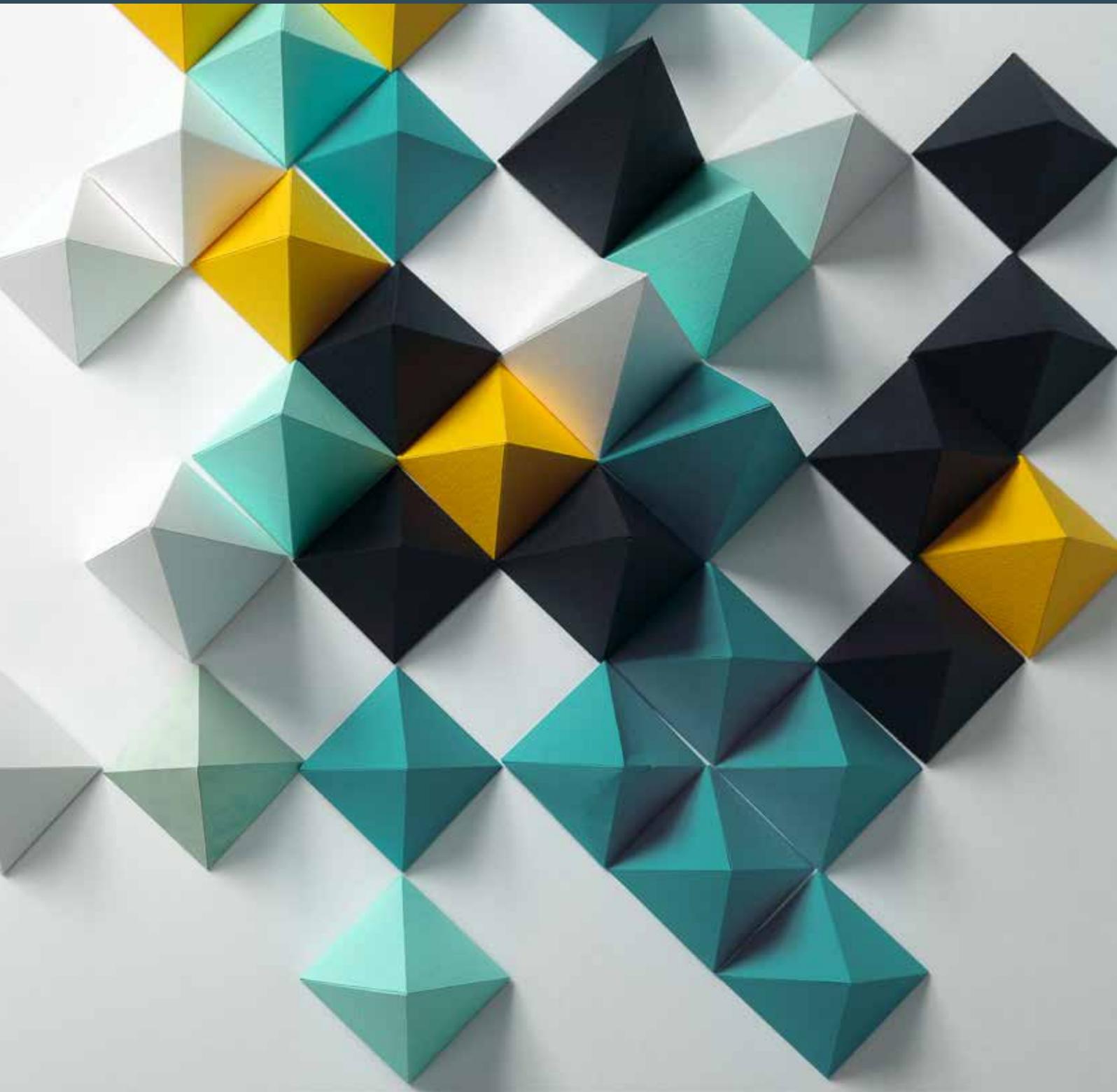


ANNUAL REVIEW

DECEMBER 2014

PHARMAC

PHARMACEUTICAL MANAGEMENT AGENCY



KEY FIGURES: COMBINED PHARMACEUTICAL BUDGET

Rx



42,885

NEW ZEALANDERS
BENEFIT FROM NEW FUNDING
DECISIONS

41.8 MILLION

NUMBER OF FUNDED
PRESCRIPTION ITEMS FILLED
(1.0% DECREASE)



3.4 MILLION

NEW ZEALANDERS
RECEIVING FUNDED MEDICINES

\$795 MILLION

YEARLY DHBS' COMBINED
PHARMACEUTICAL EXPENDITURE
(ON BUDGET)



35

NUMBER OF
MEDICINES WITH
ACCESS WIDENED



26

NUMBER OF
NEW MEDICINES
FUNDED

\$806.9 MILLION

TOTAL COMBINED PHARMACEUTICAL
EXPENDITURE BEFORE ADJUSTMENTS TO
ASSURE THAT BUDGET WAS NOT EXCEEDED

\$52.2

MILLION

IN SAVINGS ACHIEVED



KEY FIGURES: OTHER PHARMACEUTICALS

SAVINGS TO DHBS FROM LISTING
HAEMOPHILIA TREATMENTS

\$28 MILLION

KEY FIGURES: HOSPITAL MEDICINES

\$3.65 MILLION
FULL YEAR SAVINGS
TO DHB HOSPITALS FROM
HOSPITAL MEDICINES DECISIONS

\$14.6 MILLION
SAVINGS TO DHBS
OVER FIVE YEARS
AFTER COSTS OF
NEW INVESTMENTS

THE COST OF
NEW
INVESTMENTS
IN HOSPITAL
MEDICINES



\$0.6 MILLION

KEY FIGURES: HOSPITAL MEDICAL DEVICES

\$1.12 MILLION
ANNUAL SAVINGS TO DHBS
FROM NATIONAL CONTRACTS



\$4.6 MILLION

SAVINGS TO DHBS OVER FIVE YEARS
FROM NATIONAL CONTRACTS



PHAR

Pharmaceutical Man

CONTENTS

CHAIRMAN'S REVIEW	04
CHIEF EXECUTIVE'S REVIEW	06
THE FACTORS FOR CONSIDERATION	08
THE BIOSIMILAR FILGRASTIM STORY	10
IMATINIB – MANAGED MEDICINE CHANGE	12
TOP 20 MEDICINES	13
TE WHAIORANGA	14
THERAPEUTIC GROUP REVIEW	16
THERAPEUTIC GROUP SUMMARIES	18
NAMED PATIENT PHARMACEUTICAL ASSESSMENT	29
PHARMAC'S SENIOR LEADERSHIP TEAM	30
PHARMAC DIRECTORY	31

DELIVERING QUALITY OUTCOMES THROUGH CHANGE HAS BEEN ONE OF PHARMAC'S BIGGEST CHALLENGES OVER THE PAST YEAR.

Chairman Stuart McLauchlan



It's often said that change is a constant in the health sector and that has certainly been the case for those affected by PHARMAC's decisions over the past year. The difference this time has been that PHARMAC has been making changes to itself as well as around the funding of pharmaceuticals and working with changing sector partners. This has led to a challenging year, but one that has positioned PHARMAC well to deliver on the high expectations now placed on it.

A hallmark of successful organisations is that they can go through periods of change, adapt and continue to perform. It has been pleasing to see PHARMAC navigate through change and continue to deliver high quality outcomes for New Zealanders. This is a positive for the health sector overall, as PHARMAC is now playing a much bigger role and has greater influence.

DECISION-MAKING

One of the biggest projects during the year, involving multiple opportunities for input from stakeholders, was the change to our decision-making framework, as part of our review of our Operating Policies and Procedures. The decision criteria review involved 12 community forums and a national consultation event in Wellington in early 2014. In total nearly 400 people attended these events.

From this process PHARMAC will be moving to a new framework for making its pharmaceutical funding decisions – the biggest change to the way PHARMAC makes decisions in over 20 years. There's more about the change to Factors for Consideration on P6.

EXPANDING ROLE

The past year was the first in which PHARMAC managed a national list of hospital medicines, and also the first time it ran the contracting process for the full immunisation schedule which it took on in 2012/13.

There have been immediate benefits from PHARMAC's involvement. Access to hospital medicines is now nationally consistent – people have the same access to medicines regardless of where they live. And in the first year PHARMAC reached agreements that will save District Health Boards \$12.7 million over five years after deducting the cost of new investments. Those investments include medicines never previously funded in DHB hospitals, including pegfilgrastim (to treat low white blood cell count in cancer patients), risedronate (for osteoporosis and Paget's disease), and paliperidone (for schizophrenia).

Management of the immunisation schedule resulted in two new vaccines – rotavirus and varicella – being added to the nationally funded list along with an improved pneumococcal vaccine Prevenar 13. These decisions, along with maintaining funding for the previously funded vaccines, will have long-term health benefits. For example, PHARMAC estimates that rotavirus vaccination alone could avoid up to 1200 hospital admissions per year.

PHARMAC has also been active in contracting for hospital medical devices. This work is expanding rapidly, and already there are more devices listed on the Pharmaceutical Schedule than pharmaceuticals. Early savings have been modest but increased savings will come as more DHBs take up the opportunities as this work continues to expand.

By October 2014, the cumulative value over five years of PHARMAC's work in hospital medicines and medical devices will deliver additional savings to DHBs of more than \$100 million. Significant hospital medicines savings will commence in January 2015.

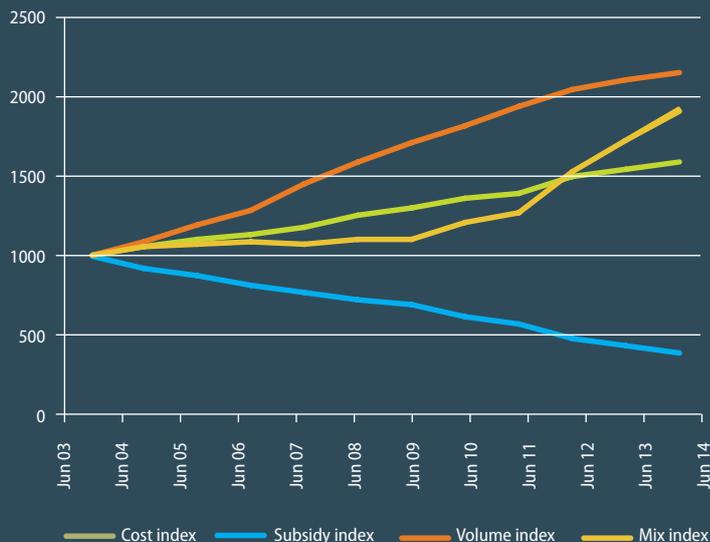
These benefits pale in comparison to the overall benefit to DHBs of PHARMAC's management of the Combined Pharmaceutical Budget. Not only do DHBs benefit through not having to fund the base growth in use (around \$40-\$60 million per annum), but when mapping the cost against the level of subsidy paid in 2003, they saved more than \$5 billion (and \$1.2 billion last year alone).

PHARMACEUTICAL PRICE, VOLUME AND MIX

PHARMAC managed combined pharmaceutical funding on budget at \$795 million in 2013/14.

The number of prescriptions funded was 41.8 million, with some 3.4 million patients receiving funded medicines. PHARMAC estimates that 42,885 additional patients will benefit from PHARMAC's decisions implemented over the past 12 months.

This graph is an index that shows the price, volume and mix of medicines over 20 years. While price, volume (the number of medicines prescribed) and mix (the various types of medicines funded) all climb, the subsidy index (actual price paid) has declined in real terms. This demonstrates that the increased access to medicines has been achieved through reducing medicine subsidies, rather than by restricting access to medicines. That's provided benefits for PHARMAC and the wider sector. In other words, PHARMAC is getting more medicines, for less.



CHANGES TO OUR PEOPLE

There have also been changes right across PHARMAC's Board, staff and advisory bodies. At Board level, Kura Denness left the Board and we welcomed Nicole Anderson. Kura had been one of the Board's longest-serving members and made a considerable contribution to PHARMAC through her role chairing the Board's Audit and Forecast Committee.

The clinical advisory committee PTAC added two new members – Christchurch GP Dr Simon Wynn Thomas, and Professor Jennifer Martin, one of Australasia's most pre-eminent figures in the field of clinical pharmacology.

Three new members joined the Consumer Advisory Committee – all of whom have their roots in Pacific communities. David Lui, Tuiloma Lina Samu and Key Frost bring complementary skills, knowledge and expertise in consumer advocacy to the Consumer Advisory Committee.

To get itself in shape for its expanded role, PHARMAC went through an internal structural change which resulted in a smaller senior leadership team, with four directors led by Chief Executive Steffan Crausaz.

With these changes now bedding in, the Board expects to see continued positive achievements across the range of PHARMAC activities.



PROFILES

SUE ANNE YEE

Senior Therapeutic Group Manager



Dr Sue Anne Yee grew up in Malaysia, studied medicine in Australia, but has called New Zealand home since joining PHARMAC five years ago.

Sue Anne works in the pharmaceutical funding team, working with clinicians and pharmaceutical companies to bring new products onto the Pharmaceutical Schedule. It's a

complex field taking in clinical, economic and market data, and other information before making recommendations on funding decisions.

"The work is never boring. It's quite innovative what we do to get things funded, either through a good deal or by targeting access in some way. You get to see things done."

"People don't always see the things we do, but a lot happens behind the scenes. It's very collaborative in the way we work with clinicians and get their advice, and often we're working with patient groups too."

"What I love is being involved in initiatives that have a national impact. It's quite different to being a clinician where you have the patient in front of you. What we do is at a different level, but we're still thinking about what it means for patients. We also have visibility of other issues like international trends, market information or service delivery across multiple therapy areas. So we have to consider the whole picture."

Sue Anne had first-hand experience of the pharmaceutical industry before joining PHARMAC, working for a small, specialised company in Melbourne called Orphan Australia.

Sue Anne has other talents too, and has been known to be quite creative.

"I like creative things and everything DIY," she says. "So I like to sew and make my own clothes, and I like to cook. It's not something I've ever trained in, but Youtube is a great teacher!"

HOW PHARMAC DOES ITS JOB IS ALL ABOUT HELPING SUSTAIN QUALITY HEALTH SERVICES FOR NEW ZEALANDERS

Chief Executive Steffan Crausaz



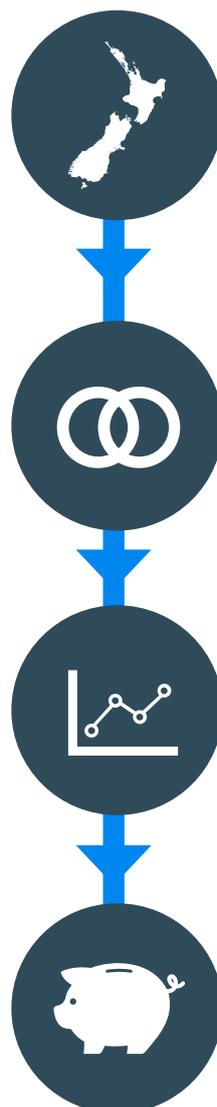
PHARMAC's in the middle of a transformation – not just in what we do, but in how we do it. We've got a very clear motivation about why we're changing the things we do and how we do them. Ultimately, it's about doing our bit to protect and sustain the world-class public health system that New Zealanders have come to expect.

The expanding role we have been talking about for some years now is well underway. As well as community and cancer medicines, we now make decisions on all hospital medicines, vaccines, haemophilia treatments and have begun to negotiate contracts for hospital medical devices.

We've identified areas where we can create additional value that helps us achieve our objective – to obtain the best health outcomes for New Zealanders within available funding. We're already making measurable progress. Combined savings from hospital medicines and medical devices since July 2013 now top \$100 million over five years. - and that's just the very beginning for our work in medical devices. While we've achieved savings, we've also extended access to a wide range of products and managed costs for DHBs.

We make decisions about which products will be funded, negotiate prices and set subsidies. There are a number of ways to do this which we see as steps along a pathway to 'budget management'. Currently the different parts of our business are at various stages along that pathway (as shown on the right).

The ultimate stage is full budget management. This is how we manage a range of pharmaceuticals within the fixed Combined Pharmaceutical Budget.



NATIONAL CONTRACTING

Hospital medical devices
- wound care
- disposable laparoscopic trocars
- sutures
- interventional cardiology

MARKET SHARE PROCUREMENT

INVESTMENT MANAGEMENT

Hospital medicines
New investments and savings

BUDGET MANAGEMENT

Combined Pharmaceutical Budget
Community medicines and devices, vaccines, hospital cancer medicines, haemophilia treatments

IMPACT OF PHARMAC ON CPB EXPENDITURE OVER TIME (ACTUAL AND PREDICTED 2000 TO 2017)



TRANSFORMING HOW WE DO BUSINESS

But it's not just what we do, we're also changing how we do it. We want to continue to be an organisation that's good to do business with – bringing people on board and making them part of our processes. We are keen to be seen as a great Tiriti partner and have worked to develop authentic connections with whānau ora collectives. At this stage we have three agreements in place and will be looking at how we can work with these partners to deliver medicines-related programmes relevant to their communities.

Our policy consultations in recent years have been characterised by extensive engagement to ensure we have listened to and accommodated a wide range of perspectives. Earlier this year we released a discussion document on the issues associated with funding some high cost medicines for people with rare disorders. From the submissions received and discussions we developed a novel approach to addressing issues of competition. Our RFP for a contestable funding pilot has closed and we are taking clinical advice. We anticipate that any successful proposals would be consulted on in early 2015 and any products funded would be listed on the Pharmaceutical Schedule.

A major organisational transformation began in 2012 with the launch of our review of our Operating Policies and Procedures (OPP). Consultation led to a process of a rolling review that will lead to publishing the OPP in a more dynamic web-based format. Some of the key areas being consulted on include our decision criteria, our approach to hospital medical devices, and the Named Patient Pharmaceutical Assessment Policy (NPPA).

The decision criteria have guided our decision-making since PHARMAC's inception. These will be replaced with a decision-making framework that identified relevant factors for consideration in our funding decisions, that will come into effect later in 2015.

LISTENING BETTER

Ultimately it's about listening to the people affected by our decisions. This year we intend to survey a range of stakeholders to better understand what their concerns might be and how we might communicate more effectively with each other. We commissioned an evaluation of a major implementation – the diabetes blood glucose meters brand switch. That review reinforced some of the key learnings we had already taken on board and it also pointed out some other areas where we had room to improve. We expect a second review of the clinical impacts of that brand switch to become available in early 2015.

Our transformation as a highly-engaged organisation will continue throughout the coming years and I welcome your feedback on how we can best do this.



THE FACTORS FOR CONSIDERATION

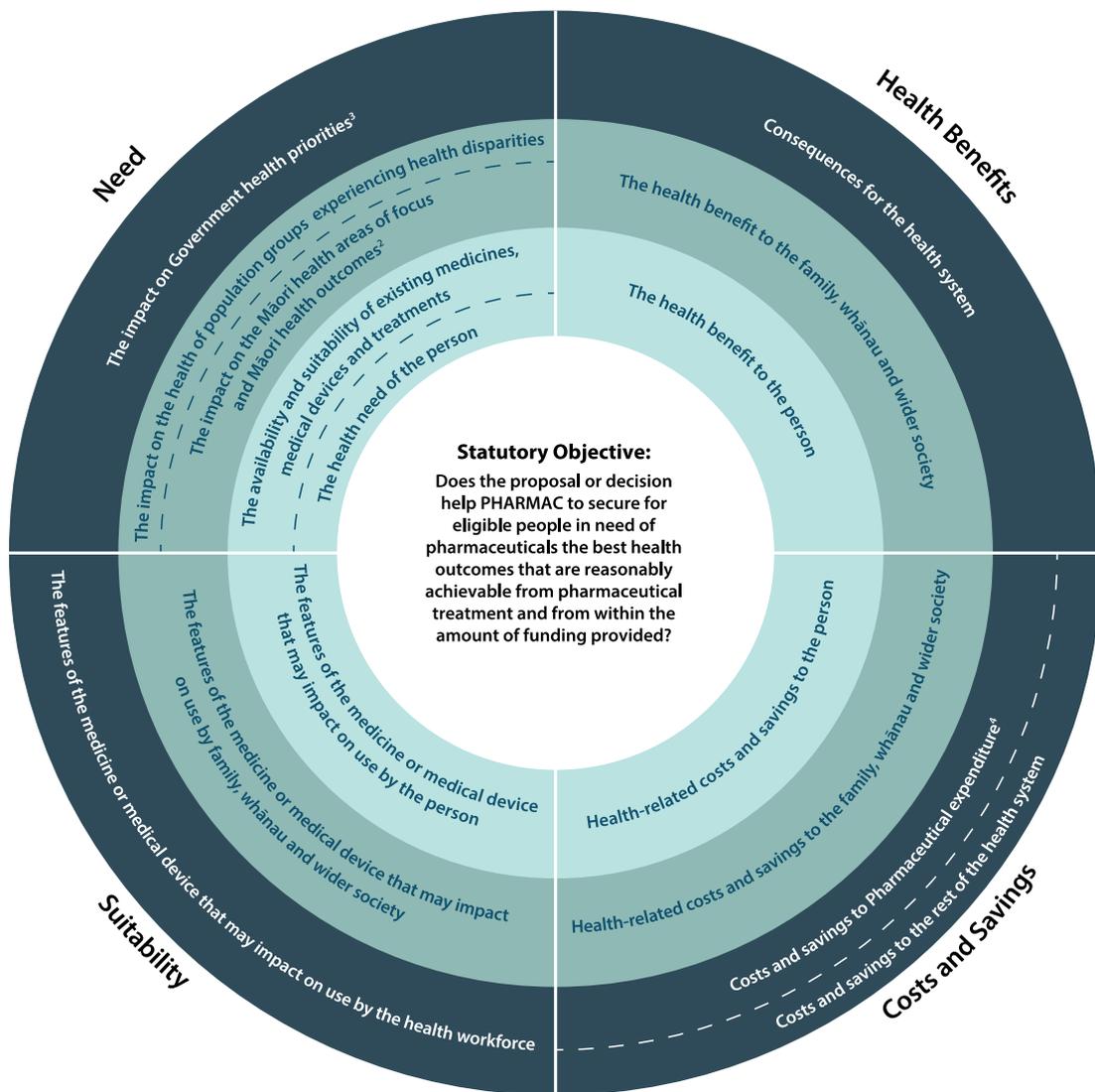
BIGGEST CHANGE TO DECISION-MAKING IN 21 YEARS

PHARMAC is embarking on one of the biggest changes in its 21-year history – changes to the way it makes decisions. This includes decisions about which medicines and medical devices will be funded. From late 2015, PHARMAC will move to 15 Factors for Consideration, a shift away from the nine Decision Criteria that have served us up until now.

We're making this change to reflect feedback we've received about how we make decisions, and also to ensure our process fits all our work, including community and hospital medicines, vaccines and medical

devices. The long lead-in time is to help us and other people adapt to the change, and we'll be communicating with people throughout the implementation process.

Over the past few years PHARMAC has been reviewing how we operate. At the same time, our work has been expanding into new areas. This has led us to look at the way we make decisions, and ask if this needs to change to better reflect our expanded role.



Health system (including health workforce)

Family, whānau and wider society

Person receiving the medicine or medical device¹

1 The person receiving the medicine or medical device must be an eligible person, as set out in the Health and Disability Services Eligibility Direction 2011 under Section 32 of the New Zealand Public Health and Disability Services Act 2000.

2 The current Māori health areas of focus are set out in PHARMAC's Te Whaioranga Strategy

3 Government health priorities are currently communicated to PHARMAC by the Minister of Health's Letter of Expectations.

4 Pharmaceutical expenditure includes the impact on the Combined Pharmaceutical Budget (CPB) and / or DHB hospital budgets (as appropriate)

We ran a wide-ranging and lengthy consultation process through 2013 and 2014. We asked people what criteria or factors they thought should be considered when PHARMAC makes decisions. We ran 12 community forums throughout the country, which were attended by more than 300 people. The many ideas and viewpoints put forward at these forums, plus the more than 130 written submissions we received, formed the basis for a draft set of factors we consulted on in early 2014.

This second consultation also involved considerable public input, including discussion and feedback through the consultation event in Wellington in April 2014.

IMPLEMENTING THE CHANGE

The issues we consider when we make decisions is fundamental to PHARMAC's work, so it's important people understand what the new Factors are and how the change is going to occur. We've intentionally not specified a 'go live' date, because we want to be careful to ensure we are all ready for change.

This is going to involve clear and regular communication over the coming months to help people prepare.

PHARMAC'S STATUTORY OBJECTIVE TO SECURE FOR ELIGIBLE PEOPLE IN NEED OF PHARMACEUTICALS, THE BEST HEALTH OUTCOMES THAT CAN REASONABLY BE ACHIEVED, AND FROM WITHIN THE AMOUNT OF FUNDING PROVIDED.

INTRODUCING THE FACTORS FOR CONSIDERATION

The 15 Factors for Consideration will replace the current Decision Criteria.

We will use the Factors to help us to determine if a funding decision would help us to achieve our statutory objective.

The Factors will not be weighted or applied rigidly, and not all Factors will be equally relevant to every funding decision we make.

The circular diagram (left) represents the three levels of impact that we take into account (to the person; the person's family, whānau and wider society; and to the broader health system), across the different dimensions PHARMAC considers when making funding decisions (need, health benefits, costs and savings, and suitability).

WHAT HAS CHANGED?

PHARMAC can take into account a wider breadth of impact, acknowledging that the health impacts of a funding decision may fall beyond the person receiving the medicine or medical device. These Factors are captured in the middle circle of the Factors diagram related to 'family, whānau and wider society'.

PHARMAC can take into account the health needs of Māori as a specific Factor for Consideration. This acknowledges our commitment to Te Tiriti o Waitangi. We will consider the specific health areas that are important to Māori communities as identified through Te Whaioranga (our Māori Responsiveness Strategy). We will also consider disparity in health among Māori relative to the rest of the New Zealand population.

PHARMAC can consider the health impact on a broader group of populations that are facing health disparities. This includes the significant disparities that currently exist with Pacific people living in New Zealand. Population groups facing health disparities may be characterised by ethnicity, location, demographic or socioeconomic position.

The Factors for Consideration are designed to make the things PHARMAC may take into account for a decision more explicit and transparent.

APPLYING THE FACTORS FOR CONSIDERATION?

The Factors will guide our thinking when considering a funding decision.

The Factors fall within four dimensions:

- **Need:** Need is about the disease, condition or illness. Within the 'need' dimension we consider the impact of the disease, condition or illness on the person, their family or whānau, wider society, and the broader New Zealand health system.
- **Health benefit:** Health benefit is about the potential health gain from the medicine or medical device being considered. For example, vaccines have a population health benefit which is taken into account. A device that supports a new type of surgical procedure, which has health benefits for patients, would similarly be captured within this dimension.
- **Costs and savings:** We consider the health-related costs and savings to the person and their family, whānau and to wider society. The cost and savings to the health system covers both the cost and savings to the pharmaceutical budget and to the wider health system. For example, funding a medicine might lead to savings in hospitals through reducing demand for infusions. In this situation, the medicine might cost more, but there's an overall benefit through reducing demand for hospital services.
- **Suitability:** Suitability considers the non-clinical features of the medicine or medical device that might impact on health outcomes. For example, how easy the medicine or medical device is to use for a health worker, is still taken into account.

WHEN WILL THE FACTORS FOR CONSIDERATION COME INTO EFFECT?

The changes are complex, so we need to take the time to ensure people understand them and that we know how to apply them consistently. As well, there are many documents and references to the current decision-criteria which will need to be updated so that there is a seamless transition. We will be talking with people throughout 2015, before the Factors come into effect, to help familiarise people with the Factors.

We're planning to introduce the Factors from late 2015 and will let people know of the confirmed 'go-live' date in mid-2015.

The PHARMAC website has more information including an interactive diagram of the Factors for Consideration, and supporting information providing more detailed explanation on each of the factors.

MORE FOR LESS

THE BIOSIMILAR FILGRASTIM STORY

Biosimilars are a recent innovation in pharmaceuticals that have brought competition to the biologic medicines market. The first funded biosimilar in New Zealand was Zarzio, a biosimilar brand of filgrastim introduced in 2012. The price reduction and expanded patient access that resulted from this competition underscores the importance of biosimilars for future PHARMAC activity.

WHAT ARE BIOLOGICS AND BIOSIMILARS?

Unlike most traditional medicines that are made through chemical processes, biologic products are made of, or from, living things like yeasts, bacteria or animal cells. They usually have a more complex structure than other medicines.

Competitor products of biologic medicines are known as 'biosimilars' – these are highly similar versions of an approved biologic medicine.

To be approved by regulators, biosimilar medicines must have demonstrated comparable quality, safety and efficacy to an approved biologic, such that there is no clinically meaningful difference.

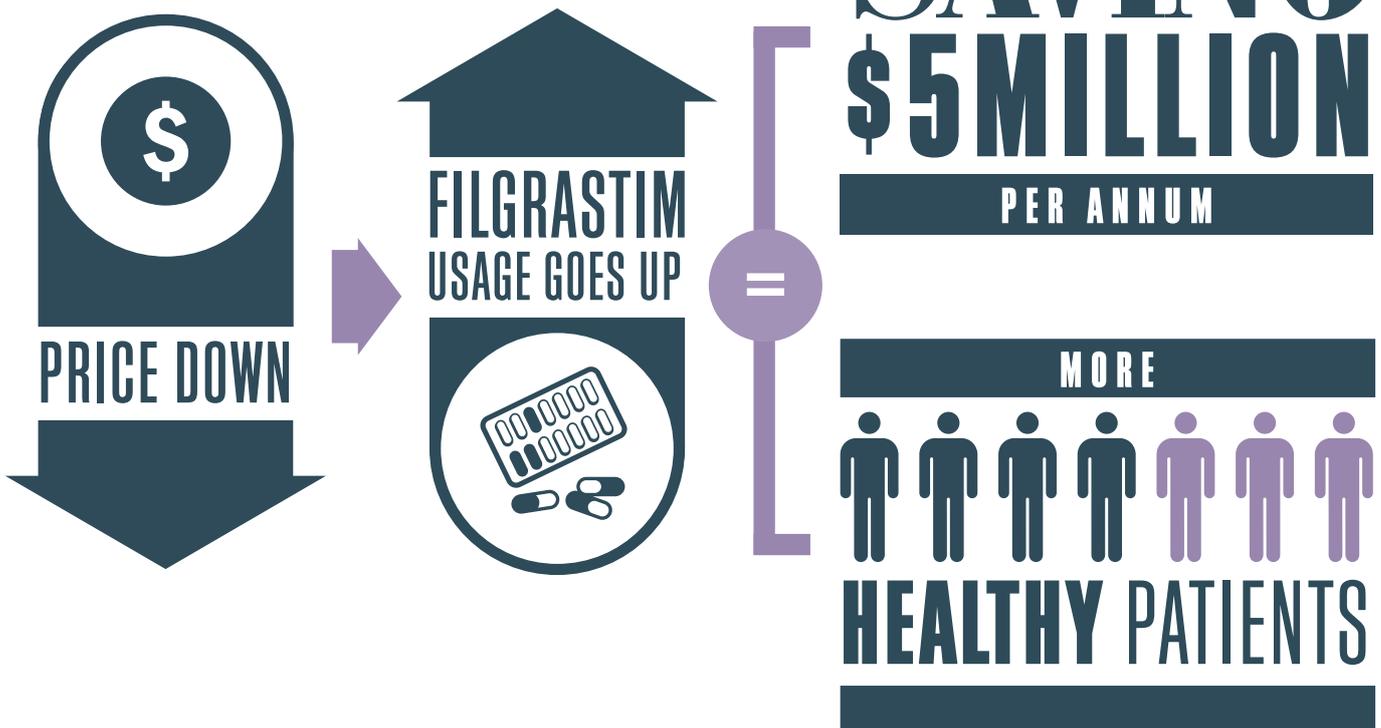
FILGRASTIM AND PEGFILGRASTIM

Filgrastim, also known as GCSF (granulocyte colony stimulating factor), is a biologic medicine used to treat low white blood cell count in people undergoing chemotherapy treatment for cancer. Pegfilgrastim is a long acting version of filgrastim. One injection of pegfilgrastim is equivalent to around 11 injections of filgrastim.

Historically, because of their relatively high cost, filgrastim and pegfilgrastim's use had been limited – both in terms of the type of patients treated and the dosing or number of injections. This meant there were health benefits to be unlocked through funding an equally effective but lower cost alternative.

BIOSIMILAR FILGRASTIM

In 2011 PHARMAC became aware of biosimilar brands of filgrastim being approved internationally. PHARMAC ran a commercial process, seeking proposals from companies marketing original and biosimilar filgrastim brands. As a result we awarded a sole supply contract to Sandoz for its biosimilar brand of filgrastim, Zarzio – the first biosimilar drug funded in NZ – in late 2012.



IMPACT OF THE CHANGE

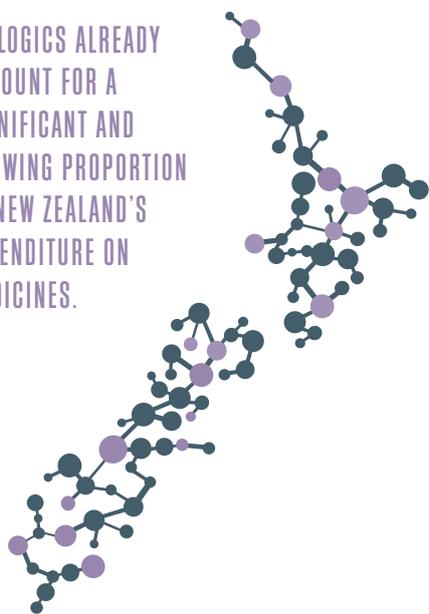
The effect of competition was immediately obvious. Zarzio was funded at a lower price compared to the original brand of filgrastim (Neupogen) and this gave PHARMAC the opportunity to allow wider funded access. Soon after, having lost some market share to biosimilar filgrastim, the supplier of pegfilgrastim (Neulastim), which remains on patent, reduced its price offering further savings. So overall, the introduction of biosimilar filgrastim has significantly reduced the costs of the total GCSF market. In addition, there has been a nearly 25% expansion in usage which is still growing.

While the cost reduction was significant and had wider effects, leading to increased usage which means more patients are receiving benefit from these important treatments.

Introducing biosimilar competition has sent a signal to suppliers about PHARMAC's future intentions to harness the benefits of competition where possible for biologic medicines. The filgrastim story shows that this competition can spill over to similar products that remain on patent, creating even greater savings.

Biosimilars are likely to be increasingly important in New Zealand healthcare. In 2014, PHARMAC introduced another biosimilar – for the growth hormone somatropin – and many other biosimilars are in the pipeline. Of the competitive processes PHARMAC has run to date where there is biosimilar competition, half have been awarded to the originator brand and half to a biosimilar.

**BIOLOGICS ALREADY
ACCOUNT FOR A
SIGNIFICANT AND
GROWING PROPORTION
OF NEW ZEALAND'S
EXPENDITURE ON
MEDICINES.**



FILGRASTIM CHANGE – A VIEW FROM THE FRONT LINE

Increased use of GCSFs (filgrastim and pegfilgrastim) has led to significantly improved health outcomes for cancer patients. That's the finding of clinicians from MidCentral Regional Cancer Treatment Services, reported at the NZ Society for Oncology 2014 Conference.

Biosimilar competition meant PHARMAC could improve funded access to GCSFs, which are used to treat neutropaenia, or low white blood cell count, in people undergoing chemotherapy.

Neutropaenic fever is a serious condition which can cause chemotherapy delays or dose reductions which can compromise efficacy. In severe cases it can be fatal.

Dr Richard Isaacs, Medical Oncologist and Head of Department at MidCentral DHB, said GCSFs had previously been given to women only after they had experienced an episode of neutropaenic fever. After the 2012 funding change, the MidCentral Service began giving GCSFs to all women receiving high-risk chemotherapy to prevent neutropaenic fever.

"The impact of this change for patients and hospitals has been dramatic," says Dr Isaacs. "Previously around one third of women receiving docetaxel-based chemotherapy suffered from neutropaenic fever. We now see it in less than seven percent."

"To put this in context, for every 100 women treated we now avoid 25 of them experiencing neutropaenic fever."

"The introduction of lower cost biosimilar filgrastim and the subsequent price reduction on pegfilgrastim means we use fewer hospital resources and deliver optimal chemotherapy more safely to more women with breast cancer."

IMATINIB MANAGED MEDICINE CHANGE

AROUND **225**
PATIENTS TAKE
IMATINIB
FOR CML

PHARMAC SWITCHED
PATIENTS TO A GENERIC
RESULTING IN A PRICE
REDUCTION OF
>85%

\$12M
ANNUAL SAVINGS
GENERATED BY
CHANGING TO GENERIC
IMATINIB

When medicines come off-patent it means generic versions can be sold in competition with the original. That's an opportunity to make savings, releasing medicine funding for other purposes. This was the case this year with imatinib, a lifesaving medicine for people with leukaemia.

Imatinib (Glivec) is an expensive product – costing more than \$60,000 for a year's treatment, so there was potential for large-scale savings. In making the changes, PHARMAC was careful to communicate with patients and health professionals to help people adjust to the new brand of imatinib, and to a change in the way their medicine was delivered to them.

Overall, the change to generic imatinib went smoothly. It generated \$12 million of savings to the pharmaceutical budget which are available to reinvest in new medicines. At the same time, people have continued to have funded access to their medicine, and continue to receive high-quality care through their specialists and community pharmacists.

GLIVEC – AN EARLY 'SMART DRUG'

Imatinib – initially marketed as the Glivec brand – was the first in a new class of medicines used to treat chronic myeloid leukaemia (CML) a type of cancer that affects certain types of white blood cells. Before its introduction in the early 2000s, the only treatment options for patients with CML were bone marrow transplantation or chemotherapy and daily interferon infusions which caused serious side effects. Neither of these treatments was very effective with only around 30% of CML patients surviving to five years with these older treatments. With imatinib treatment, survival improved to over 95%.

Imatinib targets the genetic mutation that causes CML, and only targets the cancerous cells. It is regarded as one of the first 'smart' drugs to be designed specifically to target the particular genetic mutation that leads to cancer. As the treatment is in pill form, it's convenient for people to take which is very important when facing life-long daily treatment.

Glivec was first funded in New Zealand in 2003, both for patients with CML and for patients with advanced gastrointestinal stromal tumours (GIST), another form of cancer caused by a similar genetic mutation.

OPPORTUNITY FOR SAVINGS

Glivec is an expensive medicine, with the daily cost of CML treatment around \$160. Over the course of a year this adds up to about \$60,000 per patient.

So even with comparatively small numbers of patients – about 225 taking imatinib for chronic myeloid leukaemia – there were opportunities to make considerable savings.

Most medicines have a patent which gives them protection from competition for a period of time. By 2013 Glivec's New Zealand patent had expired, and competition was available. If PHARMAC could harness that competition to get the medicine at a lower price, people taking the medicine could still obtain the same health benefits while savings could be made. PHARMAC was keen to take advantage of this opportunity, but aware that any change would have to be carefully managed.

In 2012 PHARMAC ran a request for proposals for sole supply of imatinib for CML. Clinical advice was an important part of the decision-making process. PHARMAC sought this clinical advice from its main advisory committee PTAC and its Cancer treatments subcommittee. Both committees provided advice on the suitability of the potential new products and how PHARMAC should manage a brand change.

GENERIC INTRODUCTION

In late 2013 PHARMAC awarded sole supply to a generic brand of imatinib supplied by New Zealand company AFT Pharmaceuticals. AFT's price for imatinib was 87% lower than Glivec's price – reflecting the continuing effect of competition PHARMAC sees through its commercial activity.

Glivec's high price had also seen it distributed directly to patients rather than dispensed via community pharmacy as occurs with the majority of other medicines. The price reduction through the brand change created the opportunity to shift distribution to the usual community pharmacy route, putting it on the same basis as all other patients' medicines.

HELPING PATIENTS CHANGE TO THE NEW BRAND

International and national research shows that even with the same amount of active ingredient, small changes with medicines, such as the colour, name change or packaging change, can cause concern and issues for patients. So PHARMAC kept clinicians and people taking imatinib informed before, during and after the introduction of the generic to help support a smooth transition.

This transition occurred smoothly over a three-month period, beginning 1 April 2014. As people had been well informed and understood the process, PHARMAC received very few requests for additional information.

TOP 20 MEDICINES BY PRESCRIPTIONS

CHEMICAL NAME	SCRIPTS	CURRENT RANKING
Paracetamol	2,490,000	1
Aspirin	1,350,000	2
Omeprazole	1,230,000	3
Amoxicillin	1,210,000	4
Atorvastatin	980,000	5
Metoprolol succinate	970,000	6
Ibuprofen	900,000	7
Salbutamol	840,000	8
Simvastatin	830,000	9
Amoxicillin with clavulanic acid	760,000	10
Cilazapril	700,000	11
Cholecalciferol	680,000	12
Influenza vaccine	680,000	13
Prednisone	590,000	14
Zopiclone	530,000	15
Metformin hydrochloride	520,000	16
Diclofenac sodium	510,000	17
Loratadine	490,000	18
Flucloxacillin	480,000	19
Felodipine	450,000	20

TOP 20 MEDICINES[#] BY COST

by ex manufacturer cost (ex GST and rebates)

CHEMICAL NAME	COST	CURRENT RANKING
Adalimumab	\$62,210,000	1
Trastuzumab	\$28,390,000	2
Dabigatran	\$26,960,000	3
Fluticasone with salmeterol	\$25,900,000	4
Budesonide with eformoterol	\$20,500,000	5
Etanercept	\$19,600,000	6
Imatinib mesilate	\$17,320,000	7
Insulin glargine	\$15,930,000	8
Rituximab	\$15,770,000	9
Bortezomib	\$14,540,000	10
Tiotropium bromide	\$12,970,000	11
Risperidone	\$12,470,000	12
Blood glucose diagnostic test strip	\$12,320,000	13
Sodium valproate	\$9,970,000	14
Efavirenz with emtricitabine and tenofovir disoproxil fumarate	\$9,930,000	15
Venlafaxine	\$9,520,000	16
Octreotide LAR (somatostatin analogue)	\$9,310,000	17
Epoetin beta [erythropoietin beta]	\$8,980,000	18
Varenicline tartrate	\$8,900,000	19
Fluticasone	\$8,660,000	20

* Excluding vaccines

TE WHAIORANGA

CHANGING THE WAY WE DELIVER PROGRAMMES FOR MĀORI HEALTH

PHARMAC's commitment to Māori health remains – but the way that commitment is delivered is changing.

The past year has seen the first steps towards this new future, with the signing of Memoranda of Agreement with whānau ora collectives in the Bay of Plenty.

Our He Rongoā Pai, He Oranga Whānau and One Heart Many Lives programmes have an established record that we want to continue, and we think the best way for these to be delivered in future is from the community level.

Our approach is now to enter into enduring partnerships with whānau ora collectives and to provide seed funding for specified services which they may deliver, based on an agreed annual plan. This approach is

expected to provide greater national coverage over time and support communities to develop other partnerships to assist them deliver medicines-related services that best meet their needs.

This year we have negotiated Memoranda of Agreement with two Whānau Ora collectives in the Bay of Plenty. The collectives are Ngā Mataapuna Oranga Whānau Ora Collective in Tauranga, and Te Ao Mārama Whānau Ora Collective from Ōpōtiki.

The Māori Pharmacists' Association is another key partner in delivering health programmes to Māori, and we are working on an enduring partnership with the MPA.

TE WHAIORANGA

IS BUILT ON FIVE PILLARS:

1

Advance Tino Rangatiratanga with whānau through health interventions

Te Whaioranga recognises the desire by Māori to have control over their own health and wellbeing, and seeks to support Māori through encouragement; empowerment, facilitation and service based on respect, trust and shared mutual purposes.

2

Establish and maintain authentic strategic connections

Strategic stakeholder engagement and authentic communication is core to what we do. We will work with partners in pursuit of mutual purposes. Our strength is our ability to make linkages between different groups in the health sector, across sectors and with various community groups. Current programmes such as One Heart Many Lives and He Rongoā Pai, He Oranga Whānau are examples of communities in action. We will invest in strengthening communities through encouraging flexibility, creativity and innovation. This will enable us to do more in an enhanced way.

3

Champion evidence based Māori medicine management

Strengthening the evidence base relating to Māori use of medicines is a way that PHARMAC can make a positive contribution to Māori health. By prioritising key Māori health priority areas ensures that the area of greatest need is appropriately targeted.

4

Support and engage in indigenous research and development about pharmaceutical management

PHARMAC has contributed to empowering Māori communities through the transfer of knowledge that is meaningful to communities. There is potential to further explore research and development opportunities in understanding pharmaceutical management and to share this.

5

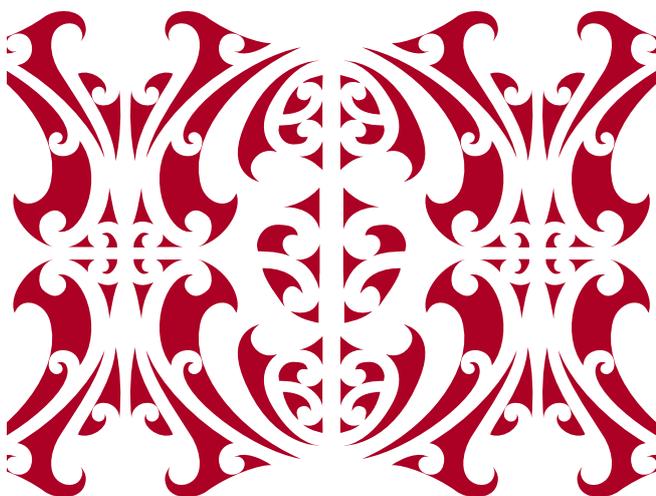
Enhance and enable internal expertise and capability in te ao Māori

PHARMAC staff must have the competence to work in both worlds – te ao Māori and te ao Pākehā. A unique skill set is required in order to advance tino rangatiratanga with whānau. This unique skill set needs to be supported with on-going professional development and support in both worlds.

TE WHAIORANGA

Te Whaioranga is PHARMAC's strategy for improving Māori health. It provides a framework for ensuring that PHARMAC responds to the particular needs of Māori in relation to medicines and sets a direction over the next 10 years, building on the gains of the past decade.

The primary goal of Te Whaioranga is "to ensure that Māori have access to subsidised medicines and use these medicines appropriately and safely."



**WE HAVE HAD A MĀORI
RESPONSIVENESS STRATEGY
SINCE 2002**

**THE CURRENT STRATEGY
TE WHAIORANGA**

AIMS TO ENSURE EQUITABLE ACCESS TO
MEDICINES *FOR* MĀORI

PROFILES

ĀTENE ANDREWS

Kaiwhakahaere Whakarata Māori /
Manager, Māori Responsiveness



It's been a winding career path that has brought Ātene Andrews to PHARMAC, and he's relishing his first foray into the health scene.

Originally from the East Coast and of Ngāti Porou descent, Ātene had a 20-year career in teaching that took him from roles in New Zealand to Niue, Aitutaki-Cook Islands and Singapore.

Along the way he touched fame as a student locking the Auckland under 21 rugby scrum with future All Black captain Gary Whetton. Later he was talked into a job as deputy principal at his old school St Stephens by then-principal Te Ururoa Flavell – now the Māori Party co-leader.

The closure of St Stephens led Ātene onto another path, into the government service. First it was as Māori cultural adviser at the Ministry of Foreign Affairs and Trade, then to the Crown Forestry Rental Trust and the Department of Labour (later MBIE) before landing at PHARMAC in 2014.

Coming from a non-health background Ātene wasn't confident of securing the PHARMAC role, but he has been surprised with what he has found.

"I'm impressed by PHARMAC's willingness to have advisory groups from the community, and listen to the Māori voice," he says. "Groups like the Consumer Advisory Committee and Te Rōpū Āwhina Māori provide strong relationships – a good foundation for future work."

"I'm really excited to be here. At first I thought it would be 3-5 years or so, but I can see it being potentially longer, there's so much we can do – and I've only been here four months!"

"I get excited about where we can take PHARMAC to make things better for Māori. We're making good progress, we've already signed two Memoranda of Agreement with whānau ora collectives, and we're working to lift the cultural competency of staff."

A new job in a new sector isn't the only adjustment Ātene is making in 2014. This year also saw the arrival of his first grandson, so it's papa Ātene as well.

THERAPEUTIC GROUP REVIEW

PHARMAC made 61 investments in medicines during the year, including 26 medicines not previously funded. This is a slightly larger total than the previous year, when PHARMAC made 60 new investments. While PHARMAC's role has grown to include hospital medicines and medical devices, budget management continues to be a significant part of PHARMAC's work. The Combined Pharmaceutical Budget (CPB) now includes funding for community pharmaceuticals, hospital cancer medicines, vaccines and haemophilia products.

PHARMAC spent the CPB budgeted by DHBs (\$795 million), and added a further \$11.9 million from the PHARMAC-managed discretionary pharmaceutical fund. Overall pharmaceutical spending was \$806.9 million, an increase of \$11.4 million on the previous year.

In addition to the decisions on community medicines and vaccines, PHARMAC's work on hospital medical devices and hospital medicines also produced measurable results.

Decisions on hospital medicines led to full year savings of \$3.7 million, which PHARMAC had available to reinvest in new hospital medicines. Over five years, the net effect of PHARMAC's work in 2013/14 alone will be savings of \$14.6 million.

In medical devices, PHARMAC negotiated contracts for more than 5,000 line items, and surpassed \$2 million in potential annual savings for DHB hospitals, that's \$10 million over five years. Decisions mean there are now more hospital medical devices listed on the Pharmaceutical Schedule than there are medicines.

KEY DECISIONS

ADALIMUMAB

Access to this treatment for arthritis and other auto-immune conditions was widened to include juvenile idiopathic arthritis and fistulising Crohn's disease. Estimated additional spending of \$800,000 in the first year.

TICAGRELOR

A new type of blood-thinning drug used to help prevent further heart attacks in people with acute coronary syndrome.

BOCEPREVIR

The first oral treatment for hepatitis C that can improve cure rates, in combination with other hepatitis C drugs, to up to 75%.

FEBUXOSTAT

Treatment for the more severe forms of gout that have not responded well to other treatments.

ROTAVIRUS VACCINE

A newly funded vaccine to protect children from a serious gastric infection. An investment of more than \$8 million per year.

RISEDRONATE

A new listing providing an alternative to currently funded osteoporosis and Paget's disease treatments.

RILUZOLE

The first funded treatment in New Zealand for motor neurone disease.

ELTROMBOPAG

Costing up to \$70,000 per patient per year, this new listing treats the rare blood disorder idiopathic thrombocytopenic purpura (ITP).

ERLOTINIB

Making this treatment for lung cancer available for newly diagnosed patients, provided they have the genetic markers that indicate the treatment will be effective.

HAEMOPHILIA TREATMENTS

Making these treatments available without budget constraint due to listing on the Pharmaceutical Schedule.

TOP 20 THERAPEUTIC GROUPS (\$millions ex GST and rebates)

GROUP NAME	MAIN USE	2011	2012	2013	2014
Immunosuppressants	Organ Transplants, arthritis	\$56.14	\$114.35	\$128.67	\$140.50
Chemotherapeutic Agents	Cancer	\$33.88	\$61.63	\$67.86	\$70.77
Inhaled Long-acting Beta-adrenoceptor Agonists	Asthma	\$36.54	\$39.87	\$43.48	\$48.41
Diabetes	Diabetes	\$32.80	\$35.85	\$39.60	\$43.07
Vaccinations	Vaccinations	–	–	\$42.37	\$42.52
Antithrombotic Agents	Stopping blood clots	\$11.04	\$26.55	\$32.14	\$41.48
Antipsychotics	Mental health (psychoses)	\$60.17	\$32.87	\$30.34	\$32.93
Antiepilepsy Drugs	Epilepsy	\$25.60	\$27.23	\$28.63	\$30.45
Antiretrovirals	HIV/AIDS, viral infections	\$16.77	\$17.77	\$21.04	\$26.46
Analgesics	Pain relief	\$24.75	\$24.76	\$24.99	\$22.43
Diabetes Management	Blood glucose monitoring	\$22.41	\$23.84	\$23.12	\$17.97
Lipid-Modifying Agents	Raised cholesterol (cardiovascular risk)	\$53.53	\$76.53	\$30.08	\$17.49
Treatments for Substance Dependence	Addiction	\$27.03	\$24.93	\$23.25	\$16.87
Antidepressants	Mental health (depression)	\$24.70	\$26.63	\$24.13	\$16.75
Anticholinergic Agents	Allergies	\$14.02	\$14.76	\$15.42	\$16.46
Drugs Affecting Bone Metabolism	Osteoporosis	\$17.46	\$14.16	\$15.36	\$15.69
Antivirals	Viral infections	\$12.72	\$15.18	\$14.88	\$14.97
Agents Affecting the Renin-Angiotensin System	Raised blood pressure (cardiovascular risk)	\$34.55	\$31.66	\$17.84	\$14.70
Beta Adrenoceptor Blockers	Heart disease	\$18.22	\$18.53	\$14.44	\$14.70
Antibacterials	Bacterial infections	\$17.49	\$17.49	\$14.46	\$13.59

PHARMAC also continued to show its responsiveness to areas of public health concern, providing funded access to a hepatitis A vaccine to assist with localised outbreaks in mid-Canterbury and the Hutt Valley. PHARMAC also responded to the needs of the national Rheumatic Fever Prevention Programme by changing the funding rules for the antibiotics needed to treat sore throats.

Savings programmes continue to be important for PHARMAC, to release funds that are locked into long-term funding arrangements. By promoting competition PHARMAC achieves savings that can then be reinvested in new medicines, or used to fund expenditure growth caused by the increased use of expensive new medicines.

The PHARMAC tender continues to be an important source of these savings. In 2013/14, the tender grew to its largest size ever and attracted a record number of suppliers and competitive bids – about 3500.

The result was savings of more than \$38 million over three years. PHARMAC awarded 246 contracts from this tender process. The contracts are important to secure supply of medicines for New Zealanders, and enable suppliers and PHARMAC to take action if supply issues arise. This close management means New Zealand continues to have fewer stock shortages than other countries.

The tender and other competitive processes can lead to New Zealanders having to change their brand of medicine to remain on a funded treatment. PHARMAC supports this process with information or by working closely with health professionals to help people adjust to new brands. Significant changes PHARMAC has assisted with in the past year include:

- A change to a generic form of the immunosuppressant tacrolimus, used mainly to prevent organ transplant rejection.
- A change to generic imatinib, which treats chronic myeloid leukaemia. This change also involved changing the way patients received their medicine.
- A change to a biosimilar form of the growth hormone somatropin. As well as changing the funded medicine, PHARMAC also changed the way the treatment is distributed to patients and the way that funding was granted.
- A move to sole supply of medicines to treat schizophrenia and other psychoses. This change began in mid-2014 and will be progressive.

THERAPEUTIC GROUP SUMMARIES

HEART DISEASE

Main changes

- Ticagrelor – a new type of blood-thinning drug used to help prevent further heart attacks in people with acute coronary syndrome.

Heart disease continues to be one of New Zealand's leading causes of death. PHARMAC took further steps to assist management of heart disease through funding for the new generation blood thinner ticagrelor (Brilinta) from 1 July 2013.

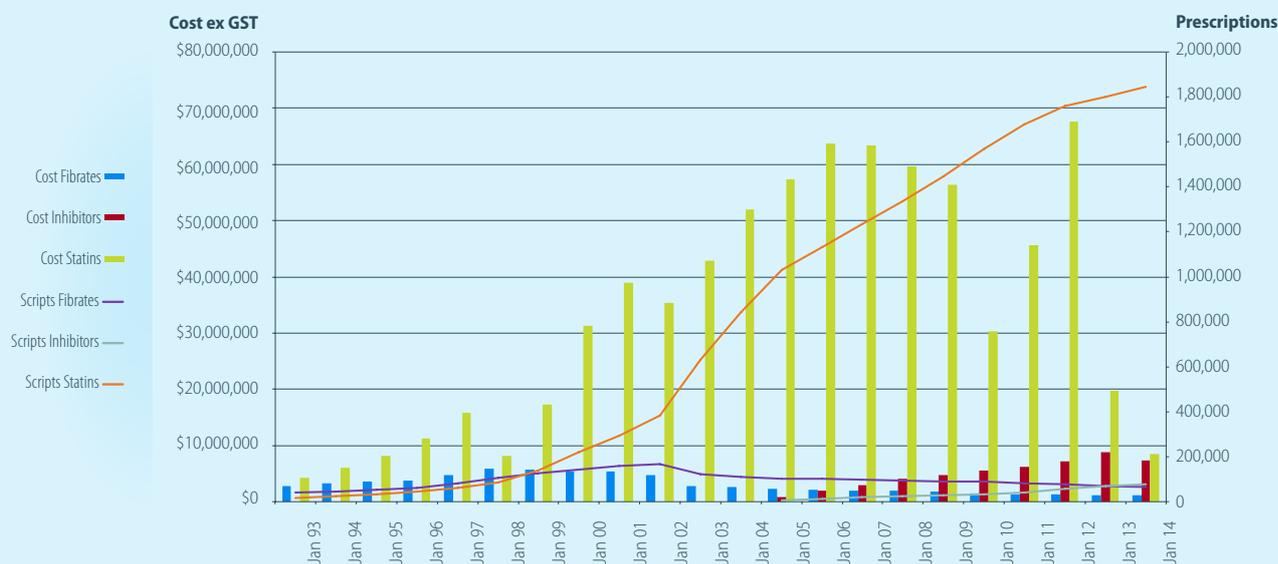
Anti-platelet therapy thins the blood to help prevent future heart attacks. Ticagrelor is a new type of anti-platelet agent, and is expected to be used alongside or instead of current treatments such as low-dose aspirin, clopidogrel and prasugrel.

Ticagrelor is for people who have had particular types of heart attack, known as ST-elevation myocardial infarctions (STEMI), and non ST-elevation myocardial infarctions (NSTEMI).

Clinical trials have shown ticagrelor to be more effective than clopidogrel in preventing further heart attacks.

PHARMAC estimates up to 12,000 people over five years will receive funded ticagrelor treatment, at a cost of about \$14.3 million per year, which is partly offset by confidential discounts negotiated with the supplier.

Cholesterol Management



NEW TREATMENT FOR HEART DISEASE WELCOMED

By Eileen Goodwin on Sat, 6 Jul 2013

A newly funded drug does not make acute coronary syndrome patients feel better, but it improves their safety, Dunedin Hospital cardiologist Gerard Wilkins says.

Associate Prof Wilkins said ticagrelor (branded as Brilinta), which Pharmac has agreed to fund from July 1, had been available on a special release for the past year, under agreement with drug company AstraZeneca. That "tenuous" arrangement ended now the drug was publicly funded.

"It's welcome because it gives us another choice for people who have coronary stents put in, to stop clotting after that.

"It's a pill that doesn't make them feel any better; it just stops the catastrophic occasional event of stents blocking off, or a further heart attack. It isn't about comfort; it's about safety after these kind of events."

Ticagrelor was shown to be more effective than clopidogrel in a direct comparison trial. Most patients had or would move from clopidogrel to the newly funded drug, he said.

"It is just one more useful step forward in this area."

Otago Daily Times 6 July 2013

PROFILES

JANET MACKAY

Senior Implementation Lead



If you want to push Janet Mackay's buttons, just get her talking about the psychology of health.

That's one of the things that attracted her to working at PHARMAC, where she works in the implementation programmes team. The team provides information for people whose brand of medicine is changing, and provides

support for evidence-based prescribing for doctors. They often work with the doctors or nurses who have day-to-day dealings with patients to work out how to make medicine brand changes as easy and effective as possible.

Some recent work PHARMAC has been involved in with Auckland University's department of psychology has been of particular interest to her.

"I'm passionate about the work we're doing with Auckland University looking at generic medicines. It links in strongly with my interest in psychology. We're looking at the reasons people are less likely to trust a generic. Their responses are real but the reasons are psychosomatic. It's really fascinating."

Janet arrived at PHARMAC after working for Regional Public Health in Wellington. The roles are similar, but PHARMAC operates at a different level with programmes operating nationally.

"What I like about working here is that projects change all the time. So every time a product changes or a new product is listed it's a new group of patients and pharmacists and clinicians that you get involved with and link with.

"The process can be the same but different groups of people are involved. You get to learn a lot about particular pharmaceuticals, what they're used for, and about the people who use them.

"People at PHARMAC debate things all the time, which helps to stimulate new ideas. It's a real thinking organisation. Everyone gets involved with everything, and everyone's opinion is valued and considered. I really like that."

But it's not all work – Janet also finds time to volunteer at a local church music group for pre-schoolers and their mums, nannies and caregivers.

"It helps to give some balance in my life," she says. "Plus I get to hang out and play music with the kids, which is really cool."

THERAPEUTIC GROUP SUMMARIES

MUSCULOSKELETAL

Main changes

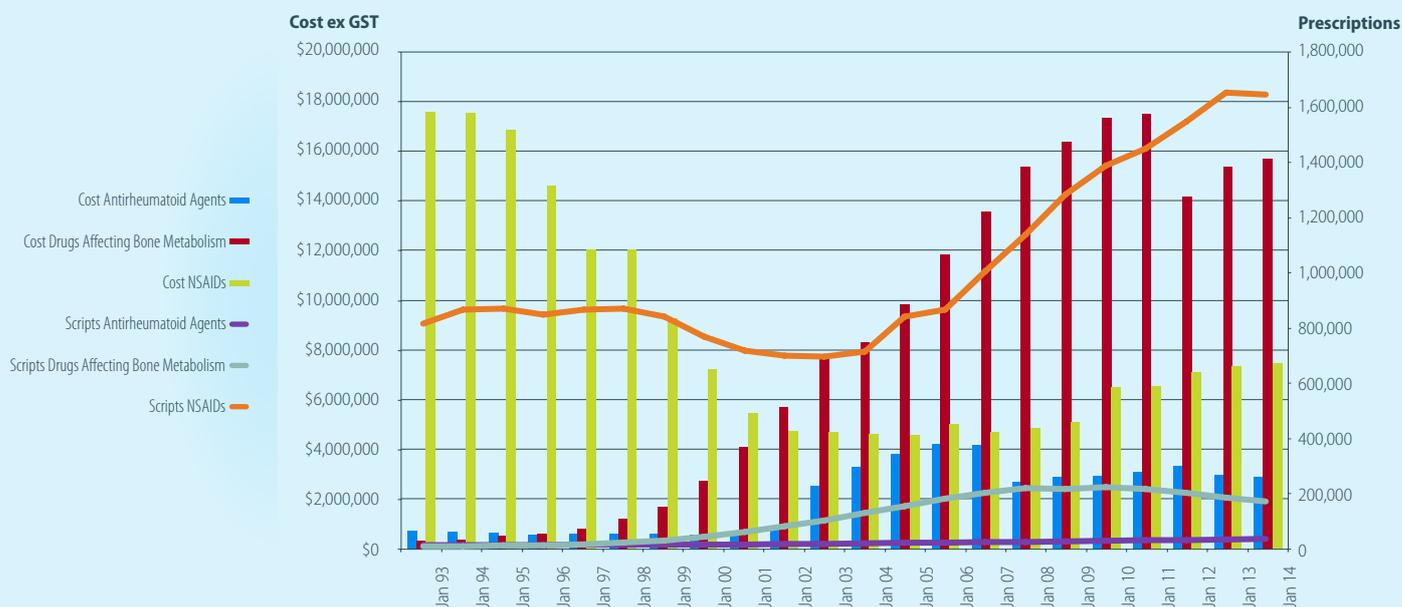
- Febuxostat – treatment for the more severe forms of gout that have not responded well to other treatments.
- Risedronate – a new listing providing an alternative to currently funded osteoporosis and Paget's disease treatments.

A further treatment became funded for people with severe gout – a painful form of arthritis associated with high levels of uric acid in the blood – when febuxostat (Adenuric) was added to the Schedule during 2014.

Febuxostat is a newer pharmaceutical that provides an alternative second-line treatment to benzbromarone. PHARMAC expects funding for febuxostat to account for about \$5 million in spending over five years.

Risedronate was listed as a further treatment for osteoporosis. Risedronate is a newer generation bisphosphonate, a class of medicines that is also funded through products like alendronate and etidronate. Risedronate is the first of these newer generation bisphosphonates to be listed without any Special Authority criteria, meaning people can have the medicine if their doctor decides it could be of benefit to them.

Musculoskeletal



INFECTIONS

Main changes

- Boceprevir – the first oral treatment for hepatitis C that can improve cure rates, in combination with other hepatitis C drugs, to up to 75%.
- Changes to Practitioner Supply Order rules to enable delivery of antibiotics to children in the Rheumatic Fever Prevention Programme.

Hepatitis C treatment

PHARMAC funded a new oral treatment for hepatitis C during the year.

Taken orally, boceprevir is taken as a triple therapy with pegylated interferon and ribavirin. Though it can achieve cure rates up to 75%, there are still tolerability issues for some patients with interferon.

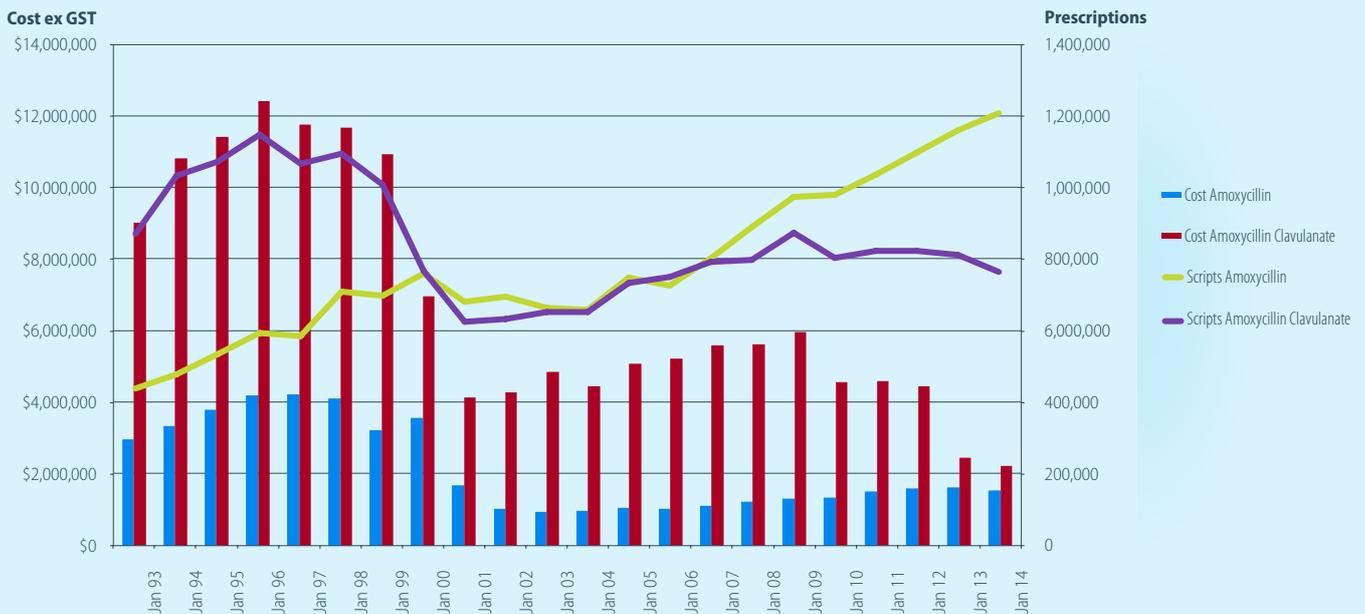
Antibiotics

PHARMAC changed the Pharmaceutical Schedule rules for dispensing antibiotics, to support the goals of the government’s Rheumatic Fever Prevention Programme.

PHARMAC changed dispensing rules so the amount available through a Practitioner’s Supply Order (PSO) is increased, for the antibiotics amoxicillin, phenoxymethyl penicillin, and erythromycin. These are the antibiotics mainly used to treat ‘strep’ throat, which can lead to the heart condition rheumatic fever.

Previous rules only allowed doctors and nurses to carry small quantities of antibiotics that could be given directly to patients. The changes make it easier for children being treated through the rheumatic fever prevention programme to get the antibiotics they need quickly.

Antibacterials



THERAPEUTIC GROUP SUMMARIES

MENTAL HEALTH

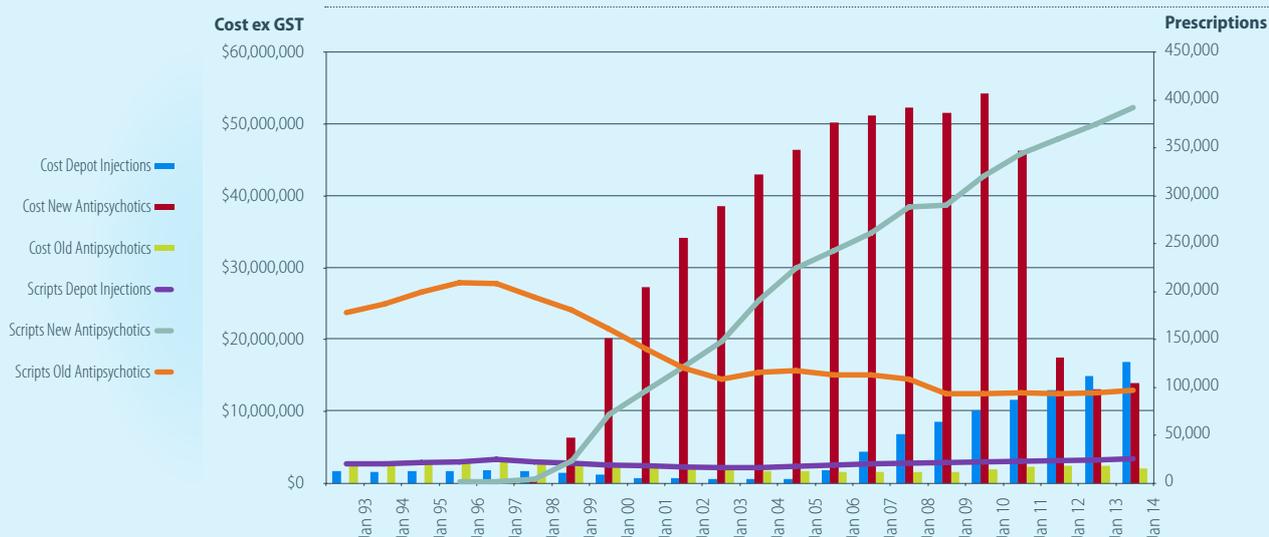
Main changes

- Listing of paliperidone depot injection.
- Removal of Special Authorities from Arrow-Venlafaxine, mianserin and buspirone.

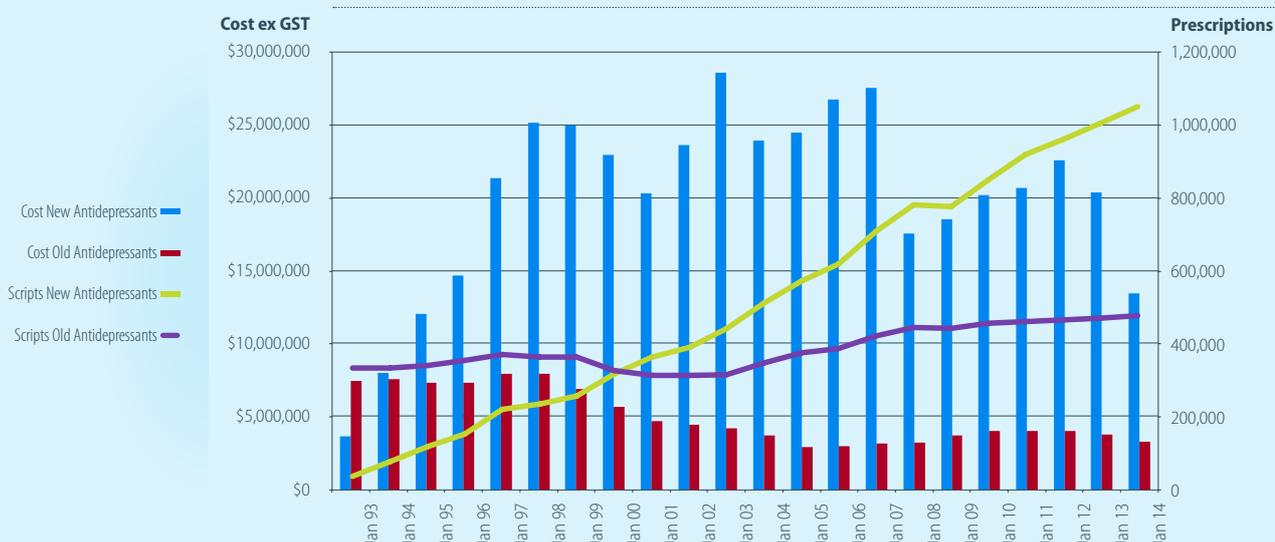
On 1 May 2014 we funded a new antipsychotic depot injection, paliperidone depot (Invega Sustenna). This is similar to risperidone depot (Risperdal Consta) which was already funded, but paliperidone depot can be given monthly rather than fortnightly. This is an advantage for patients, who generally prefer less frequent injections, and for the health system as these treatments are generally administered by a healthcare professional.

We removed a number of Special Authorities from mental health pharmaceuticals in the 2013/14 financial year, including from the antidepressants mianserin and venlafaxine (Arrow-Venlafaxine XR brand only) and the anxiolytic buspirone. This means greater access for patients and less administrative burden for clinicians.

Antipsychotics



Antidepressants



BLOOD AND BLOOD PRODUCTS

Main changes

- Eltrombopag – a new listing for the rare blood disorder idiopathic thrombocytopenic purpura (ITP).
- Haemophilia treatments – making these treatments available without budget constraint due to listing on the Pharmaceutical Schedule.

PHARMAC funded a new drug to treat a rare and potentially fatal blood disorder, idiopathic thrombocytopenic purpura (ITP). People with the disorder have low numbers of the blood platelets that help with clotting. Without treatment, people with ITP are at risk of severe bleeding.

Eltrombopag (Revolade) can increase platelet counts and reduce the bleeding risk.

Funding for eltrombopag is targeted to people who have already tried other available treatments, including having their spleen removed.

About 40 people are likely to receive funded eltrombopag per year at a cost, before confidential rebates, of up to \$70,000 each per year, making it one of the more expensive treatments to be listed on the Pharmaceutical Schedule.

Also during the year, PHARMAC assumed funding for haemophilia treatments that had previously been funded out of DHB non-pharmaceutical budgets. With this funding now managed by PHARMAC from the combined pharmaceutical budget, this freed up DHB funds for investment in other healthcare.

NEUROLOGY

Main change

- Riluzole – the first funded treatment in New Zealand for motor neurone disease.

The first funded pharmaceutical treatment for Amyotrophic Lateral Sclerosis (ALS), the most common form of motor neurone disease, was funded from 1 October 2013.

ALS is a progressive, and ultimately fatal, neurological degenerative disorder where people lose control of their movements. Riluzole treatment aims to slow progression of the disease, which in turn could extend patients' lives and improve their quality of life.

PHARMAC estimates that nearly 100 people will receive the funded treatment within three years, at a gross cost of approximately half a million dollars per year.

PROFILES

CHRIS PECK

Strategic Development Adviser



Chris Peck is adjusting to some major changes in his life. Earlier this year he was married, and the couple are now expecting their first baby in February next year.

"Yes – exciting times ahead," says Chris. "Everyone is telling me how much my life is going to change when the baby arrives, I'm really looking forward to it."

Both Chris and wife Jess hail from the deep south – if you listen closely enough you can still hear Chris's Southland burr. But they're now confirmed Wellingtonians with established jobs in the capital. In Chris's case his role at PHARMAC began in 2006, via a Bachelor of Commerce in economics and operations research at Canterbury University, and a graduate position at the Ministry of Education.

"Education is a big ministry and you feel quite a small part of it," explains Chris. "PHARMAC appealed because it's smaller and you can really see how your work influences PHARMAC's decisions, and ultimately how that affects people."

Chris initially joined PHARMAC as an analyst, looking at pharmaceutical usage data so PHARMAC knew how much was being spent – essential for its budget-management role. More recently he's finding fresh fields to use his problem-solving skills as a strategic development adviser in the pharmaceutical funding systems team. The team looks across PHARMAC's work to see that the Pharmaceutical Schedule rules and funding systems work effectively and efficiently.

Chris has also been doing some career development work, and this has confirmed why he has found the PHARMAC work so rewarding.

"It's the alignment of values," he says. "PHARMAC's a thinking organisation that aims to have a positive influence in the health sector. It's all about helping people. A lot of that aligns with my career and values."

"Plus it's just really interesting work, with some interesting problems to solve. We're driven by the outcomes we can get, led by the evidence that's available. I really like that."

THERAPEUTIC GROUP SUMMARIES

VACCINES

Main changes

- Listing hepatitis A vaccine to combat an outbreak in Ashburton and the Hutt Valley.
- Adding varicella, rotavirus and improved versions of other vaccines to the national immunisation schedule.
- Confirming influenza vaccine suppliers for the next three 'flu' seasons.

Immunisation Schedule changes

PHARMAC's management of vaccines saw changes in three main areas that led to improved vaccines coverage for New Zealanders, at an overall reduced cost. Changes agreed by PHARMAC took effect from 1 July 2014.

For the first time PHARMAC ran the contracting process for the full national immunisation schedule, and this led to some major changes including the listing of two new vaccines for varicella (chickenpox), and the gastric infection rotavirus. There were also improved versions of other vaccines added, including the pneumococcal vaccine Prevenar 13.

The rotavirus vaccine decision is expected to have the greatest impact. The illness mainly affects children and can lead to hospital admission. Adding the vaccine to the schedule will cost \$8.5 million per year (gross), and could prevent up to 1200 hospital admissions per year.

The rotavirus vaccine, an oral liquid, is given to babies within the first eight months.

Varicella vaccine is funded to protect the most at-risk patients – children with reduced immune systems (for example, because of chemotherapy). It is also funded for people in direct contact with these children, a practice known as 'cocooning'.

For pneumococcal disease, Prevenar 13 protects against an additional three strains of invasive pneumococcal disease compared to its predecessor.

PHARMAC also listed improved versions of the current meningococcal vaccine, changing to a conjugated meningococcal C or meningococcal A, C, Y and W135 vaccine, listed a conjugated monovalent meningococcal C vaccine, and expanded eligibility rules so that children whose immune systems are weakened, for example by chemotherapy, will be able to have further vaccine boosters funded.

Hepatitis A

PHARMAC moved to support measures to control outbreaks of the infectious hepatitis A virus. These included outbreaks in Ashburton and the Hutt Valley in 2013.

PHARMAC listed a hepatitis A vaccine that could be used in Canterbury District Health Board vaccination clinics.

The Canterbury DHB programme aimed to immunise all children aged 1-4 in the Ashburton district, because these children could pass the virus on, even if they didn't have symptoms themselves.

Influenza vaccine supply

PHARMAC secured GSK and Abbott Pharmaceuticals as suppliers for the national influenza vaccine programme for the next three years.

More than a million doses of influenza vaccine are distributed each year. Under the agreements GSK will provide initial supply with a guaranteed 250,000 doses of Fluarix, while Abbott's Inluvac will provide the majority of doses.

Influenza strains included for each of the 2014-2016 seasons are determined by the World Health Organisation. New Zealand's medicines regulator Medsafe will need to approve the vaccine each year before it is used in the immunisation programme.

RESPIRATORY

Main changes

- Wider access to Seretide – a combination asthma inhaler.
- Price reductions on fluticasone (Flixotide) and salmeterol (Serevent).

An agreement with GlaxoSmithKline (GSK) led to widened access to the combination asthma inhaler Seretide. PHARMAC removed the Special Authority criteria from Seretide, which had until then been used by 74,000 New Zealanders with chronic asthma. Removing the Special Authority means Seretide can be prescribed for anyone doctors think require it.

Along with price reductions on fluticasone and salmeterol, the changes to Seretide and the listing of two new medicines (eltrombopag and zanamavir), the agreement will produce savings greater than \$20 million over five years.

Seretide was previously one of the highest-cost medicines by gross spending on the Pharmaceutical Schedule, accounting for \$21.4 million of subsidies last year.

Asthma



THERAPEUTIC GROUP SUMMARIES

CANCER AND IMMUNOSUPPRESSANTS

Main changes

- Erlotinib – making this treatment for advanced lung cancer available for newly diagnosed patients, provided they have the genetic markers that indicate the treatment will be effective.
- Imatinib – change to a generic brand for chronic myeloid leukaemia.
- Adalimumab – access to this important treatment for arthritis and other auto-immune conditions was widened.
- Brand change for the immunosuppressant tacrolimus.

Lung cancer treatments

PHARMAC extended funding for the targeted tyrosine kinase inhibitor (TKI) lung cancer treatment erlotinib (Tarceva) from 1 January 2014.

The two fully funded TKIs, erlotinib and gefitinib (Iressa) have changed the way aggressive lung cancer is treated, and improved the prospects of people diagnosed with lung cancer. Lung cancer is not the most common cancer in New Zealand, but is the leading cause of cancer deaths.

TKIs are more effective than platinum-based chemotherapy, but only for people with advanced lung cancer that has a particular genetic marker. Patients are identified using epidermal growth factor receptor (EGFR) testing. For people with the marker, targeted TKIs are a more effective, less toxic, and more convenient treatment than standard chemotherapy. In addition to being more effective, because TKIs are an oral tablet people can take them at home, and they don't have a lot of the nasty side-effects compared with traditional platinum-based chemotherapy, which can be difficult for patients to tolerate.

The funding decision from 1 January 2014 means both erlotinib and gefitinib are funded for people who are newly diagnosed with advanced lung cancer and who have not previously had platinum-based chemotherapy. Erlotinib is also funded for people whose disease has progressed having previously received platinum-based chemotherapy.

Adalimumab (Humira), an immunosuppressant that is mainly used to treat rheumatoid arthritis and other auto-immune conditions, continues to be the highest expenditure medicine on the Pharmaceutical Schedule. Total spending in the year was \$62.2 million, although this is partly reduced by confidential rebate arrangements with the supplier. During the year, PHARMAC provided wider access to adalimumab to also include juvenile idiopathic arthritis and fistulising Crohn's disease.

Imatinib brand change

PHARMAC changed the funded brand of imatinib, and how the medicine is distributed to patients. About 225 people who take imatinib for chronic myeloid leukaemia were affected by the changes.

The change to Imatinib-AFT will save about \$12 million per year – an 87% price reduction. Imatinib-AFT replaced the previously funded Glivec brand, which had introduced this new class of protein-tyrosine kinase inhibitor drugs that have turned chronic myeloid leukaemia into virtually a manageable chronic condition.

Because Glivec was a high-cost drug, PHARMAC had managed its distribution directly to patients. However, with the change to the less expensive AFT brand, PHARMAC transitioned this distribution back into the normal community pharmacy supply chain.

PHARMAC worked closely with patients, prescribers and pharmacists, communicating with them throughout the change process to ensure a smooth transition.

Glivec remains subject to patent for its use in patients with gastrointestinal stromal tumours (GIST) and so this brand remains funded for people with this disease (about 80 people).

(See full story on p10)

Tacrolimus

PHARMAC changed the funded brand of tacrolimus, which is mainly used to prevent organ transplant rejection.

Following a competitive process, PHARMAC changed the funded brand to Sandoz. The change meant 1300 patients would need to change the funded tacrolimus they were prescribed to the new brand, except for a very small number of patients who have had an intestinal transplant.

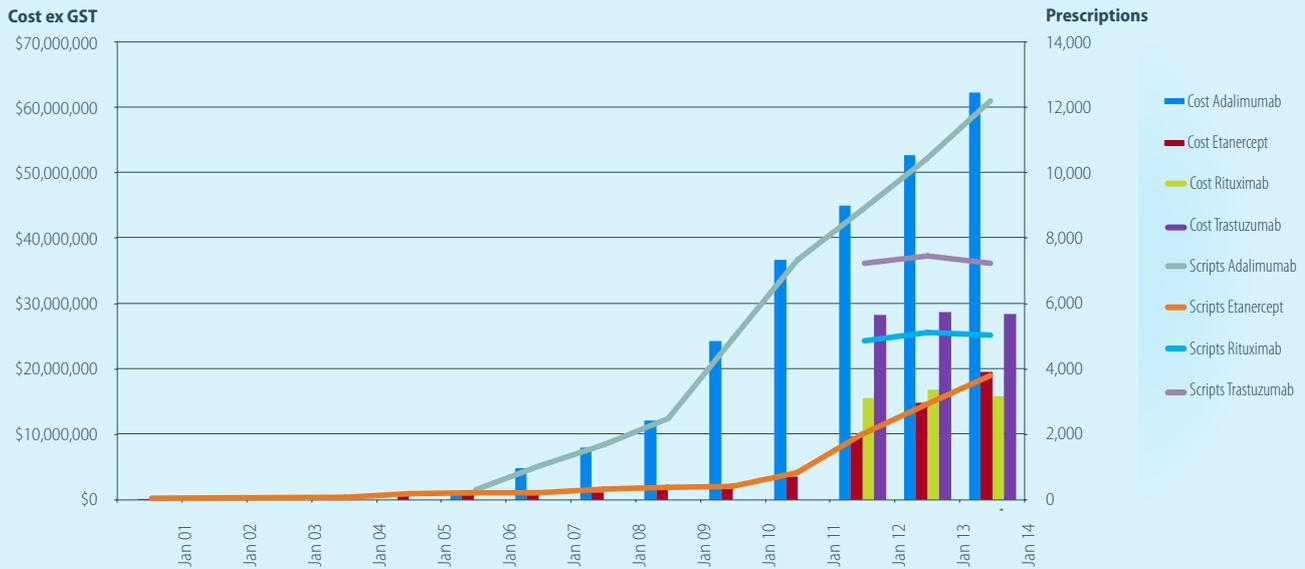
The brand change will produce savings of about \$4 million annually. This is important because they can be used to fund further medicines or healthcare, which leads to greater health gains all-round.

Aware of the importance of keeping patients stable on tacrolimus, PHARMAC worked closely with organ transplant centres to make sure the change was managed carefully. Transplant clinical teams monitored patients' progress and levels of tacrolimus in blood samples, and were asked to provide regular updates to PHARMAC if any issues arose. We also worked with clinicians and pharmacies who had patients with an exceptional circumstances (or NPPA) approval for tacrolimus to ensure the appropriate patients also transitioned smoothly.

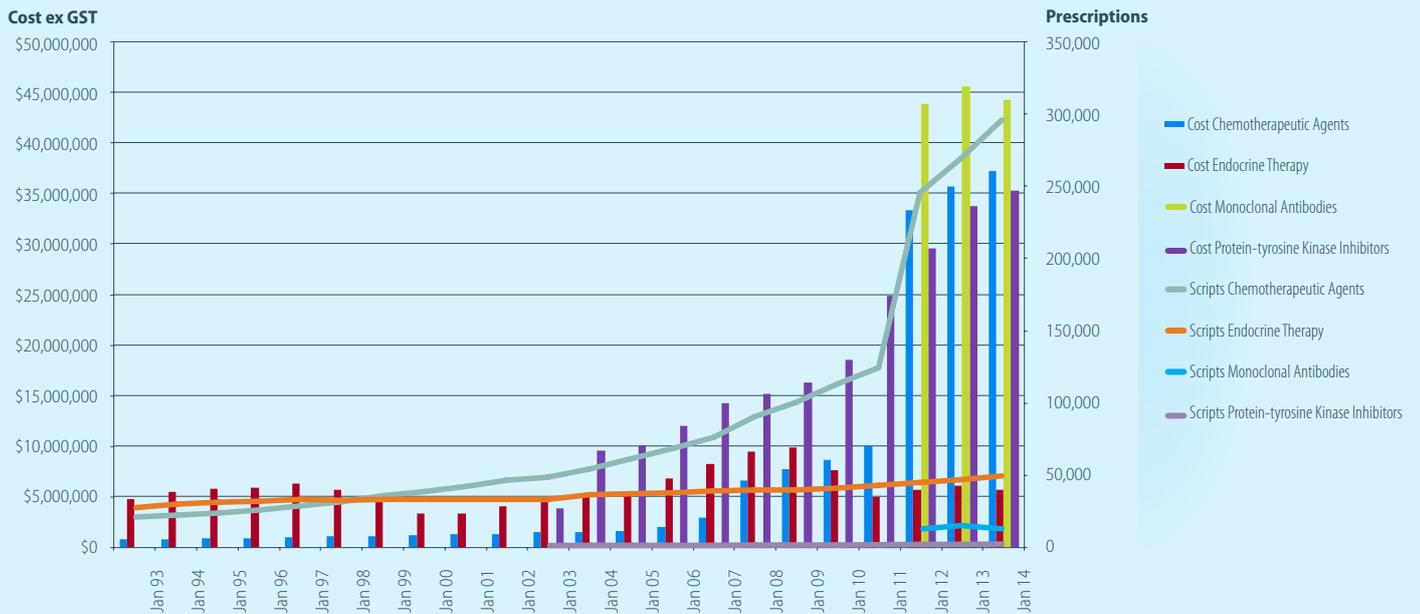
To support this process, PHARMAC provided patient and health professional information that could be customised to suit each patient's needs.

PHARMAC appreciates the considerable effort from transplant co-ordinators and transplant nurses to help patients adapt to this change.

Fusion Proteins and Monoclonal Antibodies



Oncology Agents





LIVING THROUGH LUNG CANCER

(Reproduced with permission from North & South.)

When Wellington investment banker Rob Cameron, who's never smoked, was diagnosed with advanced lung cancer in 2010, his first thought was, "That's a big surprise."

His second was, "Oh shit."

But if there is a good news story in lung cancer its people like Cameron, who, four years on, has no active cancer, despite having so many tumours on his first scan that he was "lit up like a Christmas tree from my hips to my neck". Untreated, his doctor said, he had five months to live. Cameron went private, paying more than \$100,000 for his chemotherapy – "the normal blast furnace they apply to cancer" – and the biological therapy Avastin, which inhibits the growth of new blood vessels that help tumours grow.

While he quickly went into remission, his cancer returned about six months later. Ten years ago, that would have been the beginning of the end for Cameron. But the month he was diagnosed, PHARMAC announced taxpayer funding for another new drug, Tarceva, which – like its Roche stablemate Herceptin – targets a genetic mutation in the cancer cells. In Tarceva's case, it is thought to block the activity of a protein that the cells need to grow and divide. His cancer has been in remission since – on just one tablet a day.

About 10-15 percent of lung cancer patients have cancers like Cameron's that are not caused by smoking. Small cell lung cancer – the cancer associated with heavy smoking – is the most aggressive type, and usually quickly fatal. But as smoking rates and the numbers of cigarettes smoked by those who continue have dropped, so too has this type of cancer.

Although 90 percent of lung cancer patients are either current or former smokers, about 40 per cent of nonsmokers who get the disease will have the so-called EGFR mutation that Cameron had, which makes their cancer more susceptible to treatment. Another funded drug in the same category is gefitinib (Iressa), which PHARMAC has paid for since 2012.

"Suddenly we are buying years of life for people who would have died within months. If there's a mutation in the gene, we can target it with a tablet and make this more into a chronic illness," says Northern Cancer Network director Richard Sullivan.

"Our knowledge of lung cancer has grown astronomically," he says. There are many more mutations yet to be found which should lead to more and more therapies.

"When I started training 15-20 years ago, there were two or three different types of lung cancer. There's now more than 40. We had access to probably two chemotherapy drugs. It was pretty blunt and you could buy someone three to six months if you were lucky. That was about as good as it got. Every now and again you'd get a minor miracle and someone would live for a few years."

Death rates are still bad, but they are slowly falling. New Zealand's five-year lung cancer survival rate is 11 percent – it used to be just seven or eight percent.

About 200 or more lung cancer patients a year, like Cameron, will end up on the new therapies, Sullivan predicts, but he says taking a tablet isn't the whole answer.

He says Cameron has helped buy himself more time by altering his lifestyle – profoundly changing his diet and exercise, motivation and attitudes.

"You shouldn't underestimate the importance of the human body – taking a tablet is important but it's not the whole answer."

Cameron agrees. "I've been phenomenally lucky that modern medicine has come up with something that's given me a break, but I'm not wasting that break."

NAMED PATIENT

PHARMACEUTICAL ASSESSMENT

NPPA

NPPA is a mechanism to give individual named patients access to medicines they need, but which aren't funded on the Pharmaceutical Schedule. In 2012 NPPA replaced the three Exceptional Circumstances schemes that PHARMAC previously managed. Applications for assessment are made by a person's prescriber, including those in the community and public hospitals. Decisions are made using PHARMAC's nine decision criteria after obtaining clinical advice.

Applications

The number of NPPA applications received has remained similar to the previous year, and PHARMAC continues to approve more than half of the applications processed.

Applications not further considered include those where further information is sought, or where the application is withdrawn.

	Total	Approved	Declined	Automatic approval	Not further considered
Initial 2013-2014	1185	690 (58%)	23 (2%)	55 (5%)	417 (35%)
Initial 2012-2013	1263	758 (60%)	13 (1%)	118 (9%)	374 (30%)
Renewal 2013-2014	154	145 (94%)	1 (0.6%)	1 (0.6%)	8 (5%)
Renewal 2012-2013	73	68 (93%)	n/a	n/a	5 (7%)

In addition to the applications processed, there were 124 applications that did not meet NPPA prerequisites. These were for a number of reasons, such as funded alternatives being available, the medicine sought being previously declined funding by PHARMAC, or the medicine being already prioritised for Schedule funding. PHARMAC provides information to applicants to explain reasons why prerequisites are not met.

NPPA Review

As part of our wider review of Operating Policies and Procedures, we initiated a review of the NPPA policy in April 2014. The review looked at the effectiveness of the policy and sought feedback on future improvements.

The review began at our consultation event in Wellington April and sought views from a broad group of stakeholders. This feedback will feed into any decisions by the PHARMAC Board for future improvements to NPPA.

PROFILES

GREG WILLIAMS
Manager, Procurement



Greg Williams thinks he will get one shot at an iron distance triathlon (that's a long distance version). With a young family and the heavy demands of training, Greg doesn't hold out much hope of having the time for more.

Which is a shame because, as Greg says: "I do some of my best thinking in the pool". That thinking certainly helped with his previous role as a senior therapeutic group manager, where he was responsible for the group of medicines that deal with infections.

Greg led PHARMAC's new vaccines work, and was involved in an area of continued public interest, antibiotics. Over the past year he's found himself working with Canterbury public health staff regarding funding of a vaccine during the hepatitis A outbreak in Ashburton, and helping support the national rheumatic fever prevention programme.

For Greg the global issue of growing antimicrobial resistance is an everyday reality. He describes PHARMAC's role as one of 'antimicrobial stewardship'.

"It's about appropriate use," he says. "It's easy to understand how a clinician prescribes, because they are treating the patient in front of them. For us it's about balancing that personal need with population need."

"It's one of the areas in health where inappropriate prescribing for an individual can end up impacting other people's treatment. That doesn't happen with other medicines, where inappropriate use usually only affects the individual. It's a very important area."

Greg hails from Invercargill and came to PHARMAC via Otago University's school of pharmacy and six years of pharmacy practice in New Zealand and the UK.

"The work at PHARMAC is challenging," he says. "There's a commercial aspect you just don't get in community pharmacy."

"You're also interacting with clinicians who are at the top of their field in New Zealand, and are international experts. You get an understanding of treatments that can change people's lives and you work to get them funded. That's exciting."

His future at PHARMAC is changing too, as he will be bringing his knowledge of the needs of consumers, populations and clinicians to his new role as Manager, Procurement, managing the team that runs the PHARMAC tender and manages supply contracts.

PHARMAC'S SENIOR LEADERSHIP TEAM



Chief Executive: Steffan Crausaz

Steffan was appointed Chief Executive of PHARMAC in July 2012. Prior to taking up the Chief Executive position in an interim capacity in 2011, Steffan was Manager of Funding and Procurement, leading PHARMAC's commercial and health technology assessment activities. Before joining PHARMAC in 2003, Steffan trained as a pharmacist in the UK. He also worked in the pharmaceutical industry (branded and generic) while undertaking his Masters in pharmacoeconomics and pharmaceutical policy.



Operations Director: Sarah Fitt

Sarah joined the PHARMAC leadership team in April 2013. Sarah brings a breadth of experience and sector knowledge to PHARMAC having spent 12 years as Chief Pharmacist at Auckland DHB. As Director of Operations, Sarah oversees the team that manages medicines and medical devices procurement, PHARMAC's funding process and the health economics team.



Engagement and Implementation Director: Jude Ulrich

With a background in the state sector and in running her own consultancy, Jude brings a wide range of organisational experience to PHARMAC's senior leadership team. She has worked extensively in public affairs, communications and social marketing, and held functional leadership roles in the public service, tertiary education and wider state sector. Since joining PHARMAC in early 2010, Jude has managed corporate services and external relations activities. The Engagement and Implementation Directorate includes the Policy, Communications, Implementation and Māori Responsiveness Teams.



Corporate Services Director: Mark Woodard

Mark joined PHARMAC in 2014, to lead the Corporate Services directorate. Mark's career has included time as CEO of Presbyterian Support and he has also been CFO for various organisations including in the health sector. He has an MBA from Wharton and a BA from Cornell University in the United States. As Director of Corporate Services/CFO, Mark oversees the Legal, Finance, Analysis, Human Resources, Information Communications Technology, and Business Services Teams.



Medical Director: Dr John Wyeth

John joined PHARMAC in 2012 as a deputy medical director with particular responsibility for secondary care, leading PHARMAC's clinical interactions around hospital medicines and hospital medical devices. He was appointed Medical Director in 2013, and leads the team that provides clinical input to PHARMAC, including through the Pharmacology and Therapeutics Advisory Committee. The team interacts with clinicians across both the primary and secondary care sectors.

PHARMAC DIRECTORY

The PHARMAC Board

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Prof Jens Mueller JurDr, LL.M, MBA, MSAM

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Dr Marius Rademaker (PTAC, Chair, Dermatologist), Dr Peter Ganly (Haematologist), Dr Stephen Munn (Transplant Surgeon), Dr Peter Ruygrok (Cardiologist)

Panels

Adult Growth Hormone Panel, Prof Ian Holdaway (Chair, Endocrinologist), Prof. Wayne Cutfield (Paediatric Endocrinologist), Dr Penny Hunt (Endocrinologist), Assoc. Prof. Patrick Manning (Endocrinologist)

NPPA

Dr Howard Wilson (Chair, General Practitioner/Pharmacologist), Dr Andrew Herbert (Consultant Gastroenterologist), Dr Sharon Kletchko (Specialist Physician), Dr George Laking (Oncologist), Prof Carl Burgess (Professor of Medicine and Clinical Pharmacologist)

Cystic Fibrosis Advisory Panel

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Gaucher Treatment Panel

Dr Ian Hosford (Chair, Psychiatrist), Dr Timothy Hawkins (Haematologist), Dr Callum Wilson (Metabolic Consultant), Dr Mark Coates (Radiologist)

Insulin Pump Panel

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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)

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Dr Howard Wilson (General Practitioner/Pharmacologist), Dr Andrew Aitken (Cardiologist), Dr Lutz Beckert (Respiratory Physician), Dr Clare O'Donnell (Paediatric Congenital Cardiologist), Dr Kenneth Whyte (Respiratory Physician)

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Chair

Kate Russell – Chief Executive Canterbury Medical Research Foundation, Christchurch.

Deputy Chair

Anne Fitisemanu – Pacific Health, Counties Manukau DHB, Auckland (until July 2014).

Shane Bradbrook – tobacco control advocate, Wellington.

Key Frost – mental health advocate, Invercargill

Maurice Gianotti – retired, Taupo.

Barbara Greer – psychiatric nurse, life member Māori Women's Welfare League, Hokitika.

David Lui – Pacific health consultant, Mental Health Foundation of NZ Board member, Auckland

Anna Mitchell – Chairperson of Canterbury Arthritis Advocates, Christchurch (until July 2014)

Katerina Pihera – member of the Māori Public Health Leadership Group, Lakes DHB, Rotorua.

Tuiloma Lina Samu – health researcher, Auckland

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