

# PHARMAC

Pharmaceutical Management Agency

A 25 YEAR HISTORY



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1993

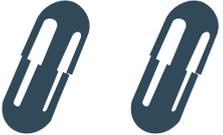


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PHARMAC

Pharmaceutical Management Agency

A 25 YEAR HISTORY

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Pharmaceutical Man



## 1993-2018 A 25 YEAR HISTORY

As PHARMAC marks 25 years, we're taking the time to reflect on our achievements, our journey so far, and our path into the future. This history of our first 25 years sets out how we got here, and celebrates the work that has seen PHARMAC become an established and trusted part of the New Zealand health system.

No one else had attempted to do what David Moore, PHARMAC's first General Manager, and his team were trying to do. As you'll read, the early days were about counterbalancing the power of pharmaceutical companies, creating order and structure to the assessment and funding of medicines, and proving that the model would provide value for New Zealanders.

Along with that success have come speed bumps PHARMAC has had to negotiate. Legal challenges, industry public relations campaigns, and public concern about changes added to the complexity of the work we were doing. PHARMAC has grown and matured and used its experience to shape how we now work.

PHARMAC has always known that the decisions we make have real impacts on everyday New Zealanders. The foundations laid and PHARMAC's ongoing success have led to its role continuing to expand. So thanks to the work of our early trailblazers, PHARMAC now has an even greater influence on the health of New Zealanders.

As we look to our future, we will hold on to the principles that have brought us here; keeping New Zealanders at the heart of our thinking, using the best evidence to support our decisions, and making good choices so that New Zealanders can continue to have funded, innovative medicines and medical devices to improve their health.

Our success has been a result of a great foundation built by previous PHARMAC staff, General Managers, Chief executives, and Board members, but we couldn't have done it alone. Expert advice from the Pharmacology and Therapeutics Advisory Committee, its subcommittees, and the Consumer Advisory Committee has strengthened our decision making. While support from the wider health sector has meant that our decisions have been successfully implemented.

PHARMAC's mission is as important as it was back in 1993, and we'll continue to work to help New Zealanders live longer and healthier lives.

Sarah Fitt  
Chief Executive



# PHARMAC

the first 20 months



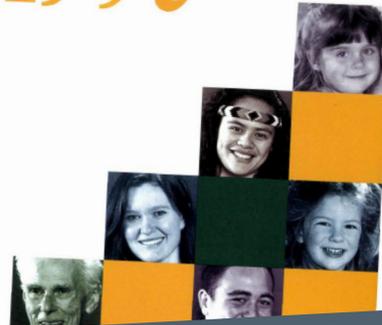
measured responsible  
decisions

# Annual Review

for the year ended 30 June

# 1995

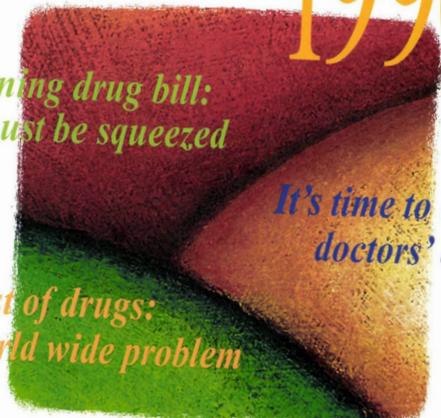
Treating more patients.  
Slowing budget growth.



# Annual Review

for the year ended 30 June

# 1996



*The ballooning drug bill:  
why it must be squeezed*

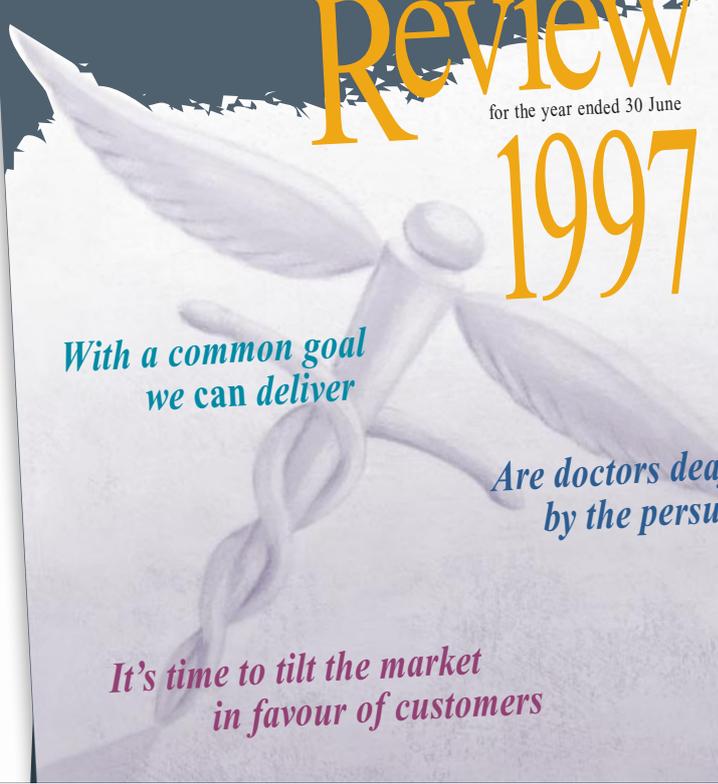
*It's time to dust off  
doctors' ethics*

*The cost of drugs:  
a world wide problem*

# Annual Review

for the year ended 30 June

# 1997



*With a common goal  
we can deliver*

*Are doctors deafened  
by the persuaders*

*It's time to tilt the market  
in favour of customers*

# 1993 - 1997

## A PRESSING NEED

PHARMAC's quarter century of activity has saved New Zealanders more than \$6 billion on the cost of medicines and medical devices and the agency's model has won plaudits from around the world.

But in late 1992, when a handful of staff moved into a small office on Lambton Quay tasked with creating the Pharmaceutical Management Agency, success was anything but guaranteed.

It was a time of fiscal austerity and the National Government had embarked on sweeping reforms that were designed to create a competitive market for the provision of health services. Major structural changes saw the Department of Health morph into the Ministry of Health and the area health boards became 23 Crown health enterprises, with government-appointed boards and expectations that they would operate on a commercial model.

A key change was the separation of the purchaser and provider roles in public health care. Four Regional Health Authorities were tasked with buying health services in a competitive market. Major productivity gains were anticipated through taking a more business-like approach to delivering public health services.

But one area was identified as posing a real challenge to the health budget - the rapidly rising price of pharmaceuticals. Through the late 1980s, spending on pharmaceuticals had risen at around 15 percent per year, much higher than other areas of health expenditure.

"One of the key problems confronting PHARMAC in July 1993 was the strong and unsustainable level of growth in pharmaceutical expenditure," wrote David Moore, PHARMAC's first general manager, in the agency's first annual report.

That escalating drug spend was largely down to a lack of bargaining power in dealing with pharmaceutical companies and an approach to drug buying that didn't always properly consider the value proposition from a patient's perspective.

"One of the things that surprised me was how little we actually knew," remembers Carolyn Gullery, one of PHARMAC's original Board members representing the Southern Regional Health Authority - PHARMAC was initially a joint venture company of the RHAs, with executives making up PHARMAC's Board of Directors.

Having come from the pharmaceutical industry herself, Gullery knew the advantage the drug companies had

with their sophisticated industry forecasting, therapeutic evaluation techniques and understanding of market dynamics.

"Where PHARMAC really made a difference is they started to think like an industry player. They brought in negotiation, they started to do trade-offs. But most importantly, they looked at value for money," says Gullery.

"It was breaking down all the marketing hype that the pharmaceutical industry has and saying, is it really worth paying more for this?"

While clarity was forming around the mission - to introduce price competition to a market where it hadn't previously existed - the practicalities of starting an agency from scratch were starting to dawn on Moore and his founding chair, Denis Tait.

The blueprint for PHARMAC, developed by Moore while he was still at the Department of Health, came to be known as the "Purple Elephant". It was a master document that covered all the ins-and-outs of the pharmaceutical supply system, from dispensing contracts to the all-important Pharmaceutical Schedule and the processes around it.

Then there was furniture to buy and IT systems inherited from the Department of Health to merge.

"In the first six months, we all clocked up 80, 90 hour weeks," says Reinhard Pauls, who joined PHARMAC in April 1993.

"It was the most fun I've ever had at work."

By June 1994 PHARMAC had published the Pharmaceutical Schedule and formulated the Decision Criteria that would guide its decision making as well as developing the initial Operating Policies and Procedures laying out its role and functions. The agency also saved \$3.1 million on pharmaceutical purchases in its first year and estimated the following year's savings would jump to \$24 million. It was a modest start, but hinted at the great potential ahead.

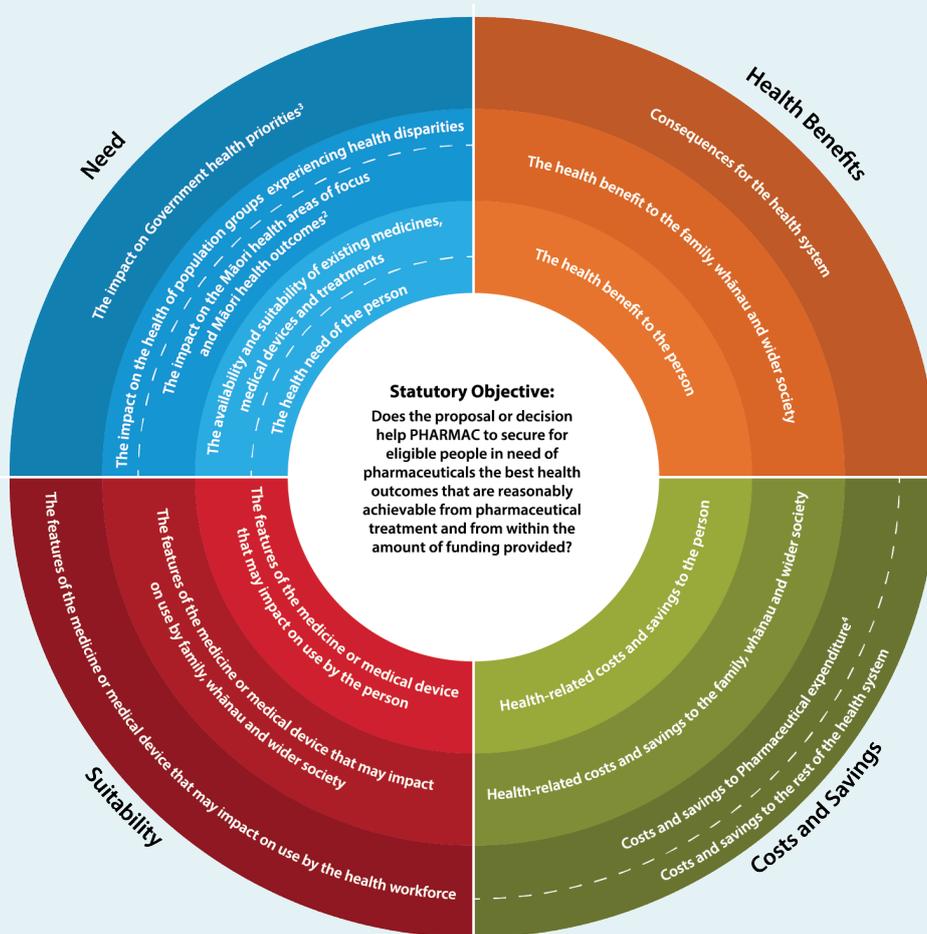
"We have had a good beginning, but it is only a beginning," Moore wrote in PHARMAC's first annual review.

"Twenty months is a short time to rebalance such large issues. The achievements to date are significant, but big challenges lie ahead."

## DECISION CRITERIA:

1. The health needs of all eligible people within New Zealand
2. The particular health needs of Māori and Pacific Peoples
3. The availability and suitability of existing medicines, therapeutic medical devices and related products and related things
4. The clinical benefits and risks of pharmaceuticals
5. The cost-effectiveness of meeting health needs by funding pharmaceuticals rather than using other publicly funded health and disability support services
6. The budgetary impact (in terms of the pharmaceutical budget and the Government's overall health budget) of any changes to the Schedule
7. The direct cost to health service users
8. The Government's priorities for health funding, as set out in any objectives notified by the Crown to PHARMAC, or in PHARMAC's Funding Agreement, or elsewhere
9. Such other criteria as PHARMAC thinks fit. PHARMAC will carry out appropriate consultation when it intends to take any such "other criteria" into account.

## FACTORS FOR CONSIDERATION:



# 1993

- PHARMAC's established as a joint venture company owned by the four Regional Health Authorities.



David Moore



Denis Tait

- David Moore is the first general manager and Denis Tait is the first chairman of the Board.
- PHARMAC begins the compilation and publication of the Pharmaceutical Schedule.

# DECISION CRITERIA

**PHARMAC in 1993 assumed the role of deciding which pharmaceuticals would receive government subsidies for use in New Zealand and which wouldn't. With that decision-making power came great responsibility.**

In early 1994 PHARMAC developed the Decision Criteria, which would form a key component of the agency's Operating Policies and Procedures.

PHARMAC had to balance the needs of patients and communities with its responsibilities to the taxpayer. Decisions about which pharmaceuticals were included on the Pharmaceutical Schedule, and therefore qualified for subsidies, needed to represent good value for money for the health benefit of all New Zealanders.

After extensive consultation, PHARMAC's Board came up with a list of nine decision criteria. These would include broad defining factors such as the health needs of "all eligible people within New Zealand", the particular health needs of Māori and Pacific peoples, the availability and suitability of existing medicines and the cost-effectiveness of meeting health needs by funding pharmaceuticals.

PHARMAC also had to take into account pharmaceutical savings targets agreed with the Regional Health Authorities and the Health Funding Authority, any direct costs to health service users and the Government's overall priorities for health spending.

"Perhaps the most obvious principle that might be applied to these decisions is to pay only for those treatments that improve health and, within our limited budget, choose the ones that improve health the most," says health economist Professor Anthony Harris, who has studied PHARMAC's decision-making processes.

Many countries around the world have taken this approach to funding pharmaceuticals, he adds.

"In general the aim has been to provide medicines at low cost to all, but to choose which medicines to subsidise by assessing their comparative value.

"Value has been taken to mean the cost of achieving a gain in years of life and the quality of life."

Ultimately funding decisions had to withstand scrutiny from pharmaceutical companies and clinicians, patients and politicians. PHARMAC's staff and Board always used the Decision Criteria in considering Pharmaceutical Schedule applications.

"It was difficult for a lot of the staff. They were put under huge pressure if PHARMAC decided not to fund something," says Richard

Waddel, who succeeded Denis Tait as PHARMAC Board chair in 2000.

"But when a new drug came out, PHARMAC always waited until there was enough evidence to justify funding it or the price came down to justify spending the money," he adds.

He remembers Board briefing dossiers of 200 - 300 pages, reflecting the complexity of the applications PHARMAC was tasked with considering.

"There was a huge amount of reading; that was to make sure we made the right decisions. The spend amount you were asked to approve could be \$30 million; it could be \$500,000."

The Decision Criteria served PHARMAC well for over two decades. But by 2013 it was clear the criteria needed to be revisited given the changing nature of PHARMAC's role in the health system and wider responsibilities, including medical devices.

The 2009 'Horn Report', the output of a Ministry of Health commissioned review of the health system, led by former Secretary to the New Zealand Treasury Murray Horn, had recommended a partial restructure of the health system. This included a recommendation for more collaboration among the district health boards and centralisation of some planning and service delivery. Some of the report's recommendations would influence the future shape and activities of PHARMAC.

That included preparing the agency to take responsibility for areas of funding outside its focus on medicines used in the community and cancer medicines administered in hospitals.

PHARMAC was about to add all subsidised hospital medicines, vaccines and hospital medical devices to its portfolio.

Consultation throughout 2013 and 2014 across New Zealand led to the development of the Factors for Consideration. This was a major change for PHARMAC. Instead of a list of nine decision criteria to consider, PHARMAC would now take a more holistic look at the relevant impact of a decision on the person, their family, whānau and wider society; and on the broader health system.

The consideration of health disparities among some population groups was made more explicit. After a lengthy period to allow all relevant parties to get up to speed on the Factors for Consideration, these took effect on 1 July 2016.

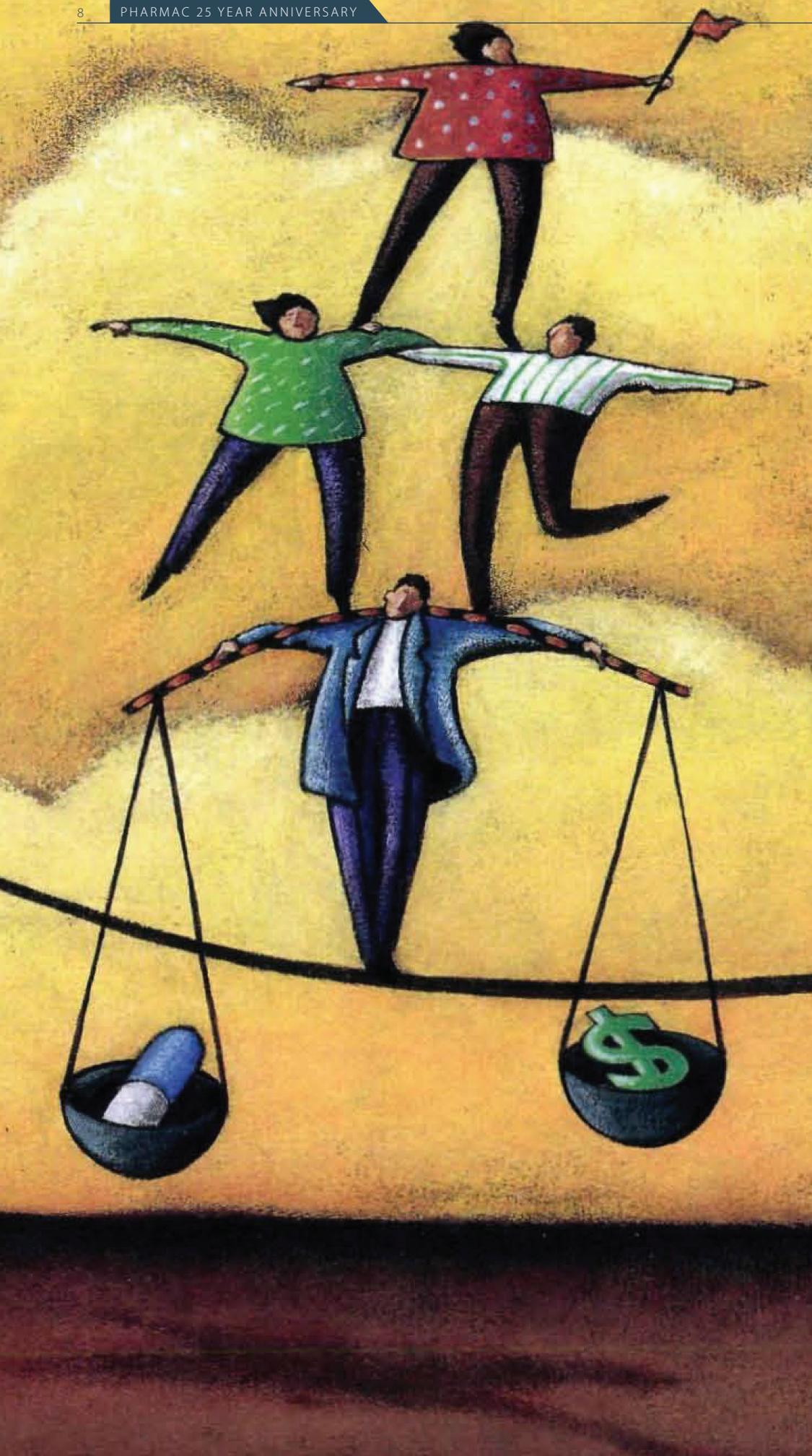
"This change has been collaborative, and reflects the considerable input of the public to our consultation," said PHARMAC's chief executive at the time, Steffan Crausaz.

"We've created an approach to decision making that is more easily understood so it's clear what we take into account when we make our funding decisions."

The extent of the public consultation and effort put into a smooth transition meant the Factors for Consideration were well-received. They remain the key tool in helping PHARMAC achieve its statutory objective of securing the best health outcomes from pharmaceutical treatment from within the funding provided.

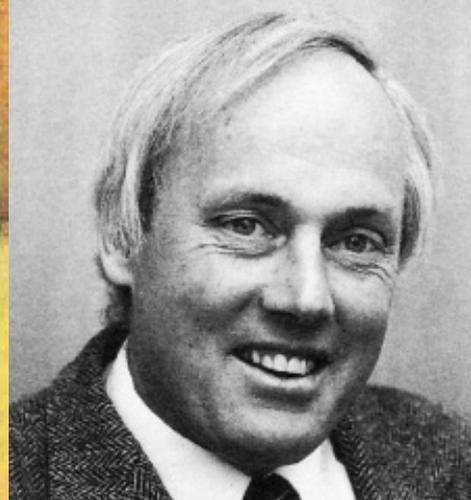
*"It was difficult for a lot of the staff. They were put under huge pressure if PHARMAC decided not to fund something"*

– Richard Waddel



# 1994

- Achieved savings of \$3.1 million in its first full year of operation.
- Created a defined set of decision criteria.
- Formalised its Operating Policies and Procedures.
- Halved the growth in pharmaceutical expenditure to 5 percent per annum.



John Hedley

# GETTING THE BALANCE RIGHT

A large part of the rationale for the creation of PHARMAC was to introduce more rigour into decision making about what medicines were to receive government subsidy.

Central to that goal was building the Pharmaceutical Schedule, a list of what would amount to around 2500 pharmaceuticals that were eligible for subsidisation. The Schedule would note any funding conditions and whether the patient was required to pay any premium on top of the normal user charge for a prescribed medicine.

Previously this type of information was drawn from various lists maintained by the Drug Tariff Unit within the Department of Health. But in its first year, PHARMAC set out to undertake a comprehensive review, a mammoth task that signalled a commitment to evidence-based decision making.

Key to that approach was the use of the Pharmacology and Therapeutics Advisory Committee (PTAC), which had existed in various forms over the preceding decades but was now formalised as the main independent expert advice group informing PHARMAC's funding decisions.

In 1993 it was a committee comprising eight senior practising doctors and chaired by Blenheim doctor, Dr John Hedley, who would lead the group for 11 years.

Hedley had sat on PTAC in its previous incarnation and felt frustrated at the decision-making processes.

"Once a product went onto the list, it was sitting pretty; there was no requirement for a pharmaceutical to continue to justify its place," he says.

Doctors from around the country would call the Drug Tariff Unit directly to lobby for specific drugs to be subsidised. Pharmaceutical representatives wielded a lot of influence, which could see different drugs with the same efficacy subsidised at different levels.

"There were all sorts of perversions," Hedley recalls.

Something had to change. Hedley and his colleagues set about establishing robust procedures that would be informed by PHARMAC's newly drawn-up Decision Criteria.

Subcommittees featuring the country's best experts were formed to focus on groups and subgroups of therapeutics.

"We invited specialists to join the subcommittees for the specific purpose of thrashing to death the clinical papers so that we had a sound clinical basis for recommending what the dose relativities were," he says.

It was intensive work, involving trawling through paper medical journals - this was before the internet made access to them instantaneous. There were lengthy teleconferences as committee members weighed up the evidence before making their recommendations to PHARMAC's Board.

In the agency's first year, PTAC was prolific, advising on more than 100 applications and assisting in group reviews. Two-thirds of the applications considered resulted in listings on the Pharmaceutical Schedule.

"There was order being established," says Hedley, who carried on his work as PHARMAC general manager David Moore was attempting to build an agency from scratch.

"For me it was a beacon of best practice," says Hedley of PTAC.

"It wasn't number 8 wire; it was Wedgwood china. I did feel like it was my baby for a long time."

*"There was order being established"*  
– Dr John Hedley

PTAC currently comprises 13 members, who are appointed by the Director-General of Health, in consultation with the PHARMAC Board.

As in the early days of PTAC, members can apply to join the Committee directly, or seek nomination by medical bodies such as the Royal New Zealand College of General Practitioners and the Royal Australasian College of Physicians.

The high calibre of senior health professionals who continue to make up PTAC shows the importance the medical profession places on its work.

Says current PTAC member Dr Giles Newton-Howes, a clinical psychiatrist from Wellington:

"For me medicine's always been about caring for the person in front of us and caring for all of the people we don't see, and I guess part of the reason I ended up doing academia is that good-quality research helps hopefully lots and lots of patients who you'll never see and actually that's exactly what PHARMAC does."

# 1995

- First court papers are filed challenging PHARMAC processes.
- 22 million prescriptions written for patients requiring medicines and special foods.
- PHARMAC files claims in the High Court against the Researched Medicines industry Association of NZ Incorporated (RMI) and Adis International Limited for alleged publication of misleading information and contempt.

# CHEAP MEDICINES, BIG IMPACT

It's the medicine that nearly 3 million New Zealanders take to relieve pain and fever and is considered by the World Health Organization to be an 'essential medicine'.

But in the mid-1990s paracetamol was still a reasonably expensive drug in New Zealand, considering it was so commonly used and 'off-patent', which meant that generic versions of paracetamol were readily available.

Generic drugs have been key to PHARMAC's buying strategy throughout its 25-year history. These are drugs that have the same chemical make-up as their brand name equivalents but are often much cheaper.

In some cases, the generic versions of paracetamol were nearly as expensive as the big name brands. In 1997 PHARMAC tried to change that by introducing a one-year experimental tender, inviting drug companies to bid to supply the New Zealand market with paracetamol.

"Paracetamol, it's like aspirin, it has been around so long everybody knows it; there is just no debate about the quality of paracetamol from one company or another," says PHARMAC founding staff member Reinhard Pauls.

"We thought that the first tender we ran had to be something where there was just no argument."

A negotiation began between PHARMAC and suppliers that saw them agree to reduce their prices for paracetamol by between 20 and 60 percent, if PHARMAC deferred tendering on 23 other medicines.

PHARMAC agreed and, in its first year, that one tender for paracetamol saw an overall price reduction of 44 percent, saving \$5.41 million over 3 years on buying the medicine. In the second year, \$25 million was saved through the tender process.

"That had never been done in pharmaceuticals before," says Pauls.

"You establish a precedent and then it gets rolled out."

Within five years of PHARMAC introducing competitive tendering for pharmaceuticals, the generics market, previously dominated locally by two companies, had moved from being high-price, low-volume to low-price, high-volume.

Now the annual invitation to tender is integral to PHARMAC's activity. Each year, PHARMAC invites pharmaceutical suppliers to provide pricing proposals for off-patent medicines listed on the Pharmaceutical Schedule.

Suppliers can bid for 'sole-subsidised-supplier status' through a blind tender process. Winning the tender comes with obvious benefits of market access at a preferential price, but the supplier must provide the 'ex-manufacturer' price for the pharmaceutical and prove it can offer adequate supply of it.

The tender process has proven successful. Nearly 2500 offers to supply pharmaceuticals were received in the 2017/18 tender round from 58 companies, and the number of suppliers participating in the tender continues to grow.

The focus of the tender has shifted over the years from being primarily about saving money to explicitly considering the suitability of medicines for patient use and prescribers and pharmacies to manage and dispense them. But the bottom line continues to improve thanks to this practice, with \$40 - 50 million saved annually.

Generic medicines are expert copies of medicines made by companies that didn't develop the original drug themselves.

Although a generic medicine costs less, it will still work as well as the more expensive medicine. All generic medicines have to be approved by Medsafe and go through bioequivalence testing to make sure that they work the same way as the original brand of that medicine.

## Number of suppliers that bid in the Tender





# 1996

- First tender (for one product, paracetamol) leads to 44 percent price reduction.
- Savings reach \$48 million by June 1996.



Reinhard Pauls

# PHARMAC RUFFLES FEATHERS

## 'Drug companies join forces against Pharmac' was the ominous headline in the *Independent business weekly* in July 1995.

PHARMAC was barely two years old, but already facing litigation from pharmaceutical companies and industry associations who were putting their differences aside to challenge the drug-buying agency.

At issue were the strategies PHARMAC was employing to manage its expenditure and seek better value for New Zealanders when it came to buying pharmaceuticals for their use.

Reference pricing was a particular bone of contention. Used by PHARMAC as part of its Operating Policies and Procedures, it saw pharmaceuticals that provided the same or similar effect, being clustered into therapeutic groups and sub groups in a bid to reduce the excessive segmentation of drugs based largely on brand marketing.

All pharmaceuticals in a given subgroup were then subsidised at the level of the lowest-priced pharmaceutical in that subgroup.

"The chemistry of a drug determined where it fitted in," explains Reinhard Pauls.

"If two drugs belonged to the same pharmacological group, say H2 antagonists and anti-ulcer medicines, then we paid the same price for it."

This was a new and frustrating regime for the pharmaceutical companies that had the potential to significantly impact their bottom line as they faced true price competition for the first time.

It was coupled with PHARMAC's policy of seeking out aggressively-priced generic drugs. By the end of 1994 this policy had enabled it to obtain a 30 percent price reduction on all H2 antagonists, which are commonly prescribed to reduce the amount of acid produced by the cells in the lining of the stomach.

Similarly, the entry of generic inhaled steroids for asthma achieved savings of \$5 million in 1994.

The use of competitive sole-supply tendering, therapeutic group reviews, bundling deals to secure numerous drugs in one purchase, and more extensive use of contracts with pharmaceutical companies were also part of PHARMAC's strategy.

It was also willing to challenge pharmaceutical companies' efforts to have patents on their drugs extended, in a bid to avoid competition from lower-priced generics.

"Glaxo asked for an extension on the patent for Zantac (ranitidine), which at that stage was the world's biggest-selling drug. They were selling a billion dollars of the stuff a year," Pauls remembers.

"They wanted an extension of the patent term, which you could get if you'd made inadequate remuneration. So we opposed that, which went on for three years."

There were threats, and in two cases concrete action, to cut pharmaceutical research and activity in New Zealand, in response to PHARMAC's way of doing business.

It wasn't just the pharmaceutical companies that were unhappy.

"There was an amazing amount of angst from the medical profession because they'd been wound up by the pharmaceutical companies," says Peter Moodie, who served as PHARMAC's medical director from 2000 to 2013.

There was a perception, even among doctors, that generic drugs were inferior.

"They were very angry, very nervous and worried about what PHARMAC was doing."

PHARMAC had to invest significant resource in engaging with health professionals to explain and justify its decision making. Here, PTAC had a big role to play, says Moodie.

The grievances of the pharmaceutical companies spilled over into the public

domain as PHARMAC's savings on drug purchases started to stack up.

"The media was being fed stories from the companies," says Moodie.

"There were patient advocacy groups that were really lobby groups [for pharmaceutical companies] who made headlines. The media attacks were pretty impressive."

PHARMAC's small team were often confronted directly with the discontent stemming from their decisions.

"You got patients ringing you; they'd be afraid they'd die because of a decision you made," says Pauls.

"It gets quite intense at that level."

But acceptance of the new regime started to grow, particularly as PHARMAC dealt with a number of high-profile legal challenges that would define future relationships with the pharmaceutical companies.

*"You got patients ringing you, they'd be afraid they'd die because of a decision you made"*

– Reinhard Pauls



# 1997

- Cumulative savings surpass \$250 million.
- Reference pricing of ACE inhibitors leads to an expected \$150 million saving on anti-hypertension drugs over the next six years.

# REDUCING PRESSURE

## Drugs used to lower blood pressure and manage heart failure would feature in PHARMAC's first major use of clinical data and reference pricing to extract significant savings.

So-called angiotensin converting enzyme (ACE) inhibitors were in growing use in the late 1990s and today are used by around 500,000 New Zealanders.

But clinical studies were revealing that there was little difference in efficacy of the various ACE inhibitors on the market, despite varying considerably in price.

In addition, PHARMAC's Pharmacology and Therapeutics Advisory Committee, was considering medical literature advising that for many patients, lower-priced diuretics, sometimes called 'water pills', were at least as effective in managing blood pressure as ACE inhibitors were.

It was a perfect opportunity to apply reference pricing to secure a subsidy decrease and PHARMAC issued a request for proposals on that basis. The results exceeded even the most optimistic expectations of PHARMAC's negotiating team.

Reductions offered by two suppliers lowered the price of ACE Inhibitors subsidised by PHARMAC to the tune of 60 percent.

"We reference priced the statin drugs and the ACE inhibitor drugs at the same time," says former PHARMAC chief executive Wayne McNee.

"We saved around \$60 million a year; it was the biggest transaction that PHARMAC had ever done."

Indeed, the savings on ACE inhibitors alone were estimated at the time to amount to \$150 million over the next six years.

It was to become a commercial model for other high-cost drug categories.

"In addition to an education campaign aimed at patients, pharmacists and prescribers, subsidies for doctors' visits to consult about the changes were made available," wrote PHARMAC Board chair, the late Denis Tait, in the agency's 1998 Annual Review.

"It was the most comprehensive exercise of its type that we have undertaken and it highlights our commitment to decisions based on careful evaluation of all the evidence, wide consultation and thorough communication of our decisions."

Evidence from the clinical literature was informing decisions. Pharmaceutical companies were fearful of missing out entirely, but others were willing to cut their margins to stay in the market. It was a formula that would underpin many impressive deals to come.

# Annual Review

for the year ended 30 June

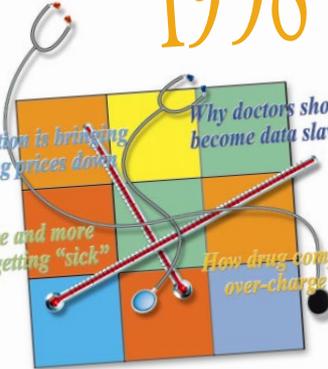
# 1998

Competition is bringing drug prices down

Why doctors shouldn't become data slaves

More and more people are getting "sick"

How drug companies over-charge



# Annual Review

for the year ended 30 June

# 2000



# Annual Review

for the year ended 30 June

# 2001



# Annual Review

# 2002



Building relationships

# Annual Review

# 2003



PHARMAC 10 years

# 1998 - 2003

## A WATERSHED LEGAL WIN

At one point in the early years of PHARMAC, according to founding general manager David Moore, the agency had more legal cases on the go than it had staff.

Litigation with the pharmaceutical industry was threatening to prove naysayers right - that the agency would collapse under the legal bombardment.

Simon Watt, a Wellington-based lawyer at Bell Gully with a background in banking law, was seconded to PHARMAC in 1995 to help ease the strain. He describes it as a "pretty torrid time".

"There were six judicial review proceedings on the go at one time, two Commerce Act cases and patent extension proceedings all involving PHARMAC," he says.

PHARMAC had 10 sets of litigation going on and no in-house lawyer.

"It was a siege mentality at that stage."

Part of Watt's role was to come up with templates for watertight legal contracts that PHARMAC's contract managers could use in the agency's agreements with pharmaceutical companies.

But while the pharmaceutical companies would happily sign on the dotted line one day, they'd be filing lawsuits objecting to a funding decision the following day.

A circuit breaker was needed and it came in 1997 and 1998 during the course of protracted legal action with French multinational pharmaceutical company Roussel Uclaf, over funding of the antibiotic Rulide (roxithromycin).

PHARMAC's Board had decided to reduce the level of subsidy on Rulide by more than half of its former level as a result of reference pricing. Roussel Uclaf claimed that was anti-competitive and sought to challenge PHARMAC's processes through judicial review.

It would prove to be a test case as the pharmaceutical company, unsuccessful at the High Court, sought redress in the Court of Appeal and eventually went all the way to the Privy Council, New Zealand's highest court.

The case validated practices around reference pricing but it and other legal action around the same time also

confirmed that PHARMAC's decisions and contracts relating to subsidised medicines were exempt from New Zealand's Commerce Act 1986, which bans other companies from anti-competitive behaviour.

The Privy Council noted that there were "sound economic reasons" for PHARMAC's actions and a "public interest in reducing expenditure on pharmaceuticals".

"When the Privy Council case was won, most of the litigation fell away, because the industry could see that having set the case law all the way to the Privy Council they weren't going to win those kinds of cases," says Wayne McNee, a former

Dunedin hospital pharmacist who was a therapeutic group manager at PHARMAC before becoming its general manager in 1998.

"That was pretty ground breaking."

*"It was a siege mentality at that stage."*

– Simon Watt

"Success at the Privy Council in 1998 in the Rulide case was perhaps the most significant confirmation our procedures are correct," wrote Denis Tait in PHARMAC's 2000 Annual Review.

But it came at a cost - PHARMAC had to spend around \$3 million on legal advice in the five years leading up to the Privy Council win. Simon Watt ended up staying at PHARMAC for 18 months, and 20 years later Bell Gully continues to provide legal advice - though the court cases are few and far between these days.

The 'contract bible' that Watt drafted for PHARMAC continues to form the basis of many of its contracts.

"We helped create a document that has been used time and time again to secure significant savings."

His fond memories of his time at PHARMAC include working alongside a fiercely intelligent group of experts, who knew the importance of the law to their work.

"When you gave legal advice, you knew it was going to be tested, not blindly accepted."

## He Rongoā Pai, He Oranga Whānau

*Whānau staying well with medicines*



He Rongoā Pai – He Oranga Whānau began as a wānanga for hauora kaimahi who work in Māori communities. It is aimed at improving knowledge and providing information to whānau about the safe and effective use of medicines and includes a component on rongoā Māori.



The Space to Breathe childhood asthma pilot was developed to promote appropriate use of inhaled corticosteroids and self-management education to improve health outcomes for children with asthma and address ethnic disparities in morbidity.



The Wise Use of Antibiotics campaign aimed to raise awareness about the use and demand for antibiotics over the winter months.

# 1998

- Decisions in the High Court and Court of Appeal and the Privy Council uphold PHARMAC's procedures in pharmaceutical expenditure management, and its exemption from the Commerce Act.
- Cumulative savings surpass \$250 million.
- Wayne McNee is appointed general manager of PHARMAC.



Wayne McNee

# WISE DRUG CHOICES

While PHARMAC's work in securing better prices for pharmaceuticals on behalf of New Zealanders was clearly paying off, the agency realised it also had to take a leadership role in advocating for better use of the pharmaceuticals it funded.

In 1998 it joined forces with the Independent Practice Associations and the Pharmacy Guild to tackle a growing issue of concern to health professionals - the misuse of antibiotics.

Antibiotics are used to attack potentially harmful bacteria, but as part of their normal defence against this attack, the bacteria can become 'used to' or resistant to particular antibiotics.

That sees antibiotics lose their effectiveness.

"It's very easy to say with all these new infections, we just need new antibiotics. No, we make sure that the antibiotics we've got, we use well," says PHARMAC's former medical director, Peter Moodie.

In 1998, the Ministry of Health sounded the alarm about growing antibiotics resistance, convening a national committee to look into the issue.

A particular area of concern was the overuse of antibiotics during the winter months, when doctors were prescribing them unnecessarily for patients with colds and influenza, which are viral infections. Those who were taking antibiotics often weren't completing their prescribed regime, exacerbating the problem further.

"It is time to explode the myth that antibiotics are a cure-all for winter ailments. They are not," said Prime Minister Jenny Shipley in May of 1999 as she launched the Wise Use of Antibiotics national campaign.

"The misuse of these drugs actually reduces their effectiveness, meaning people need increasingly potent and expensive antibiotics to cure simple ailments."

The Prime Minister had put her finger on a key issue for PHARMAC, which spent tens of millions of dollars a year on purchasing antibiotics. If antibiotic resistance grew, the agency would need to fund increasingly expensive pharmaceuticals to treat a whole host of resulting health ailments.

PHARMAC took a leading role in what was to become an annual campaign that initially centred on doctor practices with posters, leaflets and media coverage. Over the years, the Wise Use of Antibiotics broadened to appeal to the general public and crystallised around three key messages:

- Antibiotics don't do colds and flu.
- Take the lot, no matter what.
- If in doubt, check it out.

Advertisements aired on TV and radio and in newspapers and magazines.

"Do not deploy until you have identified your target!" shouts the stern general in front of his battle-ready battalion of antibiotics in the cartoon advert that aired through the winter of 2007.

"Antibiotics, never forget that bacteria are your only target! Cold and flu are viral, not bacterial infections. A virus is unaffected by antibiotics!"

The funding and other resources PHARMAC contributed to the campaign soon paid dividends. People got the message.

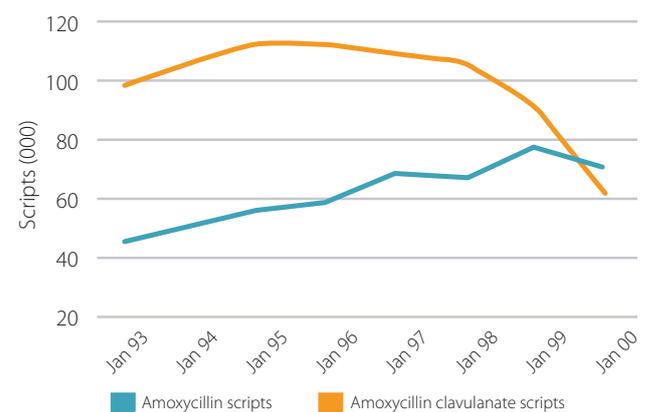
"Evidence from previous campaigns shows very high support for the campaign by both clinicians and the public, with an overall reduction in antibiotic prescribing of nearly 14.8% (1999 compared with 2000 data), and a reduction in public expectation of receiving antibiotics for colds and flu from 80% to 50% (Colmar Brunton research)," noted PHARMAC's 2001 Annual Review.

The Wise Use of Antibiotics campaign was to run annually for nearly two decades, with PHARMAC managing it for a decade, and its success informed other advocacy campaigns developed by PHARMAC over the years.

"Over time we started to think more broadly about public health and pharmaceuticals and how we could help patients avoid having to take pharmaceuticals altogether," says Wayne McNee PHARMAC's general manager at the time Wise Use of Antibiotics was launched.

These campaigns and pilot programmes would define PHARMAC as more than just a pharmaceutical management agency.

## Antibiotic prescriptions



## PHARMAC'S GROWING RESPONSIBILITY



**1993**  
**COMMUNITY MEDICINES**



**2002**  
**HOSPITAL MEDICINES**



**2004**  
**FLU VACCINE**



**2011**  
**CANCER MEDICINES**



**2012**  
**VACCINES**



**2013**  
**HAEMOPHILIA TREATMENTS**



**2014**  
**DEVICES**

# 1999

- Dr Peter Moodie is appointed medical director.
- First multi-product tender produces savings of about \$6.5 million per year.
- Cumulative savings reach \$650 million.
- Health Minister Jenny Shipley launches the Wise Use of Antibiotics campaign, the first nationwide public information campaign to be funded and coordinated by PHARMAC.



Peter Moodie

# A MARK OF TRUST

As reforms of the health sector continued into the new millennium, a change was also on the cards for PHARMAC, one that would highlight its importance to the delivery of health care to New Zealanders.

In June 2000, Health Minister Annette King released a Cabinet paper outlining the future shape of PHARMAC. The agency would become a Crown entity under the Public Health and Disability Act, 2000.

“Most medicines are too expensive for the average New Zealander to afford without Government subsidies and it is the level of these subsidies that PHARMAC negotiates,” said King at the time.

She added that PHARMAC’s exemption from the Commerce act would remain unchanged, allowing it to continue to work with health agencies and the newly created district health boards (DHBs) to lower costs.

If previous legal attempts to have PHARMAC’s funding practices ruled illegal under the Commerce Act had failed, the move to a Crown entity shored up the case for the agency’s exemption even further.

As the Health Minister noted:

“Three of the eight legal cases PHARMAC has faced in the past five years have been related to the exemption. Maintaining the status quo should limit any further testing of legal waters, avoiding costly litigation.”

From 1 January 2001 PHARMAC ceased to be a wholly-owned subsidiary of the Health Funding Authority and a limited liability company.

It was now a stand-alone Crown entity accountable directly to the Minister of Health, managing a budget with DHB funding. It was a proud moment for PHARMAC, an “endorsement of its ability”, wrote chair Richard Waddel in October 2001.

For those who had worked through the agency’s tumultuous early years, when the threat of PHARMAC being shut down due to outside pressure or legal action seemed very real, it was like a safe harbour in a storm.

“After seven-and-a-half years of consistently excellent performance, PHARMAC has earned this independence,” Waddel continued.

It was still business as usual and, as ever, the health budget was tight. But PHARMAC’s successful track record was seeing the Government gearing up to task it with more responsibilities.

In 2001, Annette King directed PHARMAC to begin managing the purchase of hospital pharmaceuticals in addition to the medicines used in the community, and to start doing assessment of new hospital cancer treatments.

This decision would lead to PHARMAC being responsible for or making decisions about a larger proportion of the country’s health spend, including hospital medical devices - \$2 billion of \$16.7 billion by the end of 2017.

The new status gave PHARMAC even more input into government decision making and tighter integration into health sector stakeholders, including the 21 fledgling DHBs.

But it also exposed PHARMAC and its decision making to even more scrutiny, which would become apparent in the years ahead as it tackled some of its most contentious funding decisions.



# 2000

- Richard Waddel succeeds Denis Tait as PHARMAC Board chair.
- PHARMAC initiates a review of its Operating Policies and Procedures



Richard Waddel



# TACKLING HEALTH INEQUITIES HEAD ON

By the turn of the millennium it was clear that PHARMAC's work was contributing to the wellbeing of New Zealanders, but some still weren't getting the full benefits of subsidised medicines.

The health needs of Māori were made a focus of PHARMAC's work in 2001 as it set about developing its first Māori Responsiveness Strategy. This would see PHARMAC reflect in its work, Te Korowai Oranga, the New Zealand Māori Health Strategy which was released in April 2001.

PHARMAC's senior staff travelled the country to meet face to face with Māori as part of a series of hui that explored barriers to access and use of medicines among Māori and looked for practical ways to overcome them.

This was the first time PHARMAC had undertaken major face-to-face consultation with Māori.

"The hui and the messages we received from them underline a very important point. If public sector health organisations such as PHARMAC are to succeed in improving people's health, it is vital that they hear the views of the end user – the patient – as part of their decision-making processes. If they don't do this, they risk making decisions that don't reach the people they are aimed at..." McNee wrote in the 2002 Annual Review.

The resulting strategy laid out PHARMAC's obligation under the Treaty of Waitangi to be as responsive as possible to Māori, and to improve Māori health. It outlined six areas where the agency would focus its efforts.

These ranged from identifying Māori health priorities and boosting resources for training and development activities, through to collecting better ethnicity data on medicines use and improving Māori representation in PHARMAC's key decision areas and governance.

Marama Parore, who had extensive experience in the public health sector and in training Māori community health workers, helped PHARMAC develop the strategy and considered it a powerful statement of intent to tackle inequalities in access to medicines.

"For people like me it gave us incredible, intense hope," says Parore, who would join PHARMAC in 2003 and spend the following decade at the agency leading PHARMAC's Māori Responsiveness Strategy.

She recalls her initial hesitancy at joining PHARMAC as a staff member.

"Aren't they the geekiest of the geeks in the health sector?" she remembers thinking to herself.

"But Wayne McNee gave me great leeway to get on with it and pathfind for PHARMAC their pathway to being more responsive to Māori."

Parore's work with PHARMAC would coincide with a proliferation of community-based Māori health providers. A great deal of effort went into working alongside them to improve access to medicines to treat conditions such as diabetes, respiratory disease, cardiovascular disease, mental health, rheumatic fever, obesity and cancer - all areas where Māori were and continue to be over-represented in health statistics.

At the same time, PHARMAC was looking internally to ensure it was living and breathing its Māori Responsiveness Strategy, with the creation of the Māori health team, and Māori appointments to the advisory committees and the Board. This was also integrated throughout all planning and accountability documents from the agency's Funding Agreement and Statement of Intent to its Annual Plan.

"You've got these very brainy young analysts doing the prioritisation process and they are already thinking, what will this mean for Māori?" says Parore.

A second Māori Responsiveness Strategy would follow, and a third taking effect in 2013 took a long term view out to 2023.

That strategy, Te Whaioranga 2013 - 2023, references not only Treaty of Waitangi obligations, but also the United Nations Declaration on the Rights of Indigenous Peoples.

"It says that agencies are enabled to take measures to create equity. PHARMAC were pretty brave to do that," says Parore.

The long-running One Heart Many Lives programme epitomises the work PHARMAC has embarked on in communities to tackle health inequity.

The kaupapa of One Heart Many Lives at its inception in 2003 was to increase the survival rate of Māori and Pacific men when it came to heart disease.

"We took the data for statins and found that brown men aren't getting them. They are going to hospital and dying. That's not a good picture, what can we do?" says Parore.

The programme expanded into the community in 2008, with free heart checks for tāne Māori and Pacific Island men at community and sporting events as well as training sessions for primary care nurses.

'Get your heart checked bro' became the unofficial catchphrase of One Heart Many Lives which carries on as an initiative of whānau ora collectives, health providers and communities.

Another PHARMAC programme, He Rongoā Pai, He Oranga Whānau, involves wānanga held around the country to improve understanding of the use of medicines in Māori communities.

Nearly 20 years of work on Māori and Pacific peoples' health has made a difference, says Parore, who continues to work on community and public health sector initiatives.

"PHARMAC let me do stuff that really made a difference."

*"For people like me it gave us incredible, intense hope"*  
– Marama Parore

# 2001

- PHARMAC becomes a stand-alone Crown entity, with an independent Board.
- PHARMAC takes over management of the Exceptional Circumstances scheme from the Ministry of Health.
- Wayne McNee becomes the first PHARMAC chief executive.
- Cumulative savings surpass \$1 billion.
- Hui are held to consult on PHARMAC's Māori Responsiveness Strategy.



Sandra Coney

# HEARING FROM THE PEOPLE WHO MATTER MOST

PHARMAC had made a big effort early on to get input from clinicians and health professionals into its evidence-based decision-making processes.

But what about the people consuming the medicines PHARMAC was working hard to secure and subsidise? A 1999 report noted that PHARMAC needed to do more to listen to the voices of the people being impacted by their decisions.

So in 2002 the agency formed the Consumer Advisory Committee (CAC), which was to give users of medicines an opportunity to present their perspectives on the best approaches for delivering effective medicines to the public and provided consumer input into PHARMAC's decision making processes.

The CAC is not directly involved in assessment of pharmaceutical funding applications but is influential in ensuring PHARMAC is thinking about consumer issues in its decisions, talking to the right people and gathering the right information.

Its founding chair was Sandra Coney, a feminist and a women's health advocate, whose work helped in the establishment of the office of the Health and Disability Commissioner and who had led a groundbreaking investigation into cervical cancer treatment during the 1980s at Auckland's National Women's Hospital.

"I was very sympathetic to what PHARMAC was trying to do, because it was trying to pay reasonable prices which would make more medicines available for New Zealanders," says Coney.

"Pharmaceutical companies very often had countries over a barrel in terms of what they were charging for products," she adds.

Coney's role as chair sent a clear signal that the new Consumer Advisory Committee would not be a tame body or box-ticking exercise. The rest of the Committee was made up of equally passionate people bringing differing perspectives to PHARMAC's role.

"They were all very seasoned activists," says Coney. "They were people who in different fields had been very effective and outspoken."

The Committee has been particularly active in advising PHARMAC on how best to consult with the public, especially on the introduction of new pharmaceuticals or changes to existing medicines and devices that may have an impact to the community of users.

Over the years it has pursued specific initiatives, such as helping non-governmental organisations (NGOs) navigate their often compromising relationships with pharmaceutical companies.

"We stuck our neck out and developed a guideline for consumer groups who were contemplating having a relationship with a pharmaceutical industry player," says Coney, who admits the move was "a bit unpopular" with the pharmaceutical companies and, initially anyway, the NGOs advocating for funding of specific medicines.

Coney had gained an insight into the influence of Big Pharma on advocacy groups in her work examining the techniques used to promote, often inappropriately, hormone replacement therapy to women.

The CAC came up with best practice suggestions for NGOs to work with pharmaceutical companies without sacrificing their independence and these guidelines have been widely adopted.

The CAC has been an integral part of shaping the way PHARMAC engages with consumers, which can be seen in the public forums PHARMAC has hosted for the Operating Procedures and Policies, the Factors for Consideration review and more recently the Pacific Responsiveness Strategy.

*"Pharmaceutical companies very often had countries over a barrel in terms of what they were charging for products"*

– Sandra Coney

Former CAC chair, Shane Kawenata Bradbrook noted in the 2016 Year in Review that "CAC has also influenced PHARMAC to become a little softer and more approachable – we see that in the way it now goes out to the community."

The CAC's influence was an important part of the development of the Pacific Responsiveness Strategy in particular. David Lui, current CAC chair notes in the 2017-2026 Strategy that, "the way that PHARMAC has gone about developing the Strategy has buy-in from the Pacific community that will underpin its long-term success."

"They truly engaged and listened to understand – and that can be seen in this final Strategy document which reflects much of what the community told PHARMAC."

The work of the CAC is as diverse as ever and the Committee, currently chaired by Auckland health consultant David Lui, who has extensive links into Pacific communities and health networks, continues to include a mix of people passionate about improving health outcomes for New Zealanders.

## SAVE THE 90 – PR CAMPAIGN TO FUND GLIVEC

“PLEA FOR ACCESS TO  
A LEUKAEMIA DRUG”

“Glivec – putting  
a pricetag on life”

“DRUG PUSHERS  
– THE CAMPAIGN FOR  
GLIVEC FUNDING”

“Cancer drug Glivec finally  
gets PHARMAC approval”

## 2002

- PHARMAC takes on the management of hospital pharmaceutical purchasing.
- Hospital Pharmaceuticals Advisory Committee (HPAC) established.
- Consumer Advisory Committee (CAC) is established. Sandra Coney is appointed the Committee's chair.
- Review of the Pharmacology and Therapeutics Advisory Committee's (PTAC's) guidelines, and of the scope and memberships of its subcommittees, is completed.

## 2003

- Cumulative savings from PHARMAC's policies surpass \$2 billion.
- The 2002-03 tender calls for bids for over 1000 line items, and produces savings of about \$23 million.
- Spending on community medicines (managed by PHARMAC) is \$512 million.

# SAVING MONEY, SAVING LIVES

PHARMAC marked its first decade of operation with an impressive statistic - over \$2 billion in cumulative savings through the policies it employed to get the best deal for New Zealand pharmaceutical users.

The use of reference pricing, tendering, bundled deals and savvy contracting underpinned the savings.

But PHARMAC's increasingly sophisticated grasp of health economics was also integral to making the case for better value pharmaceutical deals and to the fundamental task of delivering the best health outcomes to New Zealanders on a limited budget.

One of the economic evaluations used by PHARMAC to assess whether to fund a pharmaceutical is the 'quality adjusted life year'.

"Using health economics to look at the 'quality adjusted life year advantage' in terms of the New Zealand economy was fundamentally important to arguing with pharmaceutical companies that they were over-pricing the product in terms of the value to New Zealand," says Sharon Kletchko, currently Quality Risk and Clinical Governance Director at the Lakes District Health Board, with a long association with PHARMAC's Pharmacology and Therapeutics Advisory Committee.

New Zealand is known as a 'medium rich' country in health economics terms, but pharmaceutical companies were charging rich prices for access to its medicines. The equation wasn't adding up.

"For New Zealand to pay rich costs and ever-increasing costs was just not going to work for us," says Kletchko.

PHARMAC's arrival in the mid-nineties was "optimum timing" for a reset, adds Kletchko.

"Health economics was always an important part of the agency," says former PHARMAC chief executive Wayne McNee.

"Over time we built that resource up to have quite a strong analyst team, giving us advice around the cost benefit of funding a medicine. That helped us to prioritise where to put the investment for new medicines."

A funding decision facing PHARMAC as its 10th anniversary approached illustrated well the tough decision making the agency's staff had to make on a regular basis.

Against the background of a high-profile campaign to fund imatinib mesylate (Glivec) for a small group of patients, PHARMAC initially declined the funding application.

"Here was a drug that had clear clinical benefits, which represented a significant therapeutic advance for patients with chronic myeloid leukaemia (CML), but which at over \$60,000 per patient per year was extremely expensive," McNee wrote in PHARMAC's 2003 Annual Review.

Eventually, a deal was struck with the drug company to make Glivec available to a larger group of patients at a cost-effective price as part of a wider deal with Novartis involving 11 different products. The move showed that PHARMAC was willing to increase expenditure to achieve health gains. That year, 2003, PHARMAC spent \$512.4 million on medicines, an increase of 5.3 percent on the previous year. Leading up to PHARMAC's creation, the annual increase on medicine expenditure had been closer to 20 percent.

Wrote McNee: "Undoubtedly there will continue to be a tension between the competing demands for funding of new pharmaceuticals, and the constraints of working within a set budget.

"However, PHARMAC will continue to apply the policies it has developed to ensure that the pharmaceutical budget is spent to ensure fair and equitable access to subsidised pharmaceuticals for all New Zealanders."

## What is a quality adjusted life year (QALY)?

A QALY is a measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life.

QALYs are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale). It is often measured in terms of the person's ability to carry out the activities of daily life, and freedom from pain and mental disturbance.

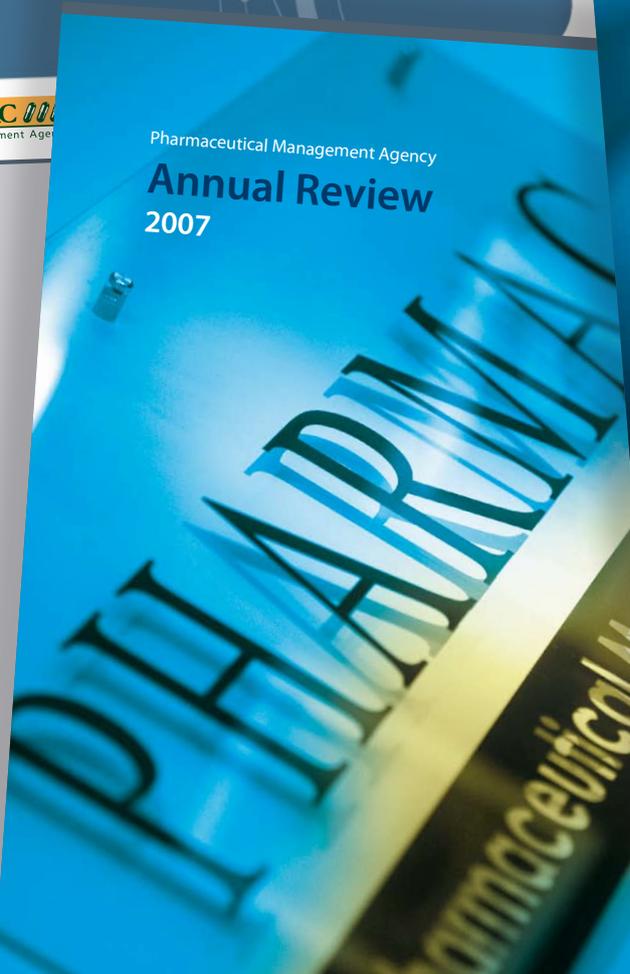


# Improving health

## Pharmaceutical Management Agency

PHARMAC's role is to improve the health of New Zealanders through the allocation of pharmaceutical spending. PHARMAC has been successful in **providing access** to more than 150 **new medicines** for patients while managing expenditure within budget. We ensure that funding decisions are ones that have a **positive effect** on New Zealanders' health. PHARMAC acts within a framework that is transparent and accountable to the Minister of Health, and the people of New Zealand.

# PHARMAC



# 2004 - 2008

## DECISION MAKING IN THE SPOTLIGHT

If conflict is essential to a good story, PHARMAC has been rich material for New Zealand's media, as controversies over key funding decisions, numerous lawsuits and emotionally charged campaigns for funding medicines have made headlines.

PHARMAC had little precedent in New Zealand back in 1993, so the agency needed to work hard to articulate to the public what its mission was. That meant working closely with the news media.

At the same time, communications consultants and lobbyists hired by the pharmaceutical industry were developing a narrative that suggested PHARMAC's presence could see New Zealanders miss out on important medicines and that research and development investment here would evaporate.

David Menkes noted in an editorial in *The Lancet* in January, 1998, that "Last year was a particularly turbulent time for the New Zealand pharmaceutical market, with the government's drugs purchaser (PHARMAC) battling against the Researched Medicines Industry (RMI)—a lobby representing 33 transnational corporations that sell brand-name drugs."

"The media attacks were pretty impressive," former medical director Peter Moodie recalls.

"When we first started, the media was being fed stories from the companies. There were passionate advocacy groups, that were really lobby groups that made headlines."

Founding general manager David Moore often found himself facing not only a multimillion dollar advertising campaign behind a drug up for funding consideration, but an associated blitz of media coverage.

"We became more active in our language," he says.

"This is an area where it helped to be an independent agency, on the fringe of government, with independent governance."

Fronting up to the media and being proactive with telling their story was essential if PHARMAC was to justify its evidence-based decision making.

PHARMAC's legal adviser Simon Watt remembers the genuinely meaningful personal stories the media latched onto, highlighting the gravity of PHARMAC's decision making.

"It felt like PHARMAC was always ruffling feathers and therefore always under attack about what it was doing," he says.

"PHARMAC had to find its own way to respond and deal with that."

Newspaper editorials would, on occasion, set aside editorial neutrality to advocate for a medicine to be funded.

The answer was openness, accessibility and a proactive media strategy.

"We made good use of the regional newspapers," says Moore.

"We made sure that the Annual Review was published around Christmas time, so it could get picked up in January weekend newspapers.

"We found we got quite good reach, right around the country."

Over the years, the general tone of coverage of PHARMAC and its decisions changed.

"It was the slowly changing attitude of the medical profession and of the public as well," says Moodie.

The media's growing acceptance of and support for PHARMAC's role is reflected in a New Zealand Listener editorial published in March 2016, at the height of public debate over the funding of Keytruda (pembrolizumab).

*"The media attacks were pretty impressive."*

— Peter Moodie

"Inevitably, politics and simple human compassion have aligned on one side of this issue, with Pharmac's firmly evidence-based assessment on the other," the Listener pointed out.

"Pharmac must prevail. We have in this centralised drug-buying and funding agency a world-leading model," it concluded.

A Sunday Star Times headline from later in 2016, 'Anatomy of a drug deal', went inside the negotiations over Keytruda.

"Two plots playing out side-by-side – one publicly, the other backstage – the actors in each, acutely aware of lives hanging in the balance," wrote Sunday Star Times reporter Stacey Kirk.

PHARMAC has had to weather its fair share of negative headlines and column inches of criticism. But overall, its current and past leaders agree that the media's coverage of PHARMAC has been fair, and that the media plays a vital role in holding it to account.

"Overall, I'd have to say we get pretty good press, on balance," says McLauchlan.

Adds Moodie: "It's a credit to the New Zealand media that they became more insightful and started to ask more questions."





Carl Burgess

## 2004

- PHARMAC assumes responsibility for purchasing influenza vaccine.
- Pilots of One Heart Many Lives cardiovascular risk management campaign take place in Porirua and Gisborne.

## 2005

- Centralised purchasing of haemophilia products produces savings of \$30 million.
- Associate Minister of Health Peter Dunne initiates *Medicines New Zealand* review.

## 2006

- Wayne McNee is seconded to Department of the Prime Minister and Cabinet; Matthew Brougham is appointed acting chief executive.
- One Heart Many Lives expands into Hawke's Bay and Northland.



# 2007

- Controversy over the funding of Herceptin for breast cancer leads to a group of patients seeking a judicial review of PHARMAC's decisions.
- First PHARMAC Forum is held.
- Medicines New Zealand and its associated action plan are published.
- Wise Use of Antibiotics launches new campaign 'Kick that bug'



Matthew Brougham

# MOVING FORWARD TOGETHER

## In December 2007 the Government introduced the *Medicines New Zealand* strategy and action plan, creating, for the first time, an overarching strategy for the use of medicines in New Zealand.

It was a major piece of work, led by Associate Minister of Health Peter Dunne, and would have significant implications for PHARMAC's operations from that point on.

The strategy set out three main objectives for the country when it came to medicines:

- Quality safe and effective medicines
- Equitable and affordable access
- Optimal use of medicines resulting in optimal health outcomes.

PHARMAC already played an integral role in access and optimal use of medicines, and through late 2006 and early 2007, numerous stakeholders contributed wide-ranging views on the agency's future role in evaluating, acquiring and supporting the optimal use of medicines.

While not intended as a review of PHARMAC, the strategy consultation period lent the agency a prime opportunity for self-reflection, as chief executive Matthew Brougham outlined in PHARMAC's own submission on the strategy.

The agency identified "no significant weaknesses in the structures or processes underpinning PHARMAC's operations", but saw scope for making them more effective.

"We can do a better job of taking people with us," noted Brougham, suggesting better communication and stakeholder engagement from PHARMAC were required. He also identified potential benefits from implementing a longer budget period and introducing a more competitive tendering process for new, innovative medicines, replacing the one-on-one negotiations that existed at the time.

Fundamentally, PHARMAC cautioned against re-engineering a system that had proven to be successful.

"Some interest groups are likely to call for radical change of some systems and structures to advance their own particular interests and priorities," wrote Brougham.

"However, from our perspective as an agent of government and the public at large, the public interest is already served very well, and is best served by continuing evolutionary development (as the Ministry proposes), rather than revolutionary wholesale change."

The strategy, in its final form, satisfied that need identified by the government and health sector and consumer stakeholders for more coherence and transparency in the medicines system.

For PHARMAC, the action list included implementing a regular forum for stakeholders - both funding applicants and consumers - to comment on PHARMAC's operations.

The district health boards (DHBs) and PHARMAC would move to a principles-based approach for setting the community pharmaceuticals budget and PHARMAC would start publishing summaries of decisions on medicines funding applications.

The operational guidelines and terms of reference for PHARMAC's Pharmacology and Therapeutics Advisory Committee and Consumer Advisory Committee respectively were to be reviewed to ensure appropriate checks and balances and clear accountability.

It flagged a review of the Exceptional Circumstances funding and criteria and PHARMAC was charged with developing a system to ensure people had access to funding in certain circumstances when decisions led to brand changes in medicines.

The strategy also called for nationally coordinated decision making, funding, and procurement of vaccines, which would foreshadow PHARMAC's assuming responsibility for procuring vaccines on a nationwide basis.

By November 2008, when Brougham wrote his briefing to incoming Minister of Health Tony Ryall, PHARMAC's actions had all been completed or advanced.

But the agency saw particular additional scope for PHARMAC to play a role in the 'optimal use of medicines' category of the strategy. As Brougham had written in PHARMAC's submission on the strategy:

"In our view, the health gains which can be achieved by improving the use of medicines potentially significantly outstrip any gains which can be made on the supply side."

The following years would see an increased focus on demand-side initiatives at PHARMAC as it pursued that 'optimal use' goal.

The Medicines New Zealand strategy and accompanying action plan served to provide the greater cohesion and cooperation across the health sector its architects had desired. A second action plan was released in 2009 and a third in 2015, *Implementing Medicines New Zealand 2015 to 2020*, introduced legislative changes to more effectively deal with new technologies, such as medical devices and cell and tissue therapies.

Medicines New Zealand provides an overall framework for PHARMAC's operations today and is notable for the consensus of opinion on the fundamentals for a healthy medicines system that underpin it.



# 2008

- Matthew Brougham is appointed chief executive.
- PHARMAC begins implementing Medicines NZ actions.
- He Rongoā Pai, He Oranga Whānau (Whānau Staying Well with Medicines programme) is launched.
- Demand Side team becomes Access and Optimal Use.

# HARD CHOICES

## In December 2008 the new National Government decided to fund a 12-month course of Herceptin for women with early stage breast cancer, outside of the PHARMAC model

PHARMAC's Pharmacology and Therapeutic Advisory Committee had been unconvinced by the evidence for Herceptin's efficacy and advised PHARMAC to fund a nine week treatment course. There were also side-effects - serious heart problems that affected a small minority of Herceptin users.

But worldwide, Herceptin was being spoken of in the media as a 'wonder drug' and breast cancer advocacy groups had mounted a sustained campaign for it to be funded.

Rarely in the history of PHARMAC had a medicines funding decision become so politicised, as National, then in opposition, during the 2008 election campaign promised to make 12 months of Herceptin treatment available. But the controversy was not without precedent.

On coming to power in 1999, the previous Labour Government had directed the Health Funding Authority to instruct PHARMAC's Board to fund beta-interferon drugs for the treatment of multiple sclerosis.

Herceptin generated a whole different level of public debate in early 2008. But internally, PHARMAC's experts held their nerve. They remained unconvinced that a longer course of Herceptin, which cost up to \$100,000 including clinic fees, would deliver any greater benefits than the nine-week treatment. The opportunity cost, however, would be huge.

PHARMAC also contributed to the international literature on Herceptin. In a paper published in *The Lancet* in May 2008, leading New Zealand health experts and PHARMAC staff, including future chief executive Steffan Crausaz, expressed concern that Herceptin was being talked up as an effective medicine despite incomplete clinical trial data being published.

"Failing to publish inconclusive results can mean wide (and wasteful) use of ineffective treatments, or even unnecessary illness

and death if the reported risks of harms are underestimated," they wrote.

"Clearly adjuvant Herceptin is effective, but how best to use it appears to have been hampered by some publication choices that presently are unclear."

This was PHARMAC relying on its Decision Criteria to come up with a robust funding decision. Ultimately politics won and the Government funded the drug directly through the Health Ministry.

PHARMAC graciously assisted the Government, providing information to inform its negotiations with drug company Roche to procure Herceptin, which was not funded out of PHARMAC's budget, but from another area of the health budget.

With the distance of a decade, PHARMAC's senior management from that era remain satisfied they made the right decision.

"It's a credit to PHARMAC that they were able to hold that line," says former medical director, Peter Moodie.

Indeed, Health Minister Jonathan Coleman admitted as much in 2015, as PHARMAC was considering whether to fund another cancer medicine - Keytruda.

"The research shows that nine weeks, which were funded previously, is actually just as good as 52 weeks, but I think lessons have been learned," he told TV3's Paul Henry show.

"You're not a pharmacologist, you're not a doctor: PHARMAC have the best possible advice and they've got to make the best decision in the interests of New Zealanders," he added.

Despite its disagreement with the Government over Herceptin, PHARMAC remained open to funding longer duration regimens of the treatment – if stronger evidence for its medical efficacy and cost effectiveness emerged.

In early 2007, just before it confirmed funding of the nine-week Herceptin regime, PHARMAC sought to cut through the uncertainty by supporting the international SOLD clinical trial, which sought to compare the efficacy of the twelve month and nine week treatment regimes.

The trial ran from 2007 to 2014 and included 2176 patients, 160 of them from New Zealand. By late 2017 the results were in – the two regimes were similarly effective, but there were reduced side effects, cost and inconvenience for patients on the nine-week regime.

*"PHARMAC have the best possible advice and they've got to make the best decision in the interests of New Zealanders."*

– Health Minister Jonathan Coleman

# CONTRIBUTING TO DISCUSSION, OPEN TO DEBATE

While PHARMAC's staff and independent advisers draw heavily on medical peer-reviewed literature in their decision making, they are also prolific contributors to the literature themselves.

That is born of a desire to draw on the agency's experience and data to inform the work of clinicians and public health practitioners both here and around the world.

From its early days, PHARMAC staff were submitting articles, letters and editorials to esteemed journals including BMJ, The Lancet, JAMA, New England Journal of Medicine and Pharmacoeconomics.

The agency's strongest presence, unsurprisingly, has been in the New Zealand Medical Journal, which is published by the New Zealand Medical Association and has a proud publication history stretching back to 1887.

PHARMAC authors feature in dozens of NZMJ articles from the past 25 years. Indeed, PHARMAC has an arrangement with the New Zealand Medical Association to provide free access on the internet to NZMJ articles with PHARMAC authors.

This is a commitment to open access publishing that reinforces PHARMAC's statutory objective, "to secure for eligible people in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided".

The peer-reviewed literature, letters and editorials span all aspects of PHARMAC's operations – from decisions about funding of statins, to the impact of direct-to-consumer advertising on health consumers to explanations of the PHARMAC model itself.

One name features prominently as an author or co-author on dozens of PHARMAC-related papers – Scott Metcalfe. The public health physician and PHARMAC's Chief Adviser, Population Medicine has been with the agency as a staff member or contractor for 23 years.

Metcalfe's name can often be found alongside those of PHARMAC chief executives, PTAC members and academics, on a wide range of articles fastidiously researched and well articulated.

In 2002 Metcalfe, Matthew Brougham and Wayne McNee were writing in HealthcarePapers, offering words of advice to health sector leaders in other countries struggling with crippling pharmaceutical costs.

"If you want to avoid bankruptcy, first you have to know what you can afford to spend," they wrote.

"From our observations as a public agency responsible for setting drug subsidies in New Zealand, operating within a budget constraint may better help to achieve many of the desired outcomes."

Often PHARMAC will add to the primary research base, as it did in 2014 when it used data from the Pharmaceuticals Collection administrative claims database, to measure how the use by diabetics of blood glucose test strips funded by PHARMAC compared with published guidelines.

Often, the medical literature is also used to defend and justify PHARMAC processes and decision making. The agency has taken a proactive stance in engaging with its critics, correcting misinformation and offering insights into its processes.

Wrote Metcalfe, Peter Moodie and Wayne McNee in a 2003 NZMJ article responding to criticism of PHARMAC's approach to funding statins in the late 1990s:

"Our perspectives differ, but we do agree on the desirability of open and vigorous debate."

PHARMAC's funding decisions are regularly contentious. But a commitment to informed discussion and regular contributions to the medical literature have won the agency respect, even from its strongest critics.



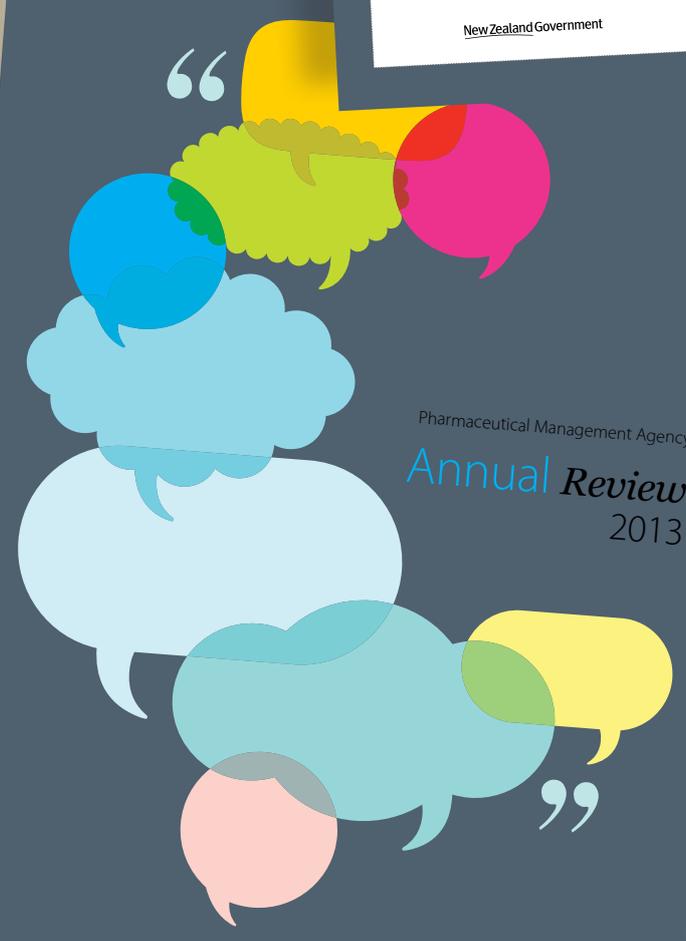
Pharmaceutical Management Agency  
Annual Review 2009

Pharmaceutical Management Agency  
Annual Review 2010

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Annual Review 2012

Pharmaceutical Management Agency  
Annual Review 2013



# 2009 - 2013

## SPECIAL CASES

The bulk of funding invested in medicines managed by PHARMAC goes to treat conditions and diseases that affect large numbers of patients - from arthritis to asthma, diabetes to depression.

But it is a little known fact that around 80 percent of patients receiving funded medicines in New Zealand, account for just 9 percent of the Combined Pharmaceutical Budget (CPB). Most people's medicine needs are met very efficiently, while a small number of patients require highly specialised and often expensive medicines.

That latter group comprises a relatively small number of patients with rare and sometimes hard-to-treat conditions. Part of running an equitable process for acquiring medicines is considering the needs of those patients with so-called 'exceptional circumstances.'

Since its early days, PHARMAC has allocated some of its budget each year to treat people with medicines that fall outside of the Pharmaceutical Schedule funding process.

Three schemes are operated by PHARMAC as part of the Exceptional Circumstances framework, designed to offer access to community, hospital and cancer medicines for individuals who can demonstrate that they meet exceptional circumstances criteria.

"They might be the only person in New Zealand with their particular condition," explains Carolyn Gullery, an original PHARMAC Board member.

"They might be the only person who needs that particular product rather than the normal one we use."

"There might only be two cases in New Zealand and it is going to cost a million dollars per case. If it is such a huge benefit, it is very, very hard when you say it doesn't fit the criteria. You are dealing with a person's life," says former PHARMAC chair Richard Waddel.

Decisions considered by the Exceptional Circumstances Panel, which consisted of up to six clinicians, could be particularly contentious.

"These were very difficult cases because you had to review the emergent literature," says Sharon Kletchko, who considered many funding decisions as a member of the Panel.

"For someone interested in pharmaco-therapeutics and rare conditions it was groundbreaking stuff."

She remembers, in the early days, reams of paper spitting out of her fax machine as medical research was sent to her

ahead of the Panel's regular Tuesday night teleconference to consider the applications.

Often a person's clinical circumstances would meet the spirit or intent of the conditions within the Pharmaceuticals Schedule, but not meet the technical requirements. PHARMAC allowed some discretion in decision making and the Exceptional Circumstances Panel was on the frontline of that decision making.

"We had a budget and weren't allowed to go beyond it without PHARMAC giving approval. It meant that we as clinicians carried the decision," says Kletchko.

In 2010 PHARMAC opened consultation as part of a review of its Exceptional Circumstances scheme. This resulted in the creation in 2012 of the Named Patient Pharmaceutical Assessment (NPPA) policy, a new scheme with some

significant changes. Patients would no longer need to have a rare condition (be one of a maximum of 10 patients in the country with the condition) to be considered for funding and PHARMAC created a pathway to assess treatments

more quickly for patients whose condition would deteriorate or who would miss an opportunity to improve while a typical Pharmaceutical Schedule application was made.

The funding for exceptional circumstances was also doubled from \$4 million to \$8 million in the following year. It recognised the demands on the scheme and the need for greater flexibility in dealing with the most acute patient cases with the move to managing the hospital medicines portfolio.

"The new scheme is more permissive and more clearly describes PHARMAC's discretion to consider funding applications not meeting the letter of the scheme," said PHARMAC chief executive Matthew Brougham in announcing the new scheme in June 2011.

"We expect that one of the results of the change will be that more conditions experienced by small groups of patients will be considered for funding. Rarity is no longer the key consideration in examining funding applications; instead we will focus on patients with unusual clinical circumstances, or those whose conditions are urgent and serious," he added.

The Exceptional Circumstances Framework and NPPA continue to be integral to the decision-making processes of PHARMAC with thousands of applications received every year and a high level of scrutiny of decision outcomes.

*"You are dealing with a person's life"*

– Richard Waddel

# 2010

- Stuart McLauchlan is appointed chair of the PHARMAC Board.
- Kate Russell is appointed chair of the Consumer Advisory Committee.
- High Cost Highly Specialised Medicines Review and Ministerial Review Group reports are published. Government gives PHARMAC an expanded role in managing hospital medicines and medical devices.
- A review of the CAC Terms of Reference is completed.
- PHARMAC begins a review of the Exceptional Circumstances scheme.



*Stuart McLauchlan*



*Kate Russell*

# NO HOSPITAL PASS

PHARMAC's roots lay in acquiring pharmaceuticals at sharp prices for community use, with general practitioners, medical specialists and pharmacists its main path for delivering medicines to the public.

But that was to change as the Government sought to extend to the country's network of hospitals and the medical devices they use, the efficiencies PHARMAC had gained in community medicines supply.

The changes had their origins in the publication of the 2010 Ministerial Review Group (MRG) report, led by former Treasury boss Murray Horn. In looking at procurement and efficiencies in the health system, the MRG report noted the achievements of PHARMAC and recommended it be given a wider role, including vaccines, hospital medicines, and hospital medical devices.

"In particular, the MRG considers it both possible and desirable to develop a Pharmac-like process for assessing the cost-effectiveness of medical devices and prioritising them for public funding," the report noted.

From 1 July 2013 PHARMAC officially assumed responsibility for making decisions about which new pharmaceuticals would be funded for use in district health board hospitals. Previously, the agency had entered into national contracts for supply to hospitals on a case-by-case basis.

This was a major expansion of PHARMAC's responsibilities. For Carl Burgess, chair of PHARMAC's Pharmacology and Therapeutics Advisory Committee from 2003 to 2012, it was the most significant development during his tenure with the committee.

"Suddenly we were considering a whole new group of drugs which we wouldn't have considered before," he says.

PHARMAC assembled a committee of clinicians, pharmacists, DHB staff and its own staff to review hospital pharmaceuticals and consider which should be added to the Hospital Medicines List (HML), a subset of the Pharmaceutical Schedule.

"We had to go through every single drug; it took us just over a year," he says.

The Government's motivation went further than just securing better deals on pharmaceuticals for the district health boards. It was also designed to deliver consistency across the country in the medicines DHB hospitals offered to patients.

"The hospitals did their own purchasing. You had inequality to the extent that you had certain drugs, say for schizophrenia, where if the person was a resident in Nelson they couldn't get that drug," says Burgess.

"If they came across Cook Strait, they could get the drug in Wellington."

PHARMAC had already been managing DHB hospital expenditure on pharmaceutical cancer treatments (PCTs) through the Pharmaceutical Schedule, as well as determining access criteria for them.

The remit widened further when PHARMAC took over managing the funding for the National Immunisation Schedule, including purchasing vaccines, from the Ministry of Health, in the middle of 2012.

PHARMAC's founding general manager, David Moore, describes it as a "natural fit" for the agency. Vaccines are purchased from pharmaceutical companies so PHARMAC can apply its tried and tested contracting and negotiating processes and the vaccines are administered by the same community and hospital-based professionals handling other medicines PHARMAC secures access to.

The agency was now part of the effort to prevent some of the potentially fatal diseases that can affect unvaccinated children, such as polio, measles and mumps. Dealing with infectious disease outbreaks such as hepatitis A, the gastric infection rotavirus and influenza has also required a new level of responsiveness from PHARMAC.

In 2014, the first year PHARMAC ran the contracting process for the full National Immunisation Schedule, it had to respond to a hepatitis A outbreak in Ashburton and the Hutt Valley, listing an additional vaccine on the Schedule.

A move to list a rotavirus vaccine for all children from 1 July 2014 was linked to a 75 percent reduction in children up to two years old being admitted to Auckland hospitals for the illness.

Each year, PHARMAC is responsible for purchasing more than 1 million vaccines as part of the national influenza vaccine programme.

"The vaccines story demonstrates the power of the PHARMAC model - improving access to vaccines, listing more vaccines and streamlining distribution, all while containing the fiscal impacts, so that more New Zealanders can live longer and healthier lives," noted PHARMAC's 2017 Year in Review.

Says current PHARMAC Board chair, Stuart McLauchlan: "That good foundation that was set, we've been able to leverage into other areas."

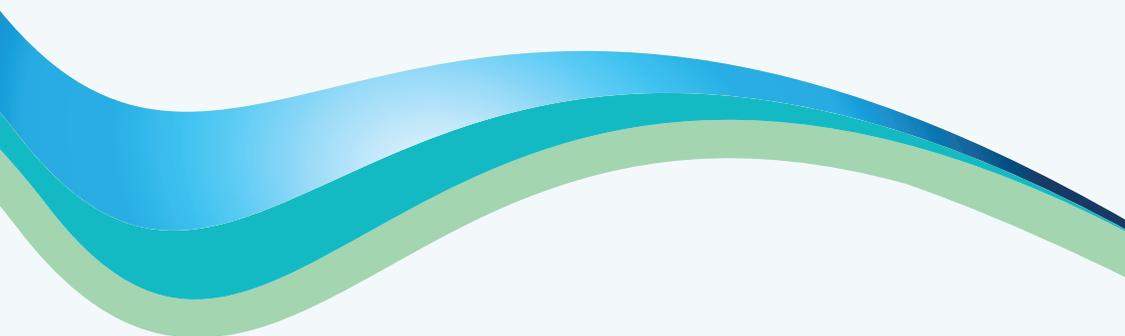
# 2011

- Matthew Brougham resigns as chief executive.
- PHARMAC creates Whānau Hauora Village at Te Matatini national kapa haka festival, Gisborne.
- Minister of Health approves the creation of a discretionary pharmaceutical fund (DPF), held by PHARMAC, to help manage inter-year pharmaceutical expenditure.
- PHARMAC Board approves changes to Exceptional Circumstances – the scheme is to become the Named Patient Pharmaceutical Assessment (NPPA).
- Funding for hospital cancer medicines (PCTs) is included in the CPB.



## Meet your meter

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



# WHAT COULD POSSIBLY GO WRONG?

PHARMAC's leadership has always been willing to move fast and innovate to bring about change in the interests of better health outcomes.

But it hasn't always gone completely to plan. In 2012 PHARMAC sought to choose a single supplier of blood glucose meters and test strips as part of a sole-supply deal that would save \$10 million a year; savings that would be reinvested to buy more medicines for more New Zealanders.

"A crowd of people, many of them angry, confronted PHARMAC last night at a public meeting to discuss a proposed brand switch of glucose meters," wrote Amanda Cameron in NZ Doctor in March 2012.

The change was to see four different brands of glucose meters replaced with one brand, CareSens. But diabetes patients around the country were alarmed - they had grown used to their glucose meters, potentially life-saving devices for type 1 diabetes patients, and Diabetes New Zealand and other groups were concerned that the big existing supplier, Roche, which had around 80 percent of the market, would pull its support for the products and the diabetes community.

"Switching at least 100,000 people's meters in the six months expected by PHARMAC will place an unreasonable burden on primary care," Paul Drury, Medical Director of the New Zealand Society for the Study of Diabetes, told NZ Doctor.

Concerns were raised about the features and quality of the new CareSens meters, though they met international standards.

PHARMAC had underestimated the level of resistance and the backlash was swift and powerful.

"We put out a request for proposal; what could possibly go wrong?" says PHARMAC's chief executive at the time, Steffan Crausaz

"It turned out a lot could go wrong."

Up to 120,000 patients were faced with moving to a new, unfamiliar product from company i-Sens. The concerns of diabetes patients soon caught the Minister of Health's attention - it was one of the top three issues on his watchlist, says Crausaz.

PHARMAC had to manage the transition over a longer period of time than usually occurs with changes of brands, with extensive consultation and support and information for consumers.

Eventually almost all people with diabetes made the transition to the new technology.

"It was one of those [transactions] where I felt, gosh my job is on the line here if we can't do it, and actually it should be; that's what you sign up for," says Crausaz.

PHARMAC had learned a valuable lesson, which it put into action when an opportunity arose to go back to the market for a new sole-supplier agreement for diabetes meters in 2017. This time around it engaged much earlier with clinicians, held consumer engagement groups, and had the proposed meters independently lab tested by New Zealand laboratories.

Following this extensive process, the decision was made to award a new sole-supplier agreement to healthcare specialist Pharmaco (NZ) Limited, which had won that 2012 contract, and an expanded range of blood glucose meters and strips was included.

"[The new deal] will benefit all New Zealanders by releasing significant savings, in excess of \$10 million over five years. PHARMAC will be able to reinvest this money and improve access to other funded medical devices and medicines for New Zealanders," said Dr Bryan Betty, PHARMAC Deputy Medical Director.

This is the PHARMAC model in action - looking for opportunities to get better health outcomes for more New Zealanders, while getting better at the way it did things.

But other issues emerged for PHARMAC that were, to some extent, outside its control.

PHARMAC has learnt the hard way over the years that you can't underestimate people's brand loyalty when it comes to changing medicine.

In 2005 PHARMAC changed the brand of the common brand of asthma inhaler, Ventolin, used by more than 540,000 people. The change introduced a new brand to people, Salamol, which was clinically the same, but tasted different, felt different, and had a small amount of alcohol in it.

Such was the loyalty to the Ventolin, described as the "trusty puffer" in an editorial in the New Zealand Medical Journal, the move wasn't popular, and there was public outcry from patients, doctors and advocacy groups alike. Some claimed it would lead to increased hospitalisations from poorly managed asthma.

The negative perceptions of the change were compounded by negative reporting in the media. One report noted that the alcohol content led to a failed road side breath test, despite the alcohol content in each puff being "less than the amount of naturally occurring alcohol found in a glass of freshly squeezed orange juice."

While PHARMAC had no concerns over Salamol's efficacy, they listened to the feedback and brought back the subsidy for Ventolin, with a part-charge, allowing people to get this funded if they wanted to.

"A number of people raised issues with PHARMAC and Medsafe about Salamol, so we moved to address those concerns," Medical Director Dr Peter Moodie said in a June 2005 media release announcing the change.

As noted in an editorial in the NZMJ in August 2005, "both patients and clinicians can be very "brand loyal" and any change to an "iconic" product needs to be handled carefully," lessons that PHARMAC has heeded when making changes to other brands of medicines.

*"It was one of those [transactions] where I felt, gosh my job is on the line here if we can't do it, and actually it should be; that's what you sign up for."*

– Steffan Crausaz



# 2012

- Steffan Crausaz is appointed chief executive.
- Funding for vaccines is included in the CPB.
- Work begins on hospital medical devices.
- First commercial process is run for a biosimilar medicine – biosimilar filgrastim (Zarzio) is funded.
- Sisira Jayathissa succeeds Prof Carl Burgess as chair of PTAC.



Steffan Crausaz



Sisira Jayathissa

# FROM MEDICINES TO DEVICES

There are consequences to being good at your job, which PHARMAC discovered in 2013, when the Government called on the agency to take on a major new piece of work.

Pharmaceuticals were a big area of health expenditure where PHARMAC had been successful in getting better value outcomes for New Zealanders, saving the taxpayer billions in the process.

But what about all the tangible things, from bandages and IV drips to dialysis machines and ward equipment, that hospitals use to treat patients and which the sector spends the best part of a billion dollars a year procuring? Could PHARMAC achieve similar results there?

The agency was up for the challenge. Former chief executive Steffan Crausaz describes the move into management of medical devices for the district health boards as among the biggest developments during his tenure leading PHARMAC.

New Zealand hospitals already had access to world-class medical equipment, but assessment and procurement of it was done on an ad hoc basis and there was inconsistency of availability across DHBs.

Effort across the hospital sector was duplicated and there was often limited research about the long-term functionality, reliability and benefit of devices.

While PHARMAC had laid a great foundation with the sector after taking on hospital medicines, it knew that assuming responsibility for medical devices would be a major undertaking requiring close consultation with clinicians and the sector and new staff with appropriate expertise.

PHARMAC took the same approach to devices that it initially took to medicines – start small, test the waters to see what worked, and then expand into other areas.

By the middle of 2014, it had 2800 medical devices listed on the Pharmaceutical Schedule and for the year had delivered savings of \$1.12 million for DHBs as a result of negotiating national contracts for the supply of selected categories of medical devices.

The savings spanned device categories such as wound care, disposable laparoscopic trocars, sutures and interventional cardiology, and, though modest at that stage, it provided important test cases for the agency's ambitious plans to expand the categories of devices and the size of the spend it was negotiating.

In 2017 Crausaz announced a bold goal - to achieve \$1 billion of savings from medical device management by 2025 to reinvest in health outcomes for New Zealanders.

"There's still a long way to go, but we are committed to completing national contracting across all device categories over the next two years," wrote Andrew Davies, the manager of PHARMAC's hospital medical devices team, in the 2017 Year in Review.

"Because these savings are in the form of price reductions on existing products, they release funding for DHBs to reinvest in other healthcare. In other words, we help DHBs achieve more with their hospital funding."

PHARMAC has been steadily expanding medical device categories since 2013. As of April 2017, PHARMAC had national contracts covering approximately \$110 million of annual expenditure, giving DHBs \$40 million in savings over five years.

Those who know the health sector and PHARMAC's role in it, know the potential to reach that 2025 target and to go further.

"I spent 14 months working with St. John, who were always under pressure to deliver a really important service for New Zealand, and had to buy their defibrillators, their cots, their ambulances," explains former PTAC member Sharon Kletchko.

"Could PHARMAC end up purchasing devices on behalf of New Zealand Health Inc in future? Absolutely."

As Crausaz came to the end of his tenure as chief executive in December 2017, the medical devices side of the agency's work had bedded in well.

"It is starting to feel like ordinary business for PHARMAC," he said.

"It is delivering really good gains."

# *Te Whaioranga*

10 years of responsiveness to Māori





# 2013

- All hospital medicines come under PHARMAC management.
- PHARMAC restructure leads to the creation of four directorates – Medical, Corporate, Engagement and Implementation, and Operations.
- Medical director Dr Peter Moodie retires after 14 years in the role. Dr John Wyeth appointed Medical Director.
- More than 300 people attend PHARMAC community forums.
- PHARMAC Board approves a 10-year strategy for responsiveness to Māori – Te Whaioranga.
- Changes to the funded brand of blood glucose meters for more than 100,000 people with diabetes are implemented releasing savings of \$10 million annually.

ANNUAL REVIEW  
DECEMBER 2014

# PHARMAC

PHARMACEUTICAL MANAGEMENT AGENCY



PHARMAC  
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## YEAR IN REVIEW 2016



PHARMAC  
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PHARMACEUTICAL MANAGEMENT AGENCY  
YEAR IN REVIEW  
2017



# 2014 - 2018

## ALL ABOUT PEOPLE

### How do you grow from a start-up to a 120-person organisation, while juggling the expectations of numerous competing stakeholders and the demands of the Government?

“Good governance and good people, that’s the key,” says former PHARMAC chief executive, Wayne McNee.

A common metaphor pops up when you talk to PHARMAC’s current and former leaders – David and Goliath. They felt, particularly in the early days, that victory was improbable. The pharmaceutical companies supplying the New Zealand market would never accept that the rules had changed.

But, against the odds, PHARMAC notched up win after win.

Former PTAC chair John Hedley refers to PHARMAC’s founding team as the “tight four” – himself, Reinhard Pauls, Win Bennett and founding general manager David Moore.

“I felt I was part of a close-knit group and we were all motivated, though we came from disparate backgrounds, to get to grips with the same problem,” he says.

“It was a given that there was waste and we wanted to see it eliminated. It was unspoken, the depth of our willingness to tackle it.”

But former chief executive Wayne McNee also remembers some tense times as his team grappled with decisions that would have major implications for patients.

“There was quite a lot of challenge internally around whether we were making the right decisions,” he says.

“We were changing people’s medication and deciding whether to fund things.”

In testing each other’s positions, the team was better able to deal with the often intense criticism its decision making provoked from the drug companies, the health sector and the public.

“It was a sort of family,” says former medical director Peter Moodie.

As Moodie watched PHARMAC grow through the 14 years he spent at the agency, he saw it take on the attributes of a mid-sized corporation.

“But it still kept that element of family.”

Carl Burgess, chair of the Pharmacology and Therapeutics Advisory Committee from 2003 – 2012 saw a large increase in PHARMAC headcount during his tenure.

“That’s a good thing,” he says.

“It has allowed younger folk to develop and learn how to make assessments, and you can use those skills for other areas.”

Despite the growth in staff numbers as PHARMAC moved into tendering, then demand-side information and advocacy campaigns, vaccines and hospital medical devices, the agency has maintained the open internal communication that was essential to success early on.

That family vibe to PHARMAC, coupled with the professionalism of its staff, has served the agency well over 25 years says current PHARMAC chair, Stuart McLauchlan.

“The culture in this organisation would be the strongest of any I’ve ever been involved in. It’s the excellence that comes through, the striving to do better.”

# 2014

- Haemophilia treatment funding is included in the CPB.
- First national contract is negotiated for hospital medical devices. In the first year of contracting, five-year savings to DHBs are \$4.6 million from all devices contracts.
- PHARMAC consults on changes to its decision-making procedure, develops the Factors for Consideration.
- Contestable funding process is run exclusively for medicines for rare disorders.
- PHARMAC manages commercial process for the National Immunisation Schedule – leads to the listing of rotavirus vaccine, and the chickenpox vaccine for at-risk children.

# THE ENVY OF NATIONS

PHARMAC's ability to secure some of the world's lowest prices for a wide range of prescribed pharmaceuticals has seen a steady stream of public health providers and health economists beat a path to its door in Wellington.

The most intense interest has come from those tasked with managing health budgets in high-income countries with a similar standard of living to New Zealand. In an article in the journal *PharmacoEconomics* in October 2014, University of Otago public health expert Robin Gauld reflected on PHARMAC's progress following its 20th anniversary.

"In comparative terms, New Zealand pays the lowest prices amongst high-income countries for a list of 30 'most prescribed' medicines - around one-third of the costs for the USA and 70 percent of Australian and British prices," he wrote.

"There are numerous examples of individual New Zealand pharmaceutical prices and patient co-payment amounts that other countries and their citizens might only dream of."

So why haven't other countries been able to replicate PHARMAC's uniquely successful model?

"We were in the right place at the right time, in a political environment where we could do it," says founding PHARMAC staff member Reinhard Pauls.

The health reforms of the early 1990s had sought to contain burgeoning health costs and, in particular, the double digit annual growth in spending on pharmaceuticals. The political will was there to let PHARMAC get to work to help make the health budget go further.

But New Zealand also had the advantage of not having a strong pharmaceutical manufacturing industry in need of protection. Those large companies that were here were mainly marketing products made overseas, or in some cases producing generic drugs.

"I think of Switzerland, where I grew up, which has a massive pharmaceutical industry, which can levy a huge amount of political pressure," says Pauls.

The same goes for numerous large countries, including the United States, the United Kingdom, Germany, France and Australia - where PHARMAC often sources pharmaceuticals from.

"We all sit in our own political economies; they've ended up in a different place from us," notes founding PHARMAC general manager, David Moore.

"The only group that has been able to be as effective as PHARMAC is the Veterans Affairs in America, where they directly purchase their pharmaceuticals; they are very clever about it."

Throughout its history, PHARMAC has been active on the international stage, sharing insights into its processes.

"We set up a sovereign buyers' club back in 1995, an opportunity to get together with the Canadians, and invite the Australians over. In those days, pharmaco-economics was a new word and there was a lot of co-development of approaches," says Moore.

Pauls remembers the frosty reception he often received from pharmaceutical company representatives at international conferences.

"The looks I got were not amusing. The pharmaceutical industry was very much afraid that this contagion would spread."

"The main lesson from PHARMAC for other systems is that it is possible to manage drug spending within a public budget while improving access to subsidised medicines," wrote Jacqueline Cummings and colleagues from Victoria University, Wellington, in the *British Medical Journal* in June 2010, mirroring independent commentary in journals around the world drawing attention

to PHARMAC's impressive track record.

But the authors noted that the PHARMAC model had attracted valid criticism.

Some wonder at PHARMAC's exemption from the Commerce Act, which effectively allows it to engage in activity that would be considered anti-competitive in the private sector. Changes in

reference-priced drugs have often seen large numbers of patients forced to change their medication and there is also criticism that New Zealand patients miss out on early access to innovative drugs.

But no system is perfect and PHARMAC is widely regarded as having struck a good balance, while faced with numerous constraints.

"PHARMAC's utilitarian approach of providing the greatest good for the greatest number within its budget has worked well," concludes Gauld in *PharmacoEconomics*, "with the caveat that some New Zealanders miss out on or have delayed access to medicines available in other countries."

The aspect of PHARMAC's success that people speak of most admirably, is its ability to continue with its model intact, through changes in government.

"Look around the world. Who has been able to replicate it? Nobody. It is just too contentious," says former chief executive Steffan Crausaz.

"If we lose it, we will never get it back again."

*"We were in the right place at the right time, in a political environment where we could do it."*

– Reinhard Pauls

# 2015

- Factors for Consideration launched
- Shane Bradbrook becomes chair of the Consumer Advisory Committee.
- Hospital medical devices line items on the Schedule exceed 10,000.
- First market share contracts are negotiated for hospital medical devices.
- PHARMAC publishes 'Mind the Gap' analysis, comparing cancer medicines funded in Australia with New Zealand.
- Largest multi-product agreement is reached, with Novartis, for 16 products.



Shane Bradbrook

# TRADE WINDS

With the vast majority of New Zealand's pharmaceuticals coming from overseas suppliers, access to medicines and the prices we pay for them are inevitably drawn up into larger issues of global trade.

So it was in 2011 when negotiation of the Trans-Pacific Partnership Agreement (TPP), a trade liberalisation deal between 12 Pacific-rim countries which had been in the works for years, began generating significant public debate.

The TPP would grant New Zealand tariff reductions on major export commodities and more favourable market access to countries including the United States, Canada, Japan and Singapore. But as the name implied, there would be some trade-offs to ensure the deal worked for all member countries.

The trade negotiations were confidential, but leaked texts of the agreement, in particular the 'health annex' section of the documents, suggested that treatment of pharmaceuticals across member countries would become a bargaining chip in negotiations.

In particular, a mooted five-year extension to drug patents outlined in some of the documents looked to have serious implications for PHARMAC, which relied on access to out-of-patent generic drugs to cost-effectively meet the needs of New Zealand medicines users.

But as the debate gathered intensity, fears emerged that the PHARMAC model itself may also be under threat, with the United States in particular considered likely to lobby for it to be dismantled to secure better terms for its pharmaceutical companies.

The headlines made disturbing reading for Carl Burgess and his colleagues on PHARMAC's Pharmacology and Therapeutics Advisory Committee.

"The concern was that they'd make a deal where PHARMAC basically wouldn't be able to exist," he says.

"Funding of generics would vanish almost overnight; there'd be more ability for American companies to take the government to court about the pricing of drugs. The price of drugs, eventually, would rise."

These concerns lingered through the following few years as diplomats shuttled around the world for successive rounds of TPP, negotiations and more leaked documents emerged.

Prime Minister John Key had admitted that drug patents could be extended under the TPP leading to higher costs in accessing medicines for the government, but publicly vowed to protect the PHARMAC model of drug funding. The opposition Labour Party listed PHARMAC's continuation unimpeded as a condition of its support of the TPP.

Watching events from afar in Canada, where he was now working in the health sector, former PHARMAC chief executive Matthew Brougham was kept up to date on trade developments by friends and former colleagues.

One day he was forwarded a news clipping with the headline: 'Hands off our PHARMAC!'

"There was a groundswell of opinion from New Zealanders that they didn't want what PHARMAC did to be compromised by trading rights that were being negotiated," he says.

While the public feared losing access to affordable medicines, those in the health sector knew well the impact trade-related changes could have on frontline health care.

*"It made me realise we'd come a long way from the days when we were having dust ups with everybody."*

– Matthew Brougham

"The staunchest advocate for this position was the medical profession," says Brougham.

"It made me realise we'd come a long way from the days when we were having dust-ups with everybody."

By 2016, the TPP negotiations were coming to a conclusion. But the election of President Trump that November would throw plans into disarray. The United

States withdrew from the agreement which was swiftly redrafted and agreed between the remaining 11 partner countries as the Comprehensive and Progressive Trans-Pacific Partnership (CPTPP).

Crucially, the much-feared patent term extensions on the table during the TPP talks were not included in the new deal which went into effect in 2017. New Zealand's maximum patent term would remain a non-extendible 20 years.

"The CPTPP will not change the PHARMAC model or its ability to negotiate the best price for medicines for New Zealanders," the Ministry of Foreign Affairs and Trade noted in March 2017, in an explainer on the implications of the new trade agreement.

"Provisions in the TPP that would have required Pharmac to make administrative changes primarily of benefit to the pharmaceutical industry have been suspended in the CPTPP"

In the end, despite years of uncertainty and heated public discussion of PHARMAC's future, it continued to be business as usual for the agency. However, international trade remains a live issue and very relevant to PHARMAC's operations as the agency weathers global forces to deliver the widest possible range of medicines and devices to New Zealanders at cost-effective prices.

# 2016

- Prime Minister John Key announces a \$124 million boost over four years for CPB.
- PHARMAC begins using the Factors for Consideration for its decision-making.
- David Lui becomes chair of the Consumer Advisory Committee.
- Nationwide series of fono is held to consult on a revised Pacific Responsiveness Strategy.
- Research funding partnership is reached with the Health Research Council.
- PHARMAC Tender moves to electronic on-line system.
- Prof Mark Weatherall is appointed Chair of PTAC.



*David Lui*



*Mark Weatherall*

# CHALLENGES AHEAD

The forces that have shaped PHARMAC over the last 25 years - huge demand for medicines on constrained budgets, rapidly evolving technology and the economics of the global medicines market - will greatly influence its next 25 years too.

Nowhere is the challenge of balancing these three factors more obvious than in the area of medical devices, where PHARMAC is responsible for securing access to an increasingly broad range of devices for use in public hospitals.

"PHARMAC is in its infancy in regards to devices," says Carl Burgess, former chair of PHARMAC's Pharmacology and Therapeutics Advisory Committee.

"It is going to take them time and it is not going to be easy because of the differences in hospitals use of devices."

Convergence of drug and device technology will also require new approaches from PHARMAC, says founding general manager, David Moore.

"The next challenge is where pharmaceuticals start to integrate with medical devices and in turn how medical devices integrate with information technology," he says.

The era of personalised medicine, the move away from a 'one size fits all' approach to treatment and care of patients with a particular condition would usher in many promising new treatments for diseases like cancer, he says.

"Cancer drugs are now a huge part of the Pharmaceutical Schedule and there will be more of them. You are increasingly seeing them linked to biomarkers - personalised medicine."

Dealing with innovative new treatments is nothing new for PHARMAC. In the last decade it has adapted to accommodate a growing number of biologic medicines, which are made from living yeasts, bacteria or animal cells and are used in insulin to treat diabetes, hormones and drugs for cancer, arthritis and a range of auto-immune disorders.

"They are not like the old chemical entities," says Moore. "They'll take more personalisation."

Former PTAC member Sharon Kletchko, says the nature of research in medicines and new treatments is changing, with more international collaboration that could have implications for how medicines come to market in future.

"All of the ground work in biological research, genetic research, proteomics is being looked at through a public health lens. Data has become a free public good internationally," she says.

Pharmaceutical companies would still play a major role in developing drugs, but the market power they have in future, as an array of new treatments emerge, is uncertain.

"We are entering into a world where value per dollar invested is going to be much more real," predicts Kletchko.

"Nobody is afraid of paying the true cost with a return. But the return has to be a just return."

New treatments won't lessen the key challenge of getting people to engage with their own healthcare," says PHARMAC's former medical director, Peter Moodie.

"It's tempting to think that medicine will solve everything and that's just not the truth."

He points to the treatment of diabetes, the largest and fastest growing health issue the country faces.

"What becomes obvious is that the new pharmaceuticals aren't the question. It is getting people to understand what their disease is and using the pharmaceutical efficiently," says Moodie.

That would mean that PHARMAC's advocacy and education programmes would have to evolve and become more sophisticated to meet the changing needs of consumers and community health providers.

"There are new methods of helping patients overcome problems they may have and it is more than just drugs," agrees former PHARMAC Board chair Richard Waddell.

All agree that a fundamental challenge will be keeping the successful model of the last 25 years intact to face the next quarter century of delivering subsidised medical treatments to New Zealanders.

"My hope for PHARMAC would be that it keeps its integrity as an honest broker of the tension between getting the right access to medicines, vaccines and medical devices and the need to not be ripped off," says former chief executive Steffan Crausaz.

"There's huge potential scope for that."



# 2017

- PHARMAC publishes new strategy, including three Bold Goals.
- Steffan Crausaz resigns as chief executive; replaced by Sarah Fitt.
- Chickenpox and shingles vaccines are added to the National Immunisation Schedule.
- Refreshed Pacific Responsiveness Strategy is launched.
- Over a 10-year timeframe, cumulative savings from PHARMAC's CPB work are \$6 billion.

# 2018

- PHARMAC begins budget management of all hospital medicines from July
- PHARMAC celebrates its 25th year



1993   2018

**PHARMAC**  
Pharmaceutical Management Agency

A 25 YEAR HISTORY

# 25 YEARS ON - A SECURE LEGACY

Some of PHARMAC's founders admit that they never expected the agency to have a long lifespan.

"Your average government department doesn't last as long as this," says Reinhard Pauls.

"PHARMAC is the only piece of the health reforms of 1993 that is still standing and going stronger than ever."

Each small victory, whether over the negotiating table or at the High Court, built on the other, to cement the stable foundation that would allow PHARMAC to go on to deliver over \$6 billion in cumulative savings on pharmaceuticals and medical devices for the people of New Zealand, extending years of life and actually saving many lives in the process.

Karen Poutasi was Director General of Health from 1995 to 2006 and admits to thinking at times that the fledgling agency may be sunk by legal action, politics, public hostility, or a combination of all three.

"Every time a challenge came up, you would get in behind but wonder if PHARMAC could sustain this challenge," she says.

"Each time it did. As time went on I got more and more confident that this little agency in a little country could in fact make this happen."

Throughout its history, PHARMAC has pursued its work with vigour, something former chief executive Matthew Brougham puts down to an unwavering belief in the mission.

"There's nothing that PHARMAC does that the rest of the world doesn't do in some shape or form; it is just that PHARMAC does it relentlessly," says Brougham, who led the agency from 2007 to 2011.

"It has become part of the organisation's DNA to behave like that and consequently it has some of the lowest prices in the world for pharmaceuticals."

The innovative approaches in tendering, reference pricing and contracting delivered incredible results, but Brougham, who was PHARMAC's Manager of Analysis and Assessment before becoming chief executive, never expected such a long run of success in negotiating cheap pharmaceutical prices.

"The tap has got to run out soon," he recalls thinking.

"We've been getting price reductions for 10 or 15 years. But it never happened."

While PHARMAC's staff weathered the highs and lows of litigation, major pharmaceutical deals and high profile advocacy campaigns, Brougham also witnessed the agency's outlook changing as its relationships with consumers, the medical profession and in particular the pharmaceutical companies matured.

"In the past I'd felt litigation was a battle of wills," he says.

"I realised that you can exist in both realms, having an open and decent conversation with people who are at the same time having a very clear dispute with you."

"They've smoothed the rough edges out," agrees former PTAC chair Carl Burgess, who sees a large part of PHARMAC's legacy consisting of its efforts to improve the use of medicines, especially by sections of society particularly impacted by health inequities.

"There's no point writing a whole load of prescriptions if people don't take the medicines," he points out.

*"Each time it did. As time went on I got more and more confident that this little agency in a little country could in fact make this happen."*

– Karen Poutasi

For founding PHARMAC Board member Carolyn Gullery, a 25-year devotion to evidence-based and transparent decision making has underpinned the agency's success.

"It is still a high-trust, open, rigorous process for making decisions about where to spend public money," she says.

"How much more would have been spent on pharmaceuticals without any further gain for the patient population?"

David Moore believes the agency's model is as fit for purpose as the day PHARMAC started in 1993.

"Is it right for the time? Absolutely."

Poutasi agrees.

"PHARMAC is a world-class organisation and it has a lot to offer others," she says.

"We should be very grateful for its contribution to the health of New Zealanders."

For Pauls, helping PHARMAC in its mission in its formative years was a "once in a lifetime" opportunity.

"How often do you get the opportunity to completely restructure a billion dollar industry? I'm quite pleased with what we did."

# PHARMAC

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