering treatment atorvastatin (11th), and the blood pressure management drugs metoprolol (6th) and felodipine (20th). Details on these changes are on page 21.

The price reduction on atorvastatin will mean that it is likely to lose its place as the top-ranked drug by expenditure next year. Its therapeutic group (lipid modifying agents) is also likely to fall from its position as the highest-cost therapeutic group (before rebates). For the 2012/13 year, this is likely to be replaced by cancer drugs.

The previous top-ranked therapeutic group by expenditure, antipsychotics, has dropped to 7th, with spending more than halved since 2010. This change is the result of a sequence of reference pricing decisions and generic competition entering the market for atypical antipsychotics, culminating in the reference pricing of olanzapine in 2011/12. As a result, spending on antipsychotics has reduced from a peak of $66 million in 2010, to $32 million this year.

Anti-ulcerants



Cancer treatments

Key decisions:

- Widened access to rituximab (Mabthera) for chronic lymphocytic leukaemia
- Funded lapatanib (Tykerb) for advanced HER2-positive breast cancer
- Funded pazopanib (Votrient) for advanced kidney cancer
- Provided open access to docetaxel – can be used for early breast cancer, metastatic prostate cancer, head and neck cancer and other cancers.

Funding lapatinib (Tykerb) and pazopanib (Votrient) in early 2012 continued the trend of new generation cancer medicines being pills patients take at home, rather than in-hospital treatments.

Lapatinib is used in patients with advanced HER2 positive breast cancer, and pazopanib in advanced kidney cancer patients. They are funded as alternatives to trastuzumab (Herceptin) for advanced HER2 positive breast cancer patients and sunitinib (Sutent) for advanced kidney cancer patients.

Pazopanib is the second targeted oral cancer treatment funded for metastatic renal cell carcinoma, following the funding of sunitinib (Sutent) in 2010.

PHARMAC provided access rules that mean that if patients experience early side effects on their first choice treatment, then they can have access to funding for the alternative treatment.

PHARMAC widened funded access to rituximab for chronic lymphocytic leukaemia (CLL) for patients who have not had rituximab before, either as a first line treatment or where their disease has relapsed following up to three prior lines of chemotherapy.

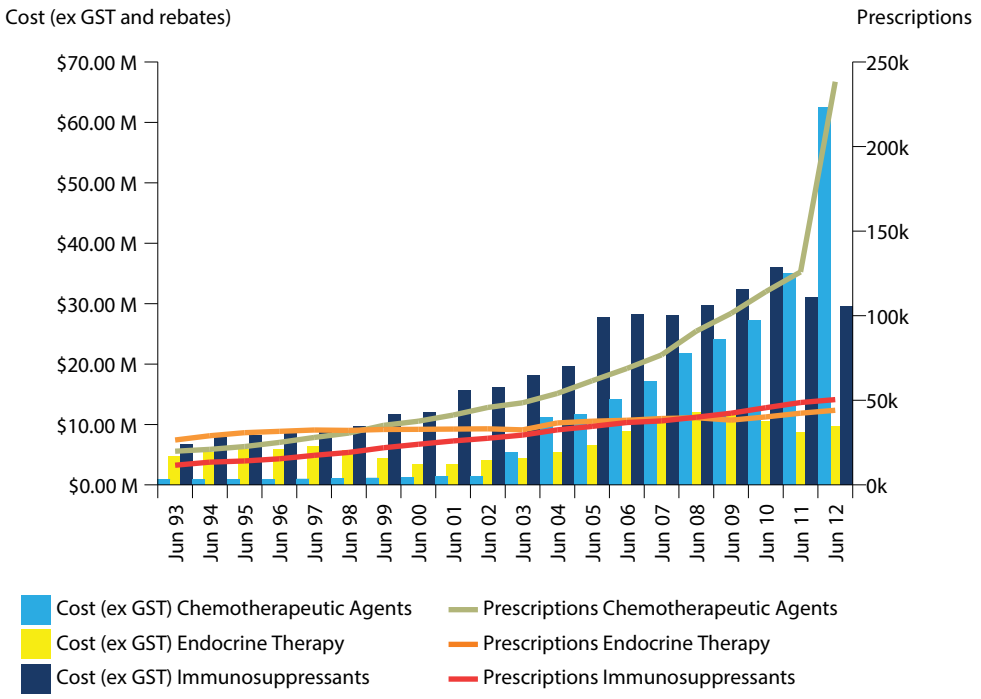
Rituximab, a cancer treatment delivered by infusion in hospital, had previously been funded for patients with lymphoma.

Leukaemia is a broad term for cancers of the white blood cells; chronic lymphocytic leukaemia is the most common form of leukaemia with around 2000 patients living with CLL in New Zealand.

PHARMAC removed the funding restrictions on docetaxel so that is funded for the treatment of patients with any type of cancer. This decision took effect from 1 July 2011. Docetaxel, a cancer treatment delivered by infusion in hospital, was previously only funded for patients with certain types of cancer under Special Authority.

Oncology Agents and Immunosuppressants

- Expenditure on cancer medicines has risen in the 2012 year as a result of PHARMAC taking over management of funding for all cancer medicines (including those used in hospitals).



Musculoskeletal

Key decisions

- Raloxifene funded for osteoporosis
- Teriparatide funded for osteoporosis
- Parecoxib listed for use in DHB hospitals

Raloxifene (Evista) and teriparatide (Forteo) were fully funded for the bone-thinning disease osteoporosis following an agreement with the supplier.

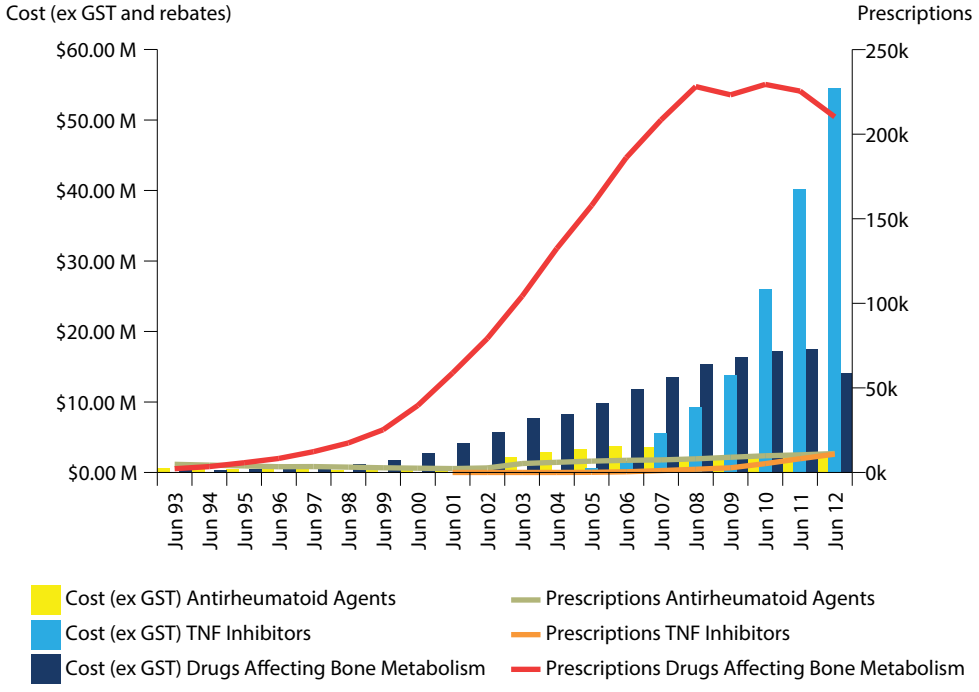
Osteoporosis mainly affects older women and is characterised by reduced bone mineral density that makes sufferers more likely to fracture bones.

Raloxifene and teriparatide are different drug classes to the previously funded treatments, which were all bisphosphonates. Having alternatives available enables doctors to better tailor treatment to individual patients.

The new drugs are funded under Special Authority criteria. Raloxifene is subject to the same access criteria as alendronate and zoledronic acid, while teriparatide – a newer agent - is a 'last line' treatment for patients with severe osteoporosis who have experienced fractures despite taking other funded treatments.

Parecoxib is an injection given to help manage pain associated with surgery. PHARMAC reached an agreement with the supplier that included a 33% reduction on current price, in return for parecoxib being included in the national hospital preferred medicines list (PML) that is currently being developed. This is a significant milestone in PHARMAC's national management of all hospital medicines, as the first national contract for a PML listing in DHB hospitals.

Musculoskeletal



- Prescription numbers for osteoporosis treatments have declined in recent years. This is mainly due to the listing of zoledronic acid, which is a once-a-year treatment and so only accounts for one prescription per patient per year (other treatments require four prescriptions).

Cardiovascular

Key decisions

- Funding for the new-generation anti-coagulant dabigatran (Pradaxa)
- Tender (brand change and savings) for the cholesterol-management treatment atorvastatin
- Brand change and savings for the cardiac drug metoprolol
- Brand change and savings for the cardiac drug felodipine
- Brand change and savings for the cardiac drug candesartan (to take effect in 2012/13).

Dabigatran

PHARMAC funded dabigatran (Pradaxa), a direct thrombin inhibitor which is a new generation of oral anticoagulant used for the treatment of atrial fibrillation, a heart rhythm disorder. Dabigatran helps prevent blood clotting and lowers the risk of stroke. It can also be used to prevent blood clotting following joint replacement.

Dabigatran is an alternative to warfarin. While all medicines (including dabigatran) have side effects that require close monitoring, warfarin is particularly difficult to manage and is sensitive to changes in patients' diet and other factors, requiring regular blood tests and associated dose adjustments. The funding of dabigatran provides another treatment option for patients. Dabigatran presents an advance when compared to warfarin because it has a fixed dosing regime, does not require frequent blood monitoring and is associated with less food and drug interactions. However, unlike warfarin, there is no direct reversal agent for dabigatran.

Dabigatran's introduction caused some controversy with concerns expressed about management of patients and excessive bleeding episodes. To help support the change, PHARMAC worked with the Haematology Society of Australia and New Zealand to develop clinical guidelines for managing bleeding side-effects from dabigatran. PHARMAC-funded BPACNZ, which produces evidence-based information and guidance for clinicians, also included information about dabigatran in its regular publication, the Best Practice Journal.

Dabigatran is a very large investment for PHARMAC. The gross expenditure on dabigatran is estimated to be $155 million over five years but this cost will be reduced through confidential rebates. PHARMAC estimates about 30,000 to 40,000 people are currently being treated for atrial fibrillation using either warfarin or aspirin, and they could potentially shift to dabigatran.

Dabigatran funding is not restricted, which means it will be funded when prescribed by any clinician for any indication; although it is only currently registered in New Zealand for the treatment of atrial fibrillation and clot prevention following total hip and knee replacements.

Brand changes

Heart drugs were a significant source of savings during the year. Overall, at least a quarter of a million New Zealanders would have noticed a change to their brand of heart medicine – atorvastatin (for raised cholesterol), metoprolol and felodipine (for raised blood pressure and heart failure). Another cardiac treatment, candesartan, was also to undergo a large-scale brand change in 2012/13.

Atorvastatin is used by about 60,000 New Zealanders. A tender decision led to PHARMAC agreeing funding for the Pfizer brand Zarator. Pfizer was already the supplier of the Lipitor brand.

The overall saving estimated by PHARMAC is $29 million over the three-year tender period ending 30 June 2015.

As the change involves two brands of the same supplier's product, PHARMAC expects little change will be noticed. The only changes are the packaging, pack size and brand name.

Metoprolol is widely used, with about 230,000 New Zealanders prescribed the drug for raised blood pressure or heart failure. PHARMAC began funding the AFT brand in June 2012 – this replaced the Betaloc brand from 1 September 2012.

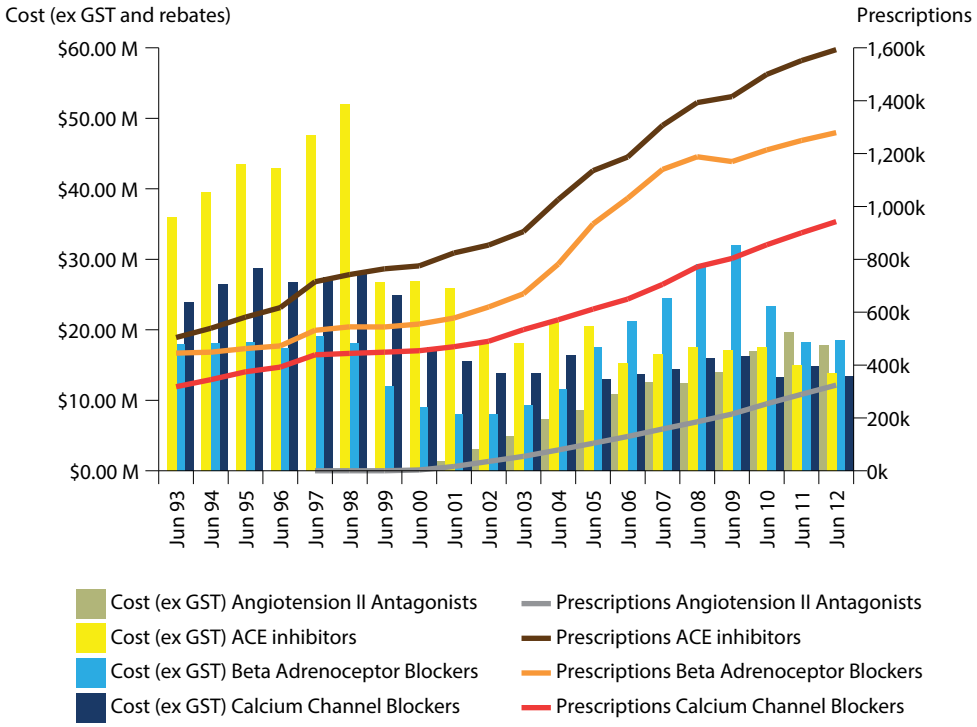
Because of the size of the patient group, DHBs paid a brand switch fee to pharmacists to recognise the work required of them to assist patients to change to the new brand.

Over the 3-year tender period, PHARMAC anticipates savings of $14.4 million from the metoprolol brand change.

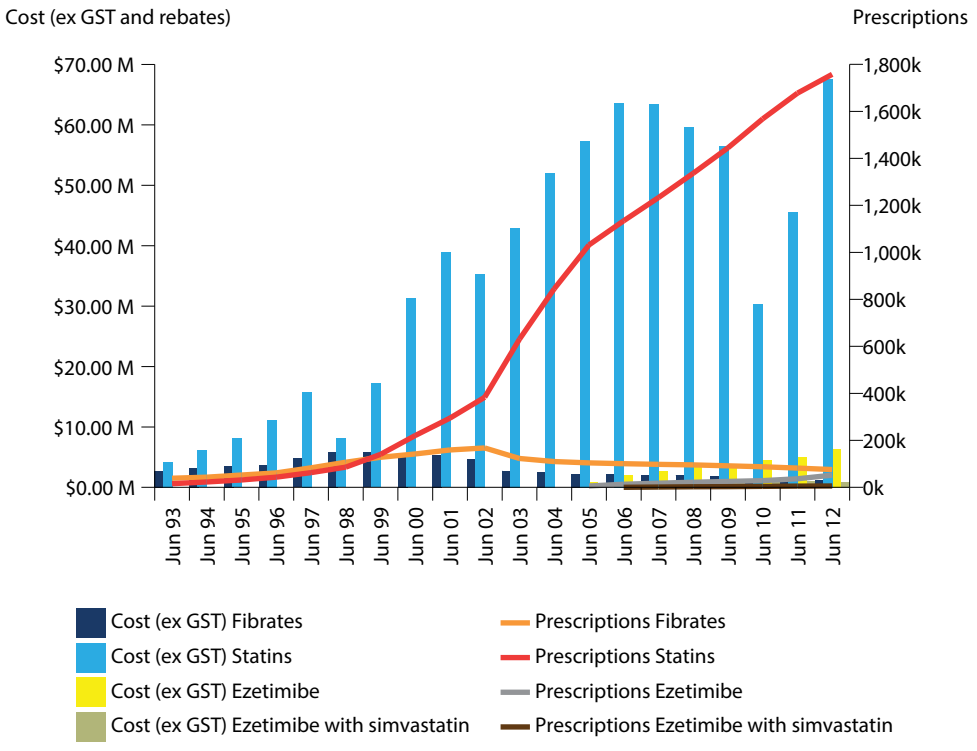
Savings of the magnitude achieved through brand changes of heart medicine are important to PHARMAC, and enable funding decisions such as the dabigatran investment to be made, knowing funds will be made available from within the current pharmaceutical budget.

BrandSwitch

Blood Pressure Management



Lipid Modifying Agents



- Expenditure reduced in 2010 financial year as a result of the listing of a generic simvastatin. Gross spending on statins has risen through to the 2012 financial year, although this spending is subject to a confidential rebate, which reduces the net cost to District Health Boards.

Mental health

Key decisions:

- Reference pricing of olanzapine
- Introduction of alternative brand of the antidepressant venlafaxine.

Antipsychotics

As part of a multi-product agreement with the supplier, PHARMAC funded a new long-acting injectable form of the antipsychotic medicine olanzapine. Olanzapine is a widely used medicine to treat a range of mental health conditions. In addition, PHARMAC introduced generic competition and reference pricing for olanzapine. The outcome has been a major price reduction where the funded generics cost approximately 4% of the Zyprexa innovator brand.

This decision led to a dramatic drop in spending on olanzapine during 2011/12 which will continue in future years.

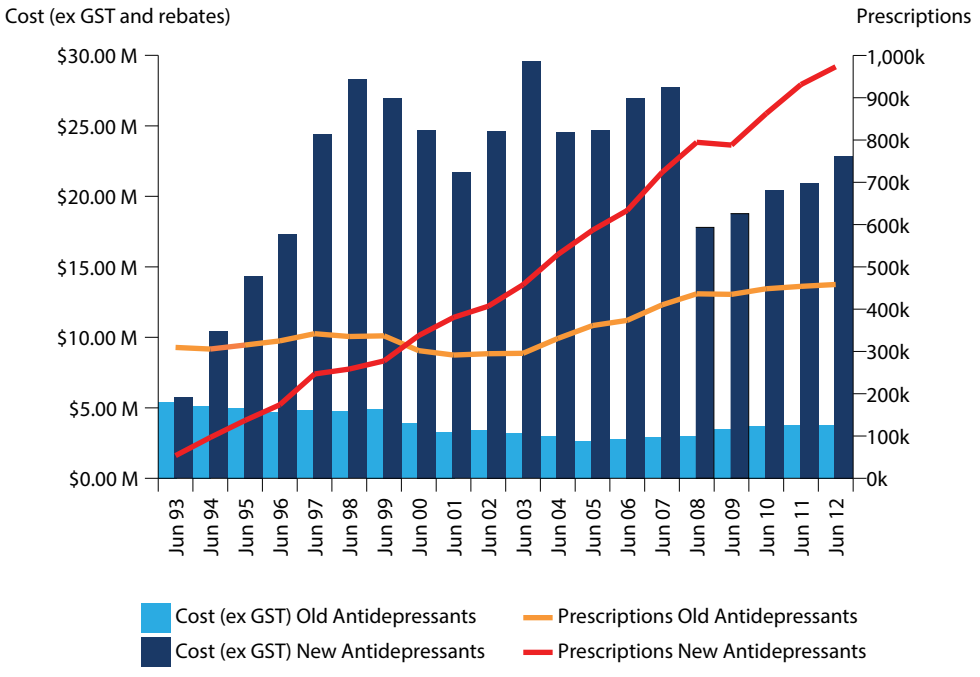
Olanzapine continues to be also funded as a tablet and as an orodispersible tablet.

Antidepressants

PHARMAC began funding the Arrow brand of venlafaxine antidepressant in August 2011, in addition to the Efexor XR brand.

PHARMAC funded Arrow-Venlafaxine XR brand of venlafaxine tablets at the same price as the Efexor capsules, and subject to the same Special Authority criteria. Further price reductions have occurred or are scheduled to occur for venlafaxine tablets and capsules which would reduce the overall expenditure on this antidepressant.

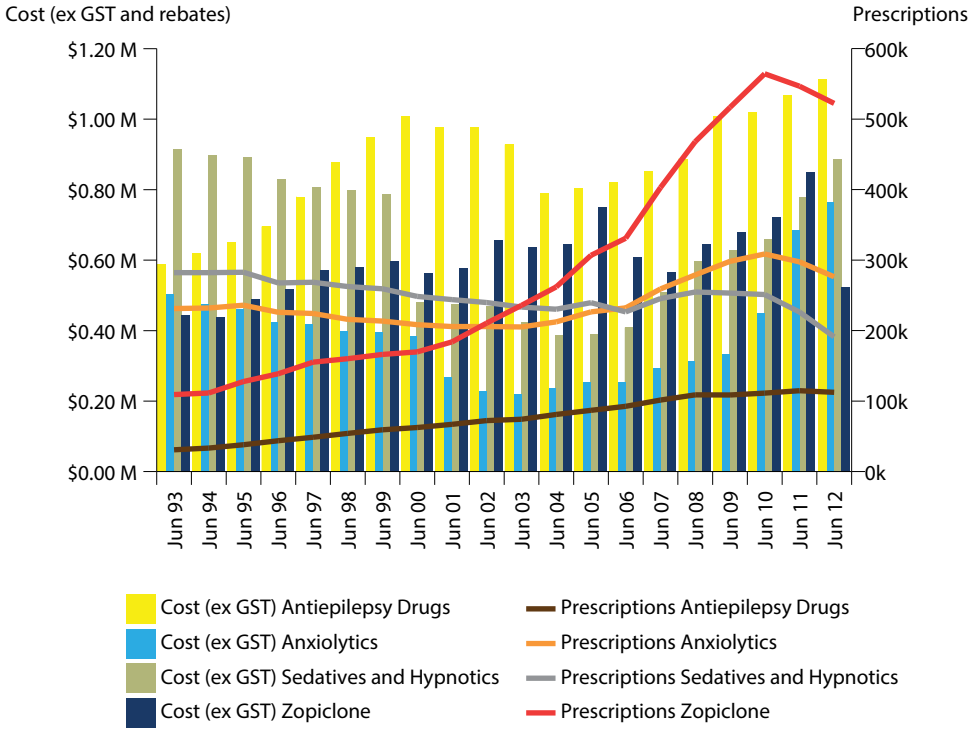
Antidepressants



- Reductions in spending on antidepressants reflect the introduction of generic competition for all antidepressant medicines. All major antidepressants are now subject to generic competition.

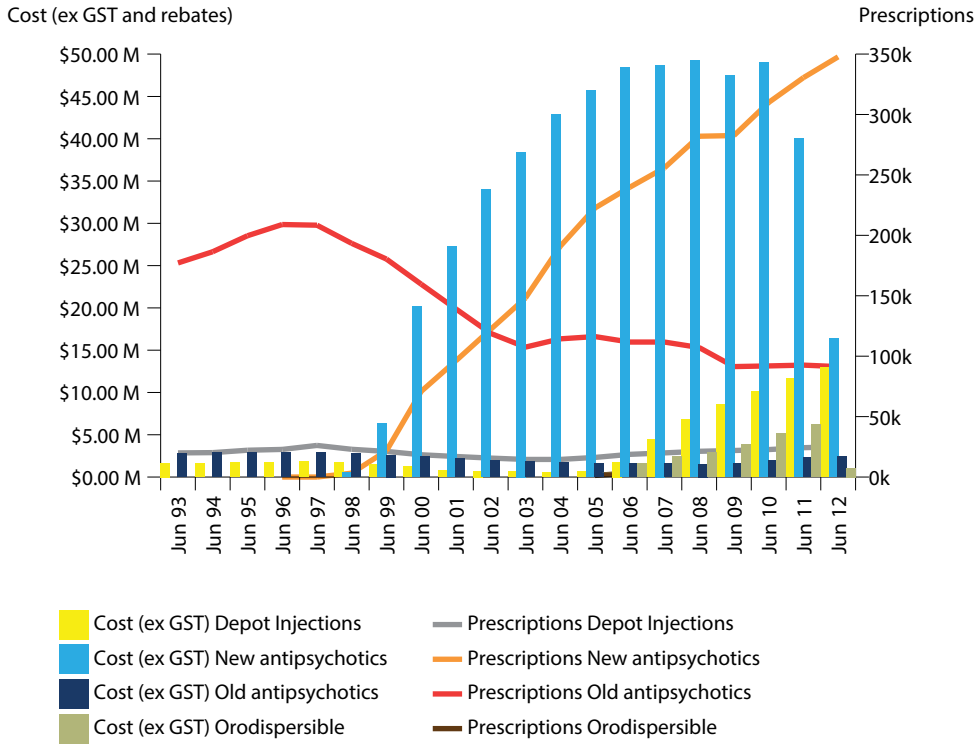
Sleeping pills

- Zopiclone has become the preferred sleeping pill treatment over the past decade, in comparison to benzodiazepines.



Antipsychotics

- New generation (atypical) antipsychotics have replaced older forms of antipsychotic (see page 14).

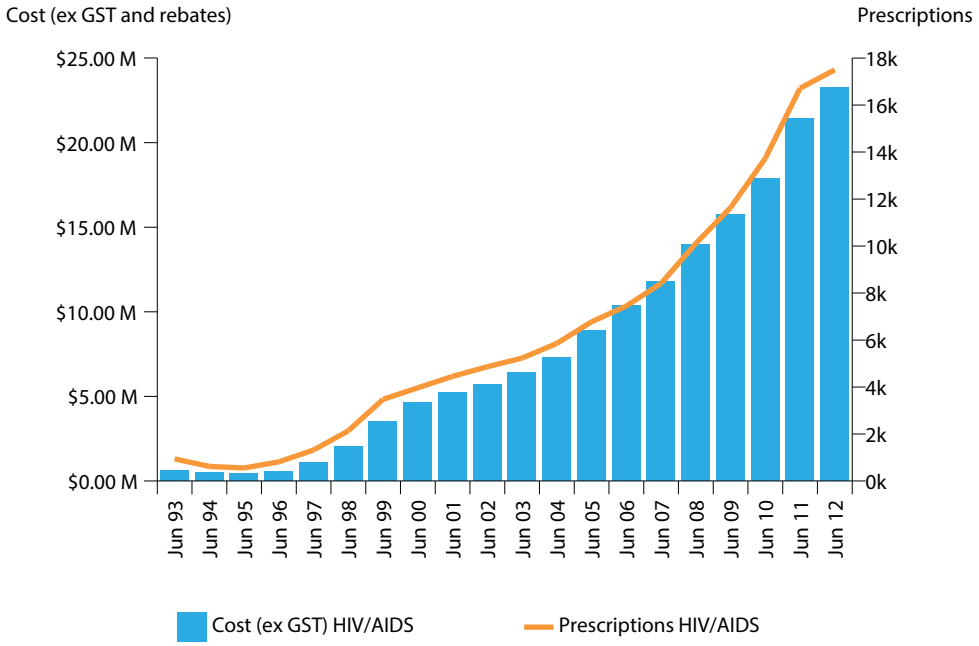


Infections

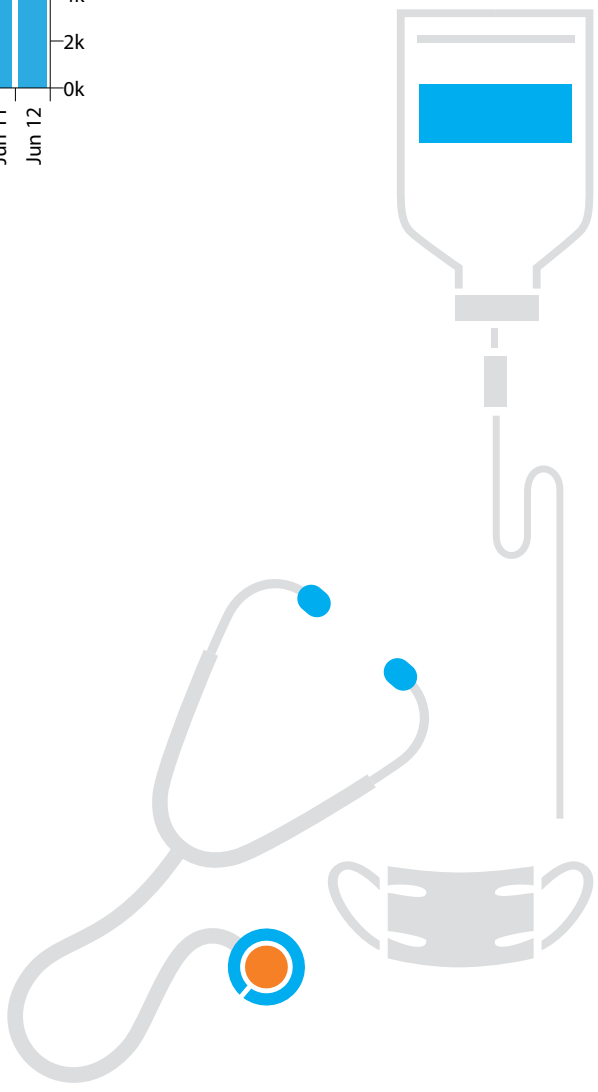
In response to community concern, PHARMAC moved to fund a treatment for babies aged under one year, who contract pertussis (whooping cough). The listing of azithromycin for children under one with whooping cough followed advice from both PTAC and the Ministry of Health that there was an urgent public health requirement for such a treatment.

As well as being funded to treat infected children, azithromycin can be prescribed as a preventive (prophylaxis) for children aged under one year of age.

HIV/AIDS



- Spending and prescription numbers for HIV/AIDS treatments has risen steadily as new technology has been introduced.



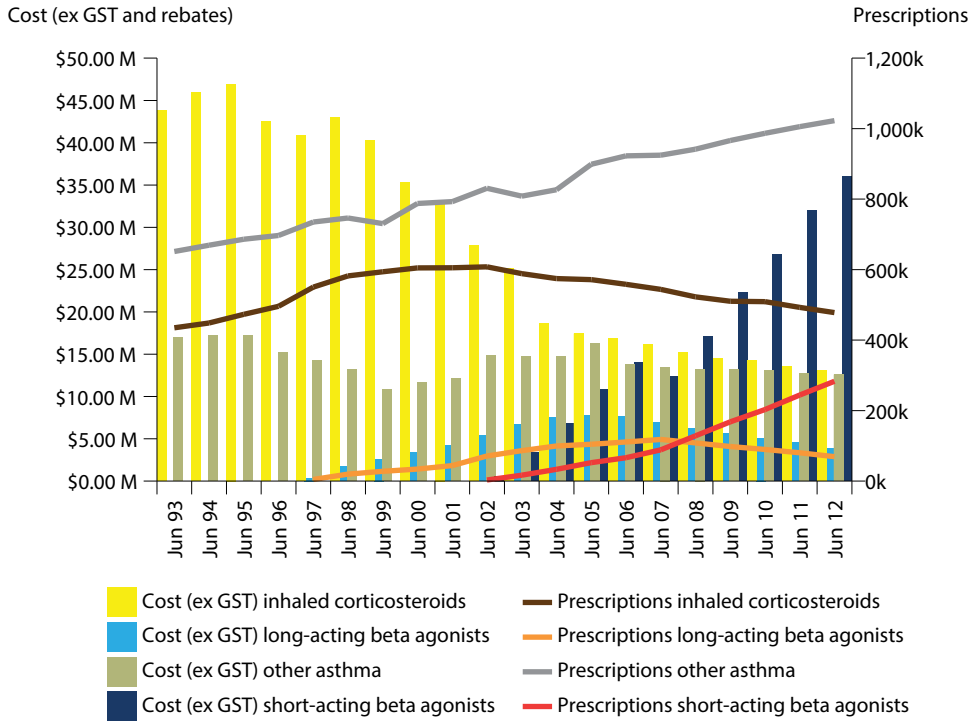
Respiratory

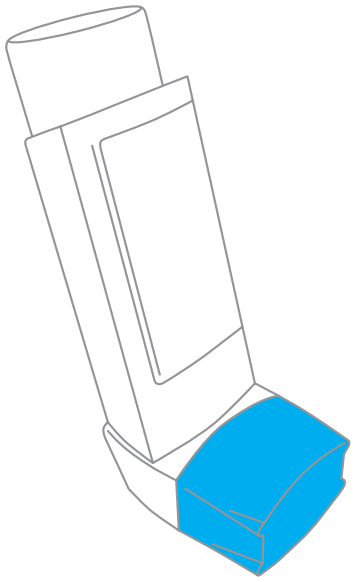
Supporting research into asthma in children

PHARMAC continued its He Tapu te Ha: Space to Breathe programme in Auckland. The programme examines whether early childhood education programmes can help young children and their families better manage asthma. The Auckland programme follows on from a 2009 pilot in Taranaki that showed that information was helpful for teachers and parents, but was unable to determine if asthma outcomes were improved.

Space to Breathe promotes a wrap-around asthma management approach in pre-school children. Clinical assessment and advice is provided, along with self-management for children and their families, and professional development and training for early childhood education teachers. The programme is delivered in early childhood education centres such as playcentres, kindergartens and day care centres. The children receive education in their early childhood education centre, and are followed up for a year to track their progress. Key indicators for the programme are the number of visits to the doctor, the number of hospital visits, and the number of children who are receiving an inhaled corticosteroid.

Asthma





Contraceptives

Key decisions

- Sole supply of the Ava 30 combination contraceptive pill
- Full funding for the 20mg combination contraceptive pill.

Approximately 240,000 women take funded contraceptive pills, with 20 brands listed on the Pharmaceutical Schedule – some of which are fully funded and some partly funded. About 100,000 of those women were affected by PHARMAC's decision to move to sole supply for one type, where six brands will reduce to two.

Arrow Pharmaceuticals will become the sole supplier of these pills (ethynloestradiol with levonorgestrel), under its Ava brand. The changes will release $3.4 million over the next three years.

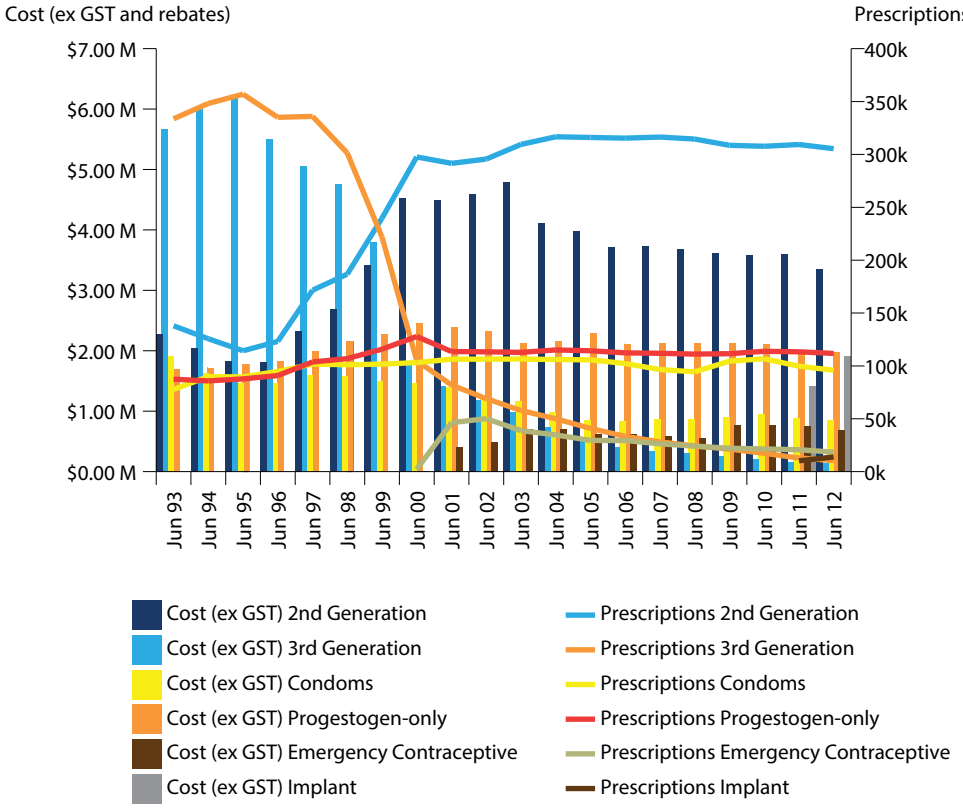
The decisions don't affect the funding of other contraceptive pills.

A feature of the changes is that a low-dose version of the combination pill became fully funded for the first time. About 16,000 women previously took this low-dose pill (Loette or Microgynon), and paid a part-charge.

The new pills are the same size, shape and, in some cases, colour, as the pills they replace.

As oral contraceptives are prescribed six-monthly, PHARMAC introduced an extended transition to the new brands.

Contraceptives



- The use of 3rd generation hormonal contraceptives reduced significantly (along with a concurrent rise in use of 2nd generation contraceptives) with the publication of information raising safety concerns about 3rd generation pills.

Diabetes

Key decisions:

- Insulin pumps funded on the Pharmaceutical Schedule for the first time (from 1 Sept 2012)
- Funding three blood glucose testing meters and test strips from CareSens range produces $10 million per annum savings
- Ketone urinalysis sticks funded
- Intermediate-acting insulin aspart funded.

There was a high level of public engagement around our proposed changes to the funding of diabetes testing equipment. Towards the end of 2011, PHARMAC sought proposals from the suppliers of diabetes products including insulin pumps, ketone testing equipment and blood glucose testing meters and strips.

Consultation on funding proposals occurred from February 2012. These proposals were:

- To list insulin pumps on the Pharmaceutical Schedule for the first time
- To fund three meters from the CareSens range
- To fund ketone urinalysis sticks
- To fund insulin aspart.

The proposals to fund insulin pumps and Caresens blood glucose meters drew the most interest, with approximately 3000 responses received to consultation. This was because part of the proposal involved stopping funding meters other than the CareSens brand.

Responding to the issues raised in consultation, PHARMAC made changes to its proposal when it announced funding decisions, begining from 1 September 2012. The main changes were:

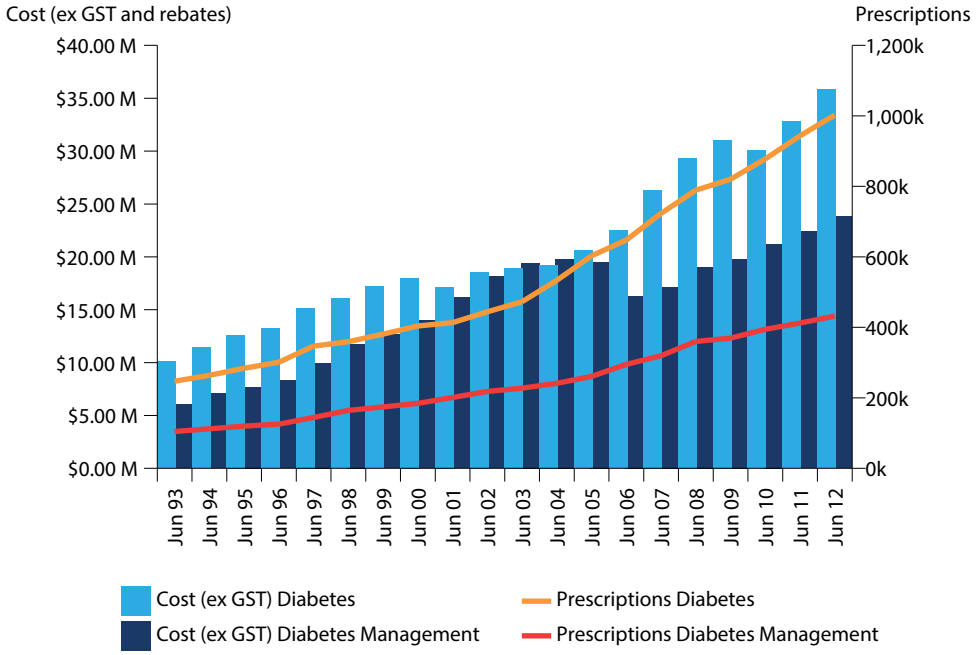
- The introduction of a meter with additional functionality (CareSens N POP) which was not included in the original proposal
- People who were using an Accu-Chek Performa Combo meter with an Accu-Chek Combo insulin pump prior to 1 June 2012 were eligible for funded Accu-chek test strips
- People using a Freestyle Optium as their only meter for both blood glucose and ketone testing prior to 1 June 2012 were eligible for continued funding of the Optium blood glucose test strip.

The insulin pumps decision was significant in that, prior to PHARMAC's involvement, insulin pumps and consumables had not been funded consistently on a nationwide basis.

Changes to the blood glucose testing meters and strips was estimated to save District Health Boards $10 million per year.

PHARMAC is running events to support people changing to the CareSens meters.

Diabetes


Cost (ex GST and rebates)
Prescriptions
$40.00 M
$35.00 M
$30.00 M
$25.00 M
$20.00 M
$15.00 M
$10.00 M
$5.00 M
$0.00 M
1,200k
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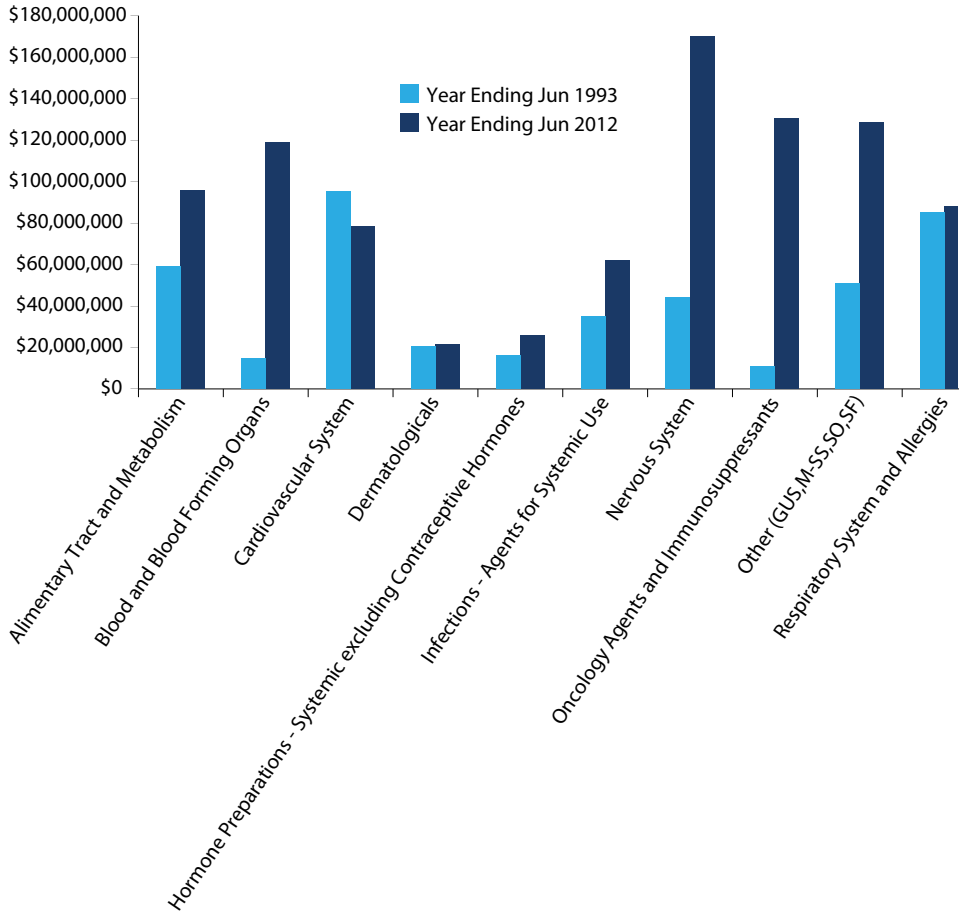
Jun 11
Jun 12
Cost (ex GST) Diabetes
Cost (ex GST) Diabetes Management
Prescriptions Diabetes
Prescriptions Diabetes Management

Changes in Therapeutic Group Cost 1993-2012



Exceptional Circumstances and NPPA

A new policy was implemented during the year to assess funding applications for medicines not listed on the Pharmaceutical Schedule. The policy, Named Patient Pharmaceutical Assessment (NPPA), replaces and streamlines the previous Exceptional Circumstances (EC) schemes.

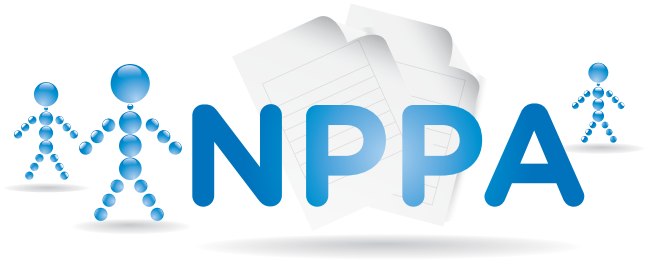
NPPA has a number of advantages over the previous EC policies:

- Rarity of the condition is no longer a criterion for funding consideration
- A new `urgent access' pathway has been defined for patients seeking rapid access to unfunded medicines (as defined by their clinical circumstances)
- There is a closer link between individual patient NPPA applications and the assessment of medicines for listing on the Pharmaceutical Schedule
- Funding applications can be submitted online.

In the first three months of NPPA, PHARMAC experienced a slight rise in the number of applications received and a higher proportion of finalised applications were approved, compared to the corresponding 3-month period the previous year.

PHARMAC's expectation is that, over time, spending on NPPA will rise initially, and then flatten off as PHARMAC moves more of the medicines funded through NPPA onto the Pharmaceutical Schedule. Another feature of NPPA is that PHARMAC routinely publishes the outcome of funding applications on its website, which gives clinicians greater information on which applications might be successful.

While NPPA is now in operation, PHARMAC also continues to manage people with ongoing approvals under the previous EC schemes. PHARMAC will continue to assess EC renewal applications using the same criteria under which those initial approvals were granted.



Exceptional Circumstances data for year 2011-2012

		Received	Approved	Declined
Community EC (CEC)	Initial	182	83	75
	Renewal	128	124	1
CEC automatic approvals	Initial	181	181	0
	Renewal	155	155	0
Hospital EC	Initial	380	289	40
	Renewal	256	247	4
Cancer EC	Initial	76	55	12
	Renewal	29	24	5
Paediatric Cancer Treatments		79	79	0
Total		1466	1237	137

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)
- 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.

Comparison of NPPA and Exceptional Circumstances funding applications (March to June)

	Initial applications	No. approved	No. declined	Decision pending	No. withdrawn
NPPA (2012)	367	219	16	73 **	59
EC (2011)	343	240	74	3	25

**Note: The outcome of applications pending decisions may lower the approval rate.*

*** The outcome of some applications will occur outside of the period therefore at the present time a higher proportion remain outstanding than for the EC applications in the comparable period.*

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Prof Jens Mueller JurDr LLM MBA MSAM

Dr Jan White MBBS, MHP, FRACMA, FNZIM (from October 2012)

PHARMAC's Management Team

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Steffan Crausaz BPharm, MSc, MRPharmS - Manager, Funding & Procurement (acting Chief Executive August 2011 to June 2012, appointed Chief Executive from 1 July 2012)

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Management Team

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

Rico Schoeler - Manager, Analysis & Assessment

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

PHARMAC's Advisory Committees

Pharmacology and Therapeutics Advisory Committee (PTAC)

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Dr Sisira Jayathissa MMedSc (Clin Epi) MBBS, MD, MRCP (UK), FRCP (Edin), FRACP, FAFPHM, Dip Clin Epi, Dip OHP, Dip HSM, MBS (chair from 1 November 2012)

Deputy Chair

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

Committee members

Dr Christina Cameron MBChB, FRACP

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

Dr Stuart Dalziel MBChB, PhD, FRACP

Dr Ian Hosford MBChB, FRANZCP, psychiatrist

Dr George Laking MD, PhD, FRACP

Assoc Prof Dee Mangin MBChB, DPH, MRNZCGP

Dr Graham Mills MBChB, MTropHlth, MD, FRACP

Prof Mark Weatherall BA, MBChB, MApplStats, FRACP

PTAC Sub-committees *(as at June 2012)*

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Cardiovascular: Dr Sisira Jayathissa (Chair, Physician), Dr Malcolm Abernethy (Cardiologist), Dr John Elliott (Cardiologist), Dr Lannes Johnson (PHO Medical Advisor), Assoc. Prof. Dee Mangin (General Practioner, Clinical Researcher), Dr Stewart Mann (Associate Professor of Cardiovascular Medicine), Dr Richard Medlicott (General Practitioner), Dr Martin Stiles (Cardiologist), Assoc. Prof. Mark Weatherall (Geriatrician), Prof. Mark Webster (Consultant Cardiologist)

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Panels

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NPPA: 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 Mark O'Carroll (Respiratory Physician), Dr Ian Shaw (Paediatrician)

Gaucher Treatment Panel: Dr Callum Wilson (Metabolic Consultant), Dr Ruth Spearing (Haematologist), Dr Mark Coates (Radiologist)

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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 Kenneth White (Respiratory Physician)

Consumer Advisory Committee (CAC)

Chair

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

Deputy Chair

Anne Fitisemanu – 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.

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