

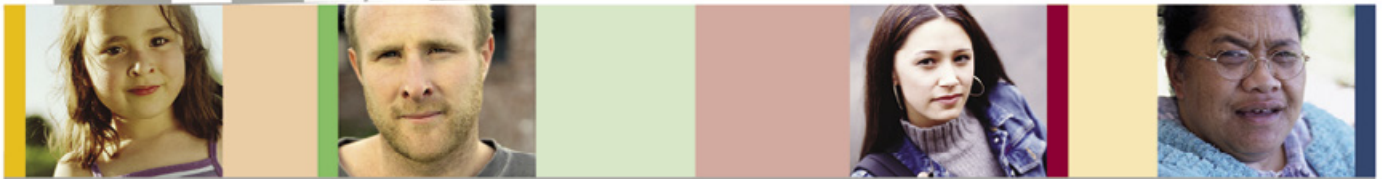
05

ANNUAL REVIEW

# 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



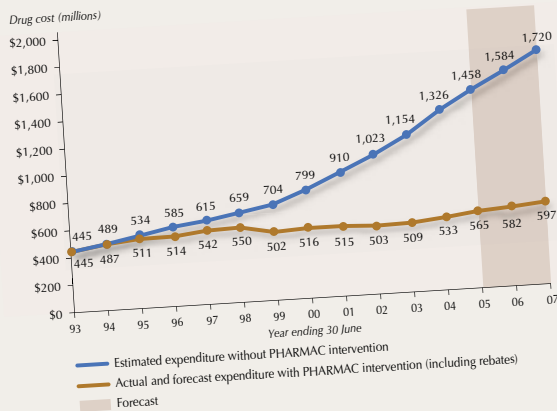
# Highlights/key events of 2004-05

PHARMAC invested in health by providing **new or expanded access** to 25 subsidised treatments

More **funded medicines** for type 2 diabetes, breast cancer, severe pain, HIV/AIDS, hepatitis C, raised cholesterol, raised blood pressure, schizophrenia

## Impact of Pharmac on Drug Expenditure over time

Without PHARMAC's activities (assuming no other price changes would have occurred), the community drug bill in 2005 would have been \$894 million higher than it was.



Nine hui were attended to **report back** on the Maori Responsiveness Strategy

We worked with DHBs and **responded** to their needs around pharmaceutical cancer treatments

We **listen to feedback** we received and responded to it

# Highlights

## In this Review:

- "Year" means year ending 30 June. For example: "this year" means the year ended 30 June 2004; "last year" means the year ended 30 June 2003; "next year" means the year ended 30 June 2005.
- Unless otherwise stated all values are in New Zealand dollars.
- Unless otherwise stated all references to expenditure are unadjusted for any rebates that may be due or paid by suppliers under risk sharing agreements.



Our **One Heart Many Lives** campaign sparked community-led projects in Porirua, Bay of Plenty and West Auckland



We **successfully** met the needs of haemophilia patients and contracted nationally for recombinant factor VIII

The National Heart Foundation adopted our One Heart Many Lives campaign messages for its **2004 Heart Week**



More people continue to **respond** to the annual **Wise Use of Antibiotics** campaign



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# Key events

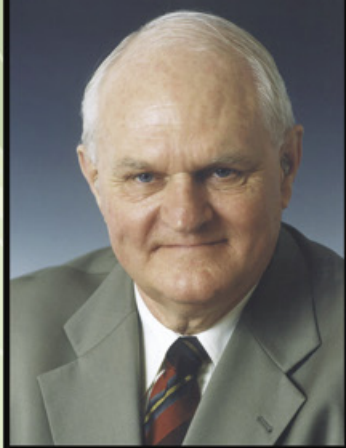
# 04-05





# 2005 has been a year of listening and learning

writes PHARMAC  
Board chairman  
Richard Waddel



**Looking back on 2005, it was a year in which PHARMAC faced a number of challenges, and the responses to these enable the organisation to look forward with confidence.**

It has been a year in which PHARMAC has listened and learned from feedback and experience. PHARMAC has responded to issues around the purchasing of influenza vaccine, and to concerns people had about a new brand of asthma inhaler. Through both these issues PHARMAC and its processes came under public scrutiny and were subject to considerable criticism. The decisions to have more than one supplier of influenza vaccine, and to continue to have two brands of subsidised salbutamol inhaler, illustrate a willingness to adapt policy

to ensure public confidence is maintained. This is a responsible pathway to take.

PHARMAC also listened to feedback from Maori on our Maori Responsiveness Strategy. Early 2005 saw PHARMAC staff and Board members visiting marae around the country to report back on the three-year-old strategy, and to seek advice on areas where we could move forward. It was pleasing to be able to report back to Maori on the progress that has been made, including improving Maori representation on bodies such as the PHARMAC Board, the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Consumer Advisory Committee, and developing programmes that respond to health areas where Maori have specific needs. The information gathered will be used to develop future work in this area, and is information that also assists PHARMAC to develop work to help all New Zealanders in need.

## **Spending on medicines**

The area of PHARMAC's business which continues to gain the most public attention, and which is also regarded as the core of PHARMAC's operations, is management of the community Pharmaceutical Schedule. During the year PHARMAC added a further

nine products to the Schedule, and widened access to 16 others. This is a good outcome, and consistent with PHARMAC's aim to continue providing New Zealanders with access to new medicines, and to widen access to those that are already subsidised.

In order to perform this subsidy role it is necessary to have continued increases in the pharmaceutical budget, and it is pleasing that we continue to be able to agree realistic forward-looking budgetary paths with District Health Boards, whose funds PHARMAC is responsible for managing.

Pharmaceutical spending was in line with the budget in 2005. The actual spend was \$564.6 million compared to the budget of \$565 million. As PHARMAC does not hold the funding but estimates spending on behalf of DHBs, this is an outstanding result.

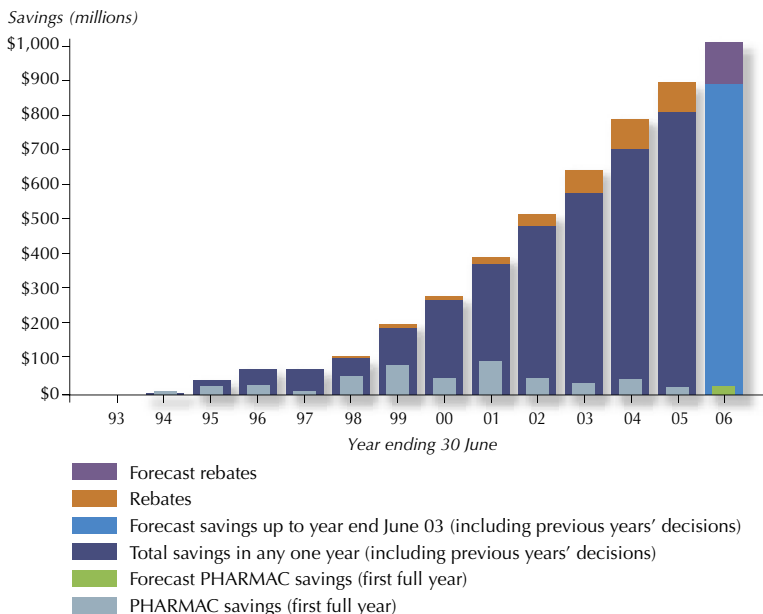
## **Assisting DHBs**

Another pleasing aspect of the year has been the work that has continued to be undertaken to develop areas where PHARMAC can assist DHBs to manage spending. In 2005 PHARMAC took over the purchasing of recombinant factor VIII, a product used to treat haemophilia. Again, PHARMAC listened to the



## Impact of PHARMAC decisions – savings and rebates

Cumulative savings, and rebates, achieved as a result of PHARMAC decisions.



feedback that was received and this helped produce a positive outcome for all concerned. Patients and clinicians are able to continue using their product of choice, while \$31 million will be saved over the next five years. PHARMAC also continued to circulate discussion documents on the economic analysis of new pharmaceuticals, and to develop its role in purchasing medicines used in DHB hospitals.

The past year also saw publication of the Auditor-General's report on the return to all-at-once dispensing. The Auditor-General agreed with PHARMAC that considerable savings are being achieved by the policy change.

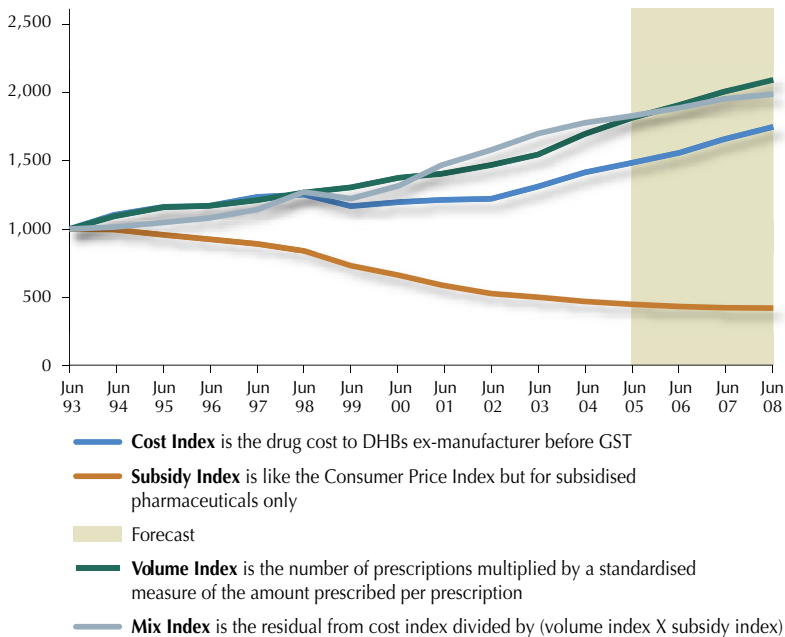
There were no changes at Board level during the year, and the continuity of membership has helped to provide a consistent approach to decision-making. I am grateful for the continued support and contributions of my fellow Board members.

Finally I want to pay tribute to Wayne McNee and the team at PHARMAC, for their continued dedication during a sometimes difficult, but ultimately rewarding year.

## Subsidy, volume, mix and cost indices

Four-quarterly moving averages

Base: four quarters ending June 1993 = 1,000.





**People love to know what's going on within PHARMAC and they aren't shy to ask.**

Wherever possible we are happy to tell people what we are doing, and how we are doing it. As a government agency, PHARMAC is ultimately accountable to the people of New Zealand. We are acutely aware that it is taxpayers' money that we are responsible for, so we're careful to ensure that it's spent in the best way possible.

It's human nature to be curious about the work that goes on. We welcome queries from people and groups and try as much as we can to let them know what is happening.

We fully support principles of transparency in our work and encourage others to do the same. It is a bit of a balancing act, though, and we have to be continually aware that much of the information we hold may be commercially sensitive, or subject to privacy laws. PHARMAC operates in a commercial environment where, in order to make its assessments and decisions, it is privy to a large amount of commercially sensitive information and has to be careful not to disclose this to third parties.

*"We fully support principles of transparency in our work and encourage others to do the same"*

Of course, any public organisation that is subject to the Official Information Act (as PHARMAC is) has nothing to gain by trying to withhold information that the Act could compel them to release. But we have gone further and published a range of documentation that enables people to look into

how PHARMAC undertakes its assessments and prioritising of pharmaceuticals.

PHARMAC's website now plays a key role in informing people about our work. When we upgraded the website in 2002 we made the decision to publish a number of new items on it. This had been requested by a number of groups as a way in which people could look more closely at what PHARMAC does and better understand the processes that take place.

Publishing documents such as minutes of the Pharmacology and Therapeutics Advisory Committee (PTAC), drug funding applications and minutes of the Consumer Advisory Committee (CAC) on the website provide a valuable window into PHARMAC's operations. Over the years there has been an effort to make public all the documents outlining our processes and to help people understand what PHARMAC does and how it does it. This has been in line with requests from organisations such as pharmaceutical companies who have urged PHARMAC to make more information available, to publish more, to be even more transparent in its business practices.

This is something we take into account when publishing the PTAC minutes. We give companies who have made applications to PTAC the chance to comment on draft minutes before they are published. This avoids commercially sensitive information being released inadvertently, while still enabling people to see what PTAC has recommended.

PHARMAC also has an open media policy and staff make regular presentations to a range of groups including District Health Board boards, to conferences and medical students. These are open forums where our aim is to help people have a better understanding of the work PHARMAC does.





## PHARMAC's transparency

- 2000: Reviewed Operating Policies and Procedures, which were then independently reviewed by Caygill/Lexchin. Consultation takes place on virtually every decision, PHARMAC also interacts more frequently with consumers
- Consumers involved in the PHARMAC process through consultation, CAC, 0800 number, website
- Website upgraded to include funding applications, PTAC minutes, CAC minutes, OPPs and other operational documents
- PHARMAC subject to Official Information Act
- Details of PHARMAC's activities published and publicised (Statement of Intent, Annual Reports, Annual Review)
- Answerable and accountable to New Zealanders, directly through the Minister of Health



work, writes Chief Executive Wayne McNe

This year we also reviewed our Operating Policies and Procedures, the document which sets out how PHARMAC operates. Again, making this document publicly available and giving people the chance to comment on our framework enhances our transparency. The OPPs were reviewed last in 2000, and were then subject to independent review. We asked interested groups for their feedback on proposed changes, and some groups made detailed submissions. We thought it would be a good idea to go back to people with some of the responses that were put forward and work with them on any proposed changes. This process was ongoing by year-end.

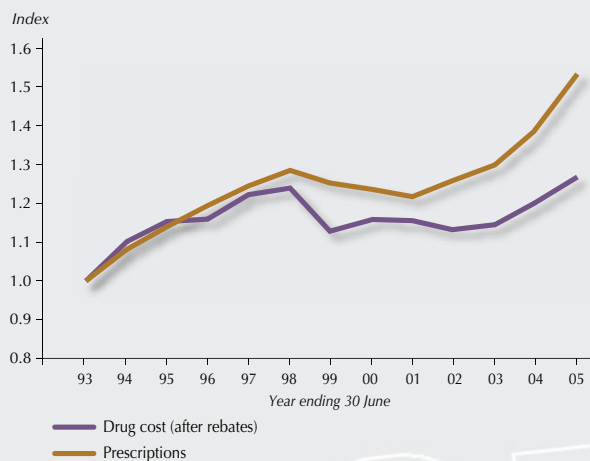
The PHARMAC Consumer Advisory Committee (CAC) raised the issue of transparency and disclosure of funding in the past year, when it asked for feedback on a discussion document it developed on New Zealand consumer health organisations receiving support from the health industry. Over 70 responses were received, and most groups agree with the principles of transparency and disclose where their funding has come from. Many already have policies in place, and some made these available as resources to share.

We think it is healthy for such a discussion to be occurring, and support the Committee's role in fostering debate. The number of responses received shows this is an issue of considerable interest.

During the past year PHARMAC has continued to focus on investing in new medicines. In all, we estimate that our 2004-05 investments saw 6721 new patients treated with subsidised medicines during the year. Some of these investments, such as tiotropium, have the capacity to reduce costs in other areas of health expenditure (such as hospitalisations). And this number of new patients will grow in future years, as more patients take the medicines that have been funded.

## Prescriptions vs expenditure

*The number of prescriptions (patients) has risen at a faster rate than expenditure over the last two years in particular. This illustrates that while expenditure is rising, pharmaceutical use (prescribing) is growing at a faster rate.*



### Key investments included:

- Pioglitazone – a new treatment for type 2 diabetes.
- Tiotropium – an inhaled drug for the treatment of chronic obstructive pulmonary disease (COPD).
- Ezetemibe – the first of a new class of medicines called cholesterol absorption blockers.
- Letrozole – a hormonal treatment (an aromatase inhibitor) for breast cancer.
- Olanzapine – a treatment for mental illness.
- Pegylated interferon alpha-2a – a treatment for chronic hepatitis C.
- Fentanyl patches – a treatment for severe long-standing pain.

Even with all this new spending we still managed to keep pharmaceutical expenditure within budget, an excellent result all round.



# Ensuring nationally-consistent access to new pharmaceutical cancer treatments is the aim



## writes Medical Director Dr Peter Moodie

Over the last two years PHARMAC has become increasingly involved in the assessment and management of medicines for the treatment of cancer (oncology). In times gone by the only oncology drugs listed on the Pharmaceutical Schedule were those used (and prescribed) in the community; with the rest purchased by hospitals from their own budgets and administered to patients in a hospital setting.

However, times have changed for two reasons; the first is that an increasing number of oncology drugs are now prescribed in tablet form (tamoxifen and aromatase inhibitors for breast cancer and imatinib for chronic myeloid leukaemia are some examples). A further and specific example is the replacement of an in-hospital infusion called 5 fluoro uracil (5FU) with a tablet called capecitabine.

This change in emphasis highlights the changing face of medicine as well as the reality that both hospital and community budgets all come from the same Vote Health "pot" and there

will, as with the change from 5FU to capecitabine, need to be flexibility with the funding source.

The second reason oncology drugs have moved increasingly to PHARMAC's responsibility was because we were developing what the British call "post code prescribing". Although the Pharmaceutical Schedule is nationally consistent (if the drug is on the Schedule it is available to all eligible citizens wherever they are in the country), in the case of some expensive oncology drugs used in hospitals, access depended on what the purchasing policy of the hospital was. Hospital A might fund it while hospital B didn't; in other words it depended on where you lived or what your "post code" was.

In 2001 the Minister of Health directed all DHB hospitals to fund a set list of oncology drugs – this list is known as the cancer treatments "basket". This ensures that the same hospital oncology drugs are available to all New Zealanders. Under the proposal that PHARMAC is currently working on,

this equity of access will be supplemented by a consistent national evaluation process with significant input from clinical oncologists. This evaluation process is already underway with a PHARMAC recommendation to DHBs enabling wider access to rituximab for non-Hodgkins lymphoma.

The ultimate outcome is that we will have a clear and efficient process for assessing, prioritising and allocating funding for new pharmaceutical cancer treatments.

Although this is undoubtedly a sensible move it is already bringing into sharp focus two issues. The first is that the newer oncology drugs are often extremely expensive; often in the range (and sometimes greater than) \$50,000 per year per patient. A new treatment for a type of brain cancer (temozolomide) or another for breast cancer (trastuzumab) are examples. If we are to make these treatments available then it is essential that we budget for them, or make savings in other areas.



How we make those  
hard decisions  
needs to be transparent.

of a process **PHARMAC** is involved in

The second and more important issue is that these drugs will force us to come to wise decisions about where our priorities lie. Although we may have our views about the science of economics, it is simply put, an attempt to allocate scarce resources in a fair way. If we have to choose, let's do it in a way everyone can understand.

It is easy and natural for us to advocate for individual patients who may benefit from high cost treatments; however we tread a dangerous path if that is how we start to make prioritisation decisions. For every patient who is treated as an exception there are others who will miss out. Although it is quite possible that an individual case will identify a principle upon which funding should be made available the arguments for funding should be principled and generalisable<sup>1</sup>.

Prioritisation and the funding of expensive therapies will ultimately be based on value judgements, but the reasoning behind those judgements needs to be as transparent as possible. It is an area where economic theory, scientific evidence and an understanding

of our own value systems need to come together.

At the end of the day everyone should be able to understand the reasoning behind a decision and regard it as fair, even if they don't like the outcome.

### The Top 20 Expenditure Groups

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

Drug Type	Year Ending 30 June				
	Jun-05	Jun-04	Jun-03	Jun-02	Jun-01
Anti-ulcerants	<b>\$68.6</b>	\$64.0	\$52.2	\$44.1	\$42.7
Lipid Modifying Agents	<b>\$60.8</b>	\$55.0	\$46.1	\$40.5	\$44.8
Antipsychotics	<b>\$48.5</b>	\$45.2	\$40.9	\$36.7	\$30.1
Agents Affecting the Renin-Angiotensin System	<b>\$29.1</b>	\$28.4	\$23.0	\$21.4	\$27.2
Immunosuppressants	<b>\$27.8</b>	\$19.7	\$18.1	\$16.1	\$15.7
Antidepressants	<b>\$27.3</b>	\$27.6	\$32.8	\$28.1	\$25.0
Anti-Epilepsy Drugs	<b>\$21.4</b>	\$20.7	\$19.0	\$17.5	\$16.0
Diabetes	<b>\$20.6</b>	\$19.2	\$19.0	\$18.6	\$17.1
Diabetes Management	<b>\$19.5</b>	\$19.8	\$19.4	\$18.1	\$16.2
Inhaled Beta-adrenoceptor Agonists – Long Acting Inhalers	<b>\$18.6</b>	\$14.3	\$10.0	\$6.0	\$4.2
Beta Adrenoceptor Blockers	<b>\$17.6</b>	\$11.5	\$9.2	\$8.0	\$8.0
Inhaled Corticosteroids – Metered Dose Inhalers	<b>\$14.5</b>	\$14.9	\$20.7	\$21.9	\$18.7
Analgesics	<b>\$14.2</b>	\$16.2	\$16.5	\$15.6	\$14.4
Antibacterials	<b>\$13.9</b>	\$13.1	\$14.6	\$15.4	\$16.2
Calcium Channel Blockers	<b>\$13.0</b>	\$16.4	\$13.8	\$13.9	\$15.6
Antimigraine Preparations	<b>\$12.4</b>	\$12.2	\$11.2	\$10.5	\$9.6
Chemotherapeutic Agents	<b>\$11.3</b>	\$10.9	\$5.1	\$1.1	\$1.2
Trophic Hormones	<b>\$10.8</b>	\$9.6	\$8.5	\$7.7	\$7.2
Calcium Homeostasis	<b>\$9.8</b>	\$8.3	\$7.7	\$5.7	\$4.1
Antianaemics	<b>\$9.2</b>	\$7.0	\$4.1	\$4.8	\$4.4

<sup>1</sup> Burls A, Austin D, Moore D. Commissioning for rare diseases: a view from the frontline. *BMJ* 2005;331:1019–1021.

# The Influence of the DRUG INDUSTRY: a British view

A report from British parliamentarians calls for greater transparency from industry



Richard Smith is Chief Executive of UnitedHealth Europe, London. He was an editor for the *BMJ* for 25 years. For the last 13 of those years, he was the editor and chief executive of the *BMJ* Publishing Group, responsible for the profits of not only the *BMJ* but of the whole group, which published some 25 other journals. He stepped down in July 2004.

## writes Dr Richard Smith

Britain's House of Commons Health Committee has recommended a fundamental realignment of the relationships between the pharmaceutical industry and government, regulators, doctors, the health service, and patients. The committee said that the industry has interdigitated itself into every aspect of health, and that government and others, including doctors, have taken the easy route of assuming that the interests of the industry and of the health services and patients are the same.

The committee's report makes clear that reducing the influence of the industry would be good for everybody, including—paradoxically—the industry itself, which could concentrate on developing new drugs rather than corrupting doctors, patient organisations, and others. Says the report: "We need an industry which is led by the values of its scientists not those of its marketing force."

The Health Committee chose to examine the influence of the drug industry because of increasing public concern that it is excessive. The committee was particularly worried by the industry's role in promoting "medicalisation" (the idea of a pill for every ill). The committee was also worried by the high prevalence of drug side effects. It heard representatives of the drug companies, patients, doctors, medical journal editors, critics of the industry, and government ministers and officials.

The government does not have to accept the recommendations from select committees, and most of the 48 recommendations made by the committee will probably be ignored. The industry is powerful as it is Britain's third most profitable economic activity (after tourism and finance) and employs 83,000 people.

In the end, the report will probably be less important for its recommendations than for having brought the important debate over the excessive influence of the industry to a broader public.

### **The All Pervasive and Persistent Influence of the Industry**

Although the pharmaceutical industry is now perceived by the public as putting profits ahead of patients' wellbeing the industry is, as the committee makes clear, a force for good. Almost all of the drugs that have transformed medicine in the past half century have been developed and manufactured by the industry.

It's also shallow thinking to see the industry as corrupters and doctors as the corrupted. As a doctor, I think that doctors are in many ways more to blame for the debased relationship between them and the industry. The industry is (mostly) behaving in ways that are "normal" within the commercial sector. It is the doctors who have departed from their ethical base when they insist on first class fares and lavish entertainment from the industry in order to attend an international conference.

The fundamental problem, says the committee, is that the industry's influence is too pervasive. Regulatory authorities, it says, are too close to the industry, meaning that they do not ensure that the industry works in the public interest. The clinical trials that are the essential evidence base for regulatory and clinical decisions are produced almost entirely by the industry, and the evidence that reaches authorities, doctors, and patients is biased. Guidelines for treating patients are distorted not only because they must be based on biased evidence but also because the organisations and people producing them will often be in hoc to the industry.

## Some Highlights

- The process of licensing drugs and the medicines' regulatory system should both be more transparent
- There should be an independent register of clinical trials
- Clinical trials should focus on using health outcomes that are relevant to patients
- More research should be undertaken into the adverse effects of drugs and the costs of drug induced illness
- The regulator should ensure greater restraint in medicines' promotion
- Tougher restriction should be placed on the prescribing of non-specialists
- Doctors should be required to declare significant sums or gifts they receive as hospitality
- The sponsorship of the drug industry should pass from the Department of Health to the Department of Trade and Industry-because the secretary of state for health cannot serve two masters (the public and the industry)

Marketing has also become ever more important for the industry. Britain has some 8000 drug company representatives, but the industry also spends millions on advertising, sponsorship, meetings, and increasingly "medical education," which often means a fine dinner and a lecture from a captive "key opinion leader" (KOL).

The report states: "Coupled with company-sponsored information from medical journals and supplements, 'medical education' materials, advertisements and sponsorship to attend conferences, workshops and other events, it is little wonder that prescribing practices are affected."

Individual journalists are also captured, and perhaps most troublesome is the way that patient organisations have become so dependent on the industry.

The consequences of all of these incestuous relationships, says the committee, are bad decisions on the regulation and prescribing of drugs, over-reliance on drugs rather than other interventions (such as dietary change, exercise, or counselling), and "medicalisation" of life's problems, including baldness, shyness, unhappiness, grief, and sexual difficulties.

### **Recommendations: "Let The Sun Shine In"**

The committee's main response to the problems it identifies is transparency – "let the sun shine in." It recommends that there be a clinical trials register "maintained by an independent body" and containing full information. Companies should be required to put the information on the register "at launch as a condition of the marketing licence." The committee also wants regulatory authorities and ethics committees to help with the design of trials to make sure that they are answering real questions. It didn't, however, recommend more public funding of trials. I believe that such funding is necessary in order to ensure that trials are

addressing the most important questions—including head to head comparisons and trials of new drugs against older drugs and non-drug treatments.

There should be, says the committee, limits on the quantity of marketing materials, particularly in the first six months after launch, and stricter controls on marketing to junior doctors, nurses, and pharmacists.

Regulatory bodies should distance themselves from the industry, and the health committee would like to see an independent review of the Medicines and Healthcare products regulatory Agency (MHRA) plus a public inquiry every time a drug is withdrawn from the market on health grounds. It's hard to see the government implementing these recommendations as inquiries are expensive and always create difficulties for government, but if bodies like MHRA and the National Institute for Clinical Excellence (NICE) are to maintain public confidence they will have to distance themselves from the industry – and be seen to do so.

Doctors' organisations, says the committee, should produce publicly available registers of doctors' links with industry. These registers – I suggest but the committee didn't – should include information on amounts of money. Otherwise, it will not be possible to separate the KOLs from the vast numbers of doctors who receive pens, lunches, trips, and other gifts from the industry. I doubt very much that doctors' organisations will adopt these recommendations until forced to do so.

The committee also wants patients' organisations to declare their connections with industry and to make clear when ubiquitous "disease awareness" campaigns are funded by industry, which is probably very common. I agree with this support for transparency, and while recognising the penury of many patients' organisations they would do well to resist the lucre of the industry as much as they can.





# Advisory committees

**Advisory committees are a considerable resource for PHARMAC to tap into and their recommendations and advice are the foundation upon which decisions are built.**

## **Pharmacology and Therapeutics Advisory Committee (PTAC)**

PTAC continued its regular sequence of quarterly meetings under the chairmanship of Wellington medical school professor Carl Burgess. The number of new medicines listed, and revisions to patient access, saw PTAC regularly asked for its recommendations on medicines, for its view on alterations to Special Authority criteria, and whether targeting was necessary in some cases. PTAC was also asked for its view on issues raised around the sole supply of salbutamol asthma inhalers (Salamol/Ventolin).

The membership of PTAC and its sub-committees remained unchanged throughout the year, with some members' terms coming up for renewal and membership being continued. The diabetes sub-committee provided input to the review of blood glucose test strip prescribing. The committee provided expert advice on the appropriate frequency of blood sugar level testing and was able to identify sub-groups for whom more

frequent testing was appropriate. This helped PHARMAC to form rules for patients to have access to subsidised test strips.

A review undertaken by a transplant immunosuppressant sub-committee produced advice that enabled PHARMAC to put together a proposal for increasing access to transplant medicines.

The Cancer Treatments sub-committee (CaTSOP) played a lead role in a review of the cancer treatments "basket" funded by DHB hospitals. This was part of PHARMAC's early work in looking at a proposal to manage funding of pharmaceutical cancer treatments on behalf of DHBs. CaTSOP was able to identify medicines in the basket that access could be widened to, and to some products that could be removed as they were not primarily used to treat cancer. This work is ongoing as PHARMAC has agreed a two-year timeframe with DHBs for taking on funding of pharmaceutical cancer treatments (see P 23).

## **Consumer Advisory Committee**

Two new members joined the Consumer Advisory Committee (CAC) in 2004-05. Te Aniwa Tutara (Ngati Whatua) and Heather Thomson (Ngatia Paeakau/Te Whanau a Apanui) add considerable knowledge and experience to the committee and bring overall membership to nine.

The committee held three face-to-face meetings during the financial year and provided advice on a number of issues, including hormone replacement therapy (HRT) and the prescribing of SSRI antidepressants, medicines which had been the source of safety concerns internationally.

The CAC developed and sought feedback on a discussion document, Health Industry Sponsorship of Consumer Health Organisations. The committee received 71 responses from a range of groups, including national and regional consumer groups, professional associations, DHBs and the pharmaceutical industry. The CAC was using this feedback to guide its next steps.

## **PTAC's purpose and structure**

### **Independent, expert evaluation and advice**

The primary purpose of the Pharmacology and Therapeutics Advisory Committee (PTAC) is to provide PHARMAC with independent objective advice on pharmaceuticals and their benefits including the pharmacological and therapeutic consequences of proposed amendments to the Pharmaceutical Schedule.

PTAC is a committee of vocationally registered medical practitioners nominated by professional bodies and appointed by the Director-General of Health.

PTAC's work includes considering and making recommendations on the medical implications of:

- all significant applications by pharmaceutical companies and/or clinicians for inclusion on the Pharmaceutical Schedule, or amendment to it where there are clinical issues to consider;
- requests by PHARMAC for de-listing;
- the management of the Schedule; and
- the need for reviews of specific pharmaceuticals or groups of pharmaceuticals.

PTAC has a generalist focus, but increasingly it seeks advice from known experts in their field, often via its sub-committees.

PTAC members and those co-opted to sub-committees are paid an hourly rate plus expenses for attendance at meetings and time spent preparing for meetings. PTAC meetings are usually held in Wellington four times a year. Sub-committees are convened as and when required.

## **Hospital Pharmaceuticals Advisory Committee**

PHARMAC sought nominations to form a new Hospital Pharmaceutical Advisory Committee and a commercial sub-committee. The PHARMAC Board appointed eight members to HPAC, and five members to the commercial subcommittee, these members are drawn from nine DHBs and represent the interests of all DHBs. HPAC provides advice on the national hospital pharmaceutical strategy and the impact of national contracts on DHBs as a whole, while the role of the commercial sub-committee is to provide advice on the financial impact to DHBs of proposed national contracts.

# Therapeutic Group REVIEW

2005 in focus



During 2005 there was a significant increase in the number of subsidised prescriptions, which rose to 27.08 million. This is a **10.7% rise** on previous years, more than double the average increase from previous years.

This increase in prescriptions shows that an even greater number of people are now having their medicines subsidised by the Government.

The jump in 2005 reflects both the impact of low-cost Primary Healthcare Organisations, and underlying growth in pharmaceutical prescribing. More prescriptions are being funded by the taxpayer because co-payments (the proportion of the prescription cost paid by the patient) have been reduced.

### New spending

The biggest single investment made during the year involved tiotropium (Spiriva), a long-acting inhaler which has been subsidised for patients with the group of respiratory illnesses known as Chronic Obstructive Pulmonary Disease (COPD). This

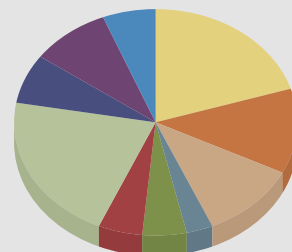
is an investment in the region of \$33 million over five years.

In all, PHARMAC has added nine new products to the Schedule, including treatments for HIV/AIDS, Type 2 diabetes, severe pain and raised cholesterol.

Key investments included:

- Pioglitazone – a new treatment for type 2 diabetes. This is one of the new generation of diabetes drugs (known as glitazones) which improve the body's ability to use insulin. Initially this treatment was targeted to patients with type 2 diabetes who were unable to use other therapies.
- Tiotropium – an inhaled drug for the treatment of chronic obstructive pulmonary disease (COPD). This respiratory condition affects mainly older

### Investment by Therapeutic Group



- Alimentary tract and metabolism (20%)
- Blood and blood forming organs (12%)
- Cardiovascular system (11%)
- Dermatologicals (3%)
- Hormone preparations – systemic excluding contraceptive hormones (5%)
- Infections – agents for systemic use (5%)
- Nervous system (21%)
- Oncology agents and immunosuppressants (7%)
- Respiratory system and allergies (9%)
- Other (genito-urinary system, musculo-skeletal system, sensory organs, special foods) (6%)

people, and tiotropium (Spiriva) provided advantages over previously-funded treatments for severe forms of the disease. PHARMAC estimates that about 40% of the spending on tiotropium will be offset by savings in other areas of healthcare – a high rate of offset for a pharmaceutical.

- Ezetemibe – the first of a new class of medicines called cholesterol absorption blockers.
- Letrozole – a hormonal treatment (an aromatase inhibitor) for breast cancer. Access was widened to enable letrozole to be funded as a first-line therapy for advanced breast cancer.
- Olanzapine – a treatment for mental illness. Access was widened to enable it to be funded for acute mania in bipolar disorder.
- Pegylated interferon alpha-2a – a treatment for chronic hepatitis C. Access was widened to include patients with other genotypes of Hepatitis C virus.
- Lopinavir with ritonavir – a rescue treatment for HIV/AIDS not responding to conventional antiviral treatments.
- Fentanyl patches – a treatment for severe long-standing pain.

In all, we estimate that nearly 7000 new patients were treated with subsidised medicines through decisions made in the 2004-05 year alone.

### **2005 medicine issues**

The most significant medicine-related issue in 2004-05 concerned an unsubsidised product, Vioxx (rofecoxib), which was withdrawn internationally following concerns that it raised the risk of patients suffering heart

disease. This was a worldwide story, and though Vioxx was subsidised through ACC and sold direct to patients, the impact in New Zealand was softened because of PHARMAC's earlier decision not to subsidise Vioxx or any other drugs in the Cox-2 Inhibitors class. Another Cox-2 Bextra (valdecoxib) was also withdrawn during the year and stronger warnings were issued about the other Cox-2 pain relievers.

The antidepressant class known as selective serotonin reuptake inhibitors (SSRIs) continued to come under scrutiny, with medicine authorities around the world either revising or strengthening safety advice to prescribers about their use, particularly for children and adolescents. This follows further evidence emerging on links between SSRIs and suicidal behaviour.

New advice was issued by the US Food and Drug Administration (FDA), and a full FDA review of SSRIs is underway. The European Medicines Agency has similarly issued warnings on the use of SSRIs. In New Zealand, Medsafe reiterated its message to prescribers that SSRIs are not recommended for under-18s, and only fluoxetine has some evidence of efficacy in that group.

In the UK, the National Institute for Clinical Excellence (NICE) revised its guidance on the use of cholinesterase inhibitors for the treatment of Alzheimer's Disease. These are medicines that PHARMAC has decided not to subsidise although some groups continue to call for public money to be spent on them. A NICE committee reviewed new evidence and came to the same

conclusion as PHARMAC – that these were medicines that were not cost-effective and not recommended in mild to moderate Alzheimer's. This process has not yet concluded.

PHARMAC asked Medsafe to conduct further testing of Salamol (salbutamol) asthma inhalers, after PHARMAC received a number of comments from patients about the inhalers clogging, or not being as effective as Ventolin. Medsafe commissioned testing, and PHARMAC responded to concerns by deferring sole supply of salbutamol for two years, and maintaining Salamol and Ventolin at the same subsidy level. The more expensive Ventolin carries a manufacturer's surcharge.

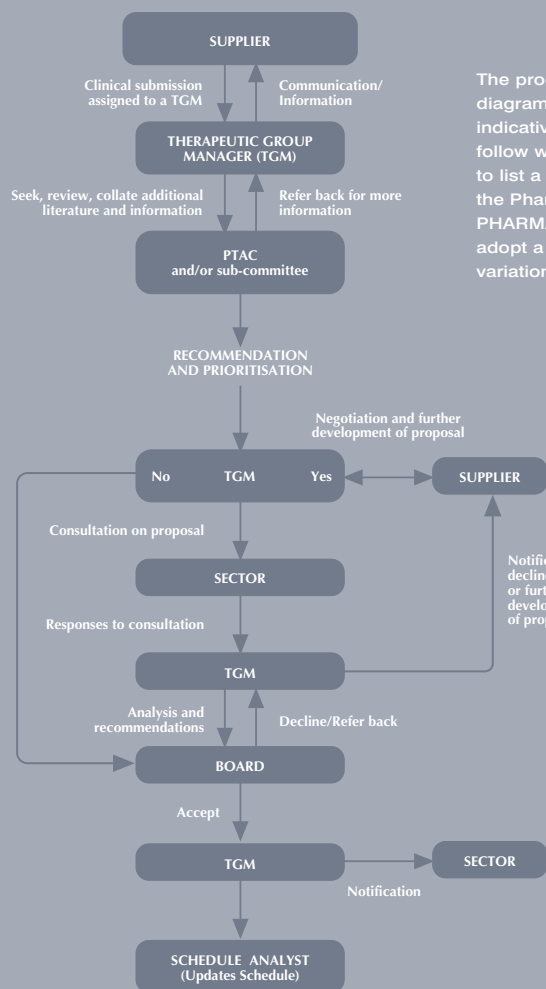
### **Demand Side**

In 2005 the One Heart Many Lives cardiovascular campaign moved into new areas like the Bay of Plenty and West Auckland, and was picked up by the Heart Foundation. And PHARMAC also worked with Environmental Science and Research scientists to highlight the risks of overusing antibiotics, as the Wise Use of Antibiotics campaign entered its ninth year.

PHARMAC and Diabetes NZ also formed a constructive relationship which will develop in the coming years, while mental health is a further area where the Demand Side team will be focusing its efforts in future.



## Process for listing a new pharmaceutical on the Pharmaceutical Schedule



The process set out in the diagram left is intended to be indicative of the process that may follow where a supplier wishes to list a new pharmaceutical on the Pharmaceutical Schedule. PHARMAC may, at its discretion, adopt a different process or variations of this process.

## Top 20 most prescribed medicines

Year ending June 2005

Most commonly prescribed subsidised drugs. Note: This does not include non-subsidised prescriptions (i.e. those paid for by the patient or those where the cost falls under the patient co-payment).

Chemical Name	Prescriptions
Paracetamol	1,362,531
Simvastatin	945,783
Omeprazole	861,652
Amoxicillin	732,711
Amoxicillin Clavulanate	724,440
Salbutamol	616,608
Metoprolol Succinate	496,776
Quinapril	403,191
Fluticasone	402,400
Frusemide	402,220
Cilazapril	369,685
Diclofenac Sodium	365,431
Aspirin	357,105
Prednisone	333,704
Bendrofluazide	327,813
Felodipine	307,620
Zopiclone	296,002
Calcium Carbonate	273,906
Thyroxine	272,149
Flucloxacillin Sodium	271,079

## PHARMAC's Decision Criteria Seeking best health value for the pharmaceutical dollar

PHARMAC seeks to operate in an open, transparent and accountable way. Its reviews and changes to the Pharmaceutical Schedule are governed by its Operating Policies and Procedures – a public document developed in-consultation with the pharmaceutical industry. The document emphasises the importance of basing decisions on the latest research-based clinical information, and it sets out criteria to be taken into account in decisions about the Schedule.

These criteria are:

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

<sup>1</sup> As defined by the Government's then current rules of eligibility.



# Cardiovascular

In November 2004 the National Heart Foundation licensed the artwork and messages from the One Heart Many Lives campaign for its national Heart Week. This was significant support and endorsement of the PHARMAC campaign and reflected the simplicity of its central message. The campaign promotes lifestyle changes such as exercise, diet and reducing smoking to reduce cardiovascular risks, and promotes medications such as cholesterol-lowering statins for people who need them.

An evaluation of the campaign in the Bay of Plenty and Porirua showed that it continues to be successful in raising awareness about cardiovascular disease.

In February 2005, the campaign entered a new phase when PHARMAC agreed to support three community-led projects in the Porirua area. The projects were led by two PHOs and a Pacific Island church, and marked a shift in the campaign with the initiative being led from community level. (see picture story below)

The projects were:

- Tumai PHO – eight week intensive clinically monitored health promotion programme for 50 participants
- Porirua Plus PHO – six month CV risk assessments for 60% of 1580 men on their practice records in the target group
- Congregational Church of Samoa – 14 week physical and nutrition programme for 50 participants

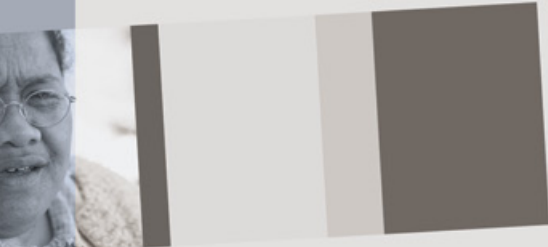
Prescriptions for statins continue to rise throughout New Zealand, and have reached an all-time high with more than 250,000 patients (over a million prescriptions) now receiving a statin. PHARMAC also listed a new treatment for raised cholesterol, ezetemibe (Ezetrol), which is the first of a new class of drugs called cholesterol absorption blockers.

Another decision during the year saw subsidies for the angiotensin II antagonist candesartan (Atacand) extended to also include patients with congestive heart failure.

### Unclogging the artery – the Porirua cardiovascular launch

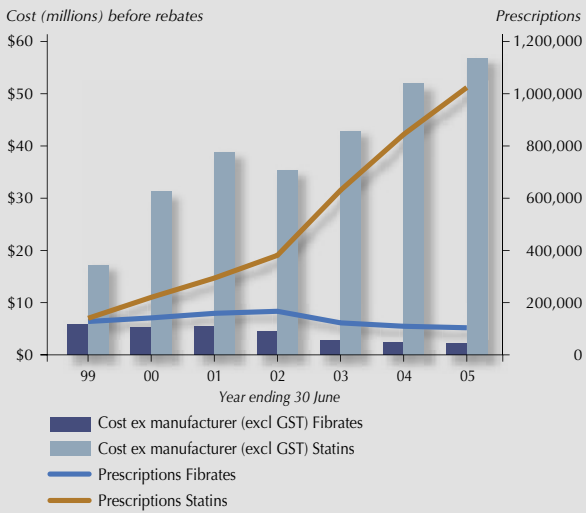
*Three Porirua community groups came together on Valentines Day 2005 to launch their campaigns to address high rates of cardiovascular disease, with the support of PHARMAC and Capital and Coast DHB. The projects were a community-led response to PHARMAC's One Heart Many Lives campaign. After a colourful formal launch in the Cook Islands Community Centre in eastern Porirua, the police stopped traffic on the main road outside the centre and people released red balloons to symbolise "unclogging the artery" – one of the ways to improve cardiovascular health.*





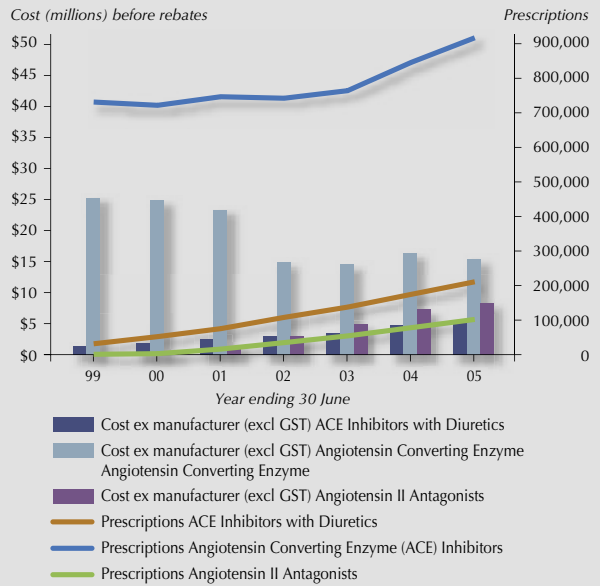
### Lipid modifying agents

Prescriptions for statins continued to increase, reflecting open access and promotion of their use. More than a million prescriptions, or a quarter of a million patients, were subsidised in 2005.



### ACE and ACE II Inhibitors

The increase in prescribing for ACE Inhibitors reflects more prescriptions being subsidised as a result of the implementation of low-cost PHOs, and the lowering of co-payments.



In February 2005, the campaign entered a new phase when PHARMAC agreed to support community-led projects in the Porirua area.

OneHeartManyLives





# Mental health

2005 in focus

Access was widened for the atypical antipsychotic olanzapine (Zyprexa), which was already fully subsidised for patients with schizophrenia. From 1 September 2004 it became funded for the treatment of acute mania in bipolar disorder. A dissolvable wafer form of olanzapine also became subsidised as a further treatment option.

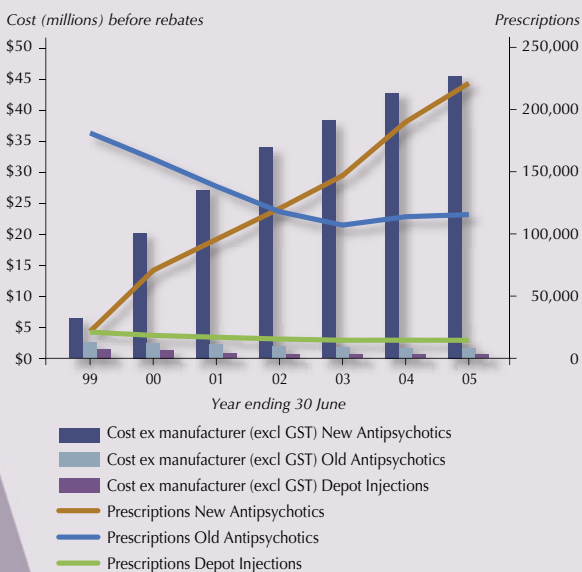
Prescribing of atypicals, and antipsychotic medicines in general, continues to climb. In 1998 antipsychotic medicines accounted for \$4.9 million of the pharmaceutical budget, and have now grown to \$47.9 million. A project is underway to look at issues

around the prescribing of the newer types of antipsychotic medicines. This will involve working with the College of Psychiatrists through the 2005–06 year.

The use of SSRI antidepressants continued to be examined by medicines authorities around the world. In New Zealand paroxetine (Aropax) continued to be the most-prescribed of the SSRI class, and it is also the most expensive. PHARMAC was continuing to monitor the prescribing of SSRIs, and received advice from PTAC and the Consumer Advisory Committee during the year. Data indicate that patient numbers continue to rise,

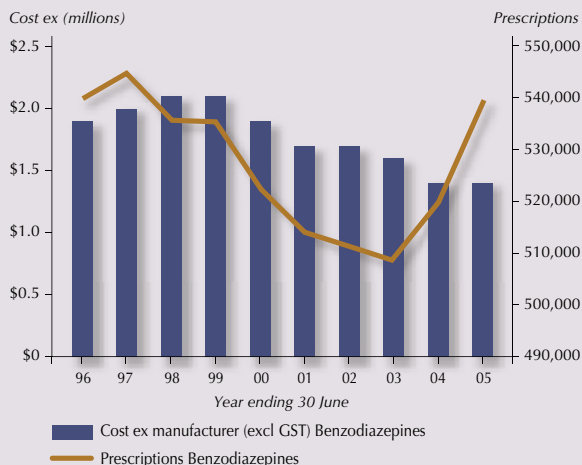
## Antipsychotics

Prescriptions and expenditure for new generation (atypical) antipsychotics continue to rise steeply.



## Benzodiazepines

A downward trend was reversed in 2004 and this has continued upwards in 2005. This may reflect more prescriptions being subsidised as a result of PHO funding, rather than an actual increase in prescribing.





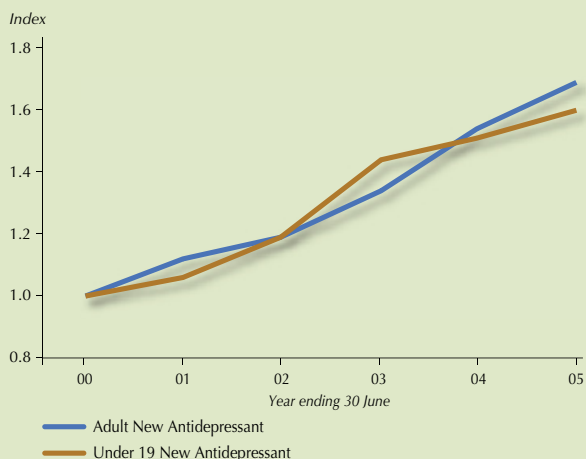
although at a lower rate than previously. It is difficult at this stage to determine whether this is a long-term trend or a temporary response to new evidence.

Overall prescribing of antidepressants continued to rise in 2005. Combined prescriptions for new and older generation antidepressants rose to 944,000 prescriptions (see graph). This equates to approximately 230,000 patients.

Prescription data show a rise in the use of benzodiazepines, after a consistent downward trend lasting six or seven years. As many benzodiazepines are low-cost, some prescriptions that would previously have fallen below the \$15 co-payment are now being subsidised, and recorded in the data. This trend appears to reflect the impact of PHOs on the cost of prescriptions, rather than an overall increase in prescribing.

### New antidepressant growth rate by age group

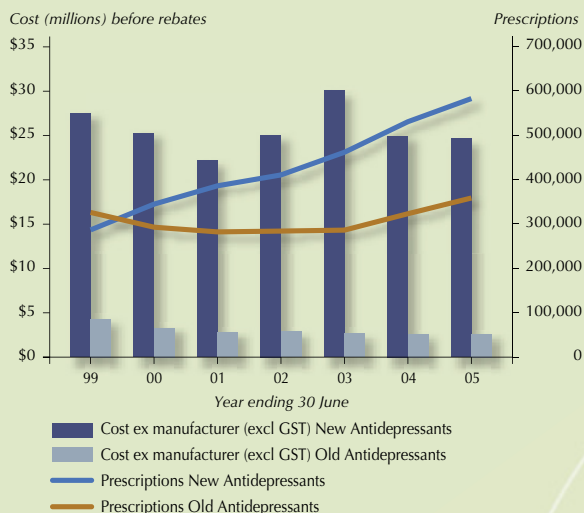
Concern has been raised internationally about prescribing of new generation (SSRI) antidepressants to young people. These have been associated with an increased risk of suicide. In New Zealand, regulatory agency Medsafe issued new prescribing advice in September 2004. Overall, under 19 patient numbers are small, and a clear trend has yet to emerge.



This graph shows that, expressed as a based index, prescribing of SSRIs for under 19 patients is increasing by a slightly lower rate than for adult (19 and over) patients.

### Antidepressants

Prescribing of new and older antidepressant types rose in 2005. Some of this rise may be attributable to more prescriptions being subsidised as a result of PHO funding.



antipsychotics  
antidepressants  
Overall prescribing of antidepressants continued to rise in 2005  
2005 in focus

# Asthma/respiratory

2005 in focus

A new subsidised option for people suffering severe respiratory diseases, such as emphysema, was funded during the year. Tiotropium (Spiriva) became fully funded on 1 February 2005 for people with chronic obstructive pulmonary disease (COPD). It is a longer-acting inhaler than the previously-funded treatments.

The decision represents PHARMAC's single biggest investment of the year, \$33 million over five years. However, a significant amount of this expenditure will be offset by savings in other areas of healthcare, such as hospitalisations. This cost offset could be as high as 40%, which

is an unusually high offset for a pharmaceutical.

PHARMAC agreed to fund a generic brand of the asthma preventer inhaler salbutamol (Salamol) from 1 February 2005. Soon after the new blue inhaler became subsidised, PHARMAC began receiving some comments from patients about the new product, which is supplied by Air Flow Products, a subsidiary company of the Asthma and Respiratory Foundation. Following an examination of inhalers commissioned by Medsafe, and pending the final outcome of tests, PHARMAC decided to defer sole supply of salbutamol until 2007. This means that two brands of salbutamol – Ventolin

and Salamol – are subsidised at the same price per inhaler.

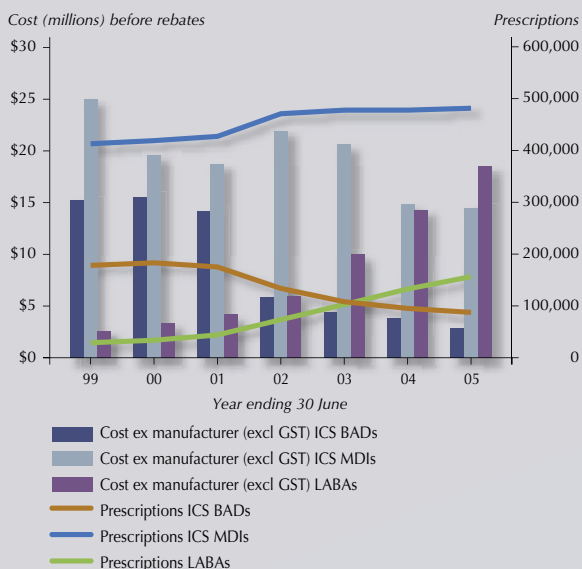
Asthma was also an area where PHARMAC's Demand Side team was active in promoting the best use of the main preventer inhalers, inhaled corticosteroids (such as beclomethasone, budesonide and fluticasone). A flip-chart for asthma educators, launched in 2004, proved so popular that a reprint was commissioned. The campaign continued to achieve a reduction in average daily doses, with analysis showing that average daily doses of inhaled corticosteroids were in the mid-range of the 5–15% reduction zone.

breathing easier



## Asthma

An increase in prescribing of LABAs, with an associated increase in cost, was the most noticeable trend in 2005. Prescription numbers were steady for the main asthma preventer inhalers (inhaled corticosteroids).



### Key:

- LABAs = long acting beta agonists
- ICS = inhaled corticosteroids
- BADs = breath-activated devices
- MDIs = metered-dose inhalers (aerosols)



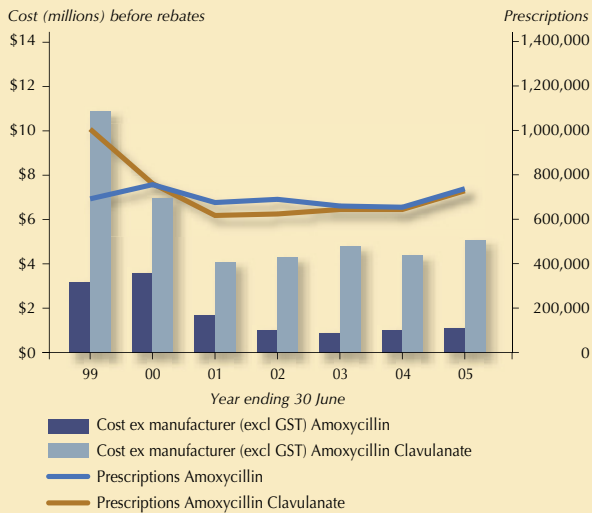
# Overview

## The Wise Use of Antibiotics campaign continued to promote the key message that antibiotics are not effective against viruses.

2005 in focus

### Antibiotics

Prescriptions for the most commonly-used antibiotics rose in 2005. This may reflect an increase in use, and may also be attributable to more prescriptions being subsidised as a result of PHO funding.



The campaign to promote the Wise Use of Antibiotics entered its ninth year with PHARMAC combining with scientists from Environmental Science and Research to highlight the dangers of overusing antibiotics. This gave the 2005 campaign a harder edge and underlined international concerns about bacteria becoming resistant to some of the most commonly-used antibiotics.

Data from ESR were used to show that some bacteria had increased their resistance to antibiotics like penicillins 35-fold since 1995. ESR's information showed that in

addition, the pneumococcal bacteria, which is responsible for some of the most common nose and throat infections, has become increasingly resistant to two of the most commonly-used antibiotic types.

The campaign continued to promote the key message that antibiotics are not effective against viruses, such as those which cause winter colds and flu, but for people to see their doctor if they are unsure. A further message emphasised that overusing these important medicines could see them rendered ineffective against common bacteria in future.

There was a slight rise in the prescribing of antibiotics which was at its highest level for four years, though still well below historical highs. This may reflect a cold winter in 2004 with a higher incidence of secondary bacterial infections, and may also be attributable to more prescriptions being subsidised as a result of PHO funding.



# How do you handle a virus attack?

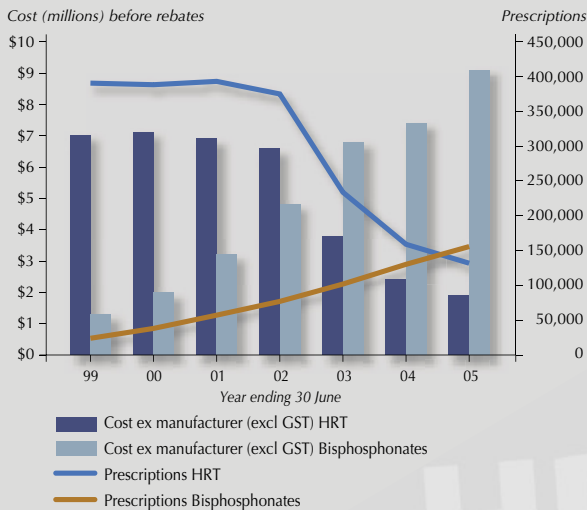


# Hormonal treatments

2005 in focus

## Hormone Replacement Therapy and Bisphosphonates

More prescriptions for bisphosphonates (for osteoporosis) are written than for hormone replacement therapy. Prescriptions for HRT declined a further 17 percent in 2005.



Prescriptions for Hormone Replacement Therapy (HRT) continued to reduce, and now 131,000 prescriptions are written per annum. This is down 17% on the previous year and nearly a third of the prescribing reached in the peak 2001 year, when 393,334 prescriptions were written. It continues the down-trend initiated when the Women's Health Initiative (WHI) trial was published in 2002, highlighting the risks of long-term use of HRT.

Following a recommendation from the Consumer Advisory Committee, PHARMAC

paid for the distribution of New Zealand Guidelines Group guidelines on HRT use, and a patient brochure on HRT developed by Women's Health Action so that prescribers and patients could have better access to information about HRT.

Access was widened to the hormonal breast cancer treatment letrozole (Femara), which became subsidised as a first-line treatment for advanced breast cancer. By year end PHARMAC was also examining access to aromatase inhibitors for some patients with early breast cancer, who were unable to take tamoxifen.

# Oncology and immunosuppression



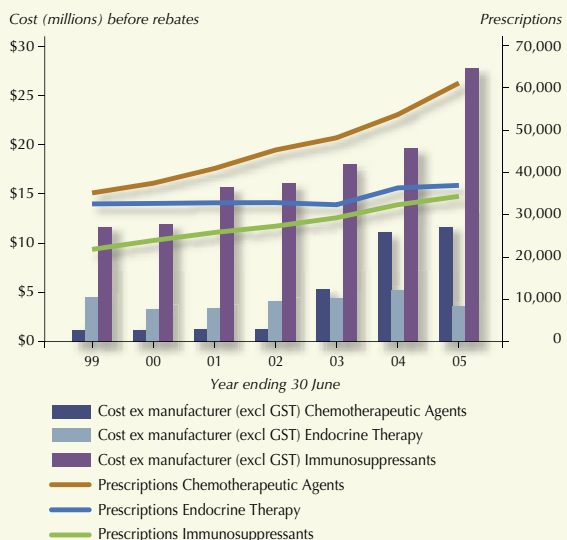
PHARMAC widened access to pegylated interferon, a treatment for hepatitis C. This medicine, combined with ribavirin, was first subsidised in 2003-04 and has been shown to have better response rates than standard interferon in combination with ribavirin.

The 2004-05 decision saw access widened to include other "genotypes" of the hepatitis C infection.

Oncology and immunosuppression agents were the fastest-growing areas of expenditure in 2004-05, with expenditure in the immunosuppressants group up by about 45% for the year.

## Oncology and Immunosuppressants

Prescriptions rose for oncology (chemotherapy) drugs in 2005 while spending on immunosuppressant drugs was close to \$20 million.

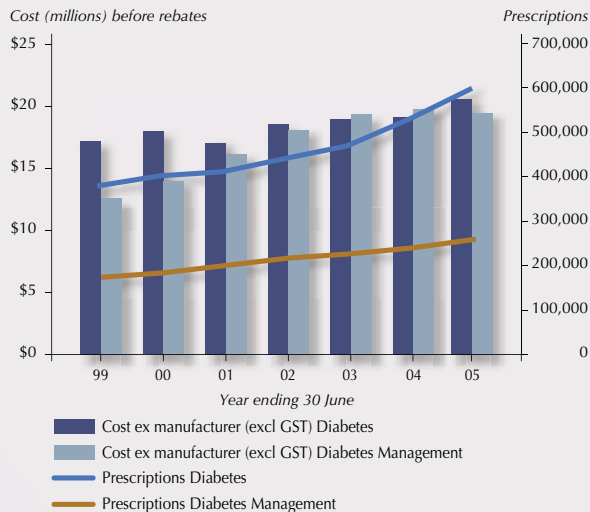


...in the 2005 year test strips accounted for \$19 million in expenditure, about the same amount spent on drugs to treat diabetes...

2005 in focus

## Diabetes

The cost of diabetes test strips (diabetes management) is illustrated by the graph. Both test strips and diabetes treatments (insulins and drugs such as pioglitazone) have similar expenditure levels.



# Diabetes

A number of decisions changed access to products for diabetes. Most significantly PHARMAC subsidised pioglitazone (Actos) a new type of medicine that improves the body's tolerance of insulin, in September 2004. Pioglitazone was initially funded for patients with Type 2 diabetes.

A new agreement with the suppliers of needles and syringes saw a decision to increase the numbers of needles and syringes for diabetes available on prescription. Under the changes, the number of insulin syringes and needles subsidised on prescription increased to 100, meaning most people would need to reuse needles less often.

Following clinical advice from the diabetes sub-committee of PTAC, PHARMAC also reduced the number of blood glucose test strips available on prescription for some patients. This followed concern that test strips were overused – in the 2005 year test strips accounted for \$19.5 million in expenditure, almost as much as was spent on drugs to treat diabetes such as insulins (\$20.6 million). People needing more regular blood glucose testing could continue to have wider access to test strips.

PHARMAC also initiated discussions with Diabetes NZ to examine ways in which the organisations can work together to improve patient resources for people with diabetes.





# PHARMAC in the wider health sector

2005 in focus

**During 2004–05 PHARMAC expanded its purchasing role for DHB hospitals into new areas where the DHBs considered national contracting would be beneficial.**

## **Pharmaceutical contracting**

PHARMAC has been negotiating national contracts for medicines used in DHB hospitals since 2002. This has been the primary focus for PHARMAC's work on behalf of DHB hospitals, with the list of hospital drugs being published as Section H of the Pharmaceutical Schedule.

At 30 June 2005 there were 445 pharmaceutical presentations under national contracts, accounting for some \$70 million, or about 50%, of hospital pharmaceutical expenditure. Predominantly the contracting has been for off-patent pharmaceuticals.

## **Recombinant Factor VIII**

Recombinant Factor VIII is a blood clotting agent used by people with haemophilia. Different purchasing arrangements had been in place in different areas of the country, and PHARMAC had been requested by DHBs to investigate negotiating national contracts for this substance.

Following discussions with the New Zealand Blood Service, PHARMAC undertook the process of negotiating supply contracts for Recombinant Factor VIII. PHARMAC received considerable feedback from clinicians and patients and formed both a clinical and commercial advisory committee to analyse the proposals. Contracts were successfully negotiated with all three suppliers of Recombinant Factor VIII, which are estimated to save DHBs \$31 million over the next five years.

## **New drug assessments for DHBs**

Over the past two years PHARMAC has been trialling a Hospital Pharmaceutical Assessment Process (HPAP). This process is designed to give all DHBs access to assessments on the cost-effectiveness of pharmaceuticals used in hospitals. Undertaking the work nationally helps reduce duplication and provides a valuable resource for hospital medicine advisory committees seeking guidance on the cost-effectiveness of new medicines.

In 2004–05 PHARMAC completed and circulated assessments on six different pharmaceuticals for DHBs, including treatments for heart disease, schizophrenia and arthritis.

In 2004–05, PHARMAC also undertook a review of the HPAP to evaluate whether the objectives set when establishing the process had been achieved. The review included surveying DHB staff and contracting an independent consultant to interview those involved in pharmaceutical assessments in several DHBs.

Of those who responded to the survey (approximately 41% response rate), 86% said they had referred to the assessments, and 68% considered that they were useful. The majority (72%) of respondents considered that the assessments were sufficiently rigorous, and more than three-quarters also agreed that HPAP had been successful in improving the consistency and quality of new drug assessments.

As a result of the review, PHARMAC has decided to continue providing this service to DHBs and, in consultation with DHBs, look for ways to improve its value to DHBs.

## **Influenza vaccine**

PHARMAC had agreed to undertake the contracting for influenza vaccine in 2004, at the request of DHBs and the Ministry of Health. An agreement was reached with Merck Sharp and Dohme and Sanofi Pasteur for the Vaxigrip brand of influenza vaccine.

Just prior to the beginning of the subsidised influenza vaccine programme, the manufacturers notified Medsafe and PHARMAC that registration would be delayed. PHARMAC and the Ministry of Health suspended sole supply of Vaxigrip and consulted with other suppliers, and were able to secure supply of enough vaccines from alternative suppliers to vaccinate all eligible people that sought the vaccine.

Subsequent talks with MSD and Sanofi saw all costs associated with gaining alternative supplies recovered, and a review will see more than one supplier in place for the remainder of the contract period.

## **New Initiatives**

PHARMAC's successes in securing contracts for hospital pharmaceuticals has seen DHBs ask PHARMAC to undertake further work. This began in 2004–05 with consultation around proposals to purchase radiological contrast

media, bulk intravenous fluids and dialysis fluids on behalf of DHBs. These projects are on target to result in national contracts for some products before the end of the 2005-06 financial year.

### Pharmaceutical cancer treatments

In 2001 the Minister of Health directed District Health Boards to fund a set list of pharmaceutical cancer treatments (the "basket") to ensure consistency of access throughout New Zealand. This is a list of cancer drugs that DHB hospitals are required to fund. Since 2002 PHARMAC has been assessing new pharmaceutical cancer treatments and providing advice to DHBs on funding, however adding new treatments or widening access has required the agreement of all 21 DHBs.

To ensure nationally-consistent access to new pharmaceutical cancer treatments, and to help streamline the process for adding new products to the "basket" the Minister asked PHARMAC to develop a proposal that would see PHARMAC managing spending on cancer drugs used in hospitals. PHARMAC consulted extensively with DHBs and the wider sector, and a number of issues were raised to be worked through.

The PHARMAC Board agreed to defer implementation of the proposal until July 2007, and agreed timelines with DHBs for a number of targets. One of the major issues is collecting data on the prescribing of pharmaceutical cancer treatments used in hospitals so that an accurate picture of use (and expenditure) is available. DHBs have been asked to put in place data collection systems and report data to PHARMAC so that a complete picture is available.

## Listing changes to the Pharmaceutical Schedule<sup>1</sup>

### Decisions made

Decision type	2005	2004	2003	2002	2001	2000	1999	Total since 1994
New Chemical entity listed	9	15	3	7	20	18	32 <sup>(4)</sup>	155
New Presentation listed	14	27	15	11	13	21	40	262
New Product listed	51	49	45	60	28	39	56	519
<b>Total new listings<sup>(2)</sup></b>	<b>74</b>	<b>91</b>	<b>63</b>	<b>78</b>	<b>61</b>	<b>78</b>	<b>128</b>	<b>926</b>
Derestriction or expanded access <sup>(3)</sup>	16	9	7	17	19	17	34	186
Changes that restrict or limit access	3	2	2	4	6	6	3	47
Delistings	59	72	196	89	135	362 <sup>(5)</sup>	51	1089

In 12 years, 926 new or enhanced products have been listed, access has been widened for a further 186 and 1089 have either been restricted or de-listed.

1. Based on the date on which decisions are implemented.
2. Does not represent the total number of products added to the Schedule, since the listing of one new chemical entity can result in the listing of more than one presentation.
3. By decision, not necessarily the number of chemical entities affected.
4. Applications for new chemical entities in the Special Foods therapeutic group were declined.
5. A higher than usual number of products were de-listed in 2000 due to sole supply arrangements and the completion of the review of Extemporaneously Compounded Products.

## Exceptional Circumstances

Exceptional Circumstances is a programme, administered by PHARMAC, that enables patients to access drugs that are not otherwise subsidised, in rare or unusual circumstances. Access is subject to approval by panels of clinicians, and operates within a budget (a sub-set of the pharmaceutical budget). Separate schemes are operated for community (CEC) and hospital (HEC) medicines.

### Community Exceptional Circumstances (CEC)

The CEC panel had 25 teleconferences during the year. In 2005 CEC expenditure was within the budget at \$2.4 million.

In the year to June 2005 there were 1134 applications under CEC. Of these 700 were new applications and the remaining 434 were renewals of previously granted approvals. Approvals are generally given for a year with a request that an update on the patient's progress be provided before renewal is granted.

Overall, 52% of initial and 97% of renewal applications were approved.

### Hospital Exceptional Circumstances (HEC)

Hospital Exceptional Circumstances (HEC) has been running for over two years. HEC is the mechanism by which DHB hospitals can fund medicines that are not listed on the Pharmaceutical Schedule for patients, once they have been discharged from hospital. The sole criterion for approval under HEC is that funding the medicine by the DHB hospital is more cost effective for the hospital than the most likely alternative intervention or outcome.

Applications are assessed remotely by the Panel of clinicians and the responses are co-ordinated by the Panel Co-ordinator. The maximum turnaround time for HEC applications is 48 hours (excluding weekends and public holidays).

A total of 1637 HEC applications were made in the year to 30 June 2005, of which 89% were approved either by the Panel or by the Panel Co-ordinator according to set criteria. The panel declined 152 applications, however some of these went on to be approved after further information was supplied.

# PHARMAC Directory



## The PHARMAC Board

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**Professor Gregor Coster** MSc, MBChB, FRNZCGP

**Adrienne von Tunzelmann** MA (Hons), Master of Public Policy

**Karen Guilliland** RM, RGON, MA, MNZM

**Helmut Modlik** BCA, MBA

**David Moore** Mcom, Dip Health Ec, CA

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**Prof. Carl Burgess** MBChB, MD, MRCP (UK), FRACP, FRCP, physician/clinical pharmacologist

### Deputy Chair

**Dr Paul Tomlinson** BSc, MBChB, MD, MRCP, FRACP, paediatrician

### Committee Members

**Dr Ian Hosford** MBChB, FRANZCP, psychiatrist

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

**Dr Peter Jones** BMedSci, MB, ChB, PhD, MRCP (UK), FRACP, physician

**Dr Jim Lello** BHB, MBChB, DCH, FRNZCGP, general practitioner

**Dr Peter Pillans** MBChB, MD, FCP, FRACP, physician / clinical pharmacologist

**Dr Anthony Ruakere** MBChB, Dip Obst, Dip General Practice, FRNZCGP, general practitioner

**Dr Tom Thompson** MBChB, FRACP, physician

**Dr Howard Wilson** BSc, PhD, MB, BS, Dip Obst, FRMZCGP, FRACGP, general practitioner

## PTAC Sub-committees

**Analgesic** – Dr Peter Jones (PTAC, physician, chair), Dr Bruce Foggo (palliative medicine specialist), Dr Derek Snelling (physician), Dr Geoff Robinson, (physician), Dr Howard Wilson (PTAC, general practitioner), Dr Jonathan Adler (palliative medicine specialist), Dr Lindsay Haas (neurologist), Dr Neil Whittaker (general practitioner), Dr Rick Acland (physician), Dr Ross Drake (paediatrician)

**Anti-infective** – Dr Paul Tomlinson (PTAC, paediatrician, chair), Dr Richard Meech (infectious disease specialist), Dr Stephen Chambers (infectious disease specialist), Dr Mark Thomas (infectious disease specialist), Dr Iain Loan (general practitioner), Dr Sandy Smith (microbiologist)

**Cardiovascular** – Prof. Carl Burgess (PTAC, physician/clinical pharmacologist, chair), Dr Allan Moffitt (general practitioner), Dr Gary Gordon (cardiologist), Dr John Elliott (cardiologist), Dr Lannes Johnson (general practitioner), Dr Miles Williams (cardiologist), Dr Peter Pillans (PTAC, Deputy Chair, physician/clinical pharmacologist)

**Cancer Treatments (CATSoP)** – Prof. Carl Burgess (PTAC, physician/clinical pharmacologist, chair), Dr Andrew Macann (radiation oncologist), Dr Anne MacLennan (palliative medicine specialist), Dr Bernie Fitzharris (oncologist), Dr Peter Ganly (haematologist), Dr Tim Hawkins (haematologist), Prof. Vernon Harvey (oncologist)

**Diabetes** – Dr Tom Thompson (PTAC, physician, chair), Dr Bruce Small (general practitioner), Dr Paul Drury (diabetologist), Dr Anthony Ruakere (PTAC, general practitioner), Dr Rick Cutfield (diabetologist), Dr Tim Kenealy (general practitioner), Pat Carlton (diabetes nurse specialist)

**Hormone and Contraceptive** – Dr Bruce Small (general practitioner), Dr Christine Roke (family planning specialist), Dr Frances McClure (general practitioner), Dr Michael Crosson (endocrinologist)

**Mental Health** – Prof. Carl Burgess (PTAC, physician/clinical pharmacologist, chair), Dr Crawford Duncan (psychiatrist), Dr Janet Holmes (general practitioner), Dr John Hopkins (psychiatrist), Dr Verity Humberstone (psychiatrist), Prof. John Werry (psychiatrist)

**Neurological** – Dr Tom Thompson (PTAC, physician, chair), Dr Alistair Dunn (general practitioner), Dr Peter Jones (PTAC, physician), Dr Lindsay Haas (neurologist), Dr William Wallis (neurologist)

**Ophthalmology** – Dr Tom Thompson (PTAC, physician, chair), Dr Allan Simpson (ophthalmologist), Dr Justin Mora (ophthalmologist), Dr Mark Elder (ophthalmologist), Dr Rose Dodd (general practitioner)

**Osteoporosis** – Dr Peter Jones (PTAC, physician, chair), Dr Anna Fenton (endocrinologist), Prof. Ian Reid (endocrinologist), Prof. Les Toop (general practitioner), Prof. Richard Sainsbury (geriatrician)

**Respiratory** – Dr Jim Lello (PTAC, general practitioner, chair), Dr Ian Shaw (paediatrician), Dr John Kolbe (physician), Dr John McLachlan (physician), Prof. Carl Burgess (PTAC, physician/clinical pharmacologist)

**Special Foods** – Dr Paul Tomlinson (PTAC, paediatrician, chair), Dr John Wyeth (gastroenterologist), Jo Stewart (dietician), Kerry McIlroy (dietician),

**Tender Medical** – Dr Paul Tomlinson (PTAC, paediatrician, chair), Geoff Savell (pharmacist), Andrea Shirtcliffe (pharmacist), Dr Jim Lello (PTAC, general practitioner) Dr Tom Thompson (PTAC, physician), Sarah Fitt (hospital pharmacist), Dr David Carroll (physician), Dr Nigel Patton (haematologist)

**Transplant Immunosuppressant** – Dr Paul Tomlinson (PTAC, paediatrician, chair), Dr Peter Pillans (PTAC, physician/clinical pharmacologist), Prof. Stephen Munn (surgeon), Dr Richard Robson (physician), Dr Peter Ruygrok (cardiologist), Dr Ken Whyte (physician)

## Consumer Advisory Committee (CAC)

### Chair

Sandra Coney (women's health advocate, Auckland), Chair

### Committee Members

Vicki Burnett (Mental Health consultant, Auckland)

Sharron Cole (National Trainer, Parents Centres, Wellington)

Matiu Dickson (Te Runanga o Kirikiriroa Chairman, Hamilton)

Dennis Paget (Grey Power, Blenheim)

Paul Stanley (Chief Executive, Ngaiterangi iwi Tauranga)

Kuresa Tiimalu-Faleseuga (social services consultant, Levin)

Te Aniva Tutara (Maori Health Manager, Waitemata DHB)

Heather Thomson (Health Manager, Te Aroha, eastern Bay of Plenty).





### **Hospital Pharmaceuticals Advisory Committee (HPAC)**

#### *Chair*

Ian Winwood (Clinical co-ordinator of Pharmacy Services, Southland).

#### *Committee Members*

Sarah Fitt (Pharmacy Manager, Auckland DHB)

Neil Aitcheson (Materials Manager, MidCentral DHB)

Paul Barrett (Pharmacy Services Manager, Canterbury DHB)

Richard Bridge (Pharmacy Manager, Hutt Valley DHB)

Jan Goddard (Manager, Pharmacy Services, Waikato DHB)

Victoria Seymour (Chief Pharmacist, Northland DHB)

Melissa Witbrock (Unit Manager, Pharmacy, Otago DHB)

### **The PHARMAC team**

#### *Chief Executive*

Wayne McNee BPharm, MPS, PG Dip Clin Pharm (Dist)

#### **Medical Director**

Peter Moodie BSc, MBChB, FRNZCGP

#### **Corporate**

Stuart Bruce MA, BA (Hons) – *Manager Corporate*

Selina Anslow Dip Bus – *Receptionist*

Karyn Brown – *Receptionist*

Simon England – *Communications Advisor*

Marama Parore-Katene, Ngati Whatua, Ngati Kahu, Nga Puhī – *Maori Health Manager*

Melanie Pemberton Fisher BA (Hons), HND (UK) – *Executive Assistant*

Liz Skelley BCA CA – *Finance Manager*

#### **Medical team**

Hayley Bythell – *Medical Director Assistant*

Jayne Chaulk MSc (Hons) – *Exceptional Circumstances Panel Co-ordinator*

Mary Chesterfield PTecC (UK) – *High Cost Pharmaceuticals Co-ordinator*

Katie Harris BA – *Hospital Exceptional Circumstances Panel Co-ordinator*

Jan Quin RCpN – *Project Manager*

Dilky Rasiah MBChB, Dip Public Health, MRACMA – *Project Manager*

Silvia Valsenti MBChB – *Panel Co-ordinator*

#### **Supply Side team**

Cristine Della Barca Dip Pharm, MPS, Dip Bus Admin – *Manager, Supply Side*

Mike Bignall BCA BSc – *Tender Analyst*

Steffan Crausaz BPharm, MSc, MRPharmS – *Therapeutic Group Manager*

Sean Dougherty BCom (Hons) – *Therapeutic Group Manager*

Jessica Nisbet – *Supply Side Assistant*

Tommy Wilkinson BPharm MPS – *Therapeutic Group Manager Intern*

Stephen Woodruffe BPhEd (Hons) BHealSc – *Therapeutic Group Manager Intern*

#### **Schedule team**

Linda Wellington Dip Pharm, MPS – *Schedule Analyst*

Kaye Wilson Dip Tchg – *Schedule Analyst*

#### **Demand Side team**

Rachel Mackay BA, NZIMR – *Manager, Demand Side (on parental leave)*

Karen Jacobs MBA, ADN – *Demand Side Manager*

Karolina Johnson – *Demand Side Assistant /Designer (resigned)*

Adam McRae BCom, BNurs – *Demand Side Manager*

#### **Analysis and Assessment team**

Matthew Brougham MSc (Hons), Dip. Health Econ. (Tromso) – *Manager, Analysis and Assessment*

Jason Arnold BSc, PG Dip Stat (Dist) – *Senior Analyst, Analysis & IT Support*

Peter Ericson – *Database Analyst*

John Geering BA, BSc – *Information Manager*

Rachel Grocott BCom (Hons) – *Senior Analyst, Hospital Pharmaceuticals Assessment*

Derek Kan, BRP (Hons) – *Analyst (resigned)*

Geoff Lawn B Mus, PG Dip Comp Sci – *Database Analyst*

Scott Metcalfe MBChB, Dip Community Health, FAFPHM – *Epidemiologist/Public Health Physician (on contract)*

### **Hospital Pharmaceuticals team**

Sarah Schmitt BSc – *Manager, Hospital Pharmaceuticals*

Andrew Davies BSc (Hons) – *Hospital Pharmaceuticals Contracts Manager*

Andrea Dick BSc, BCom – *Hospital Pharmaceuticals Contracts Manager*

Matthew Perkins BSc, BCom, PG Dip Com – *Hospital Pharmaceuticals Contracts Manager*

### **Publications available on PHARMAC's Website include:**

- The Pharmaceutical Schedule and Monthly Updates
- PHARMAC's Operating Policies and Procedures (including minutes from meetings relating to the review of these)
- PHARMAC's Annual Report to Parliament
- Minutes of PTAC and CAC meetings
- PHARMAC's Annual Business Plans
- Annual Reviews
- A Prescription for Pharmacoeconomic Analysis (an explanation of PHARMAC's methods for Cost-Utility Analysis)
- Various consultation letters
- PHARMAC's invitation to suppliers to tender for sole supply of pharmaceuticals
- Media releases
- Special Authority Forms
- Patient leaflets
- Statistics about pharmaceutical spending in New Zealand

Visit PHARMAC online at [www.pharmac.govt.nz](http://www.pharmac.govt.nz)

