PHARMAC
Pharmaceutical Management Agency

Annual Review 2003

PHARMAC 10 years on

PHARMAC

(the Pharmaceutical Management Agency) is a Crown Entity established under the New Zealand Public Health and Disability Act. Its statutory objective is to secure for those in need of pharmaceuticals the best health outcomes that are reasonably achievable from pharmaceutical treatment within the amount of funding provided. PHARMAC's primary function is to manage the national Pharmaceutical Schedule, which is a list of over 2,600 prescription drugs and related products that are subsidised by the Government. The Schedule applies consistently throughout New Zealand and is updated monthly.

The Schedule records the price of each drug, the subsidy it receives from public funds and the guidelines or conditions under which it may be funded.

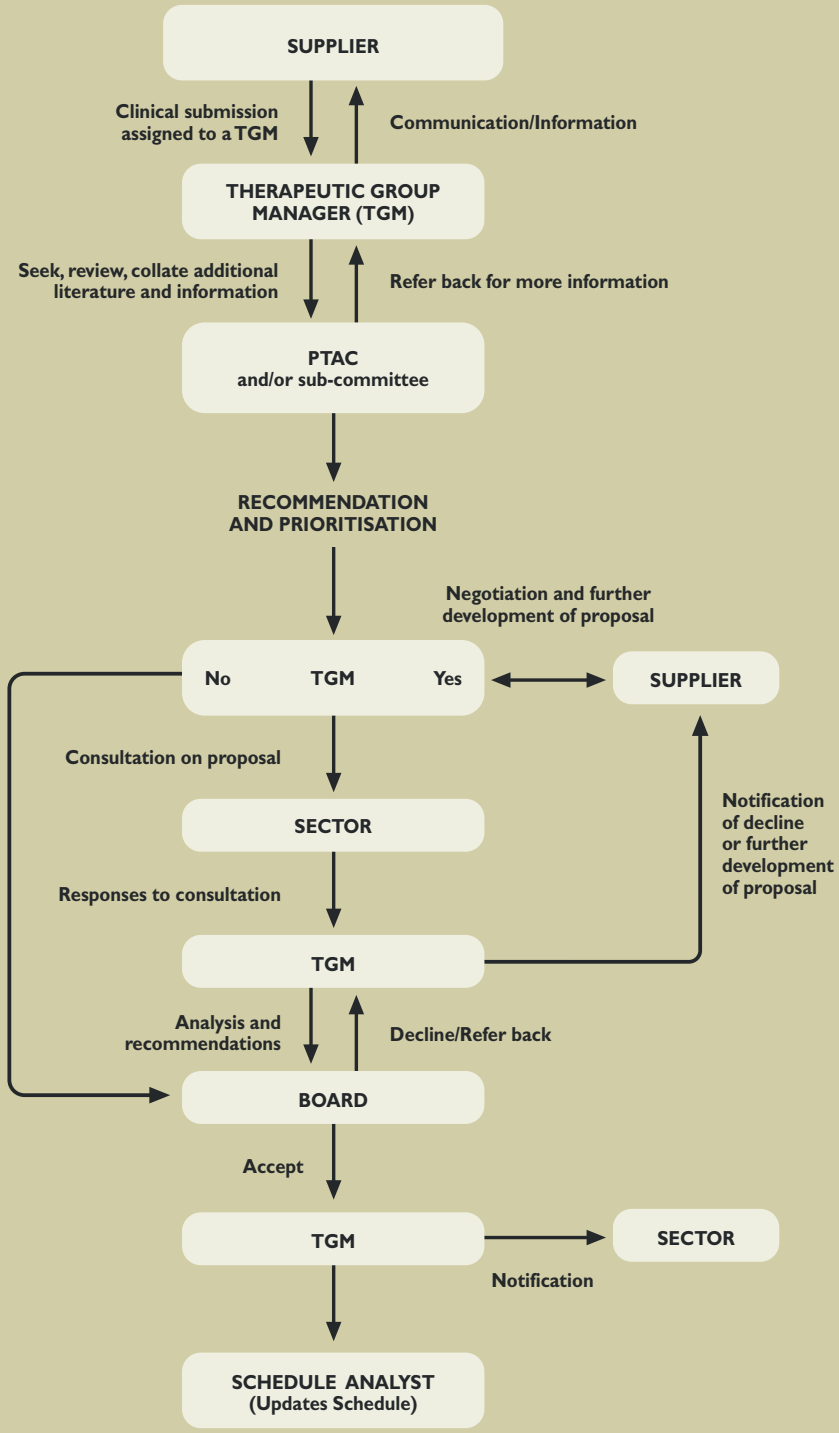
The PHARMAC Board makes the final decisions on subsidy levels and prescribing criteria and conditions with independent advice from medical experts on the Pharmacology and Therapeutics Advisory Committee (PTAC) and advice from its specialist sub-committees, and PHARMAC's managers and analysts.

In all its decisions PHARMAC seeks to balance out the needs of patients for equitable access to healthcare with the needs of taxpayers for responsible management of the costs they ultimately bear.

In this Review:

- "Year" means year ending 30 June. For example: "this year" means the year ended 30 June 2003; "last year" means the year ended 30 June 2002, "next year" means the year ended 30 June 2004.
- Unless otherwise stated all values are in New Zealand dollars.
- Unless otherwise stated all references to expenditure are unadjusted for any rebates that may be due or paid by suppliers under risk sharing agreements.

Process for listing a new pharmaceutical on the Pharmaceutical Schedule



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

Highlights of 2002-03

- Providing new or expanded access to 10 subsidised treatments, including those for chronic myeloid leukaemia, anaemia associated with kidney failure, breast cancer, heavy menstrual bleeding and osteoporosis.
- Containing community pharmaceutical expenditure growth by successfully negotiating savings worth approximately $50.3 million.
- Negotiating nationally-consistent supply contracts for 112 medicines used in DHB hospitals.
- Developing and implementing a process for assessing new pharmaceuticals for use in hospitals.
- Released and commenced implementation of the Maori Responsiveness Strategy.
- Running information campaigns such as the Wise Use of Antibiotics, Responsible Use of Inhaled Corticosteroids, and the regional pilots of the One Heart Many Lives campaign.
- Maori members appointed to PHARMAC bodies including the Consumer Advisory Committee (CAC), Pharmacology and Therapeutics Advisory Committee (PTAC) and the PHARMAC Board.
- Improvements to the administration of the Exceptional Circumstances scheme.

1993–2003

PHARMAC Board chairman Richard Waddel
reflects on a decade of achievements for the government drug-funding agency

This year PHARMAC has completed its first decade of operations. It really has been 10 years of achievement for New Zealand's drug-funding agency.

PHARMAC has come a long way from the nine-person operation set up in a small office in downtown Wellington 10 years ago. This 2003 edition of PHARMAC's Annual Review notes many of the organisation's achievements during this time, the highlights and milestones, and some of the obstacles that have been overcome as PHARMAC has established itself as one of the key players in the New Zealand health sector.

It's worth reflecting on the rationale behind PHARMAC's establishment, and how this has provided continued momentum to PHARMAC's operations. In 1993, New Zealanders were paying a pharmaceutical bill that had been increasing at the rate of up to 20 percent per year. Prices of some of the most widely-used drugs were higher than they were in comparable countries, including Australia, and the growing pharmaceutical bill was threatening to crowd out other areas of health expenditure.

PHARMAC was set up to address this problem, and since 1993 has:

- negotiated accumulated savings worth more than $2.1 billion
- managed pharmaceutical cost increases to less than 3 percent per annum
- developed its use of cost-utility analysis to become a world leader in the field
- enabled more New Zealanders to gain access to fully subsidised new medicines
- provided subsidised access to 131 new medicines

The past decade has been a period of considerable change in the health sector – we've gone from being owned by the Regional Health Authorities, to the Transitional Health Authority, to the Health Funding Authority, to being a stand-alone Crown Entity responsible for managing funding held by all District Health Boards. Through these changing times PHARMAC has continued to consistently prove its worth by bringing a fair and transparent approach to pharmaceutical funding.

Goals

It is pleasing to be able to reflect on another year in which PHARMAC has achieved its goals, which is a tribute to the continuing hard work and dedication of PHARMAC's staff. Community pharmaceutical expenditure has again been managed within the budgeted figure; targets have been met in managing hospital pharmaceutical purchasing; a number of successful Demand Side campaigns have been run. New investments have been made in treatments for such conditions as chronic myeloid leukaemia, anaemia associated with renal failure, breast cancer and gout. And PHARMAC has continued to develop its positive relationships with District Health Boards and the Ministry of Health.

Hospital pharmaceuticals has been a particular success story in the past year. Set the target of achieving $4.5 million of savings in the first year, the target had been exceeded by $400,000 within the first six months of the financial year. PHARMAC also set up a database to enable District Health Boards to share information on hospital pharmaceutical assessments, and published the list of contracted pharmaceuticals for use in hospitals. This publication, known as Section H of the Pharmaceutical Schedule, also includes the "basket" of cancer drugs that DHBs are obliged to fund, and information and processes for accessing drugs outside the list.

Our important relationships with District Health Boards have been further strengthened by the appointment of Sid Bradley, chairman of the Canterbury DHB and DHB New Zealand, as an observer to the PHARMAC Board.

PHARMAC launched its Maori Responsiveness Strategy at Parliament in September and has been progressively implementing aspects of it. Maori members have been appointed to a number of PHARMAC's bodies including the Board, PTAC and the Consumer Advisory Committee (CAC), and PHARMAC staff increased their knowledge and understanding of the particular issues that affect Maori.

In this publication last year I commented on the need to have a longer-term funding path for pharmaceuticals, to enable consistency of planning and the ability to look longer term into the future. It's pleasing to note that there has been a substantial increase of 10 percent in the pharmaceutical budget for the forthcoming year, and PHARMAC will continue to work with DHBs to secure a longer-term funding path. This will enable us to take a longer-term perspective when decisions are made. It is critical that there are funds available each year to enable PHARMAC to successfully manage expenditure, and to make new investments in pharmaceuticals. Without funding for new investments, it would become increasingly difficult for PHARMAC to continue to help improve the health of New Zealanders.

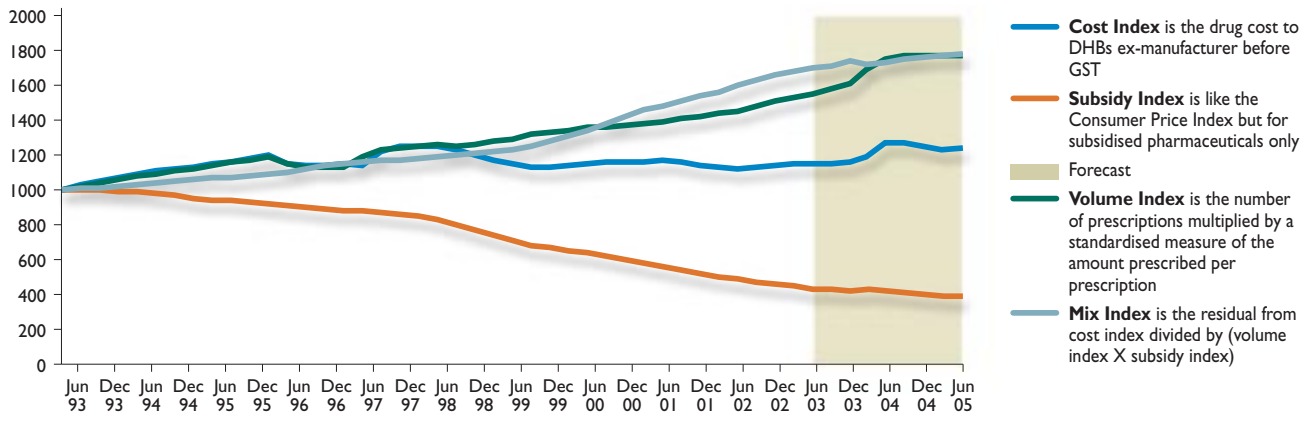
PHARMAC also consulted on a proposal to partially return to all-at-once dispensing for the most commonly used medicines. The proposal would see additional expenditure on medicines for patients, and considerable funding released to DHBs to reinvest in priority healthcare. The proposal marks PHARMAC's continued commitment to finding efficiencies in the use of healthcare funding and to providing access to additional medicines, with benefits both for patients and the pharmaceutical industry in New Zealand.[1]

Hospital pharmaceuticals has been a particular success story in the past year.

[1] *A decision to implement a partial return to all-at-once dispensing was made in early July 2003.*

SUBSIDY, VOLUME, MIX AND COST INDICES

Four-quarterly moving averages
Base: four quarters ending June 1993 = 1,000.



Change

The past year has seen further changes on the PHARMAC Board; Helmut Modlik joined from July 2002, while Liz Coutts decided not to seek reappointment when her term ended on 30 June 2003. I would like to take this opportunity to acknowledge the support and contribution of Liz Coutts and all Board members during a successful year.

In addition to its staff and Board members, PHARMAC is well served by a number of advisory committees. The past year continued the contributions of the Pharmacology and Therapeutics Advisory Committee (PTAC) and the Hospital Pharmaceuticals Advisory Committee (HPAC), while the Consumer Advisory Committee (CAC) began to provide input on a number of issues. These varied committees bring a range of views to PHARMAC and certainly help inform PHARMAC's decision-making.

Significant this year was the decision by Dr John Hedley to retire as chairman of PTAC. Dr Hedley has had a distinguished 16-year career with the committee and has been instrumental in maintaining its independence and authority and ensuring it provides expert clinical input to inform PHARMAC's funding decisions. He has made a major contribution to the robust assessment processes that are now central to PHARMAC, and he leaves with our best wishes. Professor Carl Burgess is the committee's new chair.

Finally, I would like to thank the Minister of Health, Hon Annette King for her continuing support during the past year.

PHARMAC has come a long way from the nine-person operation set up in a small office in downtown Wellington 10 years ago.

PHARMAC Chief Executive Wayne McNee writes that PHARMAC's activities in 2003 have underlined its commitment to improving the health of New Zealanders through the use of pharmaceuticals.

When PHARMAC was established as a stand-alone Crown Entity at the start of 2001, its roles and objectives were spelled out in legislation.

The legislated objective requires PHARMAC to be focussed on both good health outcomes, and obtaining value from within the pharmaceutical budget.

PHARMAC has been criticised for achieving the latter at the expense of the former. However, this overlooks the fact that PHARMAC closely considers the impact its decisions have on the health of New Zealanders, and the positive results these decisions produce.

The 2002-03 year saw a number of decisions and activities undertaken that have either been shown to, or can potentially, improve the health of New Zealanders. These fall into two categories – decisions to provide new or expanded access to drugs, and those information campaigns such as the Responsible Use of Inhaled Corticosteroids that encourage people to make optimal use of existing subsidised medicines.

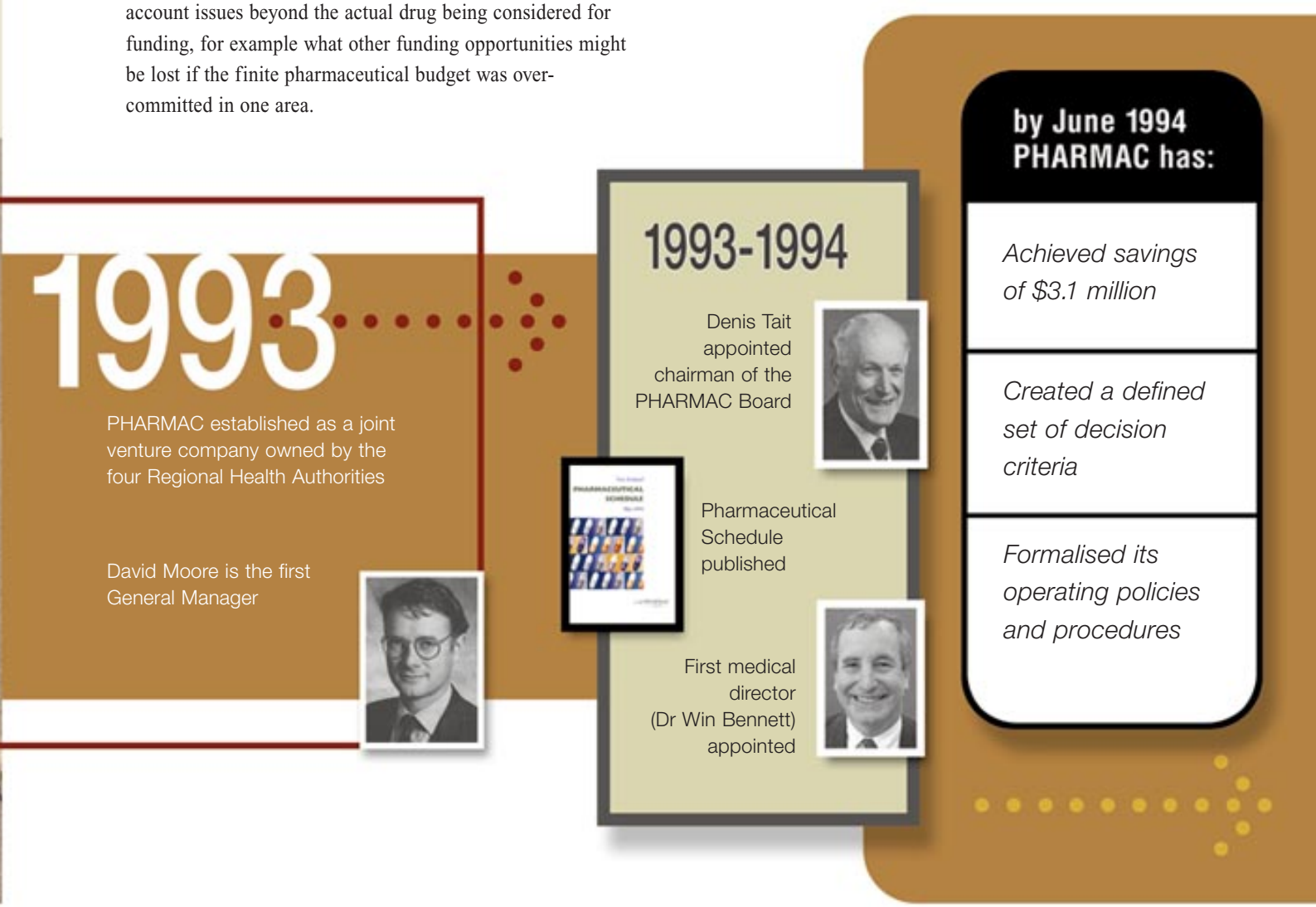
Patient impact is central to all PHARMAC decisions, and is enshrined in its decision criteria. These take into account issues beyond the actual drug being considered for funding, for example what other funding opportunities might be lost if the finite pharmaceutical budget was over-committed in one area.

This was an issue raised during our consideration of the funding application for imatinib mesylate (Glivec) during 2002. Here was a drug that had clear clinical benefits, which represented a significant therapeutic advance for patients with chronic myeloid leukaemia (CML), but which at over $60,000 per patient per year was extremely expensive.

High profile issue

Following a high-profile campaign for its funding, the PHARMAC Board declined an initial proposal to fund the drug for a clearly defined but small group of patients.

While those advocating for access to the drug were understandably focussed on its funding for all CML patients, wider issues needed to be considered such as PHARMAC's limited ability to make other investments should it commit funding to Glivec. While this approach drew some criticism, those with a broader view were able to see PHARMAC considering what economists refer to as the 'opportunity cost' – what other funding opportunities might be lost if money was spent on Glivec.



Tough but fair

This decision, which underlined the 'tough but fair' approach PHARMAC takes to its funding decisions, ultimately led to further negotiations with the supplier, and to a successful supply agreement that enabled the drug to be funded cost-effectively for a much larger group of patients.

The funding of both Glivec and another major investment during 2003, EPO (Recormon), underlined PHARMAC's willingness to increase spending in order to achieve health gains. The widening of access to Recormon, for the treatment of anaemia in kidney failure patients, would see expenditure on that drug rise by about $1.1 million per year, and for its use to double over the next three years. The decision was welcomed by renal specialists, one of whom described it as "the most significant advancement in renal anaemia in New Zealand since the introduction of synthetic erythropoietin 10 years ago".

The Recormon decision had other benefits too, which underscores another facet of PHARMAC's decision-making. Enhancing the red bloodcell count of renal failure patients, as EPO does, has the potential to reduce the need for expensive kidney transplants and dialysis. So as well as improving patient health, the decision could reduce costs elsewhere in the health sector. This isn't true for all pharmaceuticals, but is supported by evidence in the case of EPO. Despite this, the widening of access was still a cost to the health sector. A paper by PHARMAC staff, published in the New Zealand Medical Journal, further highlighted how costs and benefits across the health sector are part of PHARMAC's funding analyses.

Consistent approach

This consistent approach means that New Zealanders now have access to some of the most cost-effective medicines in the world. This year the volume of medicines prescribed has continued to rise, by a further 5.3 percent, while expenditure was managed at $512.4 million, 0.7 percent within the indicative budget. This indicates that more New Zealanders are gaining access to subsidised medicines at a managed increase in cost to the taxpayer. While there continues to be pressure applied by interest groups for individual drugs, by and large there is an acceptance of the PHARMAC approach and an acknowledgement that it is applied consistently.

Undoubtedly there will continue to be a tension between the competing demands for funding of new pharmaceuticals, and the constraints of working within a set budget. However, PHARMAC will continue to apply the policies it has developed to ensure that the pharmaceutical budget is spent to ensure fair and equitable access to subsidised pharmaceuticals for all New Zealanders.

July 95

First court papers filed challenging PHARMAC

Savings reach $48 million by June 1996

1997

First tender (for 1 product, paracetamol) leads to 44 percent price reduction

RMI launches Mayday! Mayday! Campaign

The campaign features TV and newspaper advertising and is roundly criticised in the media, and in parliament. The campaign is withdrawn later that month

Arguments over comparative effectiveness can often mask the real issues for people to access medicines, writes Medical Director Dr Peter Moodie.

Over the last 10 years PHARMAC has developed a number of tools for managing medicine prices, and at times these policies have led to significant debate with both health professionals and suppliers.

Those tools include "reference pricing", where medicines that are deemed to have the same or similar effect are funded at the same or similar price. Although this concept may have been revolutionary when it was first applied in a rigorous manner, it is now commonplace in many developed countries where there is a subsidised health service.

In New Zealand the principle has been applied to both generic versions of the same chemical through to drugs in the same class, and beyond, including angiotensin-converting enzyme (ACE) inhibitors for the management of raised blood pressure.

Policies like reference pricing have enabled New Zealand to effectively manage rising costs in a state-funded pharmaceutical system, despite a continuing growth in volume and a changing mix of medicines. Such policies overtly recognise that all pharmaceuticals have both benefits and costs.

When reference pricing is implemented there is often controversy and quite reasonable questioning of the clinical basis for the decision. The debate is primarily around safety issues and the right of the funder to make such decisions. However, it is equally important to ask the question; "If two drugs do the same or similar thing, is there a good reason for the taxpayer to pay a different price?"

If subsidy change is going to occur between non-generic drugs in the same therapeutic class, the test of inter-changeability can be quite contentious. Some clinicians will insist that head-to-head controlled trials are mandatory or at least unequivocal proof of similar outcome measurements. Others will take a more pragmatic view of a class effect.

If truly rigorous proof is needed then logically it is unlikely that "me too" drugs would ever be used in clinical practice as they rarely have been subjected to the same trials as the earlier members of the class.

However, demanding perfect proof of a class effect often can make us lose focus on the real clinical issues. Rather than concentrate on whether one particular ACE

98

Reference pricing of ACE Inhibitors leads to an expected $150 million saving over the next six years

Decisions in the High Court and Court of Appeal uphold PHARMAC's procedures in pharmaceutical expenditure management, and its exemption from the Commerce Act

Cumulative savings surpass $250 million

November 1998

Wayne McNee appointed General Manager of PHARMAC

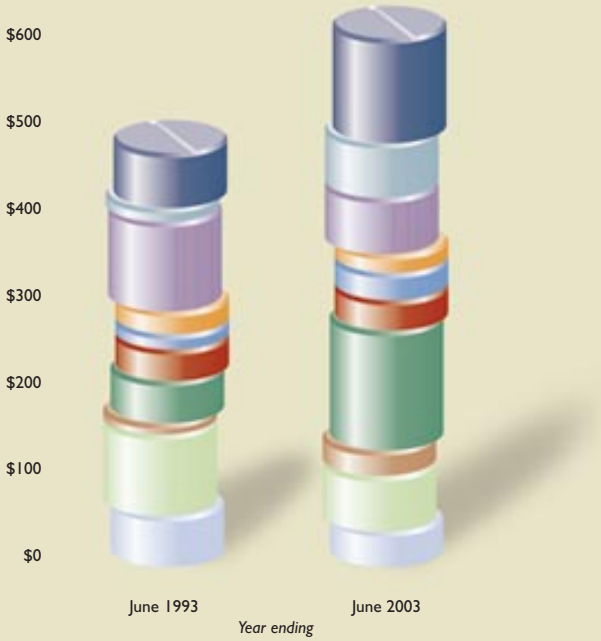
May 1999

Prime Minister Jenny Shipley launches the Wise Use of Antibiotics campaign, the first nationwide public information campaign to be funded and co-ordinated by PHARMAC

CHANGES IN THERAPEUTIC GROUP EXPENDITURE

Total subsidised, non-hospital-funded, drug cost in millions of dollars (excluding GST).

Without PHARMAC interventions, it is estimated that the drug subsidy bill this year would have been $624 million higher (this estimate is based on an assumption that no price changes would have occurred without PHARMAC's interventions).



inhibitor, beta blocker or statin is better than another, the more important issue is whether the drugs are at a price where they are cost effective, can be made widely available, and are being accessed.

This last point is underlined by a look at prescribing patterns for statins for the treatment of raised cholesterol, access to which is now essentially unrestricted. Prescribing patterns for statins vary widely from region to region, with low rates particularly in areas with low population density and in areas where there are greater proportions of Maori and Pacific people.

The issue here is that simply widening access to expensive drugs solves only a small part of the problem. Conditions like cardiovascular disease cause enormous morbidity and mortality in New Zealand, but a significant proportion of those who are entitled to statins and should be on them are simply not being prescribed them.

PHARMAC can clearly play a role by providing subsidised access to medicines. However ultimately it is the prescriber who determines who gains access to them.

Prescribing for statins leaped 65 percent last year, meaning about 55,000 more people gained access to their benefits. PHARMAC piloted a campaign, *One Heart: Many Lives*, which encouraged people to be aware of their risk of cardiovascular disease. Access to statins to lower cholesterol is a way to lower the overall risk profile.

Whether people actually gain access to these drugs is a challenge for all clinicians to face.

1999

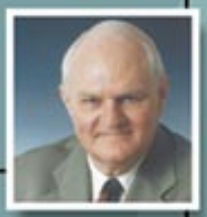
Dr Peter Moodie appointed Medical Director

First multi-product tender produces savings of about $6.5 million per year

Cumulative savings reach $650 million

2000

Richard Waddel succeeds Denis Tait as PHARMAC Board chairman



PHARMAC initiates a review of its Operating Policies and Procedures

PHARMAC becomes a stand-alone Crown Entity, with an independent Board

Wayne McNee appointed PHARMAC Chief Executive

Cumulative savings surpass $1 billion

There may be change at the top but it will be business as usual for the Pharmacology and Therapeutics Advisory Committee (PTAC), writes incoming chairman Professor Carl Burgess

I have to confess to feeling a little daunted at stepping into the shoes of a man whose time in this role goes back before PHARMAC was established.

Dr John Hedley's involvement with PTAC goes back to 1987. He has been instrumental in maintaining the committee's independence and objectivity while adapting it to continue to play a dynamic role in the PHARMAC drug assessment process.

When John was first appointed to PTAC, it provided advice to the Department of Health's Drug Tariff Unit. It's interesting to look at the minutes of his very first meeting, which noted:

> *"[Chairman Dr Bob Boyd] reminded members that although they were nominees of their professional bodies they were appointed by the Minister of Health as individuals... Although they were nominated by professional groups, members were not expected to act as their representatives and should not be providing written reports on issues considered by the committee."*

It seems that even in the late 1980s there was pressure being applied to PTAC members from outside sources.

Over the years John has drawn attention to the need for clinicians to resist these pressures, emphasised the independence and objectiveness of PTAC members, and continually highlighted the issue of conflicts of interest impacting on clinical practice.

His stance on this issue hasn't always been popular, but the growing body of opinion among physicians to address the problems created by conflicts of interest vindicates his long-held views.

The work that John and the PHARMAC team have done in refining the PTAC guidelines and refreshing the memberships of PTAC and its sub-committees has been invaluable in laying the foundation for the committee to continue its good work.

I should also like to take this opportunity to acknowledge the great amount of dedicated work of both Robin Briant and Bruce Foggo during their tenure on the committee. Their quantitative and qualitative advice added much to the deliberations of the committee and undoubtedly benefited those New Zealanders who require pharmaceuticals. Like John, their input will be missed.

For my part, I see PTAC adopting a 'business as usual' approach in the near term. This means continuing to provide timely well-informed advice to PHARMAC and managing the workload effectively.

August-November 2001

PHARMAC staff are welcomed onto Takapuwahia Marae, Porirua. One of a series of hui held to consult on PHARMAC's Maori Responsiveness Strategy

February 2002

PHARMAC takes on the management of hospital pharmaceutical purchasing

Hospital Pharmaceuticals Advisory Committee (HPAC) established

June 2002

Consumer Advisory Committee (CAC) established. Sandra Coney is appointed the committee's chair

If there is a challenge ahead, it is to maintain a sound basis for PHARMAC's decision-making through clinical advice that is free of external influence. Looking through the list of people involved with PTAC and its sub-committees, there is an enormous human resource to draw from. It's important that these people continue to have the confidence of the medical community by reaching recommendations for decisions that are evidence-based, sustainable, and in the best interests of all New Zealanders.

I welcome the opportunity to lead such a distinguished group of clinicians and look forward to the challenges ahead.

PTAC's purpose and structure

Independent, expert evaluation and advice

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

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

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

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

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

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

Professor Carl Burgess

- Professor and Head of Department, Dept of Medicine, Wellington School of Medicine
- Consultant physician, Dept of Internal Medicine, Capital Coast DHB
- Member of Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists (ASCEPT)
- Member NZ Medical Association
- Chair, SAC in Clinical Pharmacology , RACP (NZ)
- PTAC member since 2000

2002

Review of the Pharmacology and Therapeutics Advisory Committee (PTAC)'s guidelines, and of the scope and memberships of its sub-committees, is completed

Exceptional Circumstances comes under PHARMAC management

Take Control of Your Cholesterol – Health Minister Annette King launches PHARMAC's cardiovascular risk awareness campaign in April 2002 with PHARMAC medical director Dr Peter Moodie (left) and Chief Executive Wayne McNee (right).

2003

Cumulative savings from PHARMAC's policies surpass $2 billion

The Wise Use of Antibiotics campaign enters its fifth year – to date has contributed to a 16 percent drop in antibiotic prescribing

The 2002-03 tender calls for bids for over 1000 line items, and produces savings of about $23 million

David Moore, PHARMAC's first General Manager, looks back on the early days...

PHARMAC is now part of the institutional wallpaper; 10 years ago it was very different.

Back in 1993 the Government was frustrated with the management of the pharmaceutical budget, with the added stresses of ministers sometimes being sued directly by the pharmaceutical companies. New Zealand's drug prices were up to 130% higher than Australia, medical advice was only sought on an ad hoc basis, and additions to the drug tariff were ministerial decisions (subject to considerable lobbying). New Zealand's pharmaceutical budget was growing by 14% annually so there were only two options – restricted access or better management.

It seems extraordinary, but Government had never exercised its buying power. Instead everything had been promulgated by regulation, with negotiations kept quite separate from assessment and choice. The companies simply priced their drugs, then the Government generally just added them to the list. To be honest, the Government didn't really know what it *could* afford as it didn't know the cost of what it was buying.

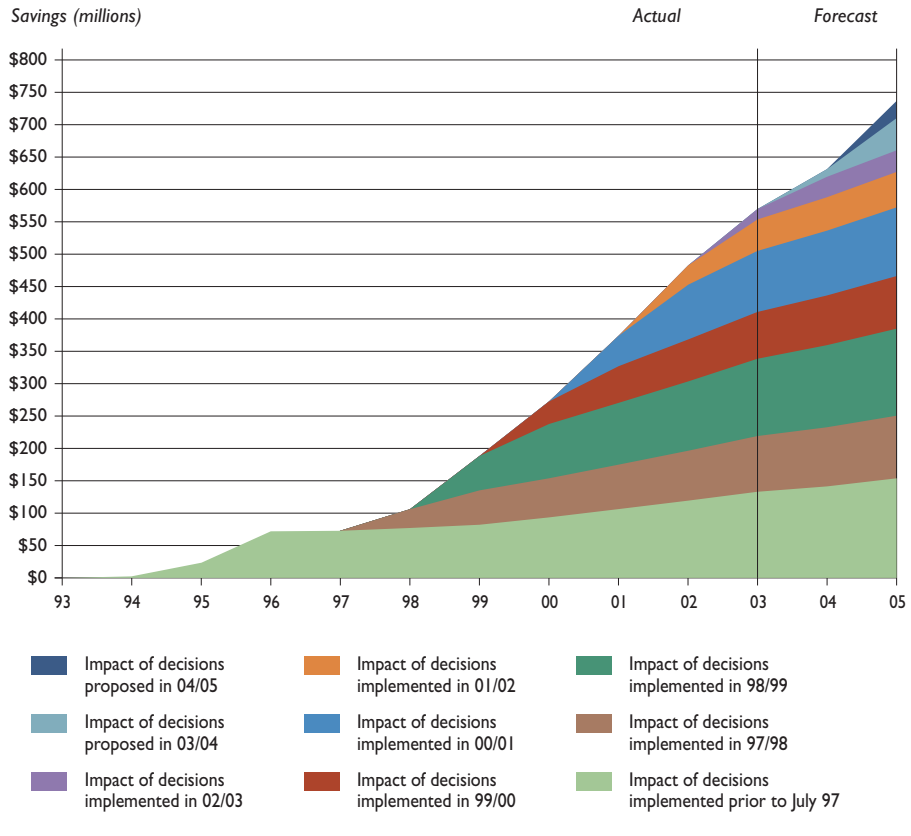
PHARMAC's origins lie in a project I managed at the Department of Health, *The Purple Elephant*, which reviewed all the arrangements for buying pharmaceuticals, pointing to a special purpose, stand-alone vehicle with qualified people to develop processes and make funding decisions, with nation-wide consistency and good governance... ready to defend the inevitable court cases. *The Purple Elephant* became PHARMAC – a notable example of innovation within Government.

PHARMAC introduced price competition to the pharmaceutical marketplace with decisions based on clinical evidence, using economic

TOTAL CUMULATIVE IMPACT OF PHARMAC'S DECISIONS

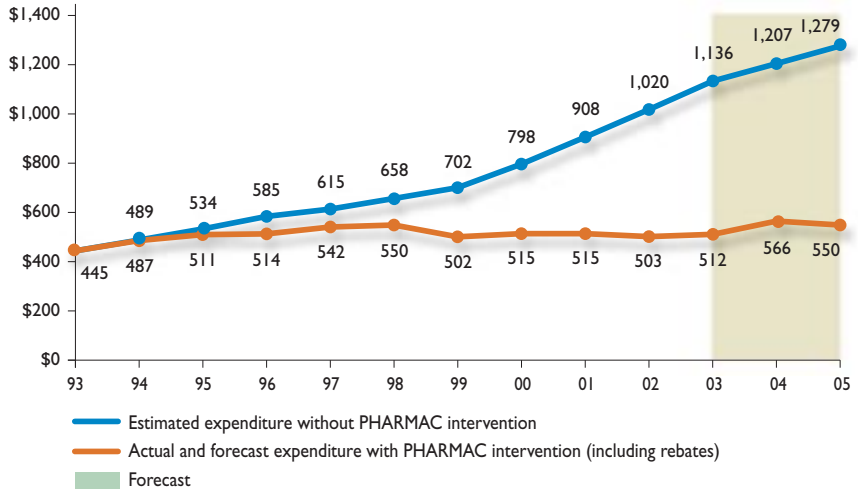
(GST Exclusive)

The chart illustrates the impact of each year's decisions on savings over time before the inclusion of rebates.



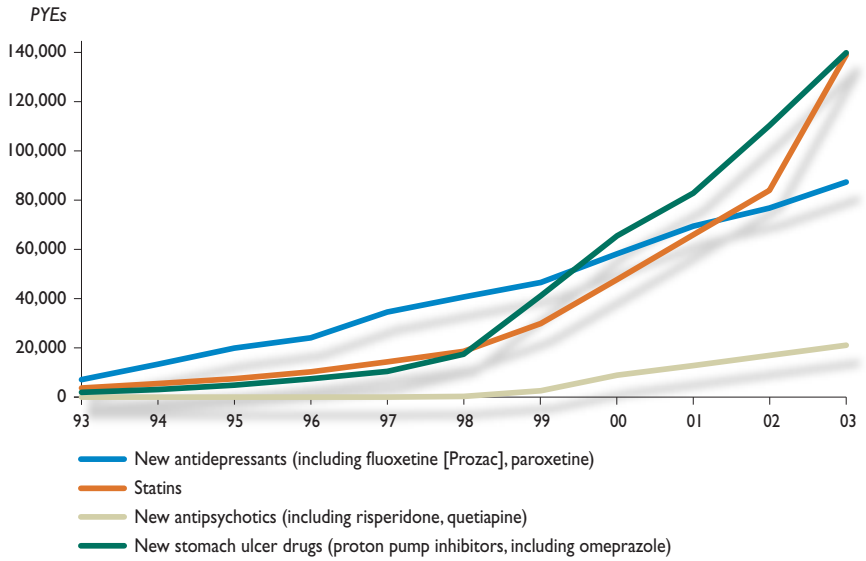
IMPACT OF PHARMAC ON DRUG EXPENDITURE OVER TIME

Total subsidised, non-hospital-funded, drug cost in millions of dollars (excluding GST).
Without PHARMAC interventions, it is estimated that the drug subsidy bill this year would have been $624 million higher (this estimate is based on an assumption that no price changes would have occurred without PHARMAC's interventions).



MORE MEDICINE FOR MORE PATIENTS – INVESTMENTS IN NEW MEDICINE

Since 1993 PHARMAC's investment in these four areas alone have given more people access to improved health through subsidised medicines.



* *Note: A patient-year equivalent (PYE) represents approximately one patient accessing each drug for a year.*

analysis to determine which drugs provided the best value. It quickly established an overview of what drugs we were buying. The first task was arranging the drug tariff into a coherent list of products treating various diseases – the Pharmaceutical Schedule. We introduced economic cost benefit studies, tapping into epidemiological data to identify how different population groups would benefit from different drugs. For the first time we could see the real costs – for example, analysis of lipid lowering drugs for cholesterol levels quickly proved their value in preventing heart disease, so the next step was focusing on the price.

1993 to 1995 was a time of dramatic changes in funding pharmaceutical developments, with many new drugs available that New Zealand simply couldn't afford such as *fluoxetine* (Prozac), treatments for schizophrenia and epilepsy, lipid lowering drugs and *omeprazole*, an innovative stomach ulcer drug. Now they're all widely available on the Pharmaceutical Schedule, and plenty more new drugs since (see graph left).

In the first three years we moved from passive management of an amorphous budget to specific therapeutic groups and very detailed costings. This enabled analysis of trends so long-term deals could be structured in key areas such as asthma, heart and stomach medications. Active involvement by medical groups was essential so advice from the Pharmacology and Therapeutics Advisory Committee (PTAC) became an integral part of every decision. Its network of specialist subcommittees is now a major strategic asset.

Early on, we picked up signals about the potential for price reductions; the most memorable was in ACE inhibitors, a commonly used heart drug, where we initially targeted a 60% reduction yet ended up with 96% (eventually). Then we moved to giving preferred access in exchange for capped

deals, which meant some pharmaceutical companies got large budget increases, whilst widening patient access to drugs. We focused on *'drug creep'*, using contractual devices to limit unnecessary dosage increases. We established the infrastructure of reference pricing, pioneered cross deals and then hooked into the reductions offered by generic drugs and *'me toos'*. Nowadays generics are taken for granted but back in 1993 people were apprehensive about them, aided by some negative publicity.

Tendering was the next development. The first one wasn't for a drug at all, it was for an asthma spacer device; then we carefully selected paracetamol as the first drug tender – it was so well known we anticipated people would be comfortable with a generic version. Nowadays, tendering is used extensively, with more than a quarter of the Schedule (by volume) being tendered.

New Zealand moved rapidly from passive purchasing to the smart, commercial contracting practices for which PHARMAC is recognised; especially now pharmaceutical budgets have become a growing problem internationally.

I anticipated we'd only have three clear years before the pharmaceutical companies appreciated the significance of our decisions, knowing their eventual reaction would severely impact on our progress. Occasionally we wondered whether PHARMAC would survive those first few years – although our initial decisions seemed relatively minor, their implications quickly grew. Such major market restructuring made it difficult for many companies – some had to retrench, others grew rapidly. Naturally the companies reacted to protect their interests, with significant litigation and a high profile media campaign in 1997. At one stage we had more court cases than staff members. It's a relief for us all that those difficult times are behind us.

10 years on and *The Purple Elephant* is in good hands, with PHARMAC's institutional knowledge embedded in the organisation. New Zealanders now understand the necessity for a capped pharmaceuticals budget and the medical profession has moved to a culture of critical appraisal and evidence-based decision-making. Yes, it's been a huge success yet the real winners have been the patients and taxpayers, with considerable health gain at an affordable cost.

Scrip Magazine publisher Dr Philip Brown examines some of the issues the pharmaceutical industry faces beyond 2003

This is an abridged version of an article that first appeared in the February 2003 edition of Scrip Magazine, published by PJB Publications.

The pharmaceutical industry worldwide faces a period of uncertainty caused both by an apparent lack of new products and the increasing use of pricing controls by governments internationally.

Before getting down to some practicalities, let me make a few comments about the core reason why the pharmaceutical industry is in such difficulties. I think that there is a single reason. It is that pharmaceutical products have such limited patent lives. No other industry faces a situation where the revenues of its major products can disappear overnight and where the goodwill established in those products likewise evaporates. What has made the situation worse, to the extent that it has distorted the development of the industry and now threatens its existence, is the fact that governments in most developed countries demand that doctors prescribe the generic version of a drug once its patent has expired.

One can argue that inherent in the genetic makeup of Research and Development (R&D)-based industry is the need for obsolescence and that the companies that will survive are the successful innovators. All that generic substitution has meant is that the rate of discovery has to be increased. R&D can be speeded up and its output increased. However, this doesn't appear to be the case and it appears that the pace of pharmaceutical research parallels the progress of biomedical research and cannot be increased at will.

The pressure from shareholders for growth coupled with the pressure arising from compulsory generic substitution has produced the chaotic situation we see in the industry today. The only way that companies have been able to satisfy their shareholders' demand for growth has been to merge and acquire, because R&D could not deliver innovative new medicines faster than the rate at which patents were expiring. It was thought that bigger research programmes would be more productive, but this ignored the fact that bioscience goes so only so fast.

So when looked at overall, all this merger and acquisition (M&A) activity has got the industry precisely nowhere. It has produced some very large

companies, T Rex-like dinosaurs, but it has done nothing to satisfy the unnatural and unsupportable demands imposed on R&D productivity by compulsory generic substitution. All of which poses the question: what can the industry do to survive and indeed, in the long term, can it survive?

Before compulsory generic substitution, companies were not overly concerned when their product patents expired. There was some erosion of revenues, but this took place at a gentle pace commensurate with the ebb and flow of R&D productivity. Prices did increase, and occasionally one company did acquire another. But the industry as a whole was not driven as it is today by government imperatives, all of which have triggered off repeated rounds of M&A activity, stop-start R&D, massive price increases for new products and hyperactive selling bordering on mania.

. . . what can the industry do to survive and indeed, in the long term, can it survive?

One view is that the distortional effects of generic substitution must be allowed to work through the system and eventually when it has wreaked its havoc, the survivors will grow back to fill the vacuum left when the dinosaurs are gone. Eventually, governments will realise that compulsory generic substitution and linked pricing policies have killed off most of the flow of much-needed new medicines and will allow sanity in the form of a more laissez-faire approach to prevail. This may be a long time coming, but I suggest that those who speak for the industry must argue the case non-stop from now on.

What lies ahead, whether we like it or not, and what lies ahead that we can influence to a greater or lesser extent? So far as the former is concerned, while governments continue to make mischief with pricing, generic substitution and other controls, the industry will under-perform as it struggles to do what cannot be done. Its activities will become even more bizarre in order to perform in an ever more bizarre marketplace.

The drugs we need to treat cancer, neurological conditions, viral diseases such as AIDS and the like, effectively will not be forthcoming for a decade or more because the biomedical basis of knowledge does not exist. We will continue to produce more of the same in all fields which will be increasingly expensive as companies try desperately to maintain revenue growth while suffering generic substitution of their leading branded medicines. The ever-increasing prices – the response to generic substitution – will attract even more government interference and so the spiral will continue towards some form of confrontation with destiny.

Thus M&A will continue to stalk the industry. On the one hand Novartis, Aventis, GlaxoSmithKline, Pfizer and others will continue in their M&A-fed habit, while on the other, family-owned firms like Roche and Boehringer Ingelheim, along with those opposed to becoming players in the M&A game, such as Lilly and Merck & Co, will remain independent. Those who maintain their individuality will have to become increasingly adept at R&D, more inventive and skilful in finding ways to access whatever promising research exists out there. It will be the companies that keep their operations at a size where new products can sustain a reasonable revenue growth and which strive to keep the flame of R&D alive that will be among the long-term survivors.

On the political front, while the companies operating in euroland are in for a beating under the new pricing rules, particularly in Spain, France and Italy, those in the US will be playing in the end-game of the 'pharmaceuticals for Medicare patients' saga with all its pricing control implications. If the industry is skilful it will go forward on the basis of self-administered price discounting schemes to avoid having federally and state-imposed regulations. If government-based pricing schemes come into play the effect will be to compound the negative influences that have so damaged the ability of the industry to perform elsewhere.

Of course all is not gloom and doom. After all, the dinosaurs were hugely successful while they existed, and the smaller animals that thrived alongside them eventually went on to inherit the earth. The largest companies will continue to grow their revenues through the forces of globalisation. The smaller companies on the greasy pole will also grow well, benefiting from the high price levels established by the pharma giants and consequent high growth rates. So even though the industry is becoming increasingly unsuited genetically for its market-place environment, it is not yet in terminal decline.

Hopefully more executives and companies will understand what needs to be done and what must be opposed to be successful.

Review by Therapeutic Group

PHARMAC has put a lot of effort into explaining its role within the New Zealand health system over the years, but misunderstandings still exist.

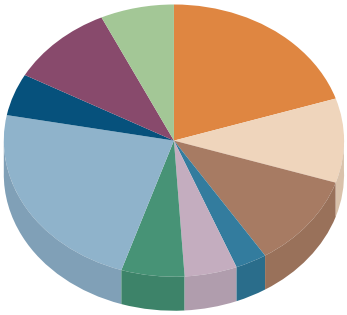
This became apparent during late 2002 when PHARMAC found itself blamed for a number of medicines running into short supply, or out of stock altogether. Many of the supply problems originated outside New Zealand and were beyond the control of the suppliers in New Zealand, let alone PHARMAC.

The reality of pharmaceutical supply is that PHARMAC only has a limited ability to influence it, particularly when supply contracts do not exist. When a supply contract has been negotiated and the company concerned is unable to fulfil its obligations, then that failure can have financial ramifications for it. However, the situation is less clear-cut for the many subsidised pharmaceuticals for which supply contracts do not exist.

In many instances the reason for supply difficulties lie offshore. This reflects New Zealand's size (less than 0.2 percent of the global pharmaceutical market), and its geographical position.

Shortages can be difficult to predict. In one instance in the past year, there was a surge in demand internationally because of an academic paper that showed enhanced results from using a particular drug. This caused a surge in demand that the manufacturer could not keep up with internationally, and this effect was also felt in New Zealand.

INVESTMENT BY THERAPEUTIC GROUP



- Alimentary tract and metabolism (20%).
- Blood and blood forming organs (10%)
- Cardiovascular system (11%).
- Dermatologicals (3%).
- Hormone preparations – systemic excluding contraceptive hormones (5%)
- Infections – agents for systemic use (6%).
- Nervous system (23%).
- Oncology agents and immunosuppressants (5%).
- Respiratory system and allergies (10%).
- Other (genito-urinary system, musculo-skeletal system, sensory organs, special foods) (7%).

Even in the United States, the world's biggest pharmaceutical market, out of stocks and supply difficulties have been a significant issue. The issue reached such heights that the American Medical Association and the American Society of Health System Pharmacists convened a summit to identify issues and propose some solutions.

The complexity of the situation was underlined by the summit identifying 33 potential solutions, including:

- Improved communication between drug regulators, manufacturers and prescribers to better predict when shortages might occur
- Improving internal communication within pharmaceutical manufacturers
- US Government to require manufacturers to notify the FDA of looming shortages
- Introduction of a Federal law to require manufacturers to give advance notice of a product discontinuation
- FDA and professional bodies to encourage health professionals to report drug product shortages to the FDA.

Simple solutions are not easy to find, and in reality New Zealand will continue to be affected by forces beyond any one agency's control.

These problems have caused PHARMAC to go looking for alternative supplies of some products during 2002-03. Some of these had yet to be registered in NZ, so had to be supplied under Section 29 of the Medicines Act. This is by no means an ideal solution but it enables patients to continue to access the medicines until Medsafe approves them.

PHARMAC's Decision Criteria

Seeking best health value for the pharmaceutical dollar

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

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

1 As defined by the Government's then current rules of eligibility.

The top 20 expenditure groups

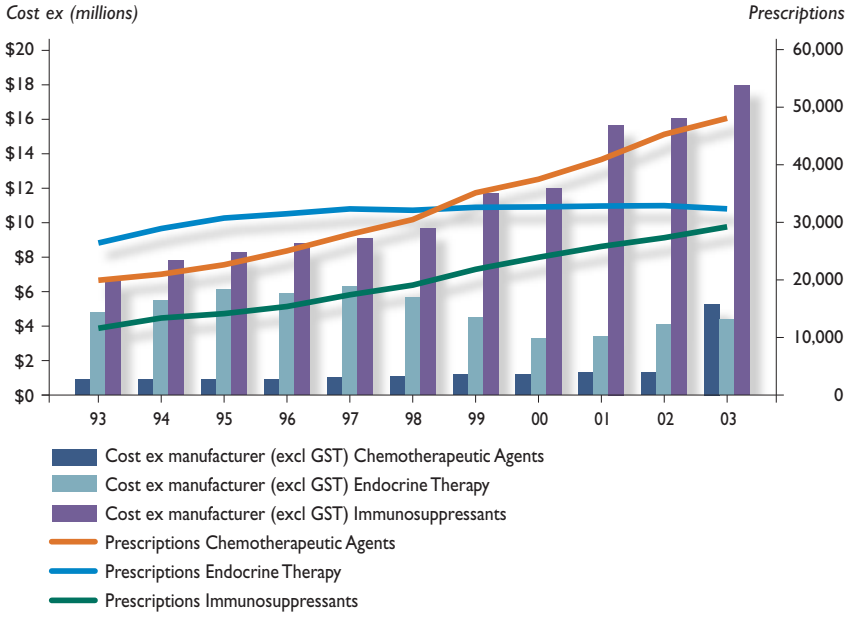
$ millions, cost ex manufacturer, GST exclusive

Drug Type	***2003***	*2002*	*2001*	*2000*	*1999*
Anti-ulcerants	**$52.2**	$44.1	$42.7	$36.1	$29.0
Lipid Modifying Agents	**$46.1**	$40.5	$44.8	$37.2	$23.7
Antipsychotics	**$40.8**	$36.7	$30.1	$23.9	$10.5
Antidepressants	**$32.7**	$28.1	$25.0	$28.6	$31.9
Agents affecting the Renin-Angiotensin system	**$23.0**	$21.4	$27.2	$27.2	$26.7
Inhaled corticosteroids – metered dose inhalers	**$20.7**	$21.9	$18.7	$19.7	$24.9
Diabetes Management	**$19.4**	$18.1	$16.2	$14.0	$12.6
Anti-Epilepsy Drugs	**$19.0**	$17.5	$16.0	$15.2	$13.7
Diabetes	**$19.0**	$18.6	$17.1	$18.0	$17.2
Immunosuppressants	**$18.0**	$16.1	$15.7	$12.0	$11.7
Analgesics	**$15.5**	$14.7	$13.7	$13.5	$13.7
Antibacterials	**$14.5**	$15.4	$16.2	$23.1	$28.3
Calcium Channel Blockers	**$13.8**	$13.9	$15.6	$17.5	$24.9
Antimigraine Preparations	**$11.2**	$10.5	$9.6	$8.3	$7.3
Inhaled beta-adrenoceptor agonists – long acting inhalers	**$10.0**	$6.0	$4.2	$3.3	$2.6
Beta Adrenoceptor Blockers	**$9.2**	$8.0	$8.0	$9.0	$11.7
Antidiarrhoeals	**$9.2**	$8.7	$8.4	$7.6	$7.4
Trophic Hormones	**$8.5**	$7.7	$7.2	$6.6	$5.5
Eye Preparations	**$8.1**	$6.7	$6.2	$5.7	$5.7
Inhaled beta-adrenoceptor agonists – metered dose	**$8.1**	$7.8	$4.7	$4.7	$4.6

Summary of decisions by therapeutic group:

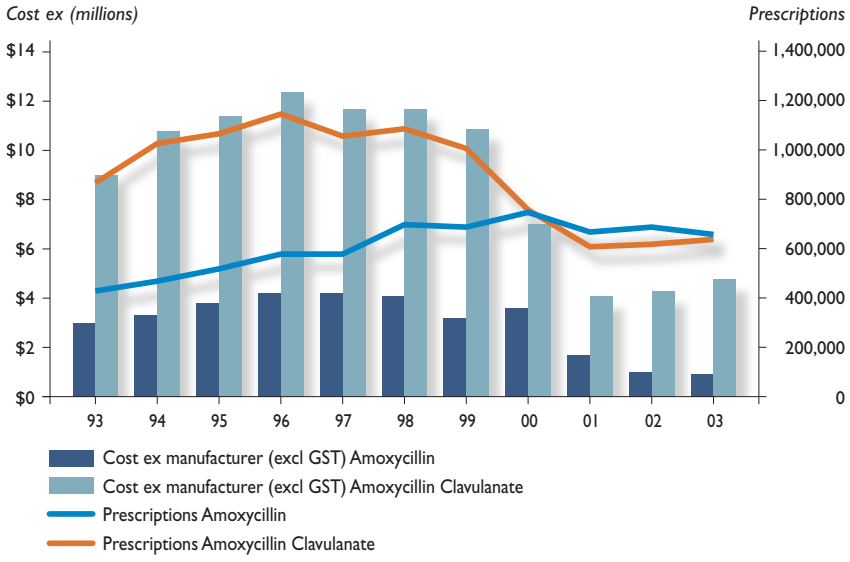
ONCOLOGY AND IMMUNOSUPPRESSANTS

The listing of imatinib (Glivec) in late 2002 was the main reason for a $4 million increase in expenditure on chemotherapeutic agents. Immunosuppression now accounts for $18 million of expenditure.



ANTIBACTERIALS

A slight decline was recorded in prescriptions for the most commonly-prescribed antibiotics during 2003. Antibiotic use continues to be the subject of a PHARMAC campaign, Wise Use of Antibiotics.



Oncology and immunosuppression

New Zealand became one of the first countries in the world to subsidise the new-generation oncology drug imatinib mesylate (Glivec) as a first-line treatment for chronic myeloid leukaemia, from 1 March 2003. This followed an agreement with the drug's supplier, Novartis, to fund it for the more advanced phases of CML, and for a form of inoperable gastro-intestinal tumour, from 1 December 2002. At that time, imatinib was only registered for use as a second-line treatment for CML, however PHARMAC agreed that if imatinib was approved by Medsafe as a first-line treatment, this too would be funded. Access was subsequently widened from 1 March 2003.

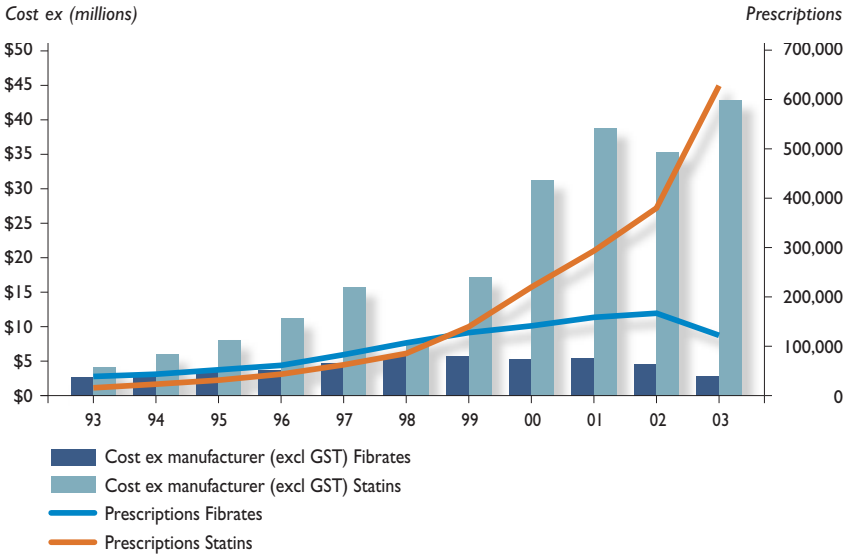
Expenditure on imatinib is expected to be in the region of $10-$11 million per year, and was $3.8m in the year to June 2003.

Access was widened to the aromatase inhibitor drug anastrozole (Arimidex), a treatment for breast cancer in post-menopausal women, from 1 November 2002. The decision is anticipated to increase expenditure on the drug by about $3.6 million over five years.

PHARMAC is also working with DHBs to help address funding and access to hospital cancer treatments. This includes examining funding mechanisms for adding products to the cancer treatments 'basket' which DHBs are required to fund, and which is published in Section H of the Pharmaceutical Schedule.

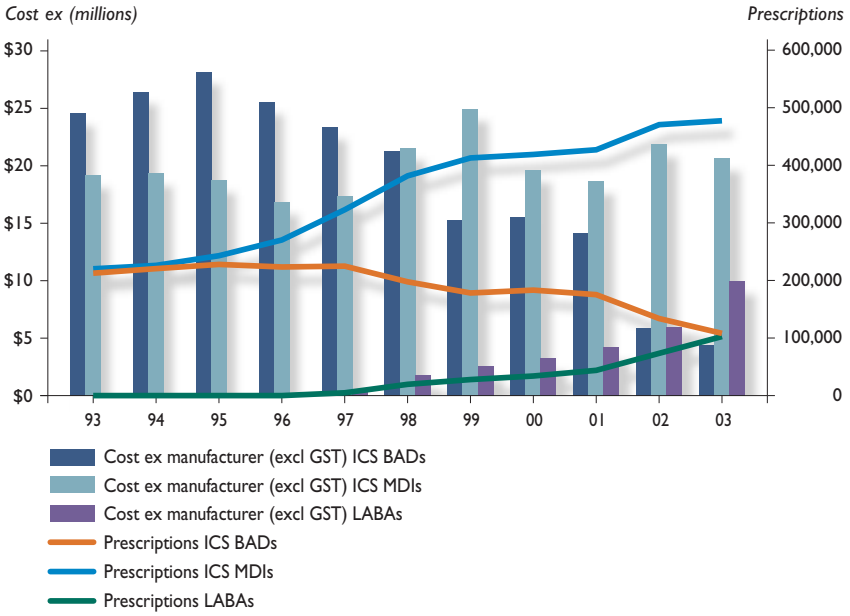
LIPID MODIFYING AGENTS

In the first full financial year since access to statins was widened, a 65 percent increase in the number of people prescribed statins led to a 20 percent increase in expenditure.



ASTHMA

A continuing rise in the number of prescriptions for long acting beta agonists saw expenditure rise $4 million in 2003. This was slightly offset by the decision to reference price inhaled corticosteroid metered dose inhalers, which produced a $1.2 million decrease in expenditure despite prescriptions increasing.



Blood and blood forming

An agreement with pharmaceutical supplier Roche led to access being widened to its brand of the anti-anaemia drug erythropoietin (Recormon). Erythropoietin (EPO) is used to boost the red blood cell count, particularly for those patients in end-stage kidney failure. This reduces the patient's dependence on dialysis and can lead to delays in them requiring kidney transplants. Expenditure on EPO was expected to increase by about $1.1 million per year.

New Zealanders continue to benefit from the improved access to statins that was provided during 2002. In the first full year of the revised access guidelines, the number of new prescriptions for statins increased 65 percent. Access to atorvastatin (Lipitor) continued to be targeted to patients with higher cholesterol levels.

Respiratory

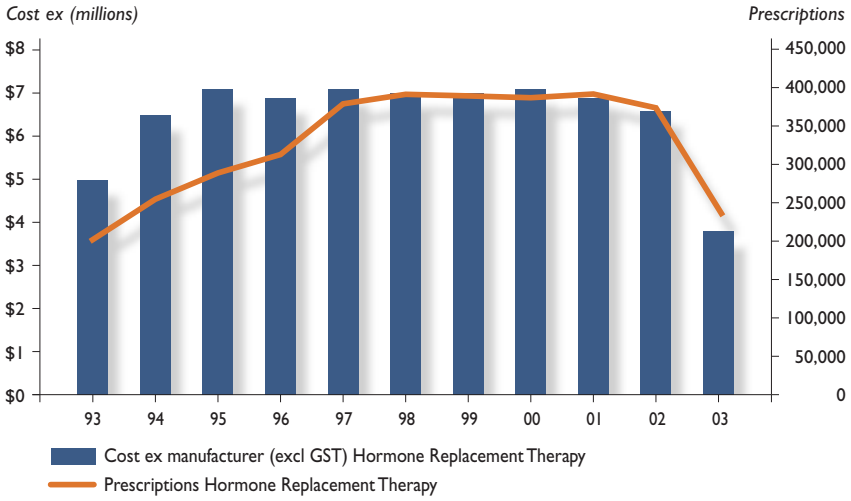
A generic form of the asthma preventer metered dose inhaler beclomethasone (Beclazone) was listed from 1 October 2002. Reference pricing of the inhaled corticosteroids therapeutic sub-group from 1 February 2003 will produce ongoing savings ($1.2 million in the 2003 year).

PHARMAC also consulted on a proposal to restrict access to high-dose inhaled corticosteroids, following concerns being expressed by the respiratory sub-committee of PTAC and in international journals. Feedback during consultation indicated that clinicians would prefer to monitor the effects of an education campaign run by PHARMAC before a decision was made on having restricted access to these drugs. PHARMAC subsequently decided not to proceed with the proposal at this stage.

Expenditure on the class of asthma drugs known as long-acting beta agonists (LABAs) continued to rise, by 65 percent.

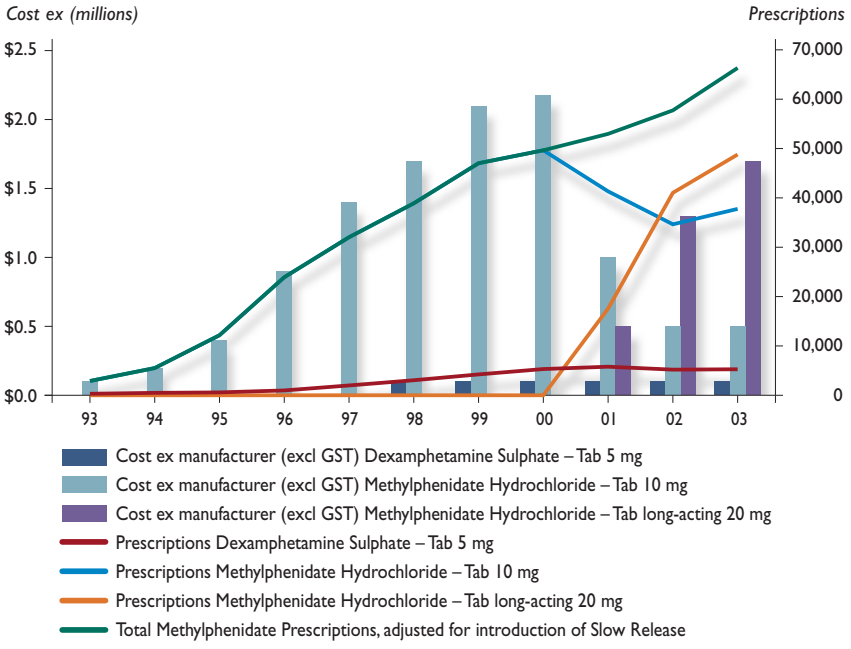
HORMONE REPLACEMENT THERAPY

A declining trend accelerated during 2003, mainly driven by the publication of international studies. Prescriptions for all HRT fell 38 percent for the year.



ADHD TREATMENTS

Prescriptions for both the long-acting and short-acting preparations of methylphenidate rose in 2003. Overall, adjusted for the introduction of slow release methylphenidate, the rate of increase rose. Most patients would be prescribed both the 10mg and 20mg strengths.



Clinician debate continues around the funding for combination inhaled corticosteroid-LABA inhalers, and whether using a combination inhaler increases compliance with medicine-taking. A combination inhaler is listed on the Pharmaceutical Schedule under Special Authority.

Hormones

A significant drop in the use of Hormone Replacement Therapy was recorded following the ceasing of the Women's Health Initiative study, and its subsequent publication in the Journal of the American Medical Association (JAMA). The researchers decided to halt the trial early because results to date showed that the risks of HRT outweighed the benefits.

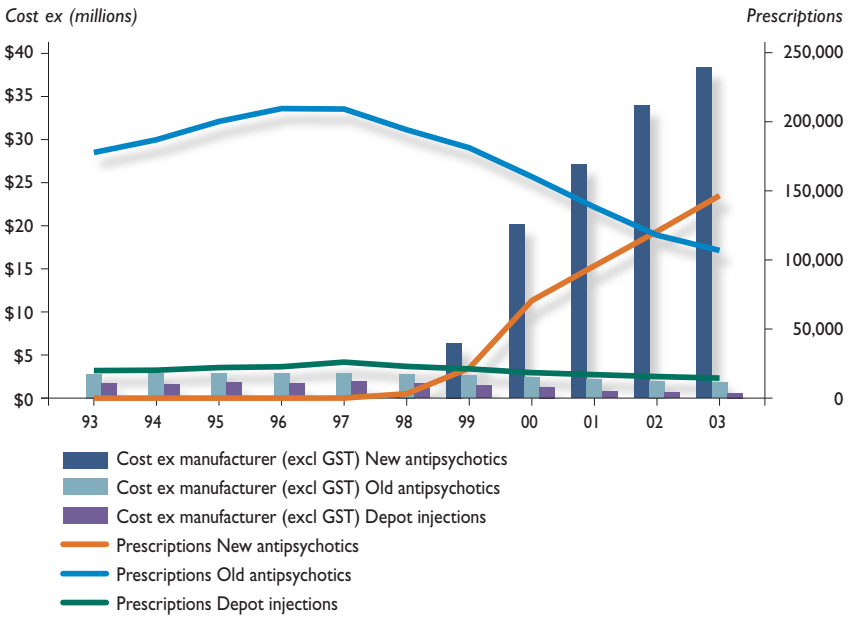
New Zealand media picked up on the messages from the JAMA paper and there was a steep decline in the number of women using HRT. For the year to June 2003, a 38 percent reduction in the number of HRT prescriptions was recorded, and resulted in a $2.8 million fall in HRT expenditure.

PHARMAC noted the findings of the WHI study and reviewed access to the drugs. After advice from the hormones sub-committee of PTAC, and input from the Consumer Advisory Committee, the PHARMAC Board decided to leave the access criteria unchanged, but to monitor use of HRT quarterly.

A new hormonal treatment for heavy menstrual bleeding, levornogestrel (Mirena) was listed on the Pharmaceutical Schedule from 1 October 2002.

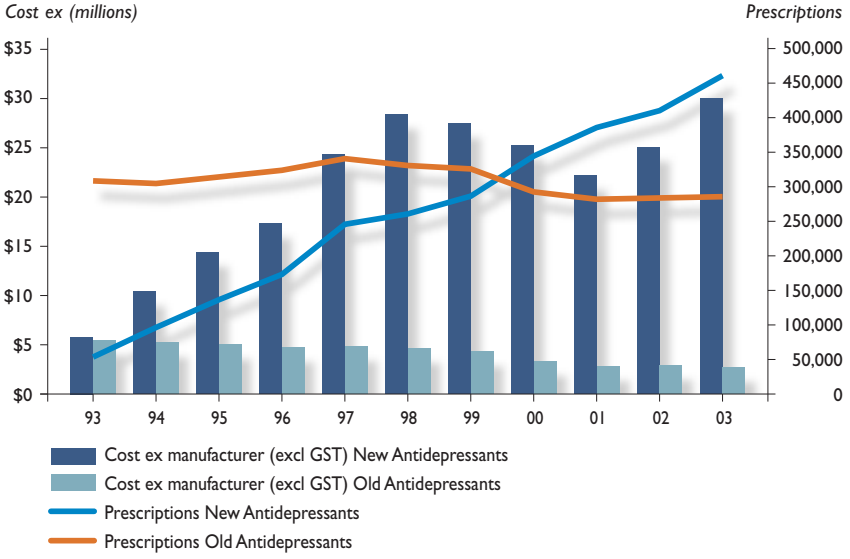
ANTIPSYCHOTICS

Data during 2003 now clearly illustrates a clinical preference for new generation (atypical) antipsychotics over older antipsychotics. Expenditure rose in line with this trend, by $4 million.



ANTIDEPRESSANTS

Prescription numbers for all antidepressants continued to rise in 2003, leading to a $4.6 million increase in expenditure in this therapeutic group.



Nervous system

New generation antipsychotics and a clinical preference for Selective Serotonin Reuptake Inhibitors (SSRIs) for treatment of depression continued to be major drivers of increased expenditure. However, an agreement with Pacific Pharmaceuticals, which became effective on 1 May 2003, will see a $4.5 million per year saving for citalopram. Another antidepressant, phenelzine (Nardil) was discontinued in New Zealand by its supplier and PHARMAC was unable to source a generic.

Paroxetine (Aropax), the most widely prescribed antidepressant in the New Zealand market, came under scrutiny both in Europe and North America over reports linking it with increased incidence of suicide and a heightened risk of pharmaco-dependence. These reports do not appear to have had an impact on the level of prescribing for paroxetine or other antidepressants in New Zealand. PHARMAC had issued a request for proposals to suppliers of paroxetine late in 2003.

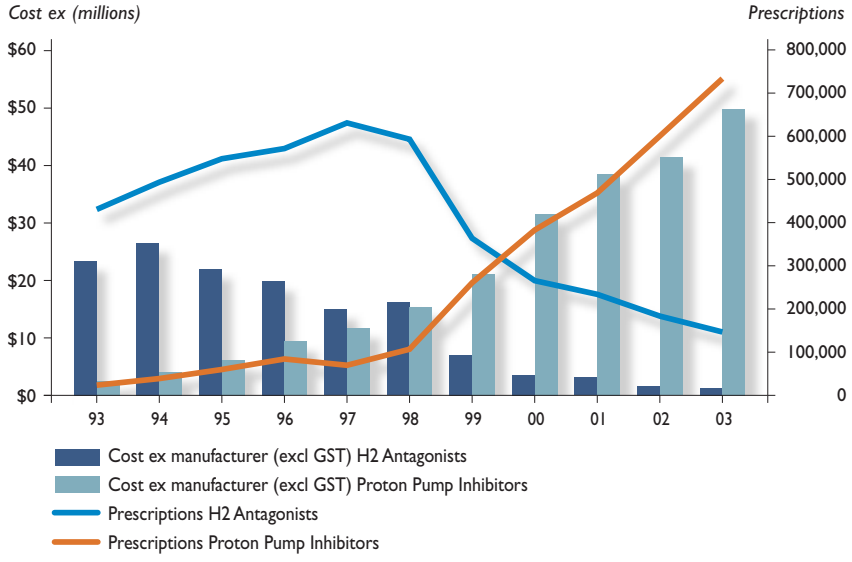
Concerns continue to be raised over the prescribing of methylphenidate for attention deficit disorder. PHARMAC notes a continuing rise in the number of prescriptions, although this does not necessarily translate into a corresponding rise in the number of patients, as patients are likely to be prescribed both dosage strengths and thus hold two prescriptions.

Alimentary

Expenditure in this area continues to grow, particularly in the class of drugs known as proton pump inhibitors (PPIs). Expenditure (before rebates) is now in excess of $50 million per annum, although this is offset by significant rebates in this area. Reference pricing was also applied to the PPI pantoprazole (Somac) from 1 November 2002.

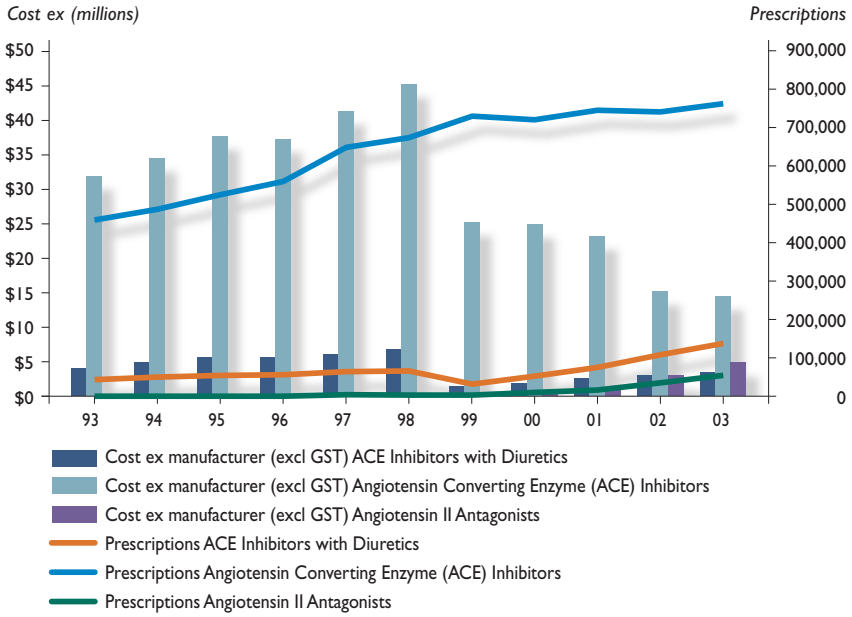
ANTI-ULCERANTS

Continuing clinical preference for proton pump inhibitors saw expenditure in this therapeutic area rise by $8.1 million in 2003. Anti-ulcerants continue to be the largest single expenditure area on the Pharmaceutical Schedule, and now account for more than $50 million annually.



ACE INHIBITORS AND ANGIOTENSIN II ANTAGONISTS

The number of people accessing ACE Inhibitors increased slightly while further price reductions saw expenditure fall for the fifth year in a row.



Internationally there are a series of lawsuits in progress concerning the patent for the PPI omeprazole (marketed as Losec in NZ). The outcome of these lawsuits will have implications for New Zealand's expenditure in this area, as the entry of a generic PPI could lead to a significant reduction in expenditure.

Cardiovascular

Savings of some $13 million over five years are expected to result from the decision to apply reference pricing in the alpha blockers therapeutic sub-group for the treatment of raised blood pressure. The decision, implemented from 1 April 2003, sees the drug terazosin (Hytrin) reference priced to doxazosin (Dosan) on a dose-equivalence basis.

Expenditure on calcium channel blockers rose following a recall and subsequent price rise for felodipine (Plendil). This price rise was almost entirely responsible for the $2.3 million increase in expenditure on cardiovascular system drugs.

PHARMAC also noted the publication of a study in the Journal of the American Medical Association, comparing a number of pharmaceutical treatments for raised blood pressure. The ALLHATT study found that thiazide diuretics, the cheapest and oldest of four drugs studied (including calcium channel blockers, ACE Inhibitors and Beta Blockers), were the most effective first line treatment for raised blood pressure. This underlines the message that just because a drug is newer or more expensive, doesn't necessarily make it better.

Demand Side activities

PHARMAC's activities in promoting the responsible use of medicines reached new heights during 2002-03 with three major campaigns featuring colourful resources and high profile media launches.

Wise Use of Antibiotics

The Wise Use of Antibiotics campaign began as an Independent Practitioner Association initiative, and has been funded and co-ordinated by PHARMAC since 1999. This year the campaign's messages remained essentially the same as previous years (don't expect antibiotics to cure winter colds and flu), and came in the form of bright new artwork and posters distributed to doctors' surgeries and pharmacies. Plunket helped relaunch the 2003 campaign and supported its messages.

The campaign has succeeded in helping the prescribing of antibiotics fall by about 16 percent since 1999.

Three-year-old Rex Thompson of Johnsonville hears about the wise use of antibiotics from PHARMAC Medical Director Peter Moodie.

One Heart Many Lives

Two regional pilots were run of this campaign, which aims to raise people's awareness of their overall risk of cardiovascular disease, and encourages them to do something about it through lifestyle modification and/or use of medication.

Pilots were run in Porirua (aimed primarily at Pacific Peoples) and Gisborne (with a focus on Maori and general population). The campaign featured the support of Maori and Pacific health providers, promotion through radio stations and newspaper advertising, and thought-provoking billboards.

Early evaluation of the pilots' impact showed a high level of recall (up to 88 percent), and further evaluation to assess if there had been any behaviour change as a result of the campaign was being carried out before a decision is made on whether to roll out the campaign nationally.

Asthma management

This campaign had a two-pronged approach, firstly working with primary care clinicians and other health professionals (pharmacists, asthma educators, practice nurses) on best clinical practice for asthma preventer medicines, and secondly material aimed at patients. The campaign supported the recommendations of the New Zealand guidelines on the diagnosis and management of adult asthma, and followed concerns being raised both internationally and in New Zealand at inappropriately high doses of inhaled corticosteroids, the main asthma preventer medicines.

Information packs were sent to prescribers from January 2003 and public promotion began following a launch in February. Advertisements with the message Wheeze In: Breeze Out, encouraging people to visit their doctor to discuss their asthma treatment, appeared in newspapers, on radio and on buses.

Subsidised training was provided throughout 2003 for community pharmacists (through the NZ College of Pharmacists) and for Practice Nurses, Asthma Educators and other nursing groups (through the Asthma & Respiratory Foundation of NZ). Training was designed to help these groups to educate patients about asthma management. The campaign will be evaluated in early 2004.

Gout brochure

PHARMAC funded and published a brochure informing people about treatment options for gout. The brochure, launched in September 2002, was published in five languages.

Green prescriptions

PHARMAC continued to provide funding for this scheme, which is run by Sport and Recreation NZ (Sparc). The programme provides a prescription for physical activity, with options and support for people to address health issues through becoming more active in their lifestyle.

30 MINUTES A DAY PUSH PLAY

SPARC ihi AOTEAROA
Sport & Recreation New Zealand

Te Rongoaa Kakariki Green Prescription

PHARMAC has a legislative function to promote the responsible use of medicines. This became one of PHARMAC's roles under the Health and Disability Act 2000 and has been part of the development of the organisation during the past 10 years.

The Demand Side Management team contracts with external parties, such as the Best Practice Advocacy Centre (to promote clinical best practice to GPs), and Sport and Recreation NZ (for the Green Prescriptions programme).

The team produces information to support changes to the Pharmaceutical Schedule, and runs education campaigns. PHARMAC aims to work with other organisations on these campaigns, and has developed a number of successful working relationships with health professional and consumer groups.

Hospital Pharmaceuticals

PHARMAC made significant progress in implementing the national hospital pharmaceutical purchasing strategy during 2003.

A list of nationally-contracted hospital pharmaceuticals, Section H of the Pharmaceutical Schedule, was first published in December 2002. It is now published three times a year and updated monthly through the Pharmaceutical Schedule Update.

By June 2003, PHARMAC had negotiated contracts for 112 chemicals, with others in the pipeline through a combined community-hospital pharmaceuticals tender and other commercial proposals. Mechanisms were also developed to enable DHB hospitals to continue using pharmaceuticals other than those under national contracts.

PHARMAC exceeded the $4.5 million savings target for hospital pharmaceuticals within the first six months of the financial year.

Progress on developing and implementing a process for assessing new hospital pharmaceuticals has been another success story during the year.

The process was approved by the PHARMAC Board in October 2002. It involves concurrent (or as near as possible) assessments by PHARMAC of pharmaceuticals assessed by DHB hospitals. The aims of this process are to:

- reduce duplication of work;
- increase communication between DHBs;
- generate discussion and aid review;
- improve the consistency and quality of assessments; and
- improve the consistency of access to new pharmaceuticals.

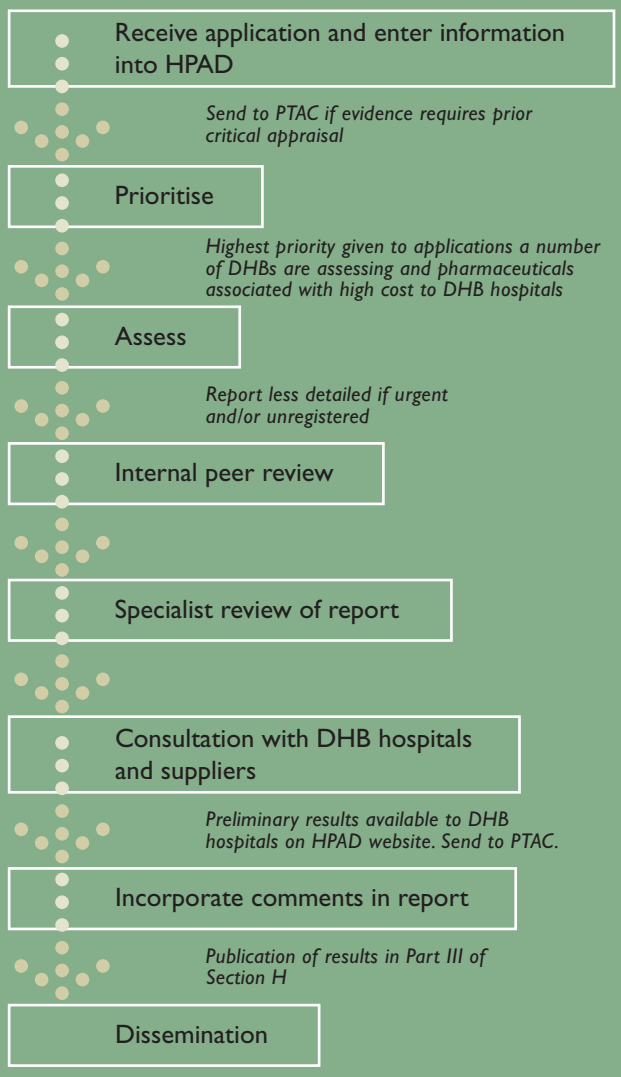
New pharmaceutical assessments are distributed to DHB hospitals for consultation, and are also available for those in DHBs to download from a secured-access website (http://www.pharmac.govt.nz/hpad). This website also provides access to the Hospital Pharmaceutical Assessment Database, which records and maintains information on assessments undertaken by DHB hospitals and PHARMAC.

To June 2003, PHARMAC had distributed eight cost utility analyses on new hospital pharmaceuticals to DHB hospitals.

The assessment process gained considerable momentum in 2003, and positive feedback has been received from DHBs.

In May 2003 the PHARMAC Board considered an interim review of the process. The PHARMAC Board was pleased with progress and recommended that the process continue in its current form (with minor amendments), at least until the full two-year review of the hospital strategy is conducted in March 2004.

New Hospital Pharmaceutical Assessment Process



Summary of PHARMAC operations

The organisation

PHARMAC has broadened its scope in 2003 and underlined its roles in such areas as management of hospital pharmaceutical purchasing, and further integrated the Exceptional Circumstances scheme and panel co-ordinators into its structure. Four Auckland-based staff, previously managed by the Ministry of Health, became the responsibility of PHARMAC and were able to work more closely on the assessment and processing of applications.

PHARMAC Board

The PHARMAC Board consists of six members who bring a range of backgrounds and skills from fields as diverse as general practice, accountancy, economics, management consultancy and midwifery to the governance of PHARMAC.

Helmut Modlik, a Wellington management consultant and a member of the Capital and Coast DHB Board, was appointed to the PHARMAC Board from July 2002.

Liz Coutts, a director since 2000, decided not to seek reappointment when her term ended on 30 June 2003.

Staffing

Two staff took parental leave during the year, though their roles have continued to be filled. Staffing changes during 2002-03 saw 13 people join PHARMAC and six resign.

PHARMAC continued to assume internal responsibility for functions which had previously been outsourced. During the year four appointments were made to managerial positions, two as a result of external recruitment and two as internal appointments.

PHARMAC now consists of 37 employees plus two independent contractors.

Exceptional Circumstances

The Exceptional Circumstances scheme provides a mechanism for patients to access non-subsidised medicines for rare or unusual conditions. Access criteria are published in the Pharmaceutical Schedule and applications are considered by a panel of practising clinicians.

The Exceptional Circumstances panel held 24 teleconferences and 1 face-to-face meeting in the year to 30 June 2003. A total of 1410 applications were received during this period. Of these, 829 were examined by the Panel and the remaining 581 were dealt with by the Panel Co-ordinator under set criteria.

Summary of EC applications:

Number of approvals	827
Number of declines	412
Number of applications ended	95[1]
Number of applications deferred	14[2]
Number of applications pending	77[3]
Number of applications withdrawn/deceased	60

Note that the total exceeds the number received as applications are dealt with on a continuous basis and some that were approved or declined during this period were actually received prior to 1 July 2002.

1 *Applications ended (the medication is now available under a Special Authority, a funded alternative is now available, or withdrawn applications). This total includes 86 applications for Ferodan oral iron solution for which EC issued approvals that were then cancelled once PHARMAC obtained a Ministry of Health endorsement to enable a schedule listing under section 29.*

2 *A number of applications were deferred back to the applicant to provide more information, 14 of these were still awaiting a reply at the end of June 2003.*

3 *Applications and further information received since last meeting and awaiting examination by the Panel, applications deferred and awaiting the provision of more information.*

Of all declined applications 62 were subsequently appealed. Of these two were referred to the PHARMAC Review Committee; with one of these being withdrawn before the review was undertaken.

The average length of time taken to deal with an EC application was 6.4 days.

Expenditure for the year was $2.35 million against a budget of $2.5 million.

Listing changes to the Pharmaceutical Schedule[1]

Decisions made *Decision type*	***2003***	*2002*	*2001*	*2000*	*1999*	*1998*	*1997*	***Total since 1994***
New Chemical entity listed	**3**	7	20	18	32[4]	14	11	**131**
New Presentation listed	**15**	11	13	21	40	33	24	**221**
New Product listed	**45**	60	28	39	56	53	20	**419**
Total new listings[2]	**63**	78	**61**	**78**	**128**	**100**	**55**	**771**
Derestriction or expanded access[3]	**7**	17	19	17	34	14	10	**161**
Changes that restrict or limit access	**2**	4	6	6	3	7	6	**42**
Delistings	**196**	89	135	362[5]	51	106	14	**953**

In 10 years, 771 new or enhanced products have been listed, access has been widened for a further 161, and 995 have either been restricted or de-listed.

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

Applications declined by PHARMAC Board[1]

Number	***2003***	*2002*	*2001*	*2000*	*1999*	*1998*	*1997*	***Total since 1994***
New chemical entities	**1**	4	32[3]	1	20[2]	2	14	**70**
New presentations	**1**	–	1	2	0	10	3	**32**
New products	**–**	–	0	0	0	2	11	**31**
Derestrictions	**–**	–	0	0	3	1	1	**11**
Totals	**2**	4	33	3	23	15	29	**144**

This year, the PHARMAC Board considered 65 applications for subsidy for 65 products, of which 63 were listed and 2 declined. The acceptance rate, therefore, was 97 percent.

1. *Based on the date on which decisions are implemented.*
2. *A higher than usual number of declined applications for new chemical entities is due mainly to the Special Foods review which resulted in 18 declines.*
3. *A higher than usual number of declined applications for new chemical entities is due mainly to the Special Foods review which resulted in 28 declines.*

Advisory committees

Nine members were appointed to the Consumer Advisory Committee (CAC), a committee established to provide PHARMAC with input from a consumer or patient perspective. Following consultation with the committee, Sandra Coney was appointed chair by the PHARMAC Board.

The committee held two meetings and also considered issues via teleconferences.

A number of changes occurred in the composition and roles of the Pharmacology and Therapeutics Advisory Committee (PTAC) and its sub-committees.

Prof Carl Burgess, a current member of PTAC, agreed to replace Dr John Hedley as chairman from August 2003. Prof Burgess' appointment will enable the committee to make a smooth transition to a new chairmanship while continuing its functions uninterrupted.

The departure of Robin Briant and Bruce Foggo and the appointment of Taranaki GP Dr Anthony Ruakere maintained PTAC's membership levels, and also provided a Maori perspective to a key PHARMAC advisory body, in line with PHARMAC's Maori Responsiveness Strategy.

There have been some adjustments made to membership of sub-committees, while the Hormonal Contraceptive Subcommittee had a name change (to Hormone and Contraceptive) to reflect a slightly broadened scope.

The range of PTAC's sub-committees has been further enhanced by the establishment of an immunosuppressants sub-committee.

The annual cost of PHARMAC

Derived from audited figures for years ended 30 June

Dollar 000s	***2003***	*2002*	*2001**	*2000*	*1999*	*1998*	*1997*	*1996*	*1995*	*1994*
Staff costs (includes Directors' and professional fees)	**2,753**	2,330	1,763	1,598	1,539	1,440	1,245	1,170	804	665
Office costs (includes depreciation, rent, phones, library, purchase of data, ordinary legal costs)	**2,801**	2,452	2,326	1,744	1,701	1,176	855	925	575	563
Responsible use of medicines**	**2,262**	2,141	0	0	0	0	0	0	0	0
Consulting services (includes PTAC, PR, general consulting, audit fees, HRM and accounting)	**1,251**	901	597	695	1,215	1,409	1,517	1,408	1,047	532
Schedule production (printing and postage only)	**267**	287	348	464	424	479	345	338	260	217
Costs associated with litigation	**242**	318	251	736	594	1,039	1,607	680	0	0
Total cost	**$9,576**	$8,429	$5,285	$5,237	$5,473	$5,543	$5,569	$4,521	$2,686	$1,977

At balance date, fixed assets comprised of $354,619 of office and computer equipment, furniture and fittings

* *Figures for 2001 are a composite of audited figures for the period 1 July 2000 - 31 December 2000, and the figures for 1 January 2001 – 30 June 2001.*

** *Traditionally funding for the responsible use of medicines had been provided as a separate funding stream from the Ministry of Health. This funding is now provided out of PHARMAC's operational budget.*

High Cost Medicines has been included in Consulting Services

Financial performance

PHARMAC managed its operational expenditure within budget in 2003, a result of efficiency in its operations and delays in the implementation of some key projects promoting the responsible use of pharmaceuticals.

Staff costs increased as PHARMAC incorporated Exceptional Circumstances and other permanent panel staff into its budget for the first full financial year. Office costs increased for the year, mainly due to higher than normal depreciation and write-offs ahead of a planned premises move.

PHARMAC also incorporated expenditure on High Cost Medicine panels into its 2002-03 budget. These Panels were traditionally funded by the Ministry of Health, but for the 2002/2003 financial year, PHARMAC funded them from its operating budget. In future, funding is to be provided by District Health Boards.

Efficiencies continue to be generated in the production of the Pharmaceutical Schedule, where costs again fell.

DIRECTORY

The PHARMAC Board

Chairman

Richard Waddel, BCom, FCA;

Directors

Professor Gregor Coster, MSc, MBChB, FRNZCGP

Liz Coutts, BMS, CA

Karen Guilliland, RM, RGON, MA, MNZM

Helmut Modlik, BCA, MBA

David Moore, Mcom, Dip Health Ec, CA

Pharmacology and Therapeutics Advisory Committee (PTAC)

Chairman

John Hedley MBChB, FRACP, FACCP, Physician

Committee Members

Carl Burgess MD, MRCP (UK), FRACP, Physician / Clinical Pharmacologist

Jim Lello BHB, MBChB, DCH, FRNZCGP, General Practitioner

Coleen Lewis MBChB, General Practitioner

Peter Pillans MBChB, MD, FCP, FRACP, Clinical Pharmacologist

Anthony Ruakere MBChB, Dip Obst, Dip General Practice, FRNZCGP, General Practitioner

Tom Thompson MBChB, FRACP, Physician

Paul Tomlinson BSc, MBChB, MD, MRCP, FRACP, Paediatrician

PTAC Sub-committees

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

Antibiotics – Dr John Hedley (PTAC, physician, chair), Dr Iain Loan (general practitioner), Dr Paul Tomlinson (PTAC, paediatrician), Dr Sandy Smith (microbiologist), Dr Mark Thomas (infectious disease specialist)

Antiretroviral Agents – Prof Carl Burgess (PTAC, physician), Dr John Hedley (PTAC, physician, chair), Dr Paul Tomlinson (PTAC, paediatrician), Dr Richard Meech (infectious disease specialist), Dr Stephen Chambers (infectious disease specialist), Dr Mark Thomas (infectious disease specialist)

Cardiovascular – Dr Allan Moffitt (general practitioner), Dr Gary Gordon (cardiologist), Dr John Elliott (cardiologist), Dr John Hedley (PTAC, physician, Chair), Dr Lannes Johnson (general practitioner), Dr Miles Williams (cardiologist), Dr Peter Pillans (PTAC, clinical pharmacologist)

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

Diabetes – Dr Bruce Small (general practitioner), Dr John Hedley (PTAC, physician), Dr Paul Drury (diabetologist), Dr Paul Tomlinson (PTAC, paediatrician), Dr Rick Cutfield (diabetologist), Dr Tim Kenealy (general practitioner), Dr Tom Thompson (PTAC, physician, chair), Pat Carlton (diabetes nurse specialist)

Hormone and Contraceptive – Dr Bruce Small (general practitioner), Dr Christine Roke (family planning specialist), Dr Frances McClure (general practitioner), Dr Michael Croxson (endocrinologist), Dr Coleen Lewis, (PTAC, general practitioner, chair)

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

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

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

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

Respiratory – Dr Ian Shaw (paediatrician), Dr Jim Lello (PTAC, general practitioner, chair), Dr John Hedley (PTAC, physician), Dr John Kolbe (physician), Dr John McLachlan (physician)

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

Tender Medical – Andrea Shirtcliffe, (pharmacist), Dr Jim Lello (PTAC, general practitioner) Dr John Hedley (PTAC, physician, chair), Dr Paul Tomlinson, (PTAC, paediatrician), Peter Cooke (pharmacist), Ms Sarah Fitt (hospital pharmacist), Dr David Carroll (physician), Dr Nigel Patton (haematologist).

Exceptional Circumstances Panel

Dr John Hedley (physician)
Dr William Wong (paediatrician)
Dr Howard Wilson (general practitioner)
Dr Mel Brieseman (public health physician)
Dr Paul Tomlinson (paediatrician)
Dr David Waite (general practitioner)

Hospital Pharmaceuticals Advisory Committee (HPAC)

Chair

Brian Ellis (Clinical Practice Group Manager, Otago)

Committee members

Stephanie Chapman (Purchasing Manager, Canterbury)

Marilyn Crawley (Pharmacy Services Manager, Waitemata)

Sarah Fitt (Pharmacy manager, Auckland DHB)

DIRECTORY (continued)

Paul Green (Material management, Auckland DHB)

Bruce Hastie (Clinical Pharmacy Manager, Counties-Manukau)

Andre Mutavidzic (Pharmacy Team Leader, Waikato)

Elizabeth Plant (Chief Pharmacist, Taranaki)

Neville Winsley (Pharmacy Manager, Hawke's Bay)

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

Julie Yee (Service Leader, Pharmacy, Capital & Coast).

Consumer Advisory Committee (CAC)

Chair

Sandra Coney (Women's Health Action, Auckland), Chair

Committee Members

Vicki Burnett (Mental Health consultant, Auckland)

Sharron Cole (National Trainer, Parents Centres, Wellington)

Matiu Dickson (Te Runanga o Kirikiriroa Chairman, Hamilton)

Anna Dillon (CanTeen National Secretary, Otago)

Deirdre Nehua (Chief Executive, Te Hotu Manawa Maori, Auckland)

Dennis Paget (Grey Power, Blenheim)

Paul Stanley (lecturer in social sciences, Tauranga)

Kuresa Tiumalu-Faleseuga (Chief Executive, Pacificare, Auckland).

The PHARMAC Team

Chief Executive

Wayne McNee BPharm, PG Dip Clin Pharm (Dist)

Medical Director

Peter Moodie BSc, MBChB, FRNZCGP

Corporate

Abby Laurenson BCA, LLB (Hons) – *Manager, Corporate*

Stuart Bruce MA, BA (Hons) – *Manager, Communications and External Relations*

Simon England – *Communications Advisor*

Jan Edwards NZ DipBus, AT, – *Finance Manager*

Melanie Pemberton BA (Hons), HND(UK) – *Executive Assistant & Web Administrator*

Jessica Nisbet – *Receptionist (General Enquiries)*

Jo Sexton – *Receptionist*

Special projects

Wendy Adams BA, BCom – *PTAC Secretary*

Jan Quin RCpN – *Project Manager*

Dilky Rasiah MBChB, Dip Public Health – *Project Manager (on parental leave)*

Panel/Pharmaceutical co-ordinators

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

Murray Silverstone – *High Cost Pharmaceuticals Co-ordinator*

Linley Lovich DipPharm – *High Cost Pharmaceuticals Co-ordinator*

Caryn Daly DipPsyNurs (Canada) – *Exceptional Circumstances Panel Assistant*

Supply side team

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

Andrew Davies BSc (Hons) – *Tender Analyst*

Natalie Ganley MSc – *Therapeutic Group Manager*

Martin Szuba MD, MBA, MSc – *Therapeutic Group Manager*

Katie Harris BA – *Therapeutic Group Assistant*

Adam McRae BCom, BNurs – *Therapeutic Group Intern*

Schedule team

Mary Chesterfield PTecC (UK) – *Schedule Administrator*

Ursula Egan BPharm – Schedule Analyst

John Geering BA, BSc – *Programmer/Analyst*

Demand Side team

Rachel Wilson BA, NZIMR – *Manager, Demand Side*

Tracey Barron DipPharm, MSc(ClinPharm) – *Demand Side Manager*

Jeanine van Kradenburg RCpN, DipNursEd – *Demand Side Manager*

Analysis and assessment team

Matthew Brougham MSc (Hons) – *Manager, Analysis and Assessment*

Jason Arnold BSc, PG Dip Stat (Dist) – *Forecast Analyst*

Sean Dougherty BCom (Hons) – *Analyst*

Derek Kan, BRP (Hons), *Analyst*

Scott Metcalfe MBChB, DComH, FAFPHM – *Epidemiologist/public health physician (on contract)*

Hew Norris BMS – *Analyst*

Hospital Pharmaceuticals team

Sarah Schmitt BSc – *Manager, Hospital Pharmaceuticals*

Rachel Grocott Bcom (Hons) – *Hospital Pharmaceuticals Analyst*

Matthew Perkins BSc, BCom, PG Dip Com – *Hospital Projects Advisor*

Publications available on PHARMAC's Website include:

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

Visit PHARMAC online at
www.pharmac.govt.nz