The process set out in this diagram is intended to be indicative of the process that may follow where a supplier or other applicant wishes a pharmaceutical to be funded on the Pharmaceutical Schedule. PHARMAC may, at its discretion, adopt a different process or variations of the process (for example, decisions on whether or not it is appropriate to undertake consultation are made on a case-by-case basis).

**The PHARMAC decision making process**

Considering evidence

- Receipt of proposal
  - Listed on PHARMAC website

Summary of proposal
- Preliminary economic assessment
- and questions for PTAC

Review of proposal by PTAC

Recommendation to PHARMAC
- Some minutes published on PHARMAC website
- Positive Recommendation
- Economic Assessment
- Prioritisation of all proposals
  - Negotiation with supplier(s)
  - Consultation on Preliminary agreement
- Summary of all relevant information prepared for board

Reaching a Decision

PHARMAC Board Decision

Implementation

Assessing Relative Value

- Request more specialised advice from Subcommittee / Experts as required
- Review by PTAC

Negative recommendation

Implementation
Highlights of 2007/08

- Medicines NZ, the strategy for the medicines system was released. PHARMAC is committed to implementing its actions
- We made 20 major funding decisions – including new medicines for migraines, mental illness and cancer
- Pharmaceutical funding was managed to less than 0.1% within budget
- Prescriptions subsidised during the year rose to 33.9 million
- We held the first PHARMAC Forum – attended by over 100 delegates from a range of stakeholder groups
- He Rongoā Pai, He Oranga Whānau was launched – Māori staying well with medicines project
- One Heart Many Lives cardiovascular risk management campaign expanded into Lakes DHB region – in addition to Hawke’s Bay and Northland
- Our Herceptin patient information booklet won a Writemark plain English award
- The PHARMAC Seminar Series continued to be fully subscribed and seen as a valuable source of improving clinical knowledge
- We relaunched our website with improved navigation and functionality, to help people better understand PHARMAC and its processes
Medicines New Zealand will define much of PHARMAC’s work for the foreseeable future

writes chairman Richard Waddel

The release of New Zealand’s first medicines system strategy, Medicines New Zealand, in late 2007, was a defining feature of the year.
The strategy defines the different roles and parts of the medicines system, and identifies key areas of focus – including quality, safety and efficacy of medicines; and the optimal use of medicines. Working with others in the medicines system, we are committed to the aims and activities of Medicines New Zealand, and this work will continue to be important into the future.

The strategy dovetailed with PHARMAC’s first forum, held in December 2007, which focused on PHARMAC’s role and possible areas of improvement. There was open and frank discussion on PHARMAC’s work and it was clear that there are differing views on many issues, largely driven by the different priorities and incentives of stakeholder groups. However, it has been pleasing to see continual improvement in PHARMAC’s key relationships over the past year.

PHARMAC’s core function is the management of District Health Board (DHB) spending on pharmaceuticals. In 2007/08, we managed spending within 0.1% of the budget figure: $635.4 million compared to a budget of $636 million. Spending so close to a budget that size, with so many moving parts across the medicines system, is a very positive result; and equates less than the cost of half a day of dispensings across New Zealand. This careful management continues PHARMAC’s record of achieving its statutory objective of maintaining spending within budget.

Funding decisions

In all, PHARMAC made 20 major funding decisions, including the lifting of specialist prescriber restrictions from 43 medicines (grouped together as one major funding decision) which can now be prescribed by more clinicians, or dispensed through community pharmacies.

New and better access to cancer drugs was a major theme in 2007/08. PHARMAC made seven decisions that widened access to existing drugs or listed new ones, including treatments for breast, colon and lung cancers, which are the most common forms of cancer. Other major decisions included widening access to the blood-thinning drug clopidogrel and the respiratory disease treatment tiotropium, and listing the new drugs ziprasidone (mental health) and rizatriptan (migraines).

The breast cancer drug Herceptin was the centre of much attention this year, after being funded from 1 July 2007. The Herceptin decision was subject to judicial review. As a result there was a further round of consultation and assessment, and ultimately a decision to remain consistent with the nine-week funding decision reached in 2007.

Optimal Use

A central theme of Medicines NZ was correct use of medicines - or “optimal use”. PHARMAC has already done extensive work through campaigns such as Wise Use of Antibiotics, and the One Heart Many Lives cardiovascular disease campaign, and this is continuing. One Heart Many Lives goes from strength to strength; this year it spread into its third DHB region (Lakes), with an opening conference in Rotorua during April. It also provided the basis for a national conference bringing together many people working in the heart health area.

High quality people

PHARMAC is served by a high-quality group of people who continue to take pride in the excellent job they perform on behalf of New Zealanders. I am also grateful for the continuing commitment and professionalism of my fellow PHARMAC Board members, and the ongoing high quality advice and input from a range of experts from clinical and consumer fields. I thank them all for the time and effort put into their deliberations.

During the year the Board appointed Matthew Brougham to the role of Chief Executive, a role he had performed in an acting capacity since July 2006. I am confident he will continue to show the leadership required for PHARMAC’s ongoing success.

Subsidy, volume, mix and cost indices

Four-quarterly moving averages
Base: four quarters ending June 2000 = 1,000.

Getting more for less:
The subsidy volume and mix indices are like the consumer price index, but for pharmaceuticals. The graph shows that while the amount of pharmaceuticals used, and their cost has been rising, the subsidy index is decreasing.
Current concerns over global economic conditions underline the need to get the greatest health benefit from taxpayer funds

writes chief executive Matthew Brougham

During the year PHARMAC had about 40-50 funding options, and the ability to fund possibly 15. In short, there were more choices available to us than we had the ability to fund – but this is always the case.

The funding options this year included some expensive and particularly challenging products, including a group of drugs called ‘TNF alpha inhibitors’ – new generation agents that treat auto-immune disorders, such as rheumatoid arthritis. At current prices for all possible uses, the drugs have a total price tag around $50 million a year (or 8 percent of current expenditure on all drugs on the Pharmaceutical Schedule).

Prices for new pharmaceuticals continue to rise, and this is not a new trend. It creates a challenge not just for PHARMAC, but for the whole health sector. With demands on health resources continuing to grow, the need for robust, sector-wide prioritisation processes will become ever more important over the next few years.

Getting the greatest benefit

If new drugs such as the TNF-alphas are to be funded, it is vital health sector managers have confidence the expenditure will provide people with more health benefits than if spent elsewhere in the sector. The central issue is ensuring taxpayer funds allocated to health are spent in a way that produces the greatest benefit.

We will never be able to fund all the demands in health, so the challenge lies in ensuring the best possible choices are made. Current concerns over global economic conditions underline the need to be careful with our spending, and to ensure the taxpayer funding we are responsible for is spent wisely and not wasted. There is not a bottomless pit of health funding, and this is certainly the case with pharmaceuticals where PHARMAC is responsible for around $650 million of public money. In a time when people are seeking assurances that public money is being well spent and appropriately managed, this is an area where PHARMAC has a well-established record.

PHARMAC continues to observe its budget constraint, and is continually looking to shift funds towards investment options that provide the greatest health benefit, and away from those that do not. These characteristics are part of PHARMAC’s core values and ensure PHARMAC remains firmly focused on making decisions that are fair, reasonable and robust.

Optimal budget size

We’ve heard criticism in the past year about New Zealand’s expenditure falling behind other countries. This may be a good thing or a bad thing, depending on your point of view – but it is usually presented negatively, and illustrated by citing figures comparing New Zealand’s per capita spend as a percentage of GDP, compared to OECD averages, or some other measure.

Such comparisons are tricky territory, particularly if based on the percentage of Gross Domestic Product (GDP). Raw data is highly misleading, even in the hands of experts, because it only shows part of the picture – it ignores factors such as price differentials, and glosses over the different needs of different countries. There’s more on this on P16.

We do need an improved process to determine the optimal size of the budget, and the medicines strategy, Medicines NZ, has identified this as work to progress (led by the Ministry of Health). But just what is the ‘ideal’ budget size, and how do we measure that?

In good shape, room to improve

Medicines NZ requires DHBs and PHARMAC to work with the Ministry of Health to improve the budget process, including through developing appropriate budget setting principles. This will help us to find the optimal size for the budget, relative to other possible health funding uses. Determining budget sizes is a matter of determining priorities that depend on systems that enable us to compare investment options on the same footing across the sector.
Overall, Medicines NZ concluded New Zealand’s medicines system is in good shape, while noting there are improvements to be made that could make it better. In particular, it focused on the way PHARMAC receives information and relays its decisions to the public. So I want to be clear, we want to hear the public’s perspective and we want our decisions to be understood, and we’ll be working hard to further improve.

I believe we have made much headway, building on work that’s been evolving over the past few years. A number of observers have noticed the changes, as I have begun to hear some positive remarks about the way PHARMAC performs its role: “they’ve got a tough job and given their budget constraint they do pretty well”. Further, we are now receiving feedback that our general communications are better hitting the mark. This is all very positive, but we’re determined our communications and engagement with others will keep improving. As we continue to implement our Medicines NZ work, our performance will get even better.

**Asking the right questions, making the right choices**

But let’s be clear on this point too; seeking to understand people’s issues and better explaining our decisions does not miraculously make the decisions easier, nor lead to PHARMAC making decisions just to be liked. Better engagement does, however, enable the debate to shift to asking the right questions – is PHARMAC using good quality processes to make well-analysed and robust decisions, and can health spending be identified elsewhere that would produce greater health gain if shifted towards pharmaceuticals, or vice versa? In other words, is New Zealand’s pharmaceutical budget the right size?

Whatever the size of our budget, we will need to make choices on how to spend it. To make these choices, we use an established decision-making framework including clinical advice from expert committees, robust economic analysis and prioritisation, and public consultation. It’s not easy and can be controversial. There are often very passionate public campaigns around new medicines, but PHARMAC needs to keep a clear head and make decisions as objectively as possible.

Medicine funding isn’t about counting votes, it is about making difficult decisions on how to allocate resources in a manner that is fair and reasonable. Clinical evidence is fundamental to this process, and evidence-based medicine must remain the bedrock of PHARMAC’s decision-making.

The graph shows PHARMAC’s influence on pharmaceutical spending. The spending pattern is rising at a slower and more manageable rate than would have occurred without PHARMAC’s activity.
Diagnosis and treatment are some of the foundation blocks of good medicine; so is the art of good communication. Health professionals can be powerful influencers on patient beliefs and behaviour, and we have all seen good therapeutic interventions undermined because the patient or their relatives could not understand or trust the advice.

If people can believe that a sugar pill can make them well, then they can equally believe a therapeutically active medicine doesn’t work for them. The power of suggestion can be powerful indeed, particularly when it comes from a person the patient trusts, like their doctor. When a patient’s medicine changes, there can be uncertainty and the messages they hear from their doctor are listened to carefully. If a doctor expresses doubt in a different brand, this can cause a patient to lose faith in what really is an effective therapeutic product.

Doctors’ influence is similar to a phenomenon most of us are familiar with and is regularly demonstrated in clinical trials, the ‘placebo effect’. This can be very strong. In fact, in some trials of antidepressant medicines, the numbers of people reporting benefits in the control (placebo) arm of the trial has been nearly the same as those in the active arm.

The pharmaceutical industry has understood for many years the importance of doctors as opinion leaders and filters of information to patients. PHARMAC and other organisations also work to improve the flow of information to doctors – and this helps them to provide advice to their patients.

Most patients trust the advice and treatment given by their own health professional. That trust is built on a number of factors including a belief that the advice given is based on both clinical training and experience. Often their lives depend on the advice and that trust will make them listen carefully even to the most casual comment.

“However, if our opinion is valued it is important that our opinion is well-informed”.

Generics – checks and balances

Over recent years the introduction of generic pharmaceuticals has become more commonplace, both in New Zealand and overseas. These medicines save our health system many millions of dollars which can be reinvested in other areas of the health sector. Interestingly in the United States, the vast majority of patients, including those who are insured, look forward to the introduction of a generic as they know that the co-payment they pay will reduce. According to the Los Angeles Times, some 56% of prescriptions written in America are filled by generics.

There are regulations in place to make sure that a generic is ‘bioequivalent’ to the innovator products they compete with – including in New Zealand through Medsafe. Generic medicines are often produced...
The Top 20 Expenditure Groups

$ millions, cost ex manufacturer, excludes rebates and GST

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Antulcerants</td>
<td>heartburn, stomach ulcers</td>
<td>$69.88</td>
<td>$75.58</td>
<td>$73.78</td>
<td>$68.64</td>
<td>$63.98</td>
<td>$52.21</td>
</tr>
<tr>
<td>Lipid Modifying Agents</td>
<td>raised cholesterol (cardiovascular risk)</td>
<td>$66.02</td>
<td>$68.86</td>
<td>$68.19</td>
<td>$60.82</td>
<td>$54.97</td>
<td>$46.09</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>Mental health (psychoses)</td>
<td>$60.48</td>
<td>$57.12</td>
<td>$53.45</td>
<td>$48.59</td>
<td>$45.19</td>
<td>$40.88</td>
</tr>
<tr>
<td>Agents Affecting the Renin-Angiotensin System</td>
<td>Raised blood pressure (cardiovascular risk)</td>
<td>$29.92</td>
<td>$29.10</td>
<td>$26.08</td>
<td>$29.12</td>
<td>$28.44</td>
<td>$23.04</td>
</tr>
<tr>
<td>Diabetes</td>
<td>Diabetes</td>
<td>$29.35</td>
<td>$26.34</td>
<td>$22.51</td>
<td>$20.60</td>
<td>$19.22</td>
<td>$18.96</td>
</tr>
<tr>
<td>Beta Adrenoceptor Blockers</td>
<td>Heart disease</td>
<td>$29.28</td>
<td>$24.52</td>
<td>$21.27</td>
<td>$17.58</td>
<td>$11.53</td>
<td>$9.23</td>
</tr>
<tr>
<td>Antiepilepsy Drugs</td>
<td>Epilepsy</td>
<td>$24.60</td>
<td>$27.85</td>
<td>$24.80</td>
<td>$21.40</td>
<td>$20.72</td>
<td>$19.02</td>
</tr>
<tr>
<td>Immunosuppressants</td>
<td>Organ transplants, arthritis</td>
<td>$23.81</td>
<td>$22.86</td>
<td>$23.35</td>
<td>$22.52</td>
<td>$14.87</td>
<td>$13.56</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>Cancer</td>
<td>$21.10</td>
<td>$16.62</td>
<td>$13.65</td>
<td>$11.32</td>
<td>$10.86</td>
<td>$5.10</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Mental health (depression)</td>
<td>$20.80</td>
<td>$30.65</td>
<td>$29.71</td>
<td>$27.33</td>
<td>$27.57</td>
<td>$32.76</td>
</tr>
<tr>
<td>Diabetes Management</td>
<td>Blood glucose monitoring</td>
<td>$19.02</td>
<td>$17.12</td>
<td>$16.28</td>
<td>$19.51</td>
<td>$19.81</td>
<td>$19.43</td>
</tr>
<tr>
<td>Analgesics</td>
<td>Pain relief</td>
<td>$18.85</td>
<td>$17.23</td>
<td>$15.69</td>
<td>$14.52</td>
<td>$16.54</td>
<td>$16.87</td>
</tr>
<tr>
<td>Calcium Channel Blockers</td>
<td>Heart disease</td>
<td>$16.01</td>
<td>$14.46</td>
<td>$13.68</td>
<td>$13.02</td>
<td>$16.37</td>
<td>$13.78</td>
</tr>
<tr>
<td>Antibacterials</td>
<td>Bacterial infections</td>
<td>$15.47</td>
<td>$14.80</td>
<td>$13.88</td>
<td>$13.94</td>
<td>$13.06</td>
<td>$14.56</td>
</tr>
<tr>
<td>Calcium Homeostasis</td>
<td>Osteoporosis</td>
<td>$15.34</td>
<td>$13.56</td>
<td>$11.84</td>
<td>$9.83</td>
<td>$8.30</td>
<td>$7.71</td>
</tr>
<tr>
<td>Inhaled Corticosteroids</td>
<td>Asthma</td>
<td>$15.17</td>
<td>$16.20</td>
<td>$16.87</td>
<td>$17.50</td>
<td>$18.68</td>
<td>$25.11</td>
</tr>
<tr>
<td>Antiretrovirals</td>
<td>HIV/AIDS, viral infections</td>
<td>$13.80</td>
<td>$11.73</td>
<td>$10.37</td>
<td>$8.88</td>
<td>$7.33</td>
<td>$6.43</td>
</tr>
<tr>
<td>Endocrine Therapy</td>
<td>Breast cancer</td>
<td>$12.20</td>
<td>$10.55</td>
<td>$8.83</td>
<td>$6.47</td>
<td>$5.33</td>
<td>$4.45</td>
</tr>
</tbody>
</table>

using newer and superior production processes, and there are significant regulatory checks and balances around production. Provided these checks and balances are in place, the public has little to fear and plenty to be satisfied with in terms of the wider benefits for the health system. However, a change in brand-name, colour or shape of a tablet can raise understandable questions in a patient’s mind.

It’s a cliché, but perception is reality. If a patient perceives a difference, or a lack of efficacy, then that is real. Some years ago when a brand of simvastatin changed, there was a ‘spike’ in adverse event reporting to the Centre for Adverse Reactions Monitoring – this despite the different brand being supplied by the same company and being made in the same factory as the previous brand.

**Subtle influences**

This is where the doctor’s or pharmacist’s role is critical. Patients need to get a fair and honest answer from health professionals. For a patient to commit to taking a medicine daily for many years, they must believe that it is doing good.

This influence can be very subtle. Is the fact that a medicine is made in a certain country relevant? A number of our generic medicines are now sourced from India, a country with a very large and highly developed pharmaceutical manufacturing infrastructure. The quality of these products is on a par with medicines from any other country, yet recent news events have revealed public unease over medicines made in Asian countries.

But we seldom get the full picture: a generic medicine made in Germany, for example, has caused public concern in recent years. And that generic was also manufactured for one of the largest research-based companies in the world – and most of those companies have very high production of generic medicines, including production in India. It has also been suggested that brand names are much simpler than chemical names, frustrating the switch to generic products – an understandable commercial strategy but what about the public interest?

“**Working with others in the medicines system, we must get past the current bias against generic medicines**”.

I’ve no doubt there will, from time to time, be safety issues identified with generic medicines – just as there can be with branded products. But that’s not a reason to distrust generics overall. If these medicines have satisfied regulatory agencies about their safety, quality and efficacy, this should ease concerns and such messages ought to be passed on to patients.

**Assurance and vigilance**

This is not to say that health professionals should ignore adverse events when they are reported. Health professionals should always be vigilant for such events and record them through the appropriate channels. However, it is important that they do not undermine the confidence of patients unnecessarily.

When PHARMAC makes a medicine change, this is sometimes accompanied by information for health professionals and for patients. This can be produced through several channels, including the Best Practice Advocacy Centre, an evidence-based information service based at the University of Otago, or through patient-oriented leaflets.

Generic medicines are a large and growing part of the medicines toolbox so we owe it to all our patients to help them adjust to changes that occur. This means reassuring where necessary, giving our patients confidence, but being vigilant for real adverse events that occur. When we over-react we risk being the object of suspicion ourselves.
Getting the most from our medicine

Everyone in New Zealand has the same entitlement to medicines, but there are differences in the way medicines are prescribed and used, and differences in people’s health status as a result, writes Manager Access and Optimal Use Marama Parore (Ngati Whatua, Ngati Kahu, Nga Puhi).

Part of PHARMAC’s role includes promoting the responsible (or optimal) use of medicines, helping everyone use the medicines that are available as well as possible.

**Why PHARMAC?**

Like others, PHARMAC wants the best possible outcomes from use of medicines. This means being focused on the way medicines are prescribed, dispensed and used by patients. Further, as the pharmaceutical budget is a product of both medicines prices and the quantity of medicines used, we need to be concerned about both price and quantity. Economists call this promoting ‘efficient expenditure’, which is jargon for making the best use of what we spend and avoiding wastage.

PHARMAC can also take a national perspective on optimal use work, which can be beneficial in terms of nationally consistent approaches and use of resources, compared to multiple campaigns in different parts of the country.

It is easy to become obsessed with the next exciting medicine, but the funding of new medicines is a very small part of what we spend each year. The medicines strategy, Medicines New Zealand, recognised this imbalance and required a stronger focus of the medicines system on optimal use. This activity has costs, but the gains from avoiding wastage and improving people’s lives can be significant.

**Addressing disparities**

Our work involves identifying usage patterns, where there is under or over prescribing, and taking steps to address disparities. One such disparity is comparative medicine use between Pacific, Māori and other New Zealanders.

We know that Māori have higher burdens of disease in areas like heart disease and respiratory illnesses and on average die sooner than non-Māori.

When these differences are taken into account, PHARMAC’s analysis shows that prescribing rates for Māori are 23% below those of non-Māori.

Particular areas of under-prescribing in Māori are in areas of high health need, such as heart disease, infections, diabetes, mental health and respiratory disease.

- Increase awareness of safe and appropriate use of medications
- Improve access to medicines
- Develop patient and whānau education resources to be used by Māori community-based health workers (kaimahi)
- Promote medications as part of managing overall healthcare.

Programmes like He Rongoā Pai are part of our Access and Optimal Use work, which is really about making best use of the medicines that are currently available.

Many of our programmes include working co-operatively with other parts of the sector, particularly District Health Boards who are the main medicine funders. Here’s a rundown on two of our campaigns and who we work alongside to put them in place.
One Heart Many Lives

One Heart Many Lives has gone from strength to strength in the Far North and Hawke’s Bay, and was further launched into Lakes (Rotorua) DHB during 2008.

Heart disease is one of the big killers of Māori men so the campaign is unashamedly aimed at this group. Compared to the rest of New Zealand, Māori men in the Lakes region die nearly 14 years earlier than average, the second-highest disparity by DHB region (only Northland is higher). We don’t think that’s acceptable.

This means these areas are being robbed of their men far too early. Heart disease is a major cause of death but it is largely a “silent killer”. The road toll is well publicised and well known, but the number of deaths from heart disease is 20 times greater.

In Lakes, the campaign’s central message is the same as in Hawke’s Bay and Northland - encouraging men to get their hearts checked and make lifestyle changes to reduce their chances of having a heart attack or stroke.

The One Heart Many Lives campaign also provided the banner to bring together primary care workers with an interest in heart disease at a conference at Te Papa, Wellington.

Supported by District Health Boards, the National Heart Foundation, Te Hotu Manawa Māori and the Ministry of Health, the conference Getting the Most for Your Patients aimed to give primary healthcare workers the knowledge and tools to assess and treat people for cardiovascular risk.

There has been a positive response to our Gut Reaction campaign, which aimed to raise awareness about high use of medicines to treat gastrointestinal problems like heartburn and dyspepsia.

Proton pump inhibitors (PPIs) like omeprazole and pantoprazole are very commonly used, but older, less expensive medicines may be more appropriate for patients. At any one time, up to 370,000 New Zealanders might be prescribed a PPI. Omeprazole alone accounts for some 1.1 million prescriptions a year and rising, making it the fourth-most prescribed medicine in the country.

The campaign was developed by PHARMAC in co-operation with a range of organisations including the College of Pharmacists, Pharmacy Guild, Pharmaceutical Society, NZ Gastroenterology Society executive, New Zealand Guidelines Group, BPAC and the DHBNZ/PHO team, to address high rates of proton pump inhibitor prescribing.

The message in Gut Reaction is simply about making sure these medicines are used optimally. The campaign started in 2007 and involved best practice messages to prescribers and pharmacists, voluntary auditing of patients and free sampling of ranitidine.

In late 2007 we sought feedback on the campaign from health professionals. This revealed a high awareness of the campaign among respondents, with the highest awareness (85%) among pharmacists.

More significantly, the survey revealed that the campaign has assisted a change in prescriber behaviour. 59% of doctors who responded said that in the past year they had reduced their prescribing of PPIs.
As the sun sets on Pfizer’s patents for atorvastatin (or Lipitor, the top selling drug of all time), so ends the era of blockbuster primary care medicines. Despite industry best efforts to extend them, patents are now expiring on the wave of blockbuster drugs developed during the therapeutic revolution of the 1970s and 80s. At the same time, fewer new drugs are being brought to market, particularly in categories of treatment prescribed by primary care professionals. The resulting changes in market dynamics will dramatically transform the pharmaceutical sector.

Manufacturers are quickly retooling corporate structures, R&D activities and sales forces to adjust. Governments must also be prepared for the opportunities and challenges of this changing pharmaceutical marketplace.

With 15+ years of evidence-based drug benefit management — and budgetary control that is envied around the world — New Zealand’s PHARMAC appears distinctly well suited to adapt to the emerging trends.

The rise of the generic

Many blockbuster drugs for common conditions have already come off patent, including leading brands of blood pressure treatments, ulcer drugs, and antidepressants. Sales of generic medicines are consequently outpacing sales of brands for the first time. An even greater shift in this direction is about to occur.

Analysts expect that brands with current sales of over US$120 billion (including Lipitor at roughly US$13 billion) will face generic competition in the next five years due to expiring patents. With so much of the modern medical arsenal now off patent, funders of medicines have an opportunity to realise the full value of generic competition. Easily said; but not often done around the world.

While generics enter global markets soon after patent expiry, policies in many countries result in modest savings. This is because most countries — including Canada, the US, Australia, and most European nations — use crude tools to stimulate price competition among generics. Typically any generic (or brand) that matches a posted target price is eligible for cover. Rather than stimulating true competition, these policies result in what is effectively ‘price fixing’ at the posted price. Generics then compete for sales volumes by paying large, secretive discounts directly to retailers.

Minimal savings are passed on to governments or consumers. The lost opportunities for generic savings due to hidden kickbacks paid to retail pharmacy chains in Canada alone are estimated to be on the order of hundreds of millions of dollars per year.

New Zealand, in contrast, is a world leader in generic acquisition and is therefore well positioned to realise the full value of increased availability of generic drugs. The now well-established generic acquisition strategies of PHARMAC ensure that generic medicines are priced at truly competitive levels and that the resulting savings flows back to the funder of these and other medicines.

In effect, PHARMAC co-ordinates generic drug purchasing within the community setting in the same manner that hospitals do. It is a simple and effective way to realise value for the health care system — one that other countries are now paying close attention to.

Assessing value, and value propositions

With few true breakthroughs in hand, many firms are betting on combination products, modified dosage forms and other strategies to prolong patent lifespans. There will be a growing emphasis on value propositions made by firms whose new products (and potentially services such as compliance monitoring) enter into older drug categories. Some argue that industry is moving away from selling pills to selling outcomes. Indeed, an increasing number of firms are working to encourage regulators to license products on the basis of proposed life-cycle approaches to monitoring safety and efficacy; and to encourage funders to cover medicines on the basis of proposed outcomes assessment.

Some of these contracts may be a win-win for firms and the public, if (and it is a big ‘if’) patient safety is not sacrificed in the rush to markets and if (another big ‘if’) clinically relevant outcomes are carefully and systematically measured and monitored in ways that generate valid information. In other words, you ultimately need proof that desired outcomes are achieved as a result of the new product and not the result of the placebo effect or other influences. It is tantamount to running clinical trials without blinded controls . . . and doing so in the very complex and politically charged “real-world” environment.

To enable this new business model, manufacturers and consulting firms are scrambling to build health economics and outcomes research capacity, often leveraging massive administrative datasets from US managed care organisations. Researchers — and I know this first hand — are very keen to participate. But the task of generating evidence that
even roughly approximates the ‘gold standard’ of clinical trials using real-world patient observation poses many technical, methodological, ethical and legal challenges.

With its experience conducting and critiquing health economic assessments of medicines, PHARMAC is also in a strong position to critically appraise the value propositions regarding emerging new medicines. PHARMAC’s traditional focus on clinically relevant outcomes will be particularly critical to assessing claims based on either pre- or post-market trials and observational studies.

Additionally, PHARMAC is rivalled only by a few major US health maintenance organisations in terms of contracting expertise. PHARMAC’s years of experience working with manufacturers to develop contracts that realise the value in pharmaceuticals will serve the New Zealand health system well in this new era of performance-based and risk-sharing pharmaceutical contracts.

**Specialist and personalised medicines**

As a growing number of treatment categories for common conditions have become the pharmaceutical equivalent of commodity markets, firms have been targeting drug development toward less common conditions where the disease burden is grave. Typically prescribed by specialists, what markets for such drugs lack in patient volume they make up in much higher potential prices per case treated.

Cancer drugs lead this wave of new specialist blockbusters, and through the identification of biomarkers that could be used to target treatments toward populations most likely to receive benefit (or least likely to be harmed), there is also an emerging trend toward personalised medicines.

Medicines that are targeted to small populations on bases of safety and efficacy pose a challenge for both firms and policy makers. Targeting raises the value per case treated, and therefore could justify a higher treatment price. However, targeting often results in population sizes too small to generate quality data regarding net treatment benefits. Moreover, failure to target what is supposed to be a customised medicine is a major risk to budgets and patients alike.

Specialised medicines pose other challenges for policy makers because of the much smaller numbers of prescribers for these drugs. These specialist prescribers are not only intensely targeted through traditional industry marketing practices; they are also the same experts who run trials to evaluate such medicines and who are invited to engage in various conflict-of-interest inducing activities, such as the speakers circuit.

Even if the challenges of conflicts of interest can be overcome, the challenges of targeted medicines will require new policy approaches. In this regard, it is fair to say that New Zealand can’t go it alone. Nor could Australia, or Canada, or any other single country of modest population size.

International co-operation will be required to help to deal with the increasing clinical, economic and ethical challenges posed by drugs for small patient populations. This will likely involve information sharing, the development of standards for health outcomes measurement (particularly as it relates to the use of surrogate markers of health improvement), and the co-ordination of efforts for real-world evidence development. Through partnership with like authorities around the world, PHARMAC could help to ‘globalise the evidence while localising the decisions.’

*Dr Steve Morgan is Associate Professor, School of Population and Public Health, at the University of British Columbia, Canada.*
There’s growing scepticism about claims promoting new pharmaceuticals, as international concern increases over what appears in the media. Issues that have made headlines this year include ‘publication bias’, when negative results are not published, and positive reporting that does not mention that the manufacturer funded the research.

Publication bias was a recurring theme and PHARMAC made a contribution through an article, co-authored by PHARMAC staff, that was published in the Lancet in May 2008. The article argued that, taking into account data not published in peer-reviewed publications, the way that Herceptin is used in most of the world may be a third less effective than originally thought.

This general theme was taken up in The Oncologist, which devoted an entire issue to publication bias, describing it as the largest barrier to transparency in oncology. The Oncologist had reported how only one in every five oncology trials is published – and only six out of every 100 industry-sponsored ones.

There’s growing scepticism about claims promoting new pharmaceuticals, as international concern increases over what appears in the media. Issues that have made headlines this year include ‘publication bias’, when negative results are not published, and positive reporting that does not mention that the manufacturer funded the research.

Publication bias was a recurring theme and PHARMAC made a contribution through an article, co-authored by PHARMAC staff, that was published in the Lancet in May 2008. The article argued that, taking into account data not published in peer-reviewed publications, the way that Herceptin is used in most of the world may be a third less effective than originally thought.

This general theme was taken up in The Oncologist, which devoted an entire issue to publication bias, describing it as the largest barrier to transparency in oncology. The Oncologist had reported how only one in every five oncology trials is published – and only six out of every 100 industry-sponsored ones.

"Uncritical reporting"

Studies published in The Journal of the Royal Society of Medicine examined media coverage of the breast cancer drug trastuzumab (Herceptin) in Australia and the UK.

In a paper examining the reporting of Herceptin in the UK’s national press, the Royal Society of Medicine’s journal concluded: “Newspaper coverage of trastuzumab has been characterised by uncritical reporting. Journalists (and consumers) should be more questioning when confronted with information about new drugs and of the motives of those who seek to set the news agenda.”

"news reports commonly overemphasise the benefits of treatments, fail to discuss their side effects, and exaggerate their uses.”

In the United States, the Journal of the American Medical Association (JAMA) published a study that reviewed 300 news stories about medication studies – all funded by pharmaceutical companies – and found 42 percent failed to mention the funding source.

Writing in the Boston Globe, one of the study’s authors said: “As a result, readers were left in the dark about an important source of study bias. Previous research has suggested that news reports commonly overemphasise the benefits of treatments, fail to discuss their side effects, and exaggerate their uses.”

Non-publication of studies was another recurring theme in the international press, particularly in the United States.

"Evidence obscured"

The New York Times was critical of Merck and Schering-Plough of failing to publish studies that raised questions about the risks of a cholesterol drug when used with statins (a common therapeutic combination).

We keep telling people we want to practice evidence-based medicine, and what we keep finding out is that much of the evidence is obscured,” said Dr Harlan Krumholz, a cardiologist at Yale when told about the previously undisclosed studies. “There is important evidence, but it’s not in public view. It’s hidden from investigators”.

Meanwhile, two American medical journals suggested Merck & Co violated scientific-publishing ethics by ghost-writing dozens of academic articles, and minimised the impact of patient deaths in trials of Vioxx, the top selling drug later linked to cardiac problems (for which PHARMAC declined funding). An editorial in JAMA said medical journals, academic scientists and drug companies all bear part of the blame for practices that undermine the integrity of medical research.

In the light of such findings, the US Association of Healthcare Journalists published guidelines calling on medical journalists to “investigate and report possible links between sources of information and those who promote a new idea or therapy”. The guidelines also exhort journalists to “report the complete risks and benefits of any treatment, along with possible outcomes of alternative approaches”. As the Boston Globe states, “the medical community has a responsibility to help journalists comply with these stipulations by ensuring medical journal articles and press releases about research emphasise commercial influences that may have biased their findings”. 

"We keep telling people we want to practice evidence-based medicine, and what we keep finding out is that much of the evidence is obscured”
UK controversies

Another tactic highlighted in 2007/08 was the use of lobby groups to promote a drug company’s cause. With the media’s attention already on pharmaceutical company funding of patient groups, this did the lobbying industry no favours.

Britain’s Guardian newspaper told the story of Cancer United, an organisation formed by a world-wide public relations company, which also runs the group’s secretariat, and which is wholly funded by drug company Roche, the maker of cancer drugs Avastin and Herceptin. European MPs have since withdrawn from Cancer United’s board, amid concerns over the funding and lack of transparency.

The British health assessment agency NICE was also involved in a controversy with Roche over Avastin, with Roche refusing to provide data about its cost-effectiveness. NICE’s head Professor Sir Michael Rawlins said, “they’re saying that they felt they could not substantiate the high prices they expected to command in relation to the benefits of the product”. Avastin typically costs $NZ10,000 per month in Britain. Rawlins added: “We have a finite amount of money for healthcare, and if you spend money one way, you can’t use it in another”.

In such an environment it was perhaps not surprising to see a shift in the relationship between pharmaceutical companies and NICE. In an interview with the Observer, Rawlins accused the industry of “overpricing new medicines to boost its profits”, and warned of “perverse incentives” to hike the prices of new drugs – including linking the pay of executives to their firm’s share price.

“Health chief attacks drug giants over huge profits”
– The Guardian

“We (NICE) are being told we are being mean all the time, but what nobody mentions is why the drugs are so expensive”. Rawlins said kidney cancer drugs – which NICE had been criticised for not recommending - could be produced for about a tenth of their current cost.

Staff profiles

Sharon Ponniah, programme manager, Access & Optimal Use

PHARMAC runs a number of health campaigns, through its Access and Optimal Use team. These campaigns aim to help people make the best use of medicines, and Sharon is at the front end of developing one of these - a new campaign for childhood asthma called ‘Space to Breathe’.

After completing her BSc Hons at Otago University, Sharon worked at the Ministry of Health, working in tobacco control and epidemiology – while actively seeking a job at PHARMAC.

“Working at PHARMAC keeps you busy and everyone is constantly juggling many balls with one hand. We have a lot of fun in the AOU team and get to do a lot of work with regions and communities, using our campaigns to engage with the people who are most in need. The work that PHARMAC does as an organisation touches a lot of people, often behind the scenes, and often unnoticed. It can be very rewarding and I am constantly in awe of the depth and level of professionalism that everyone here demonstrates.”

Sharon is a relative newcomer to PHARMAC, having only joined this year. She’s a Wellington native, and now flats in its inner city. When not studying for her PhD in public health, she likes to keep busy running around the bays as training for her annual half marathon, playing social grade tennis for the PHARMAC team she captains, sewing, or trying a new recipe out in the kitchen.

Chris Peck, analyst

“I joined PHARMAC because I wanted to work in a small, dynamic organisation. I’ve also had a keen interest in government since my mid teens when my dad was elected into parliament. The great thing about working here is that the staff have such a wide range of expertise. I’m constantly learning from those around me.”

Chris works as part of PHARMAC’s team of analysts, examining data on pharmaceutical usage patterns and monitoring spending. Before PHARMAC can make any spending decisions, it needs to know how much funding is available, and the analysts provide that knowledge.

“My job involves spending a lot of my time analysing data to inform the decisions PHARMAC makes, but because we’re so small there’s a lot of scope to be involved with other projects outside a typical analyst’s role. I’ve particularly enjoyed the involvement with stakeholders.

“At weekends I like to get out as much as possible. I play competitive football for Miramar Rangers, which dominates my time in the winter, and I try to get up Ruapehu to snowboard when possible. I also play cricket, tennis, golf and netball socially. More recently, I’ve been teaching myself acoustic guitar and have discovered a love of food, thanks mostly to my mum’s influence as a chef at the Matterhorn.

“Concern over cancer group’s link to drug firm”
– The Guardian
Pharmaceutical spending – getting more for less

New Zealanders like to compare themselves to people in other countries, and it’s no different with pharmaceuticals. But international comparisons are difficult to make because there are differences between countries that make comparisons problematic.

There is often debate around the appropriate level of pharmaceutical spending, and how this should be measured. Figures like OECD averages and the consumer price index (CPI) have been put forward as useful measures to judge New Zealand by.

Simple measures aren’t the answer

Simple measures such as number of medicines funded, expenditure as a percentage of health budget or Gross Domestic Product, or time to fund a medicine are interesting to make comparisons on, but they are not particularly meaningful. For example:

• number of medicines funded – this measures ‘inputs’, but it’s the ‘outcomes’ that are important. Simply counting the number of medicines funded doesn’t give a picture of the conditions that can be effectively treated and the health gains that result.

• expenditure as a proportion of health budget or GDP – different countries have different medicine prices, and funding priorities. Overall, New Zealand’s pharmaceutical prices are low by international standards.

• speed of decision making – quick decisions may not be quality decisions. PHARMAC works to ensure all relevant evidence is thoroughly considered, as well as long-term costs and whether the decision is affordable. Usually, medicine funders only get one shot at a decision. Once a medicine is funded, it is difficult to withdraw that funding.

What we do know from work conducted in the past year, is that since 1993 PHARMAC’s activity has led to a three-fold increase in our purchasing power.

Purchasing power tripled

Using a Pharmaceutical Price Index (illustrated in the graph below), our purchasing power in real (inflation-adjusted) terms has tripled since 1993. Part of the rationale for creating PHARMAC was to promote competition among pharmaceutical suppliers, and this has occurred in much the same way that is widely accepted in other markets (such as use of negotiation and tendering).

When new technologies emerge, these generally become cheaper over time. This is certainly the case with high-tech consumer electronics like digital cameras, DVD players or flat-screen TVs.

The same applies to pharmaceuticals, which become subject to competition and price reductions as time goes by. PHARMAC’s use of pro-competition strategies have, in some cases, led to price reductions of up to 90%. Cumulative savings exceed $300 million since our tender began.

CPI not the right measure for pharmaceuticals

The Consumer Price Index (CPI) is a recognised measure of price changes, so why not use it to measure pharmaceutical prices? The CPI is a good measure for the overall economy, but a Pharmaceutical Price Index should be used to show trends in pharmaceuticals alone. The CPI is a “headline measure”, taking into account a wide range of goods and services, including pharmaceuticals.

Within the CPI there are sub-groups that show increases over time (such as food, housing and transport), and those that show decreases (such as apparel, technology, pharmaceuticals). The price of pharmaceuticals is a contributor to the overall CPI figure, but the historic pattern of pharmaceutical prices has been deflationary, not inflationary.

Statistics NZ urges caution in using particular indexes like the CPI:

“The CPI is designed to measure the combined price movements of the tens of millions of retail transactions undertaken by people throughout New Zealand in a specified period. Any such statistical indicator is bound to have limitations for particular users and uses. However, the CPI is regarded as a good general measure of the effect of price change on the purchasing power of consumers in general.

Before attempting to use the CPI or components of the CPI to measure price change, users should also determine whether the index is the most appropriate for their needs, as it is only one of many measures of price change produced by Statistics New Zealand.”

So using the CPI’s growth to argue that pharmaceutical spending should rise is a bit like arguing DVD players should cost more now than they did 10 years ago.

And pharmaceuticals are a bit different to other consumer goods – for the most part consumers don’t pay the full price of the medicine, they only pay the co-payment (usually $3). Consumers don’t usually face cost fluctuations of subsidised medicines, so a Consumer Price Index isn’t really relevant to pharmaceuticals.

For PHARMAC, increased purchasing power is about constantly trying to get better value for money from whatever level of money we spend. This allows more to be spent on new medicines, and better health outcomes, than would be the case if prices were higher.
Top 20 most prescribed medicines

Year ending June 2008

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).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Prescriptions</th>
<th>Main use</th>
<th>07 rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>paracetamol</td>
<td>1,760,000</td>
<td>pain relief</td>
<td>1</td>
</tr>
<tr>
<td>aspirin</td>
<td>1,280,000</td>
<td>prevents heart attack and stroke (cardiovascular risk)</td>
<td>2</td>
</tr>
<tr>
<td>simvastatin</td>
<td>1,170,000</td>
<td>impaired cholesterol (cardiovascular risk)</td>
<td>3</td>
</tr>
<tr>
<td>omeprazole</td>
<td>1,100,000</td>
<td>heartburn, stomach ulcers</td>
<td>4</td>
</tr>
<tr>
<td>amoxicillin</td>
<td>890,000</td>
<td>bacterial infections</td>
<td>5</td>
</tr>
<tr>
<td>metoprolol succinate</td>
<td>820,000</td>
<td>raised blood pressure, heart disease</td>
<td>7</td>
</tr>
<tr>
<td>amoxicillin clavulanate</td>
<td>800,000</td>
<td>bacterial infections</td>
<td>6</td>
</tr>
<tr>
<td>salbutamol</td>
<td>740,000</td>
<td>asthma symptoms</td>
<td>8</td>
</tr>
<tr>
<td>diclofenac sodium</td>
<td>530,000</td>
<td>pain/arthritis</td>
<td>9</td>
</tr>
<tr>
<td>cilazapril</td>
<td>510,000</td>
<td>raised blood pressure (cardiovascular risk)</td>
<td>10</td>
</tr>
<tr>
<td>zopiclone</td>
<td>470,000</td>
<td>insomnia</td>
<td>16</td>
</tr>
<tr>
<td>prednisone</td>
<td>450,000</td>
<td>steroid treatment for asthma attacks, arthritis etc</td>
<td>15</td>
</tr>
<tr>
<td>frusemide</td>
<td>440,000</td>
<td>heart failure</td>
<td>11</td>
</tr>
<tr>
<td>bendrofluazide</td>
<td>430,000</td>
<td>raised blood pressure (cardiovascular risk)</td>
<td>12</td>
</tr>
<tr>
<td>quinapril</td>
<td>400,000</td>
<td>raised blood pressure, heart disease, diabetes</td>
<td>13</td>
</tr>
<tr>
<td>fluticasone</td>
<td>410,313</td>
<td>prevents asthma</td>
<td>14</td>
</tr>
<tr>
<td>calcium carbonate</td>
<td>377,527</td>
<td>osteoporosis</td>
<td>17</td>
</tr>
<tr>
<td>flucloxacillin sodium</td>
<td>390,000</td>
<td>bacterial infections</td>
<td>20</td>
</tr>
<tr>
<td>thyroxine</td>
<td>380,000</td>
<td>underactive thyroid gland</td>
<td>19</td>
</tr>
<tr>
<td>felodipine</td>
<td>380,000</td>
<td>raised blood pressure, heart disease</td>
<td>18</td>
</tr>
</tbody>
</table>

Annual Inflation

The essentials cost more:

- Petrol: 16.9%
- New housing: 6.1%
- Electricity: 6.5%

Small mercies?

- Early childhood education: 34.8%
- Pharmaceuticals: 14.9%
- AV equipment: 21.1%

* Dominion Post 18 Jan 2008 report on Stats New Zealand figures

Staff profiles

Jan Quin, team leader, medical team

Jan is PHARMAC’s longest-serving staff member; she’s been working at PHARMAC since mid-1994, with a few stints of maternity leave (Jan has 10 year old twins and a 7 year old).

She trained as a nurse, then worked around the world until joining PHARMAC back in its early days. “I’d been a drug company rep, so joining PHARMAC meant I really jumped the fence: PHARMAC was such a small organisation then, so we all had to do a number of roles – and work insane hours.”

Having worked in various roles in the organisation, Jan is now a team leader in the medical team, which performs roles like managing the clinical advisory committee PTAC, the Exceptional Circumstances schemes that give people with rare conditions access to unfunded medicines, and managing high-cost medicine panels. Part of the work involves keeping in direct contact with patients receiving some high-cost medicines.

“What PHARMAC does, it does well. That’s why the organisation has grown – we’re now buying some of the drugs for the hospitals, and working with healthcare professionals to promote healthy choices.

“PHARMAC has really good people, doing a hard job to the best of their ability. I tell people that I’m proud of PHARMAC, although that means I do get harangued occasionally.”

John Geering, Systems Architect, Schedule Team

John Geering trained as a mining engineer, before moving into science and then the world of computers. His current job means ensuring computers can talk to each other and smoothly integrate PHARMAC’s decisions.

Part of the Schedule Team, John’s work helps to produce the list of funded medicines (the Pharmaceutical Schedule), which comes out as a book three times a year. But it’s updated more regularly electronically, which is where John comes in.

John’s part of PHARMAC’s DNA because he’s one of the longest-serving staff members, having joined in 1995. It wasn’t exactly planned. He came to Wellington in the early 1970s, planning to head off on his OE; instead, his cautious parents persuaded him to take a job.

He’s been working in the capital city ever since; instead of doing his OE, he ended up getting married and now he’s a proud grandfather. And a busy one: tramping with his son, a dedicated gardener (essential with his south-facing garden in Wellington’s hills), and when he’s relaxing he loves tackling cryptic crosswords, sudoku puzzles and the weekly Enigma in New Scientist. But John does have a secret vice – baking bread from scratch, with lots of kneading, which he began as a way of fighting off arthritis, on the ‘use it or lose it’ principle.
Major funding decisions in 2007/08 – new patients, new spending, better health

Each year, PHARMAC invests millions of new dollars in pharmaceuticals and works to ensure these produce better health for New Zealanders. PHARMAC’s major funding decisions in 2007/08 (see table) included adding five new products to the Pharmaceutical Schedule, and widening access to six community and five cancer pharmaceuticals. Further specialist restrictions were removed for 43 chemicals and PHARMAC had to agree to substantial price increases for metoprolol and thyroxine.

### New listings

<table>
<thead>
<tr>
<th>Funding Decision</th>
<th>Month of implementation</th>
<th>Condition treated</th>
<th>Estimated no. new patients by 30 June 2008</th>
<th>Estimated no. new patients by 12 months’ implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>sirolimus</td>
<td>July 2007</td>
<td>Kidney and other organ transplant rejection</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Condoms (increased range)</td>
<td>March 2008</td>
<td>Contraception</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ziprasidone</td>
<td>August 2007</td>
<td>Schizophrenia</td>
<td>600</td>
<td>700</td>
</tr>
<tr>
<td>exemestane</td>
<td>August 2007</td>
<td>Breast cancer</td>
<td>300</td>
<td>400</td>
</tr>
<tr>
<td>macrogol 3350</td>
<td>October 2007</td>
<td>Problematic severe constipation (e.g. patients with terminal cancer requiring opiate pain relief)</td>
<td>2,100</td>
<td>2,700</td>
</tr>
</tbody>
</table>

### Widening access

<table>
<thead>
<tr>
<th>Pharma</th>
<th>Month of implementation</th>
<th>Condition treated</th>
<th>Estimated no. new patients by 30 June 2008</th>
<th>Estimated no. new patients by 12 months’ implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>capcitabine</td>
<td>July 2007</td>
<td>Duke's C colorectal cancer</td>
<td>1,400</td>
<td>1,400</td>
</tr>
<tr>
<td>tiotropium bromide</td>
<td>July 2007</td>
<td>Moderate chronic obstructive pulmonary disease (COPD)</td>
<td>2,000</td>
<td>2,000</td>
</tr>
<tr>
<td>benzathine benzylpenicillin - Inj 1.2 mega u per 2 ml (1)</td>
<td>July 2007</td>
<td>Prevention of further rheumatic fever episodes with risks of consequent heart valve and other damage (long acting injection with monthly not daily dosing)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>ondostetron</td>
<td>September 2007</td>
<td>Nausea and vomiting, particularly from cancer treatments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>losartan, losartan with hydrochlorothiazide (1)</td>
<td>June 2008</td>
<td>Renal disease, treatment-resistant raised blood pressure, etc.</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>rizatriptan wafers</td>
<td>June 2008</td>
<td>Acute migraine</td>
<td>500</td>
<td>5,000</td>
</tr>
</tbody>
</table>

### Removal of specialist restrictions for 43 chemicals (1)

<table>
<thead>
<tr>
<th>Pharma</th>
<th>Month of implementation</th>
<th>Condition treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer drugs (2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>docetaxel (1)</td>
<td>July 2007</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>trastuzumab</td>
<td>July 2007</td>
<td>Breast cancer</td>
</tr>
<tr>
<td>oxaliplatin</td>
<td>December 2007</td>
<td>Stage III (Duke's) colorectal cancer</td>
</tr>
<tr>
<td>paclitaxel</td>
<td>December 2007</td>
<td>Relapsed germ cell cancer of the testis, relapsed ovarian cancer, node-negative HER2 positive early breast cancer</td>
</tr>
<tr>
<td>vinorelbine</td>
<td>December 2007</td>
<td>Adjuvant treatment of stage IB-IIIA non-small cell lung cancer</td>
</tr>
</tbody>
</table>

### Other

<table>
<thead>
<tr>
<th>Pharma</th>
<th>Month of implementation</th>
<th>Condition treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>thyroxine (3)</td>
<td>October 2007</td>
<td>Thyroid hormone deficiency</td>
</tr>
<tr>
<td>metoprolol succinate (3)</td>
<td>December 2007</td>
<td>Raised blood pressure (cardiovascular risk), heart failure</td>
</tr>
</tbody>
</table>

Notes:

1. Insufficient or inconclusive data to provide a reliable estimate;
2. Cancer drugs are funded from the Pharmaceutical Cancer Treatment budget, which is held by DHB hospitals (not PHARMAC);
3. Price increases, no additional health gains.
More people treated
As a result of the decisions in 2007/08 an estimated 11,000 new patients were treated with these subsidised medicines. In the first full year of these decisions being implemented, PHARMAC estimates that there would be 15,000 new patients using these medicines – including 5000 new patients using rizatripan, 2700 new users of tiotropium and around 300 patients accessing trastuzumab for early breast cancer. Total expenditure over 12 months for these decisions is estimated to be between $10 and $15 million, with an additional $5 million spent on price increases for metoprolol and thyroxine.

Health gains from funding decisions
PHARMAC also assesses the health gains obtained through its investments, and measures outcomes in quality adjusted life years (QALYs). QALYs are a standard pharmacoeconomic measure to compare different medicines that do different things.

The funding decisions for the six pharmaceuticals (indication in brackets) below

- **trastuzumab/docetaxel** (early breast cancer)
- **macrogol 3350** (last line oral pharmacotherapy for constipation)
- **tiotropium** (moderate chronic obstructive pulmonary disease (COPD))
- **ziprasidone** (schizophrenia)
- **oxalaplatin** (stage III (Duke’s C) colorectal cancer)
- **vinorelbine** (adjuvant treatment of stage IB-IIA non small cell lung cancer)

are likely to lead to 6600 new patients being treated in the first 12 months after listing. These patients are estimated to gain the equivalent of 1350 full years of extra life (i.e. QALYs) over their lifetime.

Staff profiles

**Steffan Crausaz, Manager, Funding & Procurement**
Seven years ago, Steffan moved to New Zealand from Britain with his Zimbabwean wife, Kerry. He graduated as a pharmacist, and worked in the pharmaceutical industry before travelling in Africa. Now he’s a New Zealand citizen, with two Wellington-born children.

Steffan joined PHARMAC keen to use his MSc in evidence-based pharmacotherapy. He does so in leading the team that guides PHARMAC’s pharmaceutical funding applications and negotiating agreements with pharmaceutical companies.

The work is challenging and multi-faceted. “The funding and procurement team is really the core of PHARMAC’s work. We’re continually looking for areas where we can achieve the best value for the taxpayer dollar, or make a real difference in people’s lives by funding a new medicine. It’s hard work for my team, but it’s very motivating to be in a position where you can guide a medicine through a process that leads to a decision directly affecting people. It can be very rewarding.”

But life’s rather different at the weekends. “I spend a lot of time with my young family and I’ve just built a fence! Me! I’m no gardener, and I’m certainly not into Do-It-Yourself. I’m an urban person so I really appreciate Wellington’s environment.

**Moana Tane, Māori Health Manager, Access & Optimal Use**
Te Roroa, Ngati Korokoro, Ngati Wharara and Ngati Hine

Moana joined PHARMAC in mid-2008, moving from Auckland where she had been working for a Māori heart health NGO, training smoking cessation practitioners. That role meant a lot of travelling, and it was a relief for Moana to “lighten her carbon footprint” with the move to Wellington.

With a background in education and community development, Moana spent time living and teaching in Papua New Guinea and the United States. She returned to New Zealand in 2004 to work for her iwi, Te Roroa, as a researcher. This is when she heard about PHARMAC. “I went to One Heart, Many Lives, and I was so impressed by PHARMAC’s activities.”

The transition from education into health was a natural one for Moana, bringing her experience working with Māori communities together with a desire to serve her people. As part of the Māori Health and Access & Optimal Use teams, Moana is responsible for the implementation of Te Whaioranga, the Māori Responsiveness Strategy Action Plan. The plan aims to identify and address disparities in the way medicines are used by Māori, compared to the broader New Zealand population.

In the weekends, Moana finds time to knit (she has a major project currently under way) and to ride her BMW 650 motorcycle.
Review of expenditure, 2007/08

Expenditure for the year was $635.35 million (0.1% within budget). This equates to a 6%, or $36 million, increase from last year. Prescriptions increased by 7.4% over the same period.

Increases in expenditure over the year were:

- $42 million for underlying volume growth and MoH policies to reduce the cost of doctors visits and prescriptions to patients aged 25-44;
- $12 million to relax or remove eligibility criteria on medicines and remove specialist restrictions on prescribing: in effect, making the current list of medicines more accessible to patients;
- $21 million spent on funding new medicines this year and growth from funding decisions made over the past two years; and
- $5 million spent on supplier price increases for metoprolol (Betaloc) and thyroxine (Eltroxin).

Decreases in expenditure over the year were:

- $41 million saved this year through competitive processes such as Request for Proposals run over the past two years; and
- $3 million saved through the annual tender and Alternative Commercial Proposals resulting from it.

PHARMAC’s activity in medicines funding is always subject to budgetary pressures and this remained true in 2007/08. However, a complicating factor during the year was a decision by two companies to raise prices on two products with an overall budgetary impact of $5 million. The two medicines – metoprolol (Betaloc) for heart disease and thyroxine (Eltroxin) for thyroid problems – are both used by tens of thousands of New Zealanders.

While raising subsidies to match the higher price was a good move for patients, effectively it meant spending more on the same products for no net health gain, and it limited our ability to make other new investments. As a result, some potential investments that PHARMAC had been developing were not able to be implemented. In the 2007/08 financial year PHARMAC made 20 major funding decisions. This included removing prescriber-specific restrictions on 43 medicines, a move that PHARMAC is committed to as part of its work in removing system frustrations for clinicians and pharmacists.

Major decisions included widening access to the respiratory disease treatment tiotropium, and listing the new medicine ziprasidone (an antipsychotic) and rizatriptan (a treatment for migraine). Seven decisions related to cancer medicines.
Antibiotics

A prescriber shift towards narrow-spectrum amoxicillin has continued in 2008. The trend, which is in line with PHARMAC’s 11-year-old Wise Use of Antibiotics Campaign, was first noted in 2007 and has continued in the 2008 financial year.

The broader spectrum amoxicillin with clavulanic acid continues to be widely used, but its prescriptions are now outnumbered by narrow spectrum amoxicillin by more than 90,000. With a total of 890,000 prescriptions in the year, amoxicillin is the fifth-most prescribed medicine in New Zealand.

The annual antibiotics campaign was again launched in May 2008 with information showing a continued downward trend in people’s expectations of receiving an antibiotic. A survey by Colmar Brunton showed that in the 2007 winter 62% of people expected antibiotics when they visited the doctor about a cold or flu. This compares to 80% who expected antibiotics in a similar survey 10 years ago.

Figures also showed an ongoing decrease in the volume of antibiotics prescribed to six to 18-year-olds and under-six-year-olds, with almost 25,000 less prescriptions in this age group during the winter months of 2007 compared with the year before.

Antibacterials

<table>
<thead>
<tr>
<th>Cost (millions)</th>
<th>Prescriptions (000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jun '93</td>
<td>50</td>
</tr>
<tr>
<td>Jun '94</td>
<td>52</td>
</tr>
<tr>
<td>Jun '95</td>
<td>60</td>
</tr>
<tr>
<td>Jun '96</td>
<td>70</td>
</tr>
<tr>
<td>Jun '97</td>
<td>80</td>
</tr>
<tr>
<td>Jun '98</td>
<td>90</td>
</tr>
<tr>
<td>Jun '99</td>
<td>100</td>
</tr>
<tr>
<td>Jun '00</td>
<td>110</td>
</tr>
<tr>
<td>Jun '01</td>
<td>120</td>
</tr>
<tr>
<td>Jun '02</td>
<td>130</td>
</tr>
<tr>
<td>Jun '03</td>
<td>140</td>
</tr>
<tr>
<td>Jun '04</td>
<td>150</td>
</tr>
<tr>
<td>Jun '05</td>
<td>160</td>
</tr>
<tr>
<td>Jun '06</td>
<td>170</td>
</tr>
<tr>
<td>Jun '07</td>
<td>180</td>
</tr>
<tr>
<td>Jun '08</td>
<td>190</td>
</tr>
</tbody>
</table>

Cost (ex GST) Amoxycillin
| Cost (ex GST) Amoxycillin Clavulanate

Prescriptions Amoxycillin
| Prescriptions Amoxycillin Clavulanate
Access was widened to the respiratory disease medicine tiotropium (Spiriva) from 1 July 2007. The change means that tiotropium can be subsidised for patients with moderate Chronic Obstructive Pulmonary Disease (COPD) as well as more severe forms of the disease. COPD includes respiratory diseases such as chronic bronchitis and emphysema.

The decision was estimated to lead to a doubling of the number of people using tiotropium to 10,000 within five years, and to cost $10 million. This cost is expected to be partly offset by a reduction in the number of people requiring hospital treatment for COPD and complications.

The tiotropium access widening followed similar moves with long-acting beta agonist medicines (such as Oxis and Serevent) in recent years, decisions which together provide considerably wider access to medicines to treat respiratory illnesses. PHARMAC has also moved to provide more and wider access to combination inhalers (Symbicort, Seretide), that combine a preventer (such as fluticasone) and long-acting reliever in one inhaler.

A trend can now be seen towards combination inhalers for long-term asthma treatment. Prescriptions for the combination inhalers have risen to over 120,000 per year. Seretide, which was funded in 2006, now accounts for 42,000 prescriptions, while prescriptions for its individual components fluticasone and salmeterol have both declined. This underlines the growing preference for combination inhalers.

During the 2008 year PHARMAC also moved to introduce a third brand of the salbutamol short-acting reliever inhaler, listing Respigen to add to the Salamol and Ventolin brands that had been previously funded. Salbutamol accounted for some 740,000 prescriptions during the year, making it the eighth-most prescribed medicine in New Zealand.
Heart disease

As outlined on Page 21, PHARMAC maintained full funding for the beta blocker metoprolol, at an additional cost of approximately $4 million. One of the potential funding opportunities this impacted on was a proposal to widen access to the cholesterol absorption blocker ezetimibe. PHARMAC consulted on a widening of access, but with insufficient funds available this did not proceed. The ezetimibe proposal was subsequently overtaken by international studies questioning the effectiveness of the medicine, and has resulted in PHARMAC seeking further advice from its clinical advisory committees.

Access was widened to the blood pressure-lowering medicine losartan, a move that will benefit people with heart disease and diabetes.

Losartan (Cozaar), and a similar medication that combines losartan with hydrochlorothiazide (Hyzaar), were already funded to treat people with raised blood pressure.

The decision saw losartan’s access widened so it can now be used in combination with an ACE Inhibitor when appropriate. In addition, it can now be prescribed to treat the kidney disease that may result from type 2 diabetes, and so help delay progression to kidney failure.

Major decisions

- Improved access to clopidogrel (Plavix) – for cardiovascular risk reduction in aspirin-naïve patients
- Subsidy increase for metoprolol (Betaloc)
- Wider access to losartan, losartan with hydrochlorothiazide – for patients with renal disease and those with treatment-resistant blood pressure

Agents affecting the Renin-Angiotensin system

![Graph showing cost and prescriptions over time for different agents affecting the Renin-Angiotensin system](image-url)
PHARMAC continued its strategy of developing generic competition in the high-use area of proton pump inhibitors (PPIs), the most-prescribed medicines for treating gastro-intestinal disorders.

Further brands of the two most commonly prescribed PPIs, pantoprozole and omeprazole, were introduced. Omeprazole, with 1.1 million prescriptions in the past year, ranks fourth on the most-prescribed medicines list.

Multiple brands of omeprazole were introduced. Omezol was funded from 1 June 2007, and the Dr Reddy’s Omeprazole brand was funded from 1 October 2007. The Dr Reddy’s brand of pantoprazole was funded from 1 January 2008 and became the sole supply brand of that medicine from 1 June 2008.

Together, these moves towards generic competition are expected to produce significant savings in a high volume, high expenditure area of the Pharmaceutical Schedule.

At the same time, PHARMAC’s Gut Reaction campaign was encouraging medicine reviews of patients prescribed PPIs long-term, and a change to H2 antagonist medicines if appropriate.

Overall, there was a continued rise in prescribing of PPIs, which added a further 60,000 prescriptions for the year to 1.26 million prescriptions. Prescribing of H2 antagonists remained steady.

**Anti-ulcerants**

![Graph showing costs and prescriptions over time]

**Major decisions**

- Sole supply of pantoprazole (Dr Reddy’s Pantoprazole)
- Multiple brands of omeprazole (Omezol, Dr Reddy’s Omeprazole, Losec)
Mental Health

The antipsychotic medicine ziprasidone (Zeldox) was funded as a second-line treatment for people with schizophrenia and related psychoses from 1 August 2007.

Ziprasidone, another of the newer ‘atypical’ antipsychotic range of medicines, became funded for people who have tried other atypical antipsychotics (risperidone or quetiapine) but stopped using these medicines because of unacceptable side effects or inadequate response. The funding of ziprasidone was progressed to fill an unmet clinical need for an atypical antipsychotic with reduced tendency to cause weight gain.

Ziprasidone is the fifth atypical antipsychotic agent to be funded by PHARMAC. About 40,000 patients per year take one of the other four funded atypical antipsychotics (clozapine, risperidone, quetiapine and olanzapine), at an annual cost of over $58 million.

PHARMAC provided ongoing funded access to the Ritalin SR brand of methylphenidate sustained-release 20 mg tablets for those people who experienced clinical difficulties in switching from Ritalin SR to Rubifen SR, another brand of methylphenidate which was funded in 2007. Methylphenidate is used to treat Attention Deficit and Hyperactivity Disorder (ADHD), primarily in children.

The ongoing access to Ritalin SR followed some patients reporting difficulties to the Centre for Adverse Reactions Monitoring (CARM), the Otago University based organisation that tracks adverse reactions to medicines. About 10,000 people take sustained-release methylphenidate.

The number of antidepressant prescriptions continued to rise, with new generation antidepressants adding 70,000 prescriptions during the year. However, overall spending on antidepressants decreased by $10 million compared with the previous year, reflecting the impact of a generic version of paroxetine, Loxamine, which was introduced late in the 2006/07 financial year.

Major decisions

- Atypical antipsychotic ziprasidone (Zeldox) funded as a second-line treatment for people with schizophrenia and related psychoses

Attention Deficit Disorder

![Cost and Prescriptions Graph]

Antidepressants

![Cost and Prescriptions Graph]

Antipsychotics
Cancers and transplant medicines

Seven major funding decisions in the past year related to cancer medicines. This was largely made possible by additional funding earmarked for such spending in Budget 2007, much of which targeted cancer medicines used in DHB hospitals. These included oxaliplatin for colon cancer, vinorelbine for lung cancer and paclitaxel for relapsed germ cell cancer, ovarian cancer and node-negative breast cancer. Funding decisions improved treatment options for some of New Zealand's most common cancers, including lung, colon and breast cancers.

The capecitabine decision also provided the opportunity to make savings for DHB hospitals in infusion services, by moving patients from an infusion-based treatment, requiring inpatient treatment, to a pill that could be taken by patients in the community. This helped free up services that could be used for other cancer treatments.

The most significant decisions related to oxaliplatin (a further 1000 people per year treated with the drug, worth an additional $27 million over five years), trastuzumab (Herceptin) for early stage HER2-positive breast cancer ($6 million per year), and widening access to vinorelbine for adjuvant treatment of non small-cell lung cancer ($6 million).

The listing of exemestane for breast cancer provided a third aromatase inhibitor option on the Pharmaceutical Schedule.

In a further decision of benefit to cancer patients, PHARMAC amended the prescribing restrictions on the anti-nausea drug ondansetron when used in cancer patients.

The list of medicines available to treat organ transplant rejection grew, with the availability of sirolimus (Rapamune) from 1 July 2007. Sirolimus became available as a "rescue therapy" for people with organ transplants who had not tolerated, or responded to, other anti-rejection treatments.

Major decisions

- **Trastuzumab** (Herceptin) funded for HER2-positive early breast cancer (9 week concurrent with a taxane)
- **Docetaxel** (Taxotere)
  - for concurrent use with trastuzumab
- **Exemestane** (Aromasin)
  - for hormone receptor positive breast cancer
- **Oxaliplatin** (Eloxatin)
  - Stage 3 (Duke's C) colon cancer
- **Paclitaxel**
  - open access (removal of Special Authority restriction)
- **Sirolimus** (Rapamune)
  - for kidney and organ transplant rejection
- **Vinorelbine**
  - adjuvant treatment of non-small cell lung cancer

A summary of cancer medicines decisions is provided in the following table:
Existing projects

PHARMAC continued its activity in the area of hospital pharmaceuticals through management of Section H. There were 290 changes to Part II of Section H in the 2007/08 Financial Year, of which 161 were new listings, 107 were price decreases, seven were price increases and 15 delistings. Many of these changes resulted from the annual multi-product tender, with others resulting from negotiated contracts. Tenders accounted for 104 changes, resulting in net savings of approximately $550,000 per annum. Other agreements included a bundle with AstraZeneca resulting in approximately $900,000 savings in 2008, rising to $2.1 million in 2009, and a price reduction for the cancer treatment paclitaxel resulting in savings of approximately $150,000 per annum.

PHARMAC also ran a commercial process around recombinant factor VIII, for the treatment of haemophilia, as protections in the previous contracts were due to expire on 1 July 2008. Three agreements were reached, however partly as a result of exchange rate movement over the past few years, pricing overall has increased at a cost of approximately $1 million per annum.

New activities

At the beginning of 2007/08, PHARMAC was investigating the possibility of national contracting for wound care products, cardiac stents, and orthopaedic joint prostheses. However, in September 2007 the Procurement Steering Group, established by DHBs, advised PHARMAC that it was going to pursue national agreements in the areas of wound care and cardiac stents. As a result, PHARMAC’s work in this area came to an end and the project was absorbed by the DHB group.

PHARMAC established an advisory group of orthopaedic surgeons and other relevant clinical staff to advise on procurement of orthopaedic prostheses. Given this is a new therapeutic area for PHARMAC, we put significant effort into ensuring we had the appropriate people advising us on this project, and this included working with orthopaedic surgeons through the New Zealand Orthopaedic Association. We also sought information from DHBs and suppliers.

PHARMAC is now working through the advice and information obtained, and expects to come to a recommendation on options by the end of 2008.

Advisory role

PHARMAC also performed an advisory role to the Ministry of Health in its process to purchase HPV vaccine, and its activity around some emergency supplies of antidotes.

Influenza vaccine

Supply of influenza vaccine continued under agreements formed in the 2006/07 year. Approximately 755,000 doses of vaccine were supplied between March and June 2008, however this includes privately funded use. Overall, about 10,000 more doses than the previous year were supplied. This equates to about $7 million in expenditure (before rebates).

Exceptional Circumstances

PHARMAC administers the Exceptional Circumstances programmes, which enable patients to access medicines not otherwise subsidised. Separate schemes are operated for community (CEC), hospital (HEC), and cancer (CaEC) medicines.

CEC provides access to medicines not otherwise funded, for people with rare or unusual clinical circumstances. Access is subject to approval by a panel of clinicians and operates within a sub-set of the pharmaceutical budget.

HEC has been running since July 2003. This mechanism enables DHB hospitals to fund medicines in the community that are not funded through the Pharmaceutical Schedule. 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.

Cancer EC was set up in 2005. This mechanism allows DHB hospitals to fund, on application to PHARMAC, cancer medicines that are not funded through the Pharmaceutical Cancer Treatments “basket” – a list of cancer medicines that all DHB hospitals must fund.

Overall, PHARMAC received 2820 Exceptional Circumstances applications during the year, of which 2432 were approved. A breakdown of applications received and processed during the year is provided in the table.

Summary of Exceptional Circumstances Schemes

<table>
<thead>
<tr>
<th>Scheme</th>
<th>Initial</th>
<th>Renewal</th>
<th>Received</th>
<th>Approved</th>
<th>Declined</th>
</tr>
</thead>
<tbody>
<tr>
<td>CEC</td>
<td></td>
<td></td>
<td>294</td>
<td>88</td>
<td>206</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>173</td>
<td>170</td>
<td>3</td>
</tr>
<tr>
<td>CEC (automatic approvals)</td>
<td></td>
<td></td>
<td>842</td>
<td>842</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>HEC</td>
<td></td>
<td></td>
<td>734</td>
<td>578</td>
<td>156</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>406</td>
<td>397</td>
<td>9</td>
</tr>
<tr>
<td>HEC (automatic approvals)</td>
<td></td>
<td></td>
<td>99</td>
<td>99</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>CaEC</td>
<td></td>
<td></td>
<td>62(^1)</td>
<td>48</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Renewal</td>
<td></td>
<td>6</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>Totals</td>
<td></td>
<td></td>
<td>2820</td>
<td>2432</td>
<td>388</td>
</tr>
</tbody>
</table>

\(^1\) A further four applications were on hold, pending the provision of more information
Hearing from the experts –
PHARMAC’s Advisory Committees

PHARMAC has a number of advisory committees all providing important input to PHARMAC’s work as consumers, clinicians and pharmacists. It’s vital these committees are performing well, and are seen to be performing well, so optimising the advice of our advisory committees has been an ongoing theme during the year.

We heard comments during the year that some people lacked confidence in the roles and recommendations of our advisory committees. This came through during the Ministry of Health’s consultation around Medicines NZ, and was also expressed at the PHARMAC Forum in December 2007.

CAC | Consumer Advisory Committee

CAC’s role scrutinised

Some thought our Consumer Advisory Committee was not sufficiently representative of patient groups, and so its views weren’t representative of consumer groups. With over 100 health-related consumer groups in New Zealand, it would be impossible to have all interests represented on the committee, and nor is it necessarily desirable.

As defined by its Terms of Reference, the Committee’s role is to provide a consumer perspective, but it’s not intended to be “representative” of consumer groups. PHARMAC gains consumer input in a variety of ways, and the CAC is an important part of that mix. With many hundreds of consumer groups involved in health, it would be impossible to have a Committee that represented the diversity of views those groups have. We already have mechanisms for direct contact with many of these groups.

Nonetheless there will be a review of the CAC’s Terms of Reference in the 2009 year and this provides the opportunity to seek external views on the appropriate role, and membership, of this important committee.

And as part of our ongoing work in improving communications, we will be seeking to improve people’s understanding of the committee and the role it plays.

PTAC | Pharmacology and Therapeutics Advisory Committee

Changes with PTAC

Medicines NZ also touched on the relationship between PHARMAC and PTAC – the Pharmacology and Therapeutics Advisory Committee.

Fundamentally, PTAC is part of the overall PHARMAC structure and this relationship is made clear in legislation. But PTAC’s members are not part of PHARMAC – they are external experts appointed by the Director-General of Health. This distinction, and the overall relationship, are clearly made in the committee’s operating rules (now renamed the Terms of Reference).

During the medicines policy work we heard comment that PTAC shouldn’t take into account cost or cost-effectiveness in its deliberations, and should concentrate solely on clinical effectiveness data. This sounds easy, but they are difficult to separate. Doctors routinely face questions of cost and ‘opportunity cost’ in their daily practice. To not do so is to ignore the reality of health funding in New Zealand.

Further, restricting PTAC’s deliberations to just clinical issues would hamper the quality of PTAC’s advice.

The release of Medicines NZ in December 2007 identified that the current arrangements work well, however it identified two areas for review; the way PTAC members are appointed, and the way it operates, as defined by its Guidelines.

The Ministry of Health is reviewing the PTAC appointment protocol, which defines how members are appointed to the committee by the Director-General of Health.

PHARMAC’s review of the committee’s Guidelines (now called its Terms of Reference) saw public consultation on a draft revised Terms of Reference from June 2008. With publication of the new Terms of Reference, changes include:

• Publishing more minutes relating to pharmaceutical funding applications on PHARMAC’s website, including when PTAC has deferred making a recommendation. PHARMAC will also begin publishing minutes from PTAC subcommittee meetings on its website.

• The Committee’s operations – its membership, scope of activity and specific functions – have also been clarified in a number of ways. For example:
  • membership can now include senior health professionals, such as public health physicians, pharmacists or nurses – not just medical practitioners as in the past. This change reflects that many types of health professionals, not just doctors, have an interest and expertise in prescription medicines; and

• PTAC can now request that a subcommittee undertake a “rapid review”, in order to receive specialised advice from a subcommittee in a more timely way.

• The relationship between PHARMAC and PTAC has also been clarified, like making clear that PTAC can provide PHARMAC with any and all information and views it considers desirable.

These changes are intended to maintain and improve the relationship and continue PTAC’s tradition of providing objective advice to PHARMAC. Overall, the changes are designed to provide more clarity about the Committee’s role and functions, and to increase public confidence in its operations.
Director

Pharmacology and Therapeutics Advisory Committee (PTAC)

Chair
Professor 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, MBBS, 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 Tom Thompson MBChB, FRACP, physician
Dr Jim Vause MBChB, DipGP, FRNZCGP, general practitioner (resigned Dec 2007)
Dr Howard Wilson BSc, PhD, MB, BS, Dip Obst, FRMZCGP, FRACGP, general practitioner

PTAC Subcommittees
Analgesic - Dr Howard Wilson (chair, PTAC, general practitioner), Dr Ian Hosford (PTAC, psychiatrist), Dr Peter Jones (PTAC, physician), Dr Rick Acland (anaesthetist), Dr Jonathan Adler (palliative care specialist), Dr Bruce Foggo (palliative care specialist), Dr Lindsay Haas (neurologist), Dr Geoff Robinson (physician), Dr Jane Thomas (paediatric anaesthetist)

Anti-infective - Dr Paul Tomlinson (chair, PTAC, paediatrician), Dr Steve Chambers (infectious disease specialist), Dr Iain Loan (general practitioner), Dr Richard Meech (infectious disease specialist), Dr Mark Thomas (infectious disease specialist), Dr Howard Wilson (PTAC, general practitioner).

Cardiovascular - Dr Sisira Jayathissa (appointed chair, PTAC, physician), Dr Peter Pillans (Physician/Clinical Pharmacologist), Dr Malcolm Abernathy (cardiologist), Dr Lannes Johnson (general practitioner), Dr Stewart Mann (cardiologist), Dr Richard Medlicott (general practitioner), Dr Miles Williams (cardiologist)

Cancer Treatments (CaTSOP) - Prof Carl Burgess (chair, PTAC Chair, internal medicine physician), Dr Bernie Fitzharris (oncologist), Dr Peter Ganly (haematologist), Dr Vernon Harvey (oncologist), Dr Tim Hawkins (haematologist), Dr Andrew Macann (radiation oncologist), Dr Anne O'Donnell (oncologist), Dr Lochie Teague (paediatric haematologist & oncologist)

Diabetes - Dr Tom Thompson (chair, PTAC, physician), Dr Paul Tomlinson (PTAC, paediatrician), Pat Carlton (diabetes nurse specialist), Dr Nic Crook (endocrinologist), Dr Tim Kenealy (general practitioner), Dr Peter Moore (physician), Dr Bruce Small (general practitioner), Dr Jim Vause (PTAC, general practitioner)
Hormone and Contraceptive - Dr Howard Wilson (chair, PTAC, general practitioner), Dr Mike Croxson (endocrinologist), Prof Joh Hutton (gynaecologist), Dr Frances McClure (general practitioner), Dr Christine Roke (family planning), Dr Bruce Small, (general practitioner)

Mental Health - Dr Ian Hosford (chair, PTAC, psychiatrist), Dr Jim Lello (PTAC, general practitioner) Dr Crawford Duncan (psychiatrist), Dr Jan Holmes (general practitioner), Dr Verity Humberstone (psychiatrist), Professor Richard Porter (psychiatrist), Professor John Werry (psychiatrist)

Neurological - Dr Tom Thompson (chair, PTAC, physician), Dr Sisira Jayathissa (PTAC, physician), Dr Alistair Dunn (general practitioner), Dr Lindsay Haas (neurologist), Dr William Wallis (neurologist), Dr Peter Bergin (neurologist)

Ophthalmology - Dr Tom Thompson (chair, PTAC, physician), Dr Neil Aburn (ophthalmologist), Dr Rose Dodd (general practitioner), Dr Steve Guest (vitreo retinal surgeon), Dr Allan Simpson (ophthalmologist)

Respiratory - Dr Jim Lello (chair, PTAC, general practitioner), Professor Carl Burgess (PTAC chair, internal medicine physician), Dr John Kolbe (respiratory physician), Dr Ian Shaw (paediatrician), Dr John McLachlan (respiratory physician)

Special Foods - Dr Jim Lello (chair, PTAC, general practitioner), Dr Simon Chin (paediatric gastroenterologist), Kerry McIlroy (dietician), Jo Stewart (dietician), Moira Styles (dietician), Dr John Wyeth (gastroenterologist)

Tender Medical - Dr Paul Tomlinson (chair, PTAC, paediatrician), Dr Jim Lello (general practitioner), Dr Tom Thompson (physician), Ms Sarah Fitt (pharmacist), Dr Grant Howard (intensive care specialist), Geoff Savell (pharmacist), Clare Randall (Palliative Care Clinical Pharmacist), John Savory (pharmacist), Dr David Simpson (haematologist)

Transplant Immunosuppressant – Dr Paul Tomlinson (Chair, PTAC, paediatrician), Dr Peter Pillans (physician/clinical pharmacologist), Dr Peter Ganly (haematologist), Dr Peter Ruygrok (cardiologist), Dr Richard Robson (nephrologist), Dr Kenneth Whyte (respiratory physician), Dr Stephen Munn (transplant surgeon)

Consumer Advisory Committee (CAC)
Sandra Coney (chair, women's health advocate, Auckland), Vicki Burnett (mental health consultant, Auckland), Sharron Cole (Patron, Parents’ Centres, Wellington), Matiu Dickson (Te Runanga o Kāringi, chair, Hamilton), Dennis Paget (Grey Power, Blenheim), Paul Stanley (general manager, Waipareira Trust), Kuresa Tiumalu-Faleseuga (social services consultant, Levin - resigned), Te Aniwa Tutara (Māori health manager, Wairarapa DHB), Heather Thomson (health manager, Te Aroha, Eastern Bay of Plenty)

Hormone and Contraceptive - Dr Howard Wilson (chair, PTAC, general practitioner), Dr Mike Croxson (endocrinologist), Prof Joh Hutton (gynaecologist), Dr Frances McClure (general practitioner), Dr Christine Roke (family planning), Dr Bruce Small, (general practitioner)

Mental Health - Dr Ian Hosford (chair, PTAC, psychiatrist), Dr Jim Lello (PTAC, general practitioner) Dr Crawford Duncan (psychiatrist), Dr Jan Holmes (general practitioner), Dr Verity Humberstone (psychiatrist), Professor Richard Porter (psychiatrist), Professor John Werry (psychiatrist)

Neurological - Dr Tom Thompson (chair, PTAC, physician), Dr Sisira Jayathissa (PTAC, physician), Dr Alistair Dunn (general practitioner), Dr Lindsay Haas (neurologist), Dr William Wallis (neurologist), Dr Peter Bergin (neurologist)

Ophthalmology - Dr Tom Thompson (chair, PTAC, physician), Dr Neil Aburn (ophthalmologist), Dr Rose Dodd (general practitioner), Dr Steve Guest (vitreo retinal surgeon), Dr Allan Simpson (ophthalmologist)

Respiratory - Dr Jim Lello (chair, PTAC, general practitioner), Professor Carl Burgess (PTAC chair, internal medicine physician), Dr John Kolbe (respiratory physician), Dr Ian Shaw (paediatrician), Dr John McLachlan (respiratory physician)

Special Foods - Dr Jim Lello (chair, PTAC, general practitioner), Dr Simon Chin (paediatric gastroenterologist), Kerry McIlroy (dietician), Jo Stewart (dietician), Moira Styles (dietician), Dr John Wyeth (gastroenterologist)

Tender Medical - Dr Paul Tomlinson (chair, PTAC, paediatrician), Dr Jim Lello (general practitioner), Dr Tom Thompson (physician), Ms Sarah Fitt (pharmacist), Dr Grant Howard (intensive care specialist), Geoff Savell (pharmacist), Clare Randall (Palliative Care Clinical Pharmacist), John Savory (pharmacist), Dr David Simpson (haematologist)

Transplant Immunosuppressant – Dr Paul Tomlinson (Chair, PTAC, paediatrician), Dr Peter Pillans (physician/clinical pharmacologist), Dr Peter Ganly (haematologist), Dr Peter Ruygrok (cardiologist), Dr Richard Robson (nephrologist), Dr Kenneth Whyte (respiratory physician), Dr Stephen Munn (transplant surgeon)

Consumer Advisory Committee (CAC)
Sandra Coney (chair, women's health advocate, Auckland), Vicki Burnett (mental health consultant, Auckland), Sharron Cole (Patron, Parents’ Centres, Wellington), Matiu Dickson (Te Runanga o Kāringi, chair, Hamilton), Dennis Paget (Grey Power, Blenheim), Paul Stanley (general manager, Waipareira Trust), Kuresa Tiumalu-Faleseuga (social services consultant, Levin - resigned), Te Aniwa Tutara (Māori health manager, Wairarapa DHB), Heather Thomson (health manager, Te Aroha, Eastern Bay of Plenty)

Hospital Pharmaceuticals Advisory Committee (HPAC)
Ian Winwood (chair, clinical co-ordinator pharmacy services, Southland), Sarah Fitt (pharmacy manager, Auckland DHB), Neil Aitcheson (materials manager, MidCentral DHB), Paul Barrett (pharmacy services manager, Canterbury DHB), Jan Goddard (manager pharmacy services, Waikato DHB), Lesley Hawke (service manager - pharmacy, Counties Manukau DHB)

Panels
Exceptional Circumstances Panel
Dr Howard Wilson (chair, general practitioner, pharmacologist), Dr Mel Brieseman (Medical Officer of Health, Christchurch) Dr Paul Tomlinson (paediatrician, Southland DHB), Dr David Waite (physician, Capital & Coast DHB), Dr Sharon Ketchko (manager funding & planning, Nelson Marlborough DHB), Dr Andrew Herbert (consultant gastroenterologist, MidCentral DHB)

Cystic Fibrosis Advisory Panel
Dr John Kolbe (respiratory physician), Dr Ian Shaw (paediatrician), Dr Richard Laing (respiratory physician), Dr Cass Byrnes (paediatrician)

Gaucher Treatment Advisory Panel
Dr Callum Wilson (metabolic consultant), Dr Ruth Spearing (consultant haematologist), Dr Clinton Pinto (musculoskeletal radiologist)

Multiple Sclerosis Treatment Advisory Panel
Dr Ernie Willoughby (neurologist), Dr David Abernethy (neurologist), Dr Alan Wright (neurologist)

PHARMAC’s Management Team

Chief Executive
Matthew Brougham MSc (Hons), Dip Health Econ (Tromso)

Management Team
Peter Alsop - Manager, Corporate
Steffan Crausaz BPharm, MSc, MRPharmS - Manager, Funding & Procurement
Rachel Mackay BA, NZIMR - Manager, Schedule and Contracts
Dr Peter Moodie BSc, MBChB, FRNZCGP - Medical Director
Marama Parore (Ngati Whata, Ngati Kahu, Nga Puhi) - Manager, Access and Optimal Use & Māori Health Manager
Rico Schoeler - Manager, Analysis & Assessment
PHARMAC is the Government agency responsible for deciding which medicines are subsidised for New Zealanders. It manages spending on pharmaceuticals for the District Health Boards, and ensures that a comprehensive list of medicines (the Pharmaceutical Schedule) is subsidised for New Zealanders, and that the list of medicines continues to grow to meet the needs of patients.