

# Annual Review

for the year ended 30 June

# 1997

*With a common goal  
we can deliver*

*Are doctors deafened  
by the persuaders?*

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

# PHARMAC *PHARMAC (Pharmaceutical*

*Management Agency Limited) is a not-for-profit company owned (from July 1, 1997) by the Transitional Health Authority (THA). Its role is to manage the national Pharmaceutical Schedule on behalf of the Authority.*

*The Schedule is a list, updated monthly and reprinted three times a year, of almost 3,000 subsidised prescription drugs and related products available in New Zealand. The Schedule also records the price of each drug, the subsidy it receives from public funds and the guidelines or conditions under which it may be prescribed.*

*Decisions on subsidy levels, and prescribing guidelines and conditions are taken by the PHARMAC Board with input from independent, medical experts on the Pharmacology and Therapeutics Advisory Committee (PTAC), and PHARMAC's managers and analysts.*

*In taking its decisions, PHARMAC seeks to balance the needs of patients for equitable access to health care with the needs of tax payers for responsible management of the costs they ultimately bear.*

# Inside



## With shared goals we can deliver fair access from finite funds

2

PHARMAC chairman, Denis Tait, says that if everybody involved in health can agree on what is expected from drugs we **can** deliver equitable access from finite resources – despite the relentless demand for new and more expensive therapies.



## Are doctors deafened by the persuaders?

6

John Hedley, Chairman of the Pharmacology and Therapeutic Advisory Committee (PTAC) says doctors need to be more careful in their prescribing choices and be alert to the subtle and subliminal effects of drug company persuasion.



## It's time to tilt the drug market in favour of the customer

10

PHARMAC General Manager David Moore says the drug market is dominated by drug companies and it's time the customers (patients and tax payers) got a better deal. He also says the statements of drug companies need to be heard with caution.

## Review of PHARMAC's year by therapeutic group

14

## PHARMAC's operations reviewed

19

## Data on costs – rises and falls

22

## Who's who in PHARMAC and PTAC

24

### **In this publication:**

- “Year” means years ending 30 June. For example: “this year” means the year ended 30 June 1997; “last year” means the year ended 30 June 1996, “next year” means the year ended 30 June 1998.
- The word “drug” is generally used instead of the more cumbersome “pharmaceutical” or “medicine;” “doctor” is generally used instead of “physician,” or “medical practitioner;” and “health professional” is used to describe all people engaged in health and patient care.
- Specific drugs are described by chemical entity with brand names in brackets, or vice versa, for example “fluvastatin (Lescol).”
- “THA” means Transitional Health Authority which was operative from 1 July 1997, and includes its predecessors, the Regional Health Authorities (RHAs).

- Unless otherwise stated all values are in New Zealand dollars. The exchange rate at 30 June 1997 was approximately NZ\$1.00 = US\$0.65

### **Sources of material:**

- The commentaries on pages 2 to 13 were written between June and October 1997 and are derived from numerous sources including:
- the international pharmaceutical industry newsletter *Scrip* and its companion magazine – June 1996 to May 1997,
  - clippings and transcripts from various daily, periodical, and specialist media,
  - the most recent seven issues of the *Journal of Medical Ethics*.
  - and the books *Contested Ground*, and *The Disease Mongers*.
- Fully-referenced and footnoted versions of the commentaries on pages 2 to 13 are available from PHARMAC on request.

With **shared** goals  
we ***CAN*** deliver fair  
fi



*Sharing a vision*

*PHARMAC chairman, Denis Tait, says that if everybody involved in health can agree about what is expected from drugs we can deliver equitable access from finite resources – despite the relentless demand for new and more expensive therapies.*

# access from finite funds

**F**our years ago PHARMAC set out with the objective of achieving an acceptable balance between the needs of patients for equitable access to drugs and the needs of tax payers for responsible management of the costs they ultimately bear. In pursuit of that objective we have made more than 200 new drugs available on subsidy. We have reduced the price – and therefore the subsidy cost – of many drugs. We have lowered risks from cost and volume growth. And we have released funds, that otherwise would not have been available, to serve greater health care priorities. It is heartening that other countries, including Australia, are adopting some of our innovative strategies.

Unfortunately, our work is often opposed by some drug companies, doctors, pharmacists, and patient groups who complain that we deny access to useful drugs. Rarely, do they concede the reality of finite resources and invariably their concerns are based on their perspective only. A US academic put it this way: “. . . special interest groups are pressuring New Zealand’s and other governments not to be so equitable. The special interests do not want to say *me first* in so many words, so they mount an attack on *efficiency* and *waste of public money* or *inferiority of public versus private services*.”

PHARMAC’s position is that a balance between equitable access and cost is realistic if drug companies, prescribers, and patients pursue a common goal. The theme of this Review is thus: “Shared Vision.”

## More drugs, more choice

This year, we added 55 drugs to the Schedule, and improved access to 10 by de-restriction. Since 1993 we have improved access and offered wider choice to 330 drugs. Also this year we considered 84 applications for subsidy and accepted 65 per cent of them. These figures belie the complaint that our behaviour is restrictive. Details are on page 20.

## Decisions included:

- Extending, from 1 July, the availability of subsidised cholesterol-lowering statins to an estimated 90,000 more patients than the 12,500 previously on the drug. This followed a comprehensive review over two years of lipid-modifying therapies and the subsequent reference pricing of three subsidised statins. The process included consultation with the National Heart Foundation, cardiologists and other specialists, and the Royal College of General Practitioners.
- Listing the asthma drugs, salmeterol (Serevent) and fluticasone (Flixotide). Salmeterol is a new treatment for patients who are not well controlled by existing therapies.
- Listing Apomorphine injection for idiopathic Parkinson’s disease. For about 16 patients, it will delay hospitalisation. The cost of \$10 per day per patient is justified by improved health and institutional savings.
- Listing dornase alfa (Pulmozyme) for the treatment of cystic fibrosis. This drug costs about \$18,000 a year per patient.
- Listing new treatments for AIDS/HIV including protease inhibitors and lamivudine (3TC).

The listing of the asthma drugs, the protease inhibitor saquinavir, and dornase alfa were, in part, enabled by contracts with Glaxo Wellcome and Roche Products. These contracts involve risk-sharing through capped budgets and pay-backs, free supply, and price reductions on drugs already listed.

The THA made extra funds available for the supply of alglucerase (Ceredase) for the treatment of Gaucher disease. There are 16 known cases of Gaucher in New Zealand, of which 12 have been approved as likely to benefit from alglucerase. At an average cost of about \$70,000 a year for each patient it is the most expensive drug we have considered.

We responded to a Government directive aimed at reducing the number of abortions and unwanted pregnancies by fully subsidising the oral contraceptives ethinylloestradiol with norethisterone (Norimin) and ethynodiol diacetate (Femulin). We also widened access by allowing midwife prescribing of oral contraceptives, and we continue to negotiate with suppliers of other oral contraceptives to further expand the selection of brands available on full subsidy.

We also de-listed nasal sprays containing CFCs after an 18-month phase-out. Fully-subsidised CFC-free sprays are now available. We continue to review the value of this decision in the light of budget constraints.

## Relentless cost pressure

We continue to face relentless demand for drug subsidies. This year, we achieved a \$30 million respite from the introduction of monthly dispensing in May 1996. We were aware that this would deliver only a one-off gain, and that the cost pressures would soon resume. In last year’s Review we forecast, correctly, that the annual cost of drug subsidies would return to its trend line around June 1998.

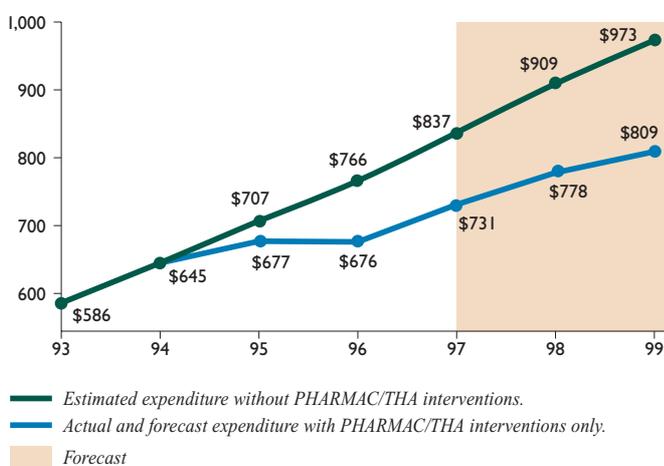
The total cost of drug subsidies this year was \$731 million, up eight per cent on last year. Over the last four years, the average annual growth rate has been 5.8 per cent. The cumulative effect has been to lift the total annual subsidy cost by nearly 25 per cent from the 1993 figure of \$586 million.

Extrapolation of the trend line of the last four years takes the drug subsidy cost to \$778 million a year by mid-1998, up six per cent. The THA budget for drugs is set at \$747 million but with more than a quarter of the year gone, it is clear that the trend line is moving up sharply and that without corrective action the final bill could rise to \$800 million.

Graph one

### EFFECT OF PHARMAC AND THA INTERVENTIONS

Total subsidised, non-CHE-funded, drug cost in \$ millions GST-inclusive, 30 June years.



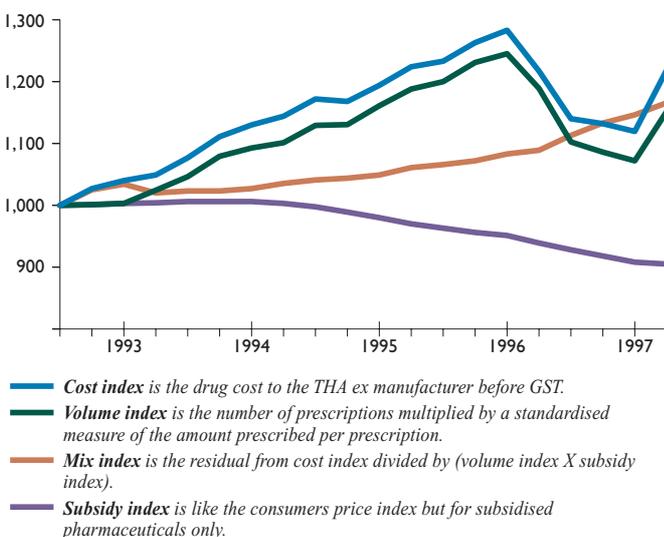
Without PHARMAC and THA interventions the drug subsidy bill this year would have been \$106 million higher, rising to \$131 million higher next year.

Graph two

### SUBSIDY, VOLUME, MIX AND COST INDICES

Four-quarterly moving averages; years end 30 June.

Base: September quarter 1992 = 1,000.



The subsidy index continues to fall while total costs continue to rise.

The Researched Medicines Industry Association (RMI) denies the growth and says that the “real” level of pharmaceutical expenditure is declining. We disagree and point out that the New Zealand experience is similar to that of other countries. For example, the newsletter Scrip reports sales growth in ten of the world’s leading markets of seven per cent in 1996 and eight per cent in 1995, and compound annual growth between 1991 and 1995 of 11.5 per cent. It also reports a forecast of annual growth worldwide of 6.7 per cent between 1995 and 2000. According to two Dutch analysts: though there are big differences worldwide in prescribing practices, two features remain constant – the unbroken rise in levels of drug use since the 1960s and an increasing concern for costs.

### New strategies

There is growing awareness within the health sector that the ballooning use of new and more expensive drugs can not be held back by PHARMAC alone. Early indications of expenditure in the 1998 year show alarming growth versus budget. We have therefore joined, with other interest groups, in an eight-pronged initiative by the THA. Working groups are now developing ways to:

- 1 *Encourage prescribers* to move patients to the lowest, effective dose using the lowest cost, suitable drug. The initial focus will be on asthma and cardiovascular drugs which together account for 40 per cent of the total drug subsidy bill. Prescribers will be targeted with information that balances drug company marketing literature.
- 2 *Make the drug market more competitive.* The tools may include sole supply (a recent example was a tender for paracetamol tablets and capsules), and contracting. Already we have had a heartening response from some drug companies to our requests for expressions of interest. We are also looking at ways to lower the entry barriers to the generic market.
- 3 *Provide pharmacists with incentives to reduce transaction costs* – including moving away from dependence on percentage mark-ups to remuneration arrangements that reflect their professional input.
- 4 *Make drug consumers more aware of prices,* the need to follow dosage instructions, the cost of waste, and the benefits of healthier diet and lifestyles. For example, the \$30 million a year we spend on subsidising drugs to treat smoking-related illnesses is more than we spend on drugs for and monitoring of diabetes. Consumer waste also occurs in other ways. A UK report found that up to half of patients with chronic illness do not take their medication in fully therapeutic doses; that one in five kidney transplant patients are not taking immunosuppressants as prescribed; and that half the patients on hypertensives have stopped medication. Of the remainder, one third are not taking enough medication to control their blood pressure.
- 5 *Investigate fraudulent claims* for drugs not dispensed, and the use of community services cards and other forms of reimbursement where there is no entitlement.
- 6 *Improve the information flow.* The aim is to develop the *PharmHouse* national prescription database to deliver information faster, at lower cost, and with more accuracy.

7 *Work with doctors* to provide incentives for them to prescribe in a more cost-effective manner. The initial focus will be helping the 53 Independent Practitioner Associations (IPAs), in which 70 per cent of general practitioners are members, to further develop the tools they now use. These include voluntary guidelines, peer review reports, monthly charting of prescribing habits against the average, follow up programmes from pharmacists, and continuing education, with some of the savings being re-invested in further cost-saving strategies.

8 *Use fewer high cost, low utility drugs.* Targets will include ACE inhibitors for blood pressure, which cost \$470 per patient per year, when often a diuretic such as bendrofluzide, will achieve the same result at \$20 a year; and laxatives and vitamins that are available on prescription and over-the-counter.

There are opportunities in some of these areas for drug companies to be involved.

**Litigation**

Three of eight legal actions in which we are involved were heard in court.

The High Court dismissed an application by Reckitt and Colman (New Zealand) Limited for judicial review of our decision not to subsidise lemon-flavoured Gaviscon. We were awarded costs of \$3,000 plus disbursements. Reckitt and Colman is appealing the decision. We are appealing the level of costs awarded.

The Commissioner of Patents accepted, in part, our view that the patent on the antacid Zantac (ranitidine) should not be extended. The court allowed an extension until only July 1998. New Zealand tax payers will thus benefit, on our estimates of net present value, by about \$38 million over five years. This action was one of several around the world in which Glaxo Wellcome sought to protect its billion dollar annual market for Zantac from generic competition.

The High Court upheld a claim by Roussel Uclaf Australia Pty Ltd and Roussel (NZ) Ltd against PHARMAC and PTAC for retention, at its former level, of the subsidy for the macrolide antibiotic, Rulide. A reduction in the level of the subsidy was due to take effect on 1 February 1996 but was stalled when Roussel was granted an interim order. We are appealing the decision. Details of these, and other actions, are on page 20.

**Thanks**

I record sincere thanks to my fellow directors for their support and to David Moore's fine team of managers and analysts; to the practising doctors at PTAC and its sub-committees who continue to provide invaluable, independent and practical advice to the PHARMAC Board; and to the many doctors, drug companies, professional medical associations and user groups who have taken the time to respond to our requests for comment and feedback. The quality of our decisions is immeasurably improved by this wide range of inputs.

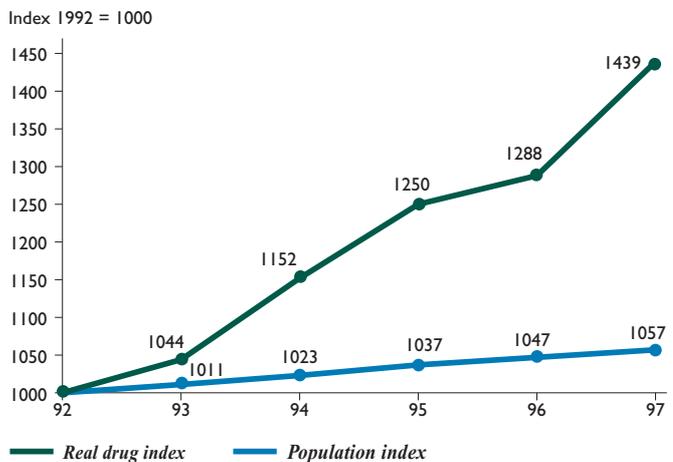


Denis Tait  
Chairman  
24 October 1997

Graph three

**REAL DRUG EXPENDITURE GROWTH VERSUS POPULATION**

Years ended 30 June. Base: 1 July 1992 = 1,000.



Sources: Drug data from Health Benefits (NZ) Ltd. Drugs deflated by drug subsidy inflation (see Subsidy Index graph two).

The real growth in drug costs is coming from increases in volumes of drugs being prescribed (prescription numbers and the volume in each prescription), and "mix" substitution: the replacement of older, lower cost drugs with newer, more expensive drugs.

**THIS YEAR**

*we made pleasing progress in . . .*

- Our relationships with some drugs companies, for example the package contracts with Roche Products and Glaxo Wellcome on a range of products, and a contract with Novartis on fluvastatin.
- Our relationships with the General Practitioners' Association, the Royal NZ College of General Practitioners and the IPAs.
- Delivering wider access to more drugs for more patients, including new drugs for AIDS/HIV, Parkinsons and Gaucher diseases, and cystic fibrosis.
- Bringing drug prices down.

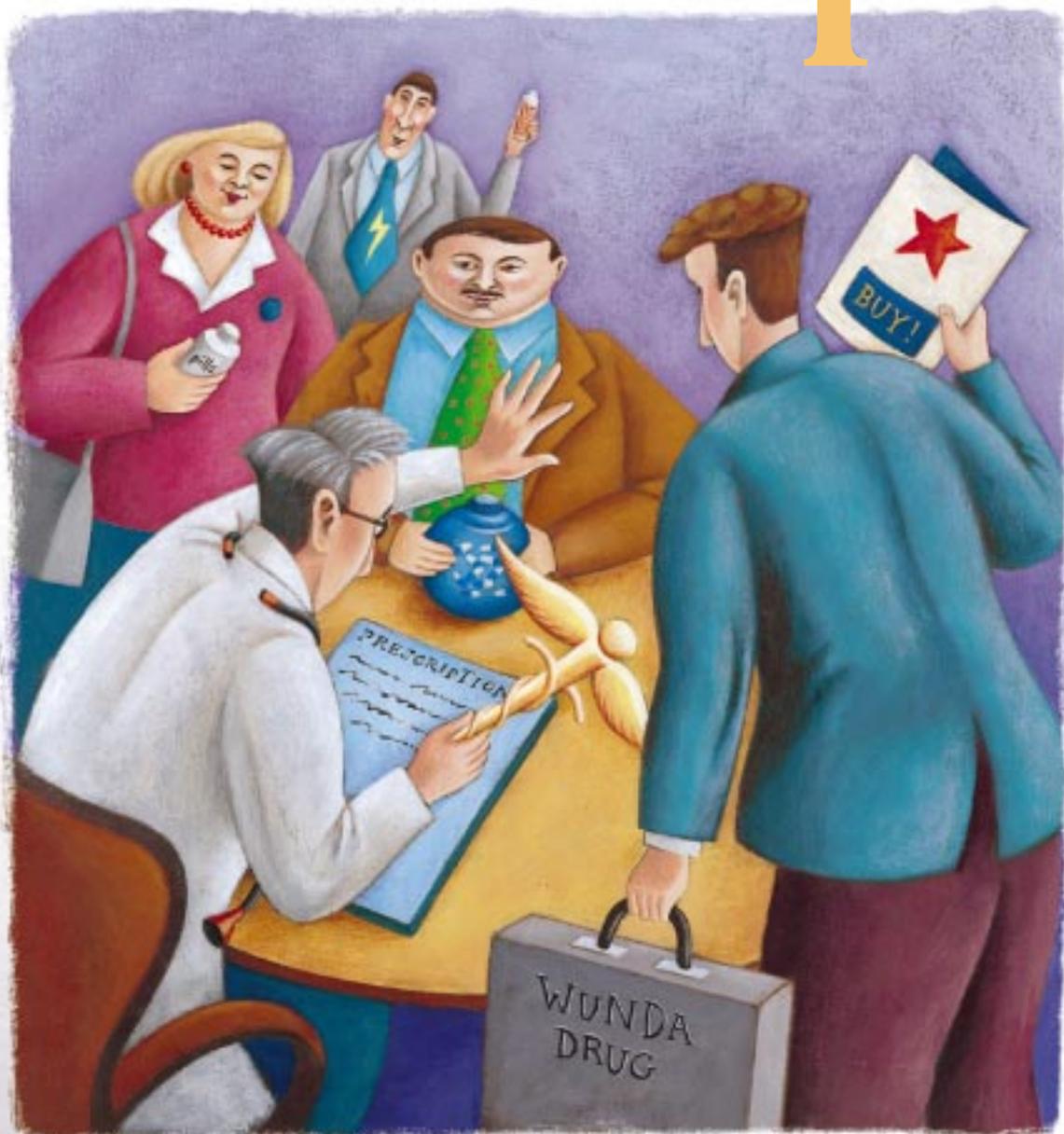
*but faced pressure from . . .*

- Ever-growing demand for new, and more expensive drugs.
- The efforts of some drug companies to obstruct our work.

*and suffered disappointment because . . .*

- We have not been able to reach a working relationship with the Researched Medicines Industry Association (RMI).

# Are doctors deafened by the pers



*Being discerning with information*

# uaders

*John Hedley, Chairman of the Pharmacology and Therapeutic Advisory Committee (PTAC), says doctors need to be more careful in their prescribing choices and be alert to the effects of drug company persuasion.*

**A**s pressure on health spending mounts it is more important than ever for doctors to make prescribing choices that are not only best for the patient but best value for the tax payer.

## IPAs and integrated care

Many doctors are doing a good job balancing these twin goals, with no evidence that patient health is being compromised. Budget holding by Independent Practitioners' Associations (IPAs) – which now represent nearly 70 per cent of all GPs – and efforts to deliver best-practice care while controlling costs, are an important step in the right direction. Many IPAs are also being more discriminating about the presence of drug company detailers and are seeking advice from other sources. And most importantly, evidence is emerging that reinvestment of cost savings is leading to the delivery of new patient services, and improvements in both the quality of care and the standards of general practice.

## Delivering the greatest benefit

The challenge is for us to resist the temptation to spend on low quality health care. Instead, we must move funds via our prescriptions to medicines that give the greatest benefit to patients – and there are many effective treatments available.

Doctors and PHARMAC need to work together, with PTAC providing expert opinion, and we should focus on the real (rather than the peripheral) issues. PHARMAC's decision on statins is illustrative. The patients who get the greatest benefit from statins are those with established heart disease. Previously, only about half of eligible high-risk patients were in fact getting statin treatment. Yet the dissent over our statin decision has focussed on marginal differences between brands of statins, rather than on overall patient benefit.

## Differences in drug costs

However, some doctors continue to prescribe with little or no regard to cost – even within IPAs. A recent study of three IPAs and three group practices in New Zealand found large differences in average prescribing costs on several measures, even after adjusting for demographic differences. For instance, the total expenditure on drugs (and diagnostic services) by the 30 highest spenders in one IPA was nearly ten times greater than that of the 30 lowest spenders. In another IPA the comparable spread was five times. On drug cost per patient, the spread between top and bottom was \$269 to \$41 over the study period; and on expenditure per drug category within one IPA, there were also big differences:

Expenditure by drug category in one IPA			
BNF Category	15 lowest-cost prescribers	15 highest-cost prescribers	Lowest as per cent of highest
Antidepressants	\$788	\$2,049	38
Cardiovascular	\$3,295	\$8,395	39
Inhaled corticosteroids	\$973	\$2,014	48
Bronchodilators	\$576	\$1,123	51

One finding of this study was that: “. . . high cost prescribers are high volume prescribers and . . . volume rather than price is the key factor in prescribing cost variation.”

Clearly, if high spending doctors prescribed in the same way as low spenders, large savings would be made. These savings would then be available for reinvestment in new therapies, such as breakthrough drugs, that can deliver real gains in health and life quality.

Although breakthrough drugs are relatively rare, it is important that when they do become available, we have the ability to pay for them. But to arrive at that point doctors need to be discerning about the difference between breakthroughs and old therapies re-packaged with an enhancement or two.

## Advertising volume

It follows that for doctors to fulfil their societal obligations and use tax payer dollars wisely, they need to be more discriminating with the information they receive.

In 1991 a New Zealand study showed that drug companies spent over \$500,000 in postage alone to send out 30 tons of print advertising to doctors. Worldwide, the second-biggest cost to drug companies, after manufacturing, is marketing – around 20 per cent of the wholesale price. Adjusted for population, New Zealand doctors are on the receiving end of about \$100 million a year of persuasion or an average of about \$25,000 per GP a year on marketing, including advertising in medical journals, free samples, detailers, written material, and trade displays. Some of these activities masquerade as “education.” All should be seen for what they are – product promotion in which the benefits are emphasised and the problems played down.

## The nature of advertising

Advertising is most effective when the message is boiled down to one or two compelling lines. Yet this is the antithesis of objective scientific inquiry. How can a complex subject like risk assessment in cardiovascular disease, for instance, be reduced to a slogan such as “So and So Drug Saves Lives.”

A study of 109 advertisements in 10 leading medical journals found a significant difference between what a group of expert reviewers thought the ads *should* say and what they actually said. The study concluded that 92 per cent violated Federal Drug Administration (FDA) advertising guidelines. In 47 per cent, side effects and contraindications were not highlighted, 28 per cent ought not to have been published and 34 per cent ought to have had major revisions before publication, said the reviewers.

This study also highlighted the difficulties of obtaining opinion that is truly independent of drug companies. The study authors, in selecting their group of reviewers, initially intended to exclude all experts who had accepted more than \$300 from the drug industry in the previous two years. They had to drop this requirement because 71 per cent of the reviewers had received money from the drug industry, with over half of those receiving more than \$5,000.

I used to think a physician I worked for once in Adelaide was a little extreme in tearing out all the ads from the American Journal of Medicine before he read it, but now I am not so sure.

## Medical conferences

In the last decade there has been a huge increase in the number of medical meetings, symposia, or consensus conferences, presumably as a response to controls on advertisements. One author calculates that the number held in the US has jumped from about 7,000 in 1975 to nearly 35,000 a year.

A paper in *The Lancet* said: “The consensus conference is open to exploitation by groups, such as pharmaceutical companies, wishing to expand their repertoire of promotional activities . . . there has lately been an increase in indirect promotion by sponsorship of publications, lectures, and continuing education, and also symposia. Many company

sponsored symposia are misleading; they mention brand names; and the proceedings are sometimes published in journals without peer review. One study of the factors that influence the prescribing decisions of GPs found that seminars, conferences, and lectures organised by pharmaceutical companies had more influence than advertisements, promotional material (samples, diaries, calendars etc), or direct mail . . . the latest covert promotional activity is the consensus conference.”

## The influence of advertising

Although doctors typically tell researchers that they are not influenced by advertising, there is evidence to suggest otherwise.

A US researcher, Avorn, in a study of 85 doctors in Boston found that when the doctors were asked about the properties of certain drugs, their answers more closely resembled the information promulgated in advertisements than that found in the scientific literature. “When a physician prescribes a medication for a patient, the act is often shaped, in a large part, by forces unrelated to the biochemical properties of the drug.” . . . They then go on to say that most studies of prescribing behaviour rely heavily on self-reporting “introducing a strong potential bias. In contrast, surveys of actual prescribing practices indicate that irrational drug choices are made frequently, despite the availability of ample empirical evidence counselling otherwise.” They concluded: “. . . the data . . . raise serious questions about the role of pharmaceutical advertising in the continuing education of physicians about drug effects.”

In a postal survey of 107 New Zealand GPs, Thomson and Trent found that 59 per cent of respondents believed their prescribing patterns were influenced by having samples available, and they cite Morelli and Koenigsberg as saying that a dispensed sample is likely to be followed by a prescription for that brand rather than an alternative.

Doctors also tend to ignore the fine print in advertisements according to a survey by MaLAM (Medical Lobby for Appropriate Marketing). Said MaLAM: “This is no surprise. We have often stressed that fine-print product information is not a user-friendly way of informing health professionals.”

## Scientific literature

One effect of the sheer scale of promotional activity is that it can undermine the unbiased exchange of scientific information. It has also led to complex inter-relationships between academia, the profession and industry which can skew the scientific literature.

A Danish researcher who analysed the published papers of 196 double-blind trials of NSAIDs in rheumatoid arthritis concluded: “Doubtful or invalid statements were found in 76 per cent of the conclusions or abstracts. Bias consistently favoured the new drug in 81 trials, and the control in only one trial. . . . Several of the biases were hidden, that is, would not be detected by analysis of the individual report.”

A US medical journalist, Lynn Payer believes: “There is a strong tendency for editors to favour publishing positive rather than negative results, because negative findings are seldom novel. . . . The net effect of editorial policy is that there exists today a substantial selection bias in favour of the publication of positive results in medical journals. The supposed self-correcting mechanisms of science, where bad studies will eventually disappear because someone proves them wrong, don’t always work as they are supposed to either.” She cites a study by Shapiro in response to a published ‘positive result.’ “When Dr Shapiro and his co-workers repeated the experiment and got a negative result, they submitted

### STRIVING FOR BALANCE

“Clinical freedom can never mean the freedom to do what is convenient and enjoyable irrespective of its costs and effects. Social values must, in a publicly-financed system, be balanced with clinical values to determine which patients will and will not get treatment. Neither the clinician nor the economist should dominate decisions about who will live in what degree of pain and discomfort and who, in extremis, will die”

*Professor Alan Maynard, Department of Health Sciences and Clinical Evaluation, University of York.*

it to the same journal. The editor did not question the validity of the study, but declined to publish the negative result, suggesting that the authors send it to another journal, and later suggesting that they write a letter to the editor.”

It follows that if statisticians analyse only published studies there is a risk that the results will be skewed by the tendency for favourable results to be published over negative results.

There can also be a problem with supplements in medical journals. Not only are these usually supported by one drug company, but the articles they contain may not have gone through the normal review process.

### Conflicts of interest and ethics

Thinking doctors should be concentrating on providing the benefits for their patients clearly identified in multiple randomised controlled trials. The challenge is for general practitioners to co-ordinate the various therapies that deliver benefits to patients.

What about the wider ethical view? Doctors have a duty to conserve society’s resources. It is unethical therefore to prescribe, endorse or support ineffective or wasteful treatments.

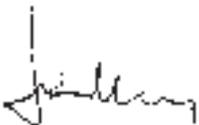
Drug advertising can lead us to conflicts of interest, where professional judgments concerning a primary interest such as a patient’s welfare, or a prescribing decision, tend to be unduly influenced by a secondary interest such as financial gain.

Gifts from drug companies are a form of promotion and can result in a minor obligation such as a continually open door to detailers who sometimes offer little more than a mish mash of pre-clinical data. For example, detailers might describe the drug’s effect on cell receptors, or the in vitro inhibitory activity, or the effect on serum concentrations. We would be better off receiving patient-oriented advice that matters.

**We should insist on the “STEP” approach. Ask the detailer for “s” for safety, “t” for tolerability (the number of dropouts in trials), “e” for effectiveness against your favourite for the condition (not an irrelevant comparator), or against placebo, and finally “p” for price.**

### Thanks

I thank my fellow PTAC members for their input and support and I pay tribute to Keith Humphries, Sharon Kletchko, Associate Professor Tim Maling, and Professor Les Toop, who retired from PTAC. My thanks also to the sub-committees of PTAC without whose input we could not properly operate. Thanks also to the increasing numbers of doctors and other health professionals who have taken the time to respond to our requests for comment and information.



John Hedley  
Chairman  
Pharmacology and Therapeutic Advisory Committee (PTAC)

## 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 advice on the pharmacological and therapeutic consequences of proposed amendments to the Pharmaceutical Schedule.

PTAC is a committee of medical specialists and general practitioners nominated by professional bodies including, amongst others, the New Zealand Medical Association, the Royal New Zealand College of General Practitioners, the Royal Australasian College of Physicians, and the Australasian Society of Clinical and Experimental Pharmacologists and Toxicologists.

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

- All significant applications by drug companies for inclusion on the 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 drugs, or groups of drugs.

PTAC’s focus is on general medicine, but increasingly it seeks advice from known specialists or experts. It also consults with the National Health Committee, sets up sub-committees for specific tasks, and sometimes undertakes its own literature searches.

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. Full meetings of PTAC are usually held in Wellington at least four times a year.

## WE WANT THE BEST OF EVERYTHING

“The truth is that most people want the best of everything: holistic care following a humanistic model for most of our health care needs, but sophisticated technology following a heroic model in emergencies. We want support in improving our lifestyles preventively and in recovering from acute bouts of illness or injury. We are willing to pay, but not too much, and we want this care for everybody, but especially for ourselves and our loved ones.”

*Andrea Steiner, Institute for Health Policy Studies, University of Southampton.*

# It's time to tilt the drug in favour of the CUS



*PHARMAC is tilting the market*

# market customer

*PHARMAC General Manager David Moore says the drug market is dominated by drug companies and that it's time the customers (patients and tax payers) got a better deal. He also says the statements of drug companies need to be heard with caution.*

## PHARMAC's role

Four years ago, PHARMAC entered this “peculiar” market in a role that could be described as that of a surrogate customer seeking value for money. By demanding lower prices and negotiating lower cost deals, we have released funds for investment in new and improved therapies – and customers have gained. We are now exploring additional, and even more effective, strategies. These include tendering, contracts with preferred suppliers, package contracts, extending the use of lower-cost generic drugs, introducing more competition into the generic market, and helping to improve the flow of information to doctors to counter drug company hard-sell.

## The generic market

In the drug market, the customer rarely does the choosing. The choice is largely in the hands of a doctor. And because neither doctor nor customer pays directly the most likely outcome is a prescription for what is perceived to be “the best” drug. Generics are often perceived as less than “the best” despite strict standards for registration.

Yet there is great potential to save money by expanding the generic market. When we analysed the price of ten widely-used drugs we found that the New Zealand price is 10 to 130 per cent higher than in the UK and Australia. The smallest difference was for the antibiotic amoxicillin; the greatest for the ulcer drug, cimetidine.

If just six key generics were subsidised in New Zealand at the lower of the Australian or UK generic price, the tax payer would save \$36 million a year. That is equivalent to the cost of operating a provincial hospital for a year. And if the price of asthma inhalers in New Zealand was the same as Australia, we would save about \$15 million a year. The biggest price difference is for Astra's Pulmicort Turbuhaler (400 mcg). It costs \$107 in New Zealand and \$NZ38 in Australia. The extra cost to New Zealand is more than \$5 million per year.

## Lowering entry barriers

A major problem with the New Zealand generic market is that the entry cost is high. An entrant first has to gain regulatory approval which usually requires bio-equivalence studies, typically costing \$100,000. Then they have to battle the brand-name companies employing a range of strategies including control of sources of supply, sometimes back to the source of raw material, tightly held agency and distribution arrangements, loyalty schemes that reward pharmacists for stocking the full range of only one supplier, and deep discounting and free stock with the benefits going to the pharmacy. We are working with the Ministry of Health to lower the cost of the regulatory hurdle, and we are considering how customers might capture more of the benefits that are presently going to pharmacists from discounting and free supply.

**I**n a recent analysis three US academics described the drug industry as “peculiar, paradoxical and quite emotional,” relying “as much on social doctrine as on scientific discovery.” At PHARMAC, we concur, and we add that the market is dominated by producers (drug companies) and gatekeepers (doctors) glued with emotive metaphors like “war on disease” and “magic bullets” and the words “life” and “death.”

This is not the sort of market that delivers value for money to the people who ultimately pay – the customers (patients) who either are, have been, or will be, tax payers. We think it's time the market was tilted in favour of the customer.

## The drug market's unique nature

When the drug market is divided into sub-markets by drug type and national boundary, one finds monopolies legalised by patent protection, and oligopolies in which one product is dominant. According to a UN agency analyst, Robert Ballance: “In general, it appears that there is only a limited degree of competition . . . the markets remain oligopolistic, marked only by changes in the leadership of firms.” This explains, in part, the often huge price differentials between countries. A US study, for example, based on the 200 most frequently dispensed drugs, representing more than 50 per cent of all prescriptions dispensed in US drugstores, found price differences of up to 500 per cent between the US, Canada and UK.

Another feature of the drug market is that customers usually possess only a fraction of the information and knowledge of the companies and the doctors. A third feature that is relevant to New Zealand's position, is size. We buy just 0.2 per cent of all the drugs sold around the world, and the total output of the world's drug companies, at about \$300 billion a year, is roughly three times that of the whole New Zealand economy. To paraphrase the words of a group of doctors concerned about drug company dominance: “compared to the might and power of the multinationals we are like a thistle in a lion's paw.”

## Encouraging generic prescribing

Doctors can play a role in bringing costs down by prescribing more generically. The facilities for this include computerised systems that offer generic alternatives when a therapy is considered, budget holding contracts of the type that are increasingly-common in GP practices in the UK and in New Zealand's IPAs, and improved information. But most of all it means making the effort to remember the chemical rather than the marketer's name.

## Package contracts

We will continue to negotiate risk-sharing contracts with drug companies. For example a contract with Roche Products (NZ) Ltd, involving several drugs, enabled us to list two very expensive drugs on full subsidy. The net present value to PHARMAC of this contract, using a discount rate of 10.5 per cent over five years, is \$4.3 million.

Another contract, with Eli Lilly & Company (NZ) Ltd, enabled us to de-restrict access to one drug and reduced our risk of cost blow out. In return, Eli Lilly agreed to an expenditure cap.

These contracts are evidence of our willingness to work with drug companies to find mutually agreeable solutions for patients.

## Opposition forces

Our call for a sharing of our vision is not however accepted unanimously. It seems inevitable that our cost-lowering strategies will always be opposed by someone because, in the words of a UN agency analyst, the drug market is made up of "a powerful network of special interest groups that benefit from the . . . regulatory system" and "any changes . . . however desirable or efficient, will be opposed by at least some of these groups."

It is a source of continual frustration to us that we have to operate in a climate of opposition. We would be less frustrated if the claims the opponents make to support their position were more candid.

## The free-riding claim

Mention the word generic, and generic companies and nations (including New Zealand) will be accused by brand-name companies of free-riding. Typically, the allegations are accompanied by estimates of \$US150 million to \$US350 million as the cost of developing and testing a new chemical entity then obtaining the approval of governments for its use.

The lament that free-riders carry none of these costs would be more credible if it came from companies that did not themselves free-ride. The drug industry invests tens of billions of dollars a year in research and development (R&D). A recent estimate at a conference in London organised by *The Economist* put the worldwide figure for 1995 at \$US42 billion. But the costs and risks of this investment are rarely borne by drug manufacturers and marketers alone. Cooperative and joint-venture research with state-funded institutes and universities is common, and new technologies are often pioneered with equity from venture capitalists. If the pioneer fails, the venture capitalist bears the loss. If the pioneer makes a breakthrough, it (or its technology) becomes a takeover target.

Drug companies also allege that free-riding causes profits to fall, though the evidence points to profits that are well able to absorb reduction. *The Economist* conference was told that there was a clear correlation between R&D and MVA (market value added). The presenter cited two leading examples. He said that between 1990 and 1995 Glaxo Wellcome spent \$US1.2 billion on R&D and its shareholders recouped \$US40 billion in MVA. Over the same period Merck, Sharp and Dohme

spent \$US1.15 billion and delivered \$US60 billion of MVA to its shareholders.

## Impressive profits

Drug companies sit regularly at the top of corporate profit tables. In the US, the return on equity for drug companies between 1960 and 1991 was 18.4 per cent compared with 11.9 per cent for all industries. In 1996, five leading international drug companies recorded a return on capital greater than 30 per cent, with Schering Plough topping the league at 62 per cent.

The claim that free-riding inhibits R&D and lowers profits looks remarkably like a case of cry wolf.

## The dry-up claim

Drug companies sometimes say that a consequence of free-riding is that fewer new drugs will enter the market. The facts suggest that rather than a "dry-up" there may very well be a flood.

The reason is that technology is finding new chemical entities faster and cheaper. According to *The Economist*: "In the old days a lab worker could produce perhaps 50 chemical compounds a year at a cost of over \$5,000 each. Now a worker using combinatorial chemistry techniques can synthesise one million molecules a year at a thousandth of the price. Using another technique, high-throughput screening, these compounds can be tested for their ability to zap diseases much faster than was possible in the days when pills were checked for their curative powers by feeding them to sick animals . . . one to four years can be knocked off the time it takes to develop a drug and the success rate for compounds in final-phase clinical trials can be doubled to 50 per cent."

## What technology offers

An outcome of these new technologies is an explosion in the number of new drugs available. *Scrip Magazine* says that at the end of 1996 there were 6,048 new drugs in active development around the world and that during 1996 a record 51 new chemical entities were launched.

In PHARMAC's pipeline, awaiting funds, is dorzolamide (Trusopt) for treating glaucoma. Awaiting decisions are 11 drugs including increased access to Interferon 2 alpha for hepatitis, and a growth hormone, and listing of insulin lispro for diabetes, and drugs for multiple sclerosis, liver disease, chlamydia, ulcers, and cancer. If all are approved, without compensating savings elsewhere, the annual drug bill could rise by up to \$35 million a year.

In addition we predict applications for subsidy over the next year or two for at least 20 new drugs, including treatments for asthma, Alzheimers, osteoporosis, diabetes, mental health, cancer, arthritis, and heart disease. The cost of approving all of these could be \$100 million a year.

## But breakthroughs are rare

What the drug companies do not say – because it would deny one of their justifications for high prices – is that few of their so-called "new" drugs offer any real breakthrough. Most are simply enhancements to existing therapies, frequently at much higher prices than the satisfactory product they seek to replace.

One academic paper says: "New drugs . . . seldom represent major therapeutic advances. After the first new drug in a class appears, follow-on drugs are at best, usually minor improvements over the originator." A Canadian agency says that of the 20 new chemical entities introduced for human use in Canada in 1995, only one, the cardioprotective Zinecard (dexrazoxane), was considered a breakthrough. The other 19 provided moderate or no therapeutic improvement over existing treatments.

## The war of words

Drug companies are adept at selling ideas and are quick to take their views direct to doctors. When PHARMAC took its decision to widen the availability of statins from 12,000 to 115,000 people and introduce reference pricing, the manufacturer of one of the higher-priced statins, Zocor, issued leaflets to pharmacies and doctors claiming, without supporting evidence, that Zocor is “the most effective” statin.

Another drug company strategy is to call for cooperation and consultation. While PHARMAC consults on a wide range of issues we are cautious about these calls and so, too, is Scrip, which in one issue said: “The pharmaceutical industry’s practice of saying one thing through its associations and doing another as individual companies has led it into trouble . . .”

Reference pricing is opposed vigorously. In New Zealand, Merck, Sharp and Dohme has commissioned an economic study, a preliminary draft of which denounces reference pricing. In Canada the research-based industry association PMAC recently lost an appeal in the British Columbia Supreme Court against reference pricing. In Italy, the drug industry association, Farmindustria, wants to postpone reference pricing and says it is open to generics but wants to introduce them gradually. And in Australia, when reference pricing was being considered, the Australian Pharmaceutical Manufacturers’ Association launched a blizzard of paper into the media, much of it inaccurate.

There is vigorous opposition to generics, too. A recent court action by Eli Lilly in Canada sought to prevent three companies from selling generic fluoxetine in the same green, grey and buff colours as Prozac, and the drug industry newsletter Scrip reported that “a number of size, shape and colour lawsuits are pending in Canada.”

Action in the international trade arena is a third example. This year, the US drug industry association PhRMA sought trade sanctions against New Zealand on the grounds that PHARMAC denies access to US drug companies. The application was declined, but meanwhile we had to divert significant resources to our defence. We note, incidentally, that over the last year PhRMA has lobbied governments and drug-buying agencies in Australia, Brazil, India, Japan, South Africa, Taiwan, and Vietnam.

The lobbying is sometimes innovative. To fight a Congressional proposal to contain the costs of drug reimbursement by using formularies, some US drug companies created and financed the Coalition for Equal Access to Medicines. This body described itself as made up of “poor people, minority members, and public health advocates.” To gain a patent extension for a drug, Wyeth-Ayerst made three attempts to slip an amending clause into an unrelated bill before the US Congress. The US generic manufacturers’ association warned Congress that Wyeth “may try again.” A US newspaper said that Glaxo Wellcome (which it said employs five full-time lobbyists in Washington and last year contracted with 50 more lobbyists including several former congressmen) “. . . is kind to politicians . . . including letting them use its corporate jet. [It] is a political force whose influence is felt in the drugstore, where customers face higher prices for certain prescriptions; [and] at the ballot box where state and national politicians, backed by Glaxo money, run for office.”

## The pain of priority setting

In conclusion I quote Professor Alan Williams, a health economist from the University of York: “Priority setting is inevitably painful, and its consequences are bound to be unfortunate for someone or other. It is therefore understandable that many people cling, with childlike naivety, to the romantic illusion that if only more resources were devoted to health care they can escape from the process altogether. But when more resources are made available, we will still have to decide which are the highest priority uses to which they should be put, so this is really no escape route at all.”



David Moore  
General Manager

## A NEED FOR PARTNERSHIP

“Governments and insurers simply cannot contemplate major budget deficits with equanimity. Only a commitment by the industry to partnership and joint responsibility in addressing problems of cost, safety, and inappropriate usage will yield long-term and durable solutions.”

*Hubert Leufkens, an academic in pharmacology, and Peter Davis, Senior Lecturer Medical Sociology, University of Auckland.*

## THE GAINS MAY BE OF SHORT DURATION

“Long experience of the literature on assessment of cost-containment efforts strongly suggests that almost any manoeuvre works initially, and that almost all cease to have significantly useful effects after a relatively short period. The results are reminiscent of the . . . Hawthorne effect . . . all experimental changes increase productivity . . .”

*Michael Simpson, Department of Psychiatry, University of Southern Africa.*

# Review by therapeutic group

*A review of the work by PHARMAC within each of its main therapeutic groups to improve access to drugs, encourage more effective use, and lower costs.*

## WHY THIS YEAR'S DATA IS DIFFERENT FROM LAST

Over the last year three factors have led to a change at PHARMAC in the way the data in this Review is presented.

### *Change to using claim date*

The Health Benefits Limited (HBL) expenditure data sets are based on claim date, approved date and cash payment date series. The dates relate to one another as follows:

**Claim date** is the date when a claim is made by the pharmacist.

**Approved date** is the date when items on claim are approved for payment by HBL.

**Cash payment date** is the date that payment for approved items is made.

The different dates give different estimates because of the time taken to receive, approve and pay out on claims.

PHARMAC has recently shifted from using cash payment and approved date series to using claim date data.

Given that we do not have data on a prescription's prescribing date, or dispensing date, claim date becomes the best accrual estimate of pharmaceuticals expenditure

available from HBL. Approved and cash date data are second best measures as their monthly variances may reflect processing issues at HBL as much as underlying usage of drugs.

### *Change to BNF groupings from ATC*

PHARMAC is currently updating its ATC therapeutic grouping software. As this is not yet complete, we have not used the ATC groupings in this Review, but have instead used the BNF groupings used by HBL.

### *North Health data*

Approximately \$9 million of prescriptions were approved for payment by the North Health RHA processing system over 1996-97, mainly in hospital pharmacy-restricted products. We are currently working on integrating this data into our database. Though we incorporate their payments in the total expenditure estimate, we were unable to break the data down by therapeutic group in time for this Review's publication.

The core activity of PHARMAC is the assessment of health technologies. This involves continual assessment of drug performance and cost, usually by reviewing trends within defined groups of drugs (therapeutic group reviews), and appraisal of applications from drug companies for subsidy for their products. Every drug is reviewed from both a therapeutic and economic perspective so that the Board of PHARMAC can take its decisions based on both medical and cost-benefit criteria.

Considerable emphasis is put on consultation, and the need for innovative solutions that either reduce the cost or the rate of growth in cost, or improve the health of New Zealanders. PHARMAC sets its review priorities by taking into account the reports of the National Health Committee, known patient needs, the size of the therapeutic group relative to total drug usage, and cost trends within that therapeutic group.

## Cardiovascular system

### Cost trends (see graph six)

Total cost was \$168 million, up 16 per cent on last year. This year's growth rate suggests that the trend line may be moving upward. The major areas of investment were angiotensin converting enzyme (ACE) inhibitors including in combination with diuretics (\$58 million) calcium channel blockers (CCBs) (\$34 million), and lipid modifying agents (\$21 million).

### Issues

In line with current thinking, we are now focusing on absolute risk. This includes consideration of risk factors such as smoking, exercise, diet, raised blood pressure, dyslipidaemia, and the ways in which these risks can be reduced, by both pharmacological and non pharmacological means.

A major issue continues to be the use of more expensive drugs for lowering blood pressure – ACE inhibitors and calcium channel blockers (CCBs) – when the cheaper, yet effective drugs thiazide diuretics and beta blockers are available. Next year we will consider how best to implement the recommendations of the 1995 National Health Committee report on the management of mildly-raised blood pressure.

The de-restriction of lipid modifying drugs, from specialist to GP use, reflects our view that drugs should be targeted to the patient rather than to prescriber groups. It is hoped that the move will give more patients access to appropriate therapy.

### Actions

*Lipid modifying agents.* Access to statins was widened to a potential 115,000 people, and reference pricing introduced. The review involved more than two years of intensive analysis and research, numerous rounds of consultation,

and the gathering of more than 50 files of documents. Reference pricing removed pricing anomalies and potentially reduces the daily cost of statins by nearly two-thirds – to \$1.05 per patient per day (the price of fluvastatin) from up to \$2.99 (the cost of simvastatin). However, the large increase in the number of patients potentially eligible could increase the total annual subsidy cost of statins. This money will come in part from the reduction in daily cost for statins but additional funds may need to be made available from elsewhere.

PHARMAC is satisfied that its decision on statins will deliver substantial health benefits to a much wider range of people than previously. However, some patients will face surcharges imposed by manufacturers unless they switch to the fully subsidised product, fluvastatin (Lescol), or the suppliers of the other statins lower their prices. Initial indications are that patients are moving to the fully subsidised alternative.

*ACE inhibitor* use continues to grow, with drugs being used mainly in the treatment of hypertension. The weighted average daily cost will be reviewed next year, and a further assessment made of their use in the treatment of mild to moderately raised blood pressure.

*Calcium channel blockers.* Despite doubt over the benefits of CCBs, particularly in the treatment of mild to moderately raised blood pressure (World Health Organisation report February 1997), their use continues to grow. Our goal is to ensure that they are used in areas of greatest benefit. On completion of the review in 1996, two suppliers initiated legal action. This action continues, and no hearing has yet taken place. For further information see page 20.

*Diuretics.* We are considering ways to improve access for patients to these inexpensive agents which have proven effectiveness, and side effect profiles similar to other antihypertensives.

*Dipyridamole.* The Special Authority criteria was again reviewed in light of the results of the European Stroke Prevention Study II. Dipyridamole is now available for use by itself for patients who require antiplatelet therapy and are aspirin intolerant.

## Respiratory system

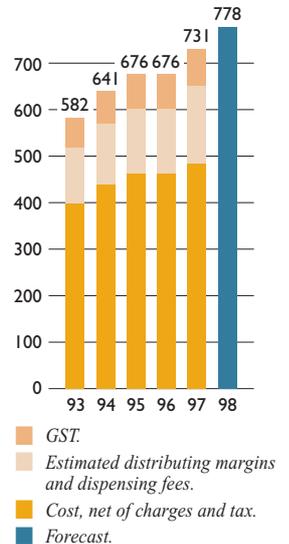
### Cost trends (see graph seven)

Total cost was \$88 million, down two per cent on last year. The major area of investment (\$49 million) is in inhaled corticosteroids. The respiratory system is the third largest therapeutic group by expenditure. Indications are that the annual cost has stabilised at around \$90 million. Year to year fluctuations around this figure appear to be due to seasonal changes in the severity of asthma.

Graph four

### SUBSIDISED DRUG COST

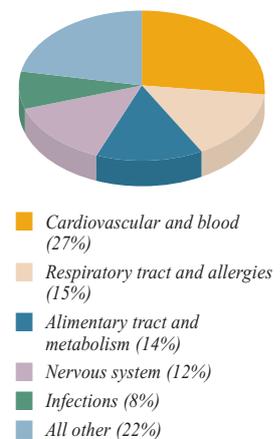
Years ended 30 June  
\$ millions



Graph five

### INVESTMENT BY THERAPEUTIC GROUP

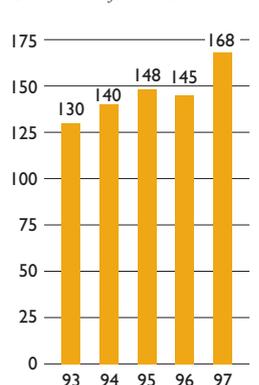
Year ended 30 June 1997



Graph six

### CARDIOVASCULAR SYSTEM

Years ended 30 June  
\$ millions before GST

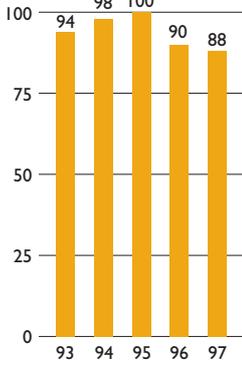


The trend line may be moving upward.

Graph seven

## RESPIRATORY SYSTEM

Years ended 30 June  
\$ millions before GST

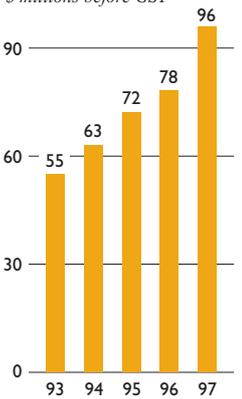


Costs appear to have stabilised.

Graph eight

## CENTRAL NERVOUS SYSTEM

Years ended 30 June  
\$ millions before GST

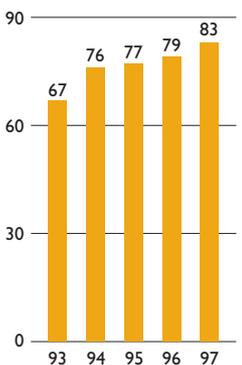


Costs are rising at a level that is quite unsustainable.

Graph nine

## GASTRO-INTESTINAL SYSTEM (includes diabetes)

Years ended 30 June  
\$ millions before GST



Costs rose by five per cent.

## Issues

Dry powder devices remain very expensive compared to metered dose inhalers. The issue of CFC free inhalers continues to be prominent. Next year we will consider strategies aimed at bringing prices down, preferably to the much lower Australian levels. We are watching the current spate of advertising of prescription medicines with interest. At this stage it is too early to know what impact advertising will have on health outcomes or expenditure on asthma treatments.

## Actions

*Long acting beta agonists.* We listed two drugs that are likely to improve the management of asthma significantly – salmeterol (Serevent) and formoterol (Foradil). Both are useful for patients who are not well controlled on other medication.

*Corticosteroids.* A new corticosteroid dry powder and inhaler, fluticasone (Flixotide), was listed under a capped budget agreement with Glaxo Wellcome.

*Dornase alfa (Pulmozyme).* Guidelines were developed to identify those patients likely to benefit from this new treatment for cystic fibrosis. The supplier, Roche Products, will pay for a trial for these patients and those who show improvement after one month will be fully subsidised. Funding was partly made available by a reduction in the reference price of allergy corticosteroid nasal sprays.

*CFC nasal sprays.* Aerosol nasal sprays containing CFCs were de-listed, marking the end of an 18 month phase out period. New CFC-free alternatives were phased in and are available as alternatives.

*Ketotifen (Zasten and Asmafen).* Reclassification as an antihistamine, after PTAC's Asthma sub-committee noted that there is little objective evidence of improvement in asthma from its use, yielded some cost savings.

## Central nervous system

### Cost trends (see graph eight)

Total cost was \$96 million, up 23 per cent on last year. The largest area of investment (\$26 million) is in selective serotonin reuptake inhibitors (SSRIs). The cost of these was up by more than 45 per cent. Investment in analgesics was \$19 million, an increase of 10 per cent.

## Issues

New drugs for neurologic and psychiatric illnesses continue to be developed and become available, particularly for schizophrenia, multiple sclerosis and Alzheimer's disease. Some of these therapies are in areas where there was no treatment previously and so are embraced eagerly. However, care needs to be taken to establish whether these drugs do have useful health benefits, and the situation is not aided by companies raising expectations.

We expect that nervous system expenditure will continue to rise dramatically over the next few years. The challenge will be to target these therapies appropriately to ensure that the patients most likely to benefit can have access to treatments.

An ongoing concern is the use of the newer antidepressants in place of the older, less expensive tricyclics. While we recognise the benefits of improved side effects for some patients, we also note that the newer drugs cost significantly more.

## Actions

*Paracetamol tender.* Following wide consultation with industry, doctor and pharmacy groups on the possibility of running a tender for the supply of paracetamol tablets or capsules, the Board decided to tender for the supply of paracetamol tablets and capsules. The result was a 44 per cent reduction in cost.

*Wider access for antidepressants.* A budget cap agreement with Eli Lilly enabled de-restriction of the SSRI fluoxetine hydrochloride (Prozac 20) from specialist to GP. This will greatly improve access while limiting the risk of expenditure growth. A dispersible form of Prozac 20 was later listed for titrating doses and for those with swallowing difficulties. The Mental Health sub-committee considered two new antidepressants. One required further clarification on clinical issues and we are negotiating with the supplier of the other.

*Apomorphine hydrochloride* was listed for the treatment of Parkinson's disease, enabling some patients to continue to work and go about their daily activities without being institutionalised.

*Interferon beta 1b (Betaferon)* was considered by PTAC and its Neurology sub-committee. It was not listed because the evidence of its efficacy for the treatment of multiple sclerosis was debatable and there was no clear evidence of a reduction in long term disability. We await further evidence of benefits and how patients, who may benefit, may be identified.

*Morphine sulphate (Kapanol).* Listing of this drug in various strengths has given prescribers more choice for treating severe pain and resulted in significant savings.

*Methadone hydrochloride.* The listing of more strengths of commercial preparations has increased patient choice and improved the ease of dispensing.

## Gastro-intestinal system

### Cost trends (see graph nine)

Total cost was \$53 million, up five per cent on last year. The major areas of investment were H<sub>2</sub> antagonists (\$17 million), and proton pump inhibitors (\$14 million). The annual growth trend for proton pump inhibitors has slowed to 30 per cent from 50 to 70 per cent last year.

## Issues

The use of ulcer healing agents continues to grow, with a record volume of H<sub>2</sub> antagonists being dispensed. However, lower prices meant a reduction in expenditure.

Rapid growth of proton pump inhibitors continues to put pressure on funding. Treatment costs remain high and further initiatives are needed to manage cost. In particular, we are frustrated at the lack of low dose, lower cost, therapies in New Zealand, as a consequence of which many patients are receiving unnecessarily high doses.

The slow uptake of H. pylori eradication therapy is also a source of frustration. We continue to work with the NZ Society of Gastroenterologists, and suppliers, to improve access to eradication therapies.

## Actions

**Proton pump inhibitors.** The listing of pantoprazole (Somac) resulted in more competition and lower prices. Reference pricing on the basis of average daily cost is estimated to have saved \$1 million this year.

**Antacids versus H<sub>2</sub> antagonists.** A new sub-committee of PTAC was formed to consider subsidies and therapeutic sub-groupings in light of the high price of antacids and alginates relative to H<sub>2</sub> antagonists. The review is expected to be completed by December 1997.

## Infections

### Cost trends (see graph ten)

Total cost was \$52 million, up two per cent on last year. The major area of investment was in penicillin antibiotics (\$20 million). The cost of antivirals rose by 33 per cent to \$9 million, largely due to herpes and AIDS treatments becoming more available.

## Issues

Concerns about antibiotic resistance remain unresolved. The issue will be considered in the 1998 year by a national committee to be coordinated by the Ministry of Health. Meanwhile, doctors need to be more diligent about prescribing pathogen-specific antibiotics and make more efficient use of laboratory tests.

Negotiations to secure fully funded phenoxymethylpenicillin at a competitive price were unsuccessful. PHARMAC continues to make this a priority.

The growing use of more expensive antibiotics, for example norfloxacin (Noroxin) in the treatment of simple urinary tract infections, was responsible for almost all the growth in antibiotic expenditure this year. Reducing the level of switching to more expensive drugs remains a key issue for PHARMAC.

There was a dramatic shift in the treatment of HIV/AIDS from a single drug to combinations of two drugs, and more recently, with the listing of protease inhibitors, to combinations of three drugs. We expect growing demand for the listing of new therapies from

among the more than 100 being developed around the world. As always, we are likely to be frustrated by a lack of long-term evidence of outcomes.

## Actions

**AIDS therapies listed.** Three new drugs were listed – one nucleoside analogue, lamivudine (3TC), and two protease inhibitors, saquinavir (Invirase) and zidovudine (Zovirax). A third protease inhibitor, indinavir (Crixivan), was listed on 1 July 1997.

**Antivirals.** Valaciclovir (Valtrex) for the treatment of herpes zoster was listed. This drug needs to be taken only three times a day compared with five times a day for acyclovir (Zovirax). As part of our 1995 agreement with Glaxo Wellcome, access to acyclovir (400mg) for the suppressive treatment of genital herpes was widened. GPs can now prescribe suppressive therapy, giving patients more timely treatment.

**Antibiotics.** A new strength of doxycycline hydrochloride was added to the list.

## Musculoskeletal and joint diseases

### Cost trends (see graph eleven)

Total cost was \$20 million, down nine per cent on last year. The overall trend is for declining cost in this therapeutic group, largely due to lower prices from reference pricing. The largest area of investment is in nonsteroidal anti-inflammatories (NSAIDs) (\$14 million), the use of which is declining.

## Issues

Expenditure continued to decline, reflecting concerns over the side effects of NSAIDs and the trend towards lower doses. We continued to be concerned about the high use of these drugs for sport injuries where more conventional treatments such as "RICE" may be more beneficial long-term. Newer NSAIDs are being developed.

## Actions

**Cyclosporin A (Sandimmun)** was listed for the treatment of rheumatoid arthritis in patients who do not respond to other therapies. We expect this listing to result in significant improvements in mobility for some patients.

## Endocrine system

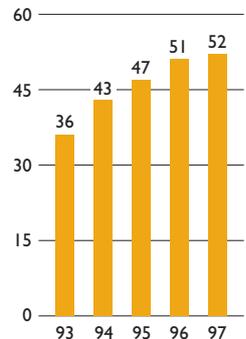
### Cost trends (see graph twelve)

Total cost was \$42 million, up 13 per cent on last year. The major area of expenditure is drugs for diabetes at \$19 million. Other areas are hormone replacement therapy (\$9 million), and corticosteroids and male sex hormones, mainly cyproterone (\$3 million). A further \$12 million is spent on diabetes monitoring systems but is not included in the endocrine group.

Graph ten

### INFECTIONS

Years ended 30 June  
\$ millions before GST

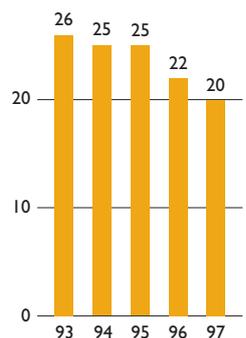


Costs may have stabilised.

Graph eleven

### MUSCULO-SKELETAL AND JOINT DISEASES

Years ended 30 June  
\$ millions before GST

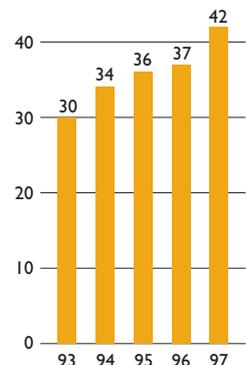


Costs are steadily falling.

Graph twelve

### ENDOCRINE SYSTEM

Years ended 30 June  
\$ millions before GST



Much of the increase comes from diabetes.

## Issues

We estimate that there are 82,000 diagnosed diabetics in New Zealand of whom 11,000 are insulin-dependent. The disease is particularly common among Maori and Pacific Islanders. The cost of complications in diabetes is high, and inevitable if good quality treatment is not provided, yet many diabetics are not receiving treatment. If the high costs of long-term complications are to be reduced, more investment is likely to be needed.

There continues to be a move away from insulin vials (syringes) towards insulin cartridges (pen needles). The cartridges are more expensive but generally more convenient. Diabetes diagnosis and management has been identified by various groups, including the Ministry of Health, as requiring particular attention.

Volume growth in hormone replacement therapy (HRT) is expected to continue. There is increasing data to support longer use of HRT for prevention of osteoporosis and coronary heart disease. HRT is now also being advocated in Alzheimer's disease. Expenditure on treatments for osteoporosis is expected to grow with the aging population and with more drugs and data on the benefits of treatment available. The most common osteoporosis drugs are HRT etidronate disodium (Didronel) and calcitriol (Rocaltrol). However, newer second generation bisphosphonate drugs are being extensively trialled for both prevention and treatment of osteoporosis. Current evidence suggests that they are equal to HRT in terms of fracture prevention, but their prices are considerably higher.

Expenditure on vitamin D derivatives for the treatment of osteoporosis remains a concern, with the move towards hormone replacement therapy a preferred option.

## Actions

*Diabetes.* The diabetes review continues. Its recommendations include increased access to syringes, pen needles, and meters. A review of blood glucose testing devices found that some have poor precision and accuracy, while others have satisfactory performance.

*HRT review.* This review was completed. HRT drugs are now grouped into nine sub-groups and a subsidy level set for each. Transdermal oestrogen patches were placed in the same therapeutic sub-groups as oral oestrogen, because PTAC's sub-committee found no evidence to suggest that for the majority of women there is any clinical advantage in using the more costly patches. Special Authority criteria were established to enable a small number of women to obtain fully subsidised patches where medical conditions prevent them from using oral products.

*Osteoporosis review.* A sub-committee is reviewing all osteoporosis drugs. Recommendations for targeting treatments were sent to suppliers and medical groups for further comment.

## Other

*Dermatology.* A growing number of applications for new and more expensive drugs is forcing a review of existing listed drugs. Several topical agents are used to treat conditions of low priority, for example mild acne. This expenditure may be better directed to higher priorities. We are concerned at continuing growth in expenditure on isotretinoin (Roaccutane) and at regional differences. Nearly half of all expenditure on Roaccutane was in Northern region. Roche Products agreed to a cap on the growth of Roaccutane above five per cent a year and this should yield significant savings.

Expenditure on psoriasis drugs such as calcipotriol (Daivonex) is also growing rapidly. Daivonex scalp solution was listed and the supplier agreed to cap maximum expenditure on all Daivonex preparations.

Cold sore creams and lotions were de-listed from 1 July 1996 after a review took into account inconclusive evidence of health gains. This releases about \$2 million a year.

Topical treatments for mild acne were de-listed from 1 July 1997; but subsidies for systemic treatments for moderate and severe acne continue. Listing of a once-daily topical corticosteroid, Advantan, is expected to save up to \$700,000 a year through a reduction in subsidy for another drug, lactulose syrup.

*Oncology and immunosuppressants.* International reports indicate that there are 315 new cancer therapies in development. This year we began to see an increase in the number of applications for oncology agents. How this likely influx of new therapies is to be funded will be a key issue next year. Our present view is that such drugs are best funded through either budget-holding oncology centres or national budgets.

*Interferon alpha 2A.* A new injection kit was listed, relieving patients of the need to reconstitute this product before self-administration.

*Cyclosporin A (Sandimmun – Neoral).* A new formulation was listed.

*Oral contraceptives.* For the first time in many years, two oral contraceptives, Norimin and Femulin, were fully subsidised, implementing a directive from the Minister of Health to help reduce the number of abortions and unwanted pregnancies. We continue to negotiate with suppliers to expand the range of fully subsidised oral contraceptives.

*Sensory agents.* Significant price increases for corticosteroid drops led to large increases in surcharges. However, the listing of Iodoxamide (Lomide) and fluorometholone (Flucon) gave patients access to a fully subsidised mild corticosteroid drop, and yielded a small saving. We are frustrated with delays in negotiating a satisfactory subsidy arrangement with the supplier of dorzolamide (Trusopt), a new treatment for Glaucoma.

# The operations of PHARMAC

*PHARMAC's 16-person team further developed its assessment systems during the year and began to shift its focus from drug costs towards health status.*

**P**HARMAC set a goal in late 1995 to offset the increase in drug costs by \$40 million (GST inclusive) by decisions taken in the 18 months to 30 June 1997. The outcome was that the cost of drugs was lowered by \$39.5 million.

## This year's work

This year, PHARMAC completed three therapeutic group reviews (lipid modifying agents, hormone replacement therapy, and cold sore creams) and started two more (osteoporosis, and antacids). Six reviews were continued at year end (long-term use of interferon, diabetes, special foods, prophylactic nitrate therapy, hormonal contraceptives, and practitioners' supply orders). Eighty four applications were considered from drug companies for listing or listing changes, of which 55 resulted in listing.

## Applications declined by PHARMAC Board<sup>1</sup>

Years ended 30 June					
Number	1997	1996	1995	1994	Total
New chemical entities	14	5	8	15	42
New presentations	3	8	3	5	19
New products	11	5	9	4	29
De-restriction	1	1	1	4	7
<b>Totals</b>	<b>29</b>	<b>19</b>	<b>21</b>	<b>28</b>	<b>97</b>

*This year, PHARMAC considered 84 applications for subsidy, of which 55 were listed and 29 declined. The acceptance rate is therefore 65 per cent.*

*1. This data does not reconcile with last year's PHARMAC Review because the basis has been changed to implementation date rather than decision date. In some cases, the application is for more than one product.*

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

Years ended 30 June					
Number	1997	1996	1995	1994	Total
New chemical entity listed	11	7	8	11	37
New presentation listed	24	23	18	23	88
New product listed	20	32	46	40	138 <sup>2</sup>
<b>Total new listings</b>	<b>55</b>	<b>62</b>	<b>72</b>	<b>74</b>	<b>263</b>
De-restriction or expanded access <sup>3</sup>	10	13	14	16	53
Changes that restrict or limit access	6	4	4	0	14
De-listing	14	0	0	0	14

*In four years 263 new or enhanced products have been listed; access has been widened to a further 53; and 28 products have either been restricted or de-listed.*

*1. This data does not reconcile with last year's PHARMAC Review because the basis has been changed to implementation date rather than decision date.*

*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 product. The total number of products added to the Schedule, as at 30 June 1997, is actually 286.*

*3. By decision, not necessarily the number of chemical entities affected.*

## Pharmaceutical Schedule

The Schedule was re-printed three times, and 12 monthly updates distributed. As a result of the input from response cards, further refinements were made to content and readability of the Schedule. The Schedule is distributed, either as a book or on floppy disk, free to doctors, pharmacists, and other groups, and sold on annual subscription to all others of \$100 for the disk and \$120 for the book. Single copies are \$22.22.

## Financial impact of PHARMAC decisions

PHARMAC decisions resulted in THA spending of more than \$80 million less in this year on pharmaceutical benefits than would have been spent if past trends continued. The reduction came mainly from price competition, and from Board decisions following therapeutic groups reviews. Details by type of product are:

### Estimated cumulative annual savings<sup>1</sup>

Years ended 30 June. In thousands of dollars

	1997	1996	1995	1994
New chemicals	2,236	927	590	(200)
New presentations	3,553	2,391	1,163	100
Subsidy changes	17,440	5,100	(11)	0
New products	32,532	27,740	21,276	1,200
Reviews	21,644	11,119	6,350	1,100
De-restrictions	(687)	(170)	0	0
De-listing	3,850	800	450	0
<b>Total saving</b>	<b>\$80,568</b>	<b>\$47,907</b>	<b>\$29,818</b>	<b>\$2,200</b>

Most savings came from price competition, and reviews that aligned subsidies for similar products.

1. Derived from estimates of savings as a result of decisions taken between 1 July 1994 to 30 July 1997. The estimates are based on full subsidised cost, which includes wholesale and retail mark-ups, dispensing fees and GST. The estimates under-estimate real savings because current data from the North Health pharmaceuticals payment system was not available at the time of calculation and was therefore not incorporated.

## Streamlining the processes

PHARMAC upgraded its office automation and accounting systems and developed a prototype for a data warehouse to integrate data from the THA and Health Benefits Ltd. The objective is to build a robust data management system that will monitor changes in dosage regimes and contracts with suppliers and enable analysis of market share by product, drug use by population segments, prescription volumes and changes in prescribing patterns. A further goal is to enable forecasting by region, by prescribers in a region, and by usage rates in given populations.

A review was also started of the General Rules in the Schedule and of the process by which annual performance targets are set and met.

Other initiatives include further enhancement to assessment and consultation systems and development of a computerised version of the Schedule.

## Open communication

We continued to offer an 0800 telephone number, a freepost facility, a home page on the Internet, and to publish a periodic newsletter for Members of Parliament. A "calculator" was added to the Internet home page to enable calculation of the cost of a given dose of any drug on the Schedule including co-payments and the manufacturer's surcharge. The practice of enclosing a

newsletter with mailings of Schedule updates continued, as did contributions to various specialist publications such as *GP Weekly*, *Pharmacy Today*, and patient magazines. Media releases were issued on all significant decisions and in response to topical issues, and we participated in a number of radio interviews, radio talk back sessions and patient group meetings.

We improved our consultation systems and extended our networks for routine consultation. Such communications activities included attendance at medical, pharmacy, and hospital pharmacy conferences in New Zealand, including the Royal New Zealand College of General Practitioners, and we met with the Artherosclerosis Society and talked directly with a number of Independent Practitioners' Associations.

## Personnel and training

At 30 June 1997, PHARMAC employed 16 people. They comprised a general manager, a medical director, a community medicine specialist on a 60 per cent contract, five therapeutic group managers, a manager of analysis and quality, a quantitative information manager, four analysts, an office manager, and receptionist. Together, they possess three medical degrees, two pharmacy degrees, three science degrees, and ten other tertiary qualifications.

Most staff continued to attend seminars on the critical appraisal of medical literature (a core skill in the assessment of drugs), all staff were trained in the use of the new data warehouse system, and some attended courses on project management, and negotiation skills.

## Litigation

Drug companies continue to pursue five court actions against PHARMAC involving judicial review and Commerce Act claims. High Court judgments were delivered in two cases.

In April 1997, the High Court dismissed an application by Reckitt and Colman (New Zealand) Limited for judicial review of our decision not to subsidise lemon-flavoured Gaviscon (alginic acid), a drug for treating gastro-oesophageal reflux disease. PHARMAC was awarded costs of \$3,000 plus disbursements. The Judge said Reckitt and Colman hoped that the new flavour would halt the decline in the use of Gaviscon; PHARMAC feared that it would. PHARMAC was not only entitled, but obligated, he said, to take cost into account in reaching its decision; and that there was also ample authority that a body deriving its authority from statute but carrying on what is at least comparable with a commercial activity, is not to have its day-to-day commercial decisions subjected to the scrutiny of review. "If more money is used to subsidise Gaviscon because a more palatable form of it is made available, this has nothing to do with therapy and may well result in less funds being available for the subsidisation of other

products within the overall limited budget. I think the defendant was justified in approaching the matter in the manner in which it has . . . lemon-flavoured Gaviscon is not the same for the purposes of the Schedule as peppermint flavoured Gaviscon.”

Peppermint-flavoured Gaviscon has been fully subsidised for several years but its use has declined by about 14 per cent a year. Prior to the court action, PHARMAC endeavoured to negotiate an expenditure cap on Gaviscon with Reckitt and Colman. Reckitt and Colman has appealed the decision. PHARMAC has appealed the level of costs awarded.

In the Rulide case the High Court ruled in favour of PHARMAC on 27 of the 28 judicial review claims. The judge essentially recognised that PHARMAC and PTAC are expert bodies and that the courts are not qualified to second-guess the substance of their decisions. Furthermore, the judge said that the tendency to use judicial review applications as a de facto appeal on the merits of PHARMAC’s decisions ought to be discouraged. Notwithstanding these positive findings, the judge invalidated PHARMAC’s decision to place Rulide and erythromycin in the same sub-group and to apply reference pricing, on the basis that PHARMAC did not act even-handedly because it did not make a concurrent decision on Klacid, a drug which the judge considered to be in direct competition with Rulide. PHARMAC has appealed this aspect of the decision and has been granted an urgent fixture in the Court of Appeal.

Three other cases against PHARMAC involve both judicial review and Commerce Act claims. These claims relate to:

- PHARMAC’s decision to list Famvir and reduce the subsidy payable for H2 antagonists by 40 per cent, resulting in savings of approximately \$13 million a year;
- PHARMAC’s sub-grouping and reference pricing decisions following the review of calcium channel blockers; and
- PHARMAC’s decisions in relation to a range of drug subsidy applications (originally 17 drugs, most of which have been withdrawn from the proceeding since it was filed).

A preliminary question on the scope of PHARMAC’s Commerce Act exemption was being heard by the High Court in October 1997, which will determine whether these three cases proceed to a substantive trial of the Commerce Act claims.

PHARMAC is pursuing two claims relating to patent issues, both with the objective of freeing up expenditure for use in other areas by facilitating greater price competition from generic drugs. In one action PHARMAC is opposing a patent extension for enalapril. In the other, PHARMAC is cooperating with the Commissioner of Patents in seeking a judicial review to determine whether the Commissioner can validly grant patents for new uses of drugs which are already covered by patents, such patent applications being known as “Swiss Claims”.

PHARMAC hopes to see a resolution to a case in which it is pursuing claims against the RMI and Health Consulting Group (HCG) for the alleged publication of misleading information and contempt of court. The RMI and HCG have counterclaimed against PHARMAC in that proceeding.

## Financial performance

Operating costs (excluding the cost of litigation) remained static over last year. But when the \$1.6 million cost of litigation is taken into account, there was an increase of 23 per cent over last year.

### The annual cost of PHARMAC

*Derived from audited figures for years ended 30 June*

Dollar 000s	1997	1996	1995	1994
Staff costs (includes Directors’ and professional fees)	1,245	1,170	804	665
Office costs (includes depreciation, rent, phones, library, purchase of data, ordinary legal costs)	855	925	575	563
Consulting services (includes PTAC, PR, general consulting, audit fees, HRM and accounting)	1,517	1,408	1,047	532
Schedule production (printing and postage only)	345	338	260	217
Costs associated with litigation	1,607	680	0	0
<b>Total cost</b>	<b>\$5,569</b>	<b>\$4,521</b>	<b>\$2,686</b>	<b>\$1,977</b>

*All of the increase in costs came from litigation. Each dollar spent managing a budget of \$731 million yielded about \$23 in savings.*

*At balance date, fixed assets comprised \$329,000 of office and computer equipment, furniture and fittings.*

## The top 15 expenditure groups

By BNF group by claim date	1993	1994	1995	1996	1997
<i>Dollars in millions, GST exclusive</i>					
Cardiovascular system	130	140	148	145	168
Central nervous system	55	63	72	78	96
Respiratory system	94	98	100	90	88
Gastro-intestinal system	47	54	53	54	53
Infections	36	44	47	51	52
Endocrine system	31	34	36	37	42
Skin	23	27	30	31	30
Musculoskeletal and joint diseases	26	25	25	22	20
Obstetrics, gynaecology, and urinary-tract disorders	17	18	18	17	18
Nutrition and blood	10	12	15	16	17
Malignant disease and immunosuppression	14	16	16	17	16
Monitoring and diagnostic agents	8	10	10	12	13
Ear, nose, and oropharynx	11	12	12	11	11
Drugs acting on the eye	6	6	6	7	7
Galenicals	1	1	1	1	1

## Increases of more than \$400,000 in 1997

By BNF groups	Dollar change	Percentage change	Percentage change
<i>Dollars in millions, GST exclusive</i>	1997 over 1996	1997 over 1996	1997 over 1992
Other antidepressant drugs	8.32*	48	484
Angiotensin-converting enzyme inhibitors	7.20	14	36
Drugs used in the treatment of hyperlipidaemia	4.82	30	151
Beta-adrenoceptor blocking drugs	3.63	18	14
Proton pump inhibitors	2.61	23	347
Antiviral drugs	2.22	33	162
Calcium-channel blockers	1.88	6	17
Management of diabetes mellitus / glucose	1.84	19	64
Control of epilepsy	1.84	19	63
Insulin	1.58	17	49
Non-narcotic analgesics	1.48	21	44
Alpha-adrenoceptor blocking drugs	1.47	34	242
Biguanides / sulphonureas	1.44	24	47
Nitrates	1.31	13	9
Female hormones	1.21	15	48
Treatment of chronic diarrhoeas	1.05	23	93
Tricyclic and related antidepressant drugs	0.70	13	-1
Combined oral contraceptives	0.70	8	4
Potassium sparing diuretics	0.64	40	51
Monoamine-oxidase inhibitors(maois)	0.58	17	45
Treatment of acute migraine attack	0.55	13	125
Thyroid hormones	0.53	89	108
Drugs used in the treatment of gout	0.50	22	23
Drugs for supraventricular arrhythmias	0.48	13	29
Acne preparations	0.46	6	60
Loop diuretics	0.43	25	3

\* Rebate on expenditure due.

## Decreases of more than \$200,000 in 1997

By BNF groups	Dollar change	Percentage change	Percentage change
<i>Dollars in millions, GST exclusive</i>	1997 over 1996	1997 over 1996	1997 over 1992
Cephalosporins, cephamycins and other beta-lactam antibiotics	-0.21	-4	34
Topical corticosteroids – plain	-0.23	-4	-3
Drugs used in nasal allergy	-0.23	-3	-4
Interferons	-0.29	-16	28
Antifungal preparations	-0.31	-9	52
Hypothalamic and anterior pituitary hormones and antioestrogens	-0.43	-12	-34
Corticosteroids and other immunosuppressants	-0.50	-9	15
Penicillins	-0.56	-3	25
Selective beta <sub>2</sub> -adrenoceptor stimulants	-0.66	-3	-10
Hypoplastic and haemolytic anaemias	-0.69	-32	71
Other adrenoceptor stimulants	-0.75	-100	n/a
Macrolides	-0.76	-14	21
Antiviral preparations, topical	-1.64	-85	-81
Corticosteroids	-1.88	-4	-7
Non-steroidal anti-inflammatory drugs (nsaids)	-2.31	-14	-30
H <sub>2</sub> antagonists	-5.94	-25	-38

## THREE STRATEGIES FOR BALANCING HEALTH NEED AND COST

PHARMAC employs three main strategies to balance patient needs and costs.

### Price competition

Price competition was previously achieved mainly through *reference pricing*.

This involves classifying drugs into therapeutic groups and further into sub-groups. A therapeutic group is a set of drugs used to treat the same or similar conditions. A sub-group is a set of drugs that produce the same or similar therapeutic effect in treating the same or similar conditions.

PHARMAC is now looking at other ways to achieve lower prices, including pay-to-play contracts, sole supply and preferred supplier arrangements. Under pay-to-play, suppliers are paid a negotiated up-front amount in return for making a product available at a lower price. Sole supply (such as tendering) and preferred supplier arrangements offer lower prices in return for increased market share for the supplier.

### Improved targeting

Some pharmaceuticals are more expensive than alternative treatments. Often they are slightly more effective than alternative treatments for many patients, perhaps because of better side effect profiles. Sometimes, they are much more effective for some patients than alternative treatments, for example the new anti-epileptic drugs.

One approach to such drugs is to develop, and widely disseminate, prescribing guidelines. These guidelines are drawn in cooperation with the relevant medical practitioners and their professional colleges, and user groups. With acyclovir, for example, the Herpes Foundation was consulted, and the final guidelines were published in the Pharmaceutical Schedule, and the newsletters of the supplier company and the Foundation. With

lamotrigine (Sabril) and vigabatrin (Lamictal), new anti-epileptic drugs, patients get access but the financial risk is managed through a capped budget and clear guidelines. For patients who do not show benefit, the therapy is discontinued.

### Risk sharing

- *Price/volume contracts* between PHARMAC and the supplier recognise that rising volume invariably results in lower marginal costs for the supplier. Typically, the contract will be at a fixed (or diminishing) price for a fixed (or increasing volume). Many generics are in this category.
- *Average daily dose contracts* shift the risk of increasing dosages of a drug to the supplier. An example of such a contract was with paroxetine hydrochloride (Aropax). A contract was negotiated with the supplier that tied the subsidy at an average daily cost that, in this instance, also corresponded to an agreed average daily dose of 20mg. The supplier gave a rebate when the average daily dose was exceeded.
- *Capped maximum annual contracts*. Under these contracts, PHARMAC pays a maximum annual fee for patient and prescriber access to a drug regardless of the volume prescribed or the number of patients requiring treatment. It provides a good balance between incentives for doctors who want to prescribe the best drug for their patients, and suppliers who want to market enough volume to reach the maximum annual fee at a given price, but no more. An example is acyclovir (Zovirax), where subsidy expenditure is fixed for five years at a fixed growth rate, restrictions on lower-strength doses have been removed to allow dispensing from pharmacies, and prescribing guidelines introduced.

# Directory

## PHARMAC Board

**J D (Denis) Tait**, *Independent Chairman.*

**P J (Phil) Edgington**, BSc(Hons),  
*Chief Executive, Central RHA.*

**V J (Victor) Klap**, BEcon, MBA,  
*Chief Executive, Southern RHA.*

**C P (Chris) Mules**, BA(Hons),  
*Chief Executive, Midland RHA.*

**G M (Garry) Wilson**, BCA, BSc, DPA, FNZIM,  
*Chief Executive, North Health.*

## Pharmacology and Therapeutics Advisory Committee (PTAC)

**John Hedley**, MBChB, FRACP, FACCP, Member  
Thoracic, Cardiac and Gastroenterology societies  
of Australia and New Zealand, Chairman.

**Peter Black**, MBChB, FRACP, Pharmacologist.

**Tom Thompson**, MBChB, FRACP, Physician.

**Paul Tomlinson**, MBChB, MRCP, FRACP, BSc,  
Paediatrician.

**Robin Briant**, MBChB, MRACP, MRCP, FRACP,  
Physician and Pharmacologist.

**Bruce Foggo**, MBChB, Dip Obst, FRNZCGP.

**Peter Pillans**, MBBCh, MD, FCP, FRACP.

**Les Toop**, MBChB, MRCGP, FRNZCGP.

**Barry Bruns**, Retired Feb.

**Keith Humphries**, Retired Oct.

**Sharon Kletchko**, Retired May.

**Tim Maling**, Retired Oct.

## PTAC sub-committees

### ANTACIDS & ALGINATES

Peter Pillans, (PTAC).  
Cliff Tasman Jones, gastroenterologist.  
Bruce Foggo, (PTAC).

### ASTHMA

Innes Asher, paediatrician.  
Carl Burgess, pharmacologist.  
Julian Crane, respiratory physician.  
John Hedley (PTAC).  
Les Toop (PTAC).  
Ian Town, respiratory physician.

### CALCIUM CHANNEL BLOCKERS

Ron Easthope, cardiologist.  
Bruce Foggo (PTAC).  
John Hedley (PTAC).  
Peter Pillans (PTAC).

### CEREDASE

Sharon Kletchko (PTAC).  
Murray Mitchell, pharmacologist.  
Ruth Spearing, haematologist.  
Lochie Teague, paediatric haematologist.

### DIABETES

Pat Carlton, diabetes nurse specialist.  
Paul Drury, diabetologist.  
Tim Kenealy, general practitioner.  
Peter Black (PTAC).  
Peter Moore, general physician.  
Russell Scott, endocrinologist.

### HORMONE REPLACEMENT THERAPY

John Hutton, obstetrician and gynaecologist,  
professor.  
Sharon Kletchko (PTAC).  
Les Toop (PTAC).

### INTERFERON ALPHA

Bruce Chapman, gastroenterologist.  
Sharon Kletchko (PTAC).  
Nigel Stace, gastroenterologist.  
Philip Wong, gastroenterologist.

### LIPID MODIFYING AGENTS

John Hedley (PTAC).  
Keith Humphries (PTAC).  
Sir John Scott, professor of medicine.  
Russell Scott, endocrinologist.  
Boyd Swinburn, Medical Director, National  
Heart Foundation.

### OSTEOPOROSIS

Peter Black, (PTAC).  
Anne Furton, endocrinologist.  
Ian Reid, endocrinologist, Associate Professor  
of Medicine.  
Richard Sainsbury, geriatrician.  
Les Toop, (PTAC).

### MENTAL HEALTH

Carl Burgess, pharmacologist.

Peter Ellis, psychiatrist.  
John Hopkins, psychiatrist.  
Anne Welsh, psychiatrist.  
Janet Holmes, general practitioner.

### SPECIAL FOODS

Rodney Ford, paediatrician.  
Gloria Le Compte, dietician.  
Kerry Maher, dietician.  
Jo Stewart, dietician.  
Cliff Tasman-Jones, gastroenterologist.

## The PHARMAC team

David Moore, MCom, Dip Health Econ,  
*General Manager.*  
Annmarie Banchy, RN, *schedule analyst.*  
Win Bennett, BMedSci, MBChB, MRNZCGP,  
*Medical Director.*  
Richard Braae, BCom (Hons), MA, *manager  
analysis and quality.*  
Matthew Brougham, MSc (Hons), *therapeutic  
group manager.*  
Suzanne Fairless, *group secretary.*  
John Geering, BA, BSc, *information systems.*  
James Harris, BSc (Hons), *Manager, Information.*  
Kyle Jones, BA BSc (Hons), *analyst.*  
Jan McCombie, RCpN, *therapeutic group  
manager.*  
Wayne McNee, BPharm, MPS, *therapeutic group  
manager.*  
Scott Metcalfe, MBChB, DComH, FAFPHM,  
*epidemiologist/public health physician  
(on contract).*  
Dilky Rasiah, MBChB, DPH, *therapeutic group  
manager.*  
Peter Sharplin, MSocSc, *analyst.*  
Linda Whatmough, *office manager.*  
Melissa Young, M Pharm, MPS, *therapeutic group  
manager.*

## For further information

*Post:* Freepost 4072, Box 10254, Wellington.  
(No stamp required).  
*Phone:* 64-4-473 0152.  
*Fax:* 64-4-473 0516.  
*Home page address:* <http://www.pharmac.govt.nz>