

**PHARMACEUTICAL MANAGEMENT
AGENCY LIMITED**

**BUSINESS PLAN
for the year 1999/2000**

PHARMAC *///*

Pharmaceutical Management Agency Ltd

PHARMAC ANNUAL BUSINESS PLAN 1999-00

Introduction

The theme for the 1998/99 business plan was consolidation, locking in the gains and fine tuning the economic tools developed. This year will involve further consolidation. However, it will also be a time to focus on a new environment amongst drug companies, a new working environment for PHARMAC, and the challenge of integrating demand side activities within PHARMAC. These changes pose new risks and opportunities.

PHARMAC had a particularly successful year in 1998/99. It was able to implement a number of transactions that increased the efficiency of the Health Funding Authority's ("HFA") investment in pharmaceuticals. They allowed a number of new medicines to be listed, and released significant funds (over \$35 million) for the HFA to invest in other healthcare.

It is vital that PHARMAC be able to continue with its strategies and to develop new strategies without disruption to its processes, if the HFA, the government, and New Zealand's taxpayers and patients are to continue to see the benefits.

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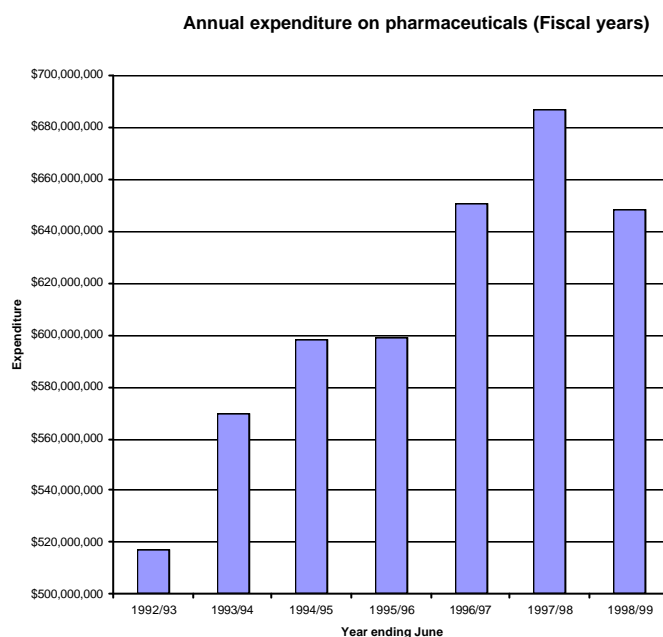
The report is divided into five parts:

1. The Outcome Of The 1998/99 Year: A Description Of The Expenditure Outcome For 1998/99.
2. A Changed Environment. A Discussion Of Important Changes And Implications For PHARMAC's Operations.
3. Where we are going. A Discussion Of Important Overall Plan Encompassing New Initiatives Planned For 1999/00.
4. Delivering This Year. Forecasts, Projects, The Pipeline, Risk Analysis And Operating Budget For 1999/00.
5. Therapeutic Group Management

1. OUTCOME OF THE 1998/99 YEAR

Commentary

The 1998/99 year saw a significant change in pharmaceutical expenditure trends. The dominant trend of strong growth was reversed with expenditure falling from \$687 m (GST excl) in 1997/98 and looking to come in even lower than the expected \$648 million in 1998/99.

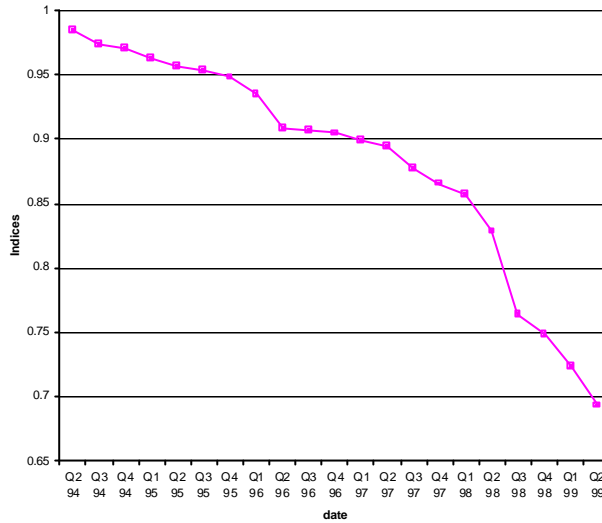


This is in line with PHARMAC's performance targets for the 1998/99 year, which were:

1. to make savings decisions with an annualised impact \$44.5 million (GST excl); and
2. assist the HFA in meeting a target annual budget of \$648 million.

The turnaround in expenditure growth reflects PHARMAC's acceleration in applying price reductions across a wide range of pharmaceuticals. This acceleration started in late 1997 and continued through the 1998/99 year.

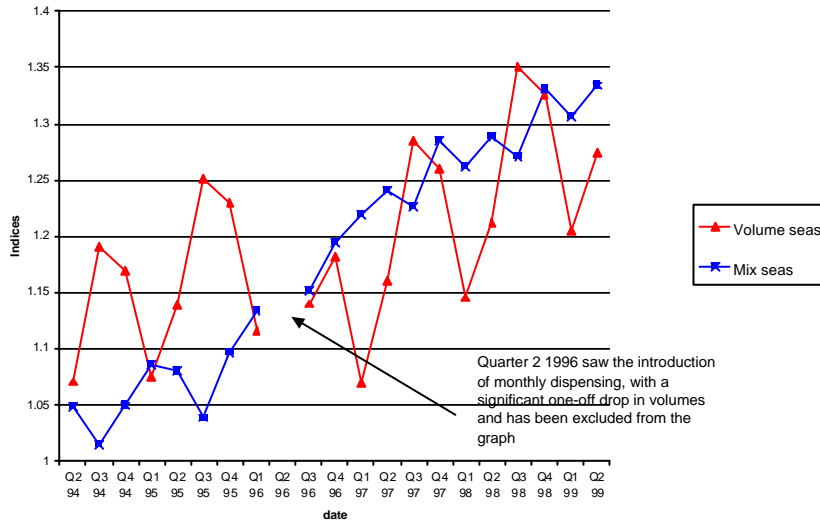
The Pharmaceutical Price Index (strong negative trend)



Note: the final 3 quarters are estimates

The reduction in expenditure is also remarkable in that it has been made in spite of strong growth in the volumes of drugs dispensed and the shift from older cheaper agents to newer more expensive ones (a process known as Mix substitution).

The Pharmaceutical Volume and Mix Indices (strong positive trends)



Note: the final 3 quarters are estimates

We currently forecast that the volume and mix growth will continue. This will place pressure on PHARMAC to continue to lower pharmaceutical prices in order to hold on to the gains made in the 1998/99 year.

2. A CHANGED ENVIRONMENT

Summary

PHARMAC has experienced a dramatic change in the external environment in the past year, with the focus shifting from litigation and antagonism from pharmaceutical suppliers to acceptance of the new environment and therefore acceptance of PHARMAC.

Following is an outline of the ways in which the environment has been changing, and our expectations for the year ahead.

Litigation

The majority of PHARMAC's litigation has now been settled or won by PHARMAC. Significant cases to be completed in the past year include:

- *Roussel v PHARMAC*

HMR Australia sought judicial review of PHARMAC's decision to place Rulide and Erythromycins in the same therapeutic subgroup and to reduce the subsidy for Rulide. The Privy Council found in PHARMAC's favour. This case is an important affirmation of PHARMAC's ability to make listing and subgrouping decisions under the OPPs.

- *RMI v PHARMAC*

The RMI alleged that PHARMAC's listing policies and practices breached the Commerce Act. The RMI also sought judicial review. This case, and two related cases, were withdrawn after the Court of Appeal upheld the High Court's ruling that PHARMAC could gain the benefit of its exemption from the Commerce Act.

- *SmithKline Beecham v PHARMAC*

SmithKline Beecham sought judicial review, and alleged breaches of the Fair Trading Act, in relation to PHARMAC's decision to list Serzone in the SSRI therapeutic subgroup and apply reference pricing. The parties settled the litigation.

Media

PHARMAC has revised its communications strategic plan during the past year. The focus has shifted towards emphasising a more co-operative approach with the industry. The aim is to complement the business-like image with an aspect of conciliation.

PHARMAC continues to see the media as a major route to raise awareness of resource allocation issues. This is an important part of PHARMAC's role, as emphasised by the former Minister of Health when he stressed that part of the HFA's role is to change patients' expectations of the health service provided by the government.

PHARMAC plans to continue the approach of publicising not just the decisions that provide large savings but those that on their own provide smaller health gain. We have found that this approach leads to numerous small supportive articles in the media that together help change the image of PHARMAC as being solely interested in cost cutting.

We propose to improve and increase our public relationship with prescribers. This is being achieved through liaison with them on media issues and releases and dealing directly in the first instance with doctors who comment publicly.

In the coming year we propose to build our image as experts on assessment and cost-benefit analysis, and in particular increase confidence in our (and PTAC's) ability to evaluate the clinical worth of pharmaceuticals.

PHARMAC continues to be well served by Cabix. We will continue to use them as media consultants.

Demand driven expenditure / direct to consumer advertising

One of the main areas of focus highlighted in the funding agreement with the Ministry of Health is the management of demand driven expenditure. This is in part managed by media, and in part by PHARMAC's demand side strategy (outlined below).

In the past year there has been a significant growth in direct to patient advertising. From PHARMAC's perspective, we do not consider that advertising to the public of prescription medicines is desirable. Direct to consumer advertising of pharmaceuticals, while potentially informative, exploits consumers' lack of medical knowledge. Such advertising may have a number of negative impacts, including:

- patient confusion;
- causing unnecessary concern among patients over their state of health;
- interference with the doctor/patient relationship;
- pressure on doctors to prescribe drugs;
- patients "shopping around" for a doctor who will prescribe a desired drug;
- inappropriate or unnecessary drug use (with adverse health and cost impacts on patients);
- forcing up pharmaceutical expenditure (where the drugs are subsidised by the Government or may be in the future);
- undermining public confidence in the state funded health care system.

During 1999/00 we expect to increase our efforts to manage the expectations of patients, and attempt to increase pressure on the pharmaceutical industry to tone down its marketing campaigns.

Demand Side

The year will see the demand side team undertaking a number of projects that are anticipated to produce measurable gains in controlling the rate of expenditure on pharmaceuticals. A systematic evaluation of the risk areas has been undertaken with specific projects being planned for implementation.

In addition, the team will continue to support supply side transactions and undertake implementation programs as they arise. A focus will be on ensuring that adequate concurrent

monitoring occurs to ensure that trends can be analysed and the effectiveness of the team monitored.

Political environment

1998/99 was a year of change in the political environment for PHARMAC. The Associate Minister of Health, Tuariki John Delamere, took a keen interest in the workings of PHARMAC, and in particular the relationship with the pharmaceutical industry.

PHARMAC has attempted to keep the Minister well briefed on issues, and informed when changes to the Schedule have been proposed. PHARMAC has also made a commitment to preparing briefings on the history of PHARMAC and the reasoning behind the current policies.

With the election no later than November, the political environment may change further. PHARMAC will need to adapt to these changes, and put in the necessary resource to ensure that all politicians and parties are aware of the need to continue to actively manage the government's expenditure on pharmaceuticals.

Physical environment

There is a possibility PHARMAC will be moving to new offices. This could consume a portion of our scarce staff resource, and may result in some downtime while we adapt to the new environment.

HFA relationship

PHARMAC sees the development of a single purchaser for government funded healthcare services as a major step forward. We consider that the relationship between the HFA and PHARMAC will continue to develop during the coming year, with considerable gains possible in terms of rationalising the approach to the management of the pharmaceuticals budget.

The HFA is recognising PHARMAC's expertise in pharmaceutical forecasting and using this in its planning. Similarly PHARMAC's experience with supply side measures for pharmaceuticals is being called upon for managing laboratory expenditure.

3. WHERE ARE WE GOING?

The overall theme for PHARMAC this year will be “more of the same – why change a winning formula?”. The Operating Policies and Procedures remain, and we will continue to strive to get best value, measured in terms of healthcare gain, from the government’s investment in pharmaceuticals.

New directions

However, we will not stand still. PHARMAC is a growing and changing organisation (to emphasise this, it is likely that by the end of this year only one of the original staff will remain at PHARMAC). In this section we look at proposals for developing the organisation and specific projects of special importance.

Further development of therapeutic group management

PHARMAC’s therapeutic group management structure has been one of its major successes. Using the embryonic “integrated care” model, Therapeutic Group Managers (“TGMs”) are well placed when negotiating with suppliers, because of the good knowledge of the therapeutic area in which they are working.

The TGM team is currently very strong, with a good mix of medical, pharmacy, and economic skills. The team is also relatively well resourced at present. This balance has been an essential part of the success of PHARMAC, and it is vital that the mix and strength is maintained to continue the balanced view PHARMAC has developed, and the level of outputs.

In the coming year we see further opportunities for TGMs. This may be as a result of closer liaison with the HFA, and the ability to consider the wider implications of PHARMAC’s decisions on the rest of the healthcare sector more effectively. There appear to be opportunities for the HFA to develop a “TGM” structure for its healthcare purchasing.

Refinements

A number of areas of operation need refining to maximise their contribution.

Targeting

During 99/00 we expect that a review of the process for special authorities will be completed by Health Benefits Limited (“HBL”), and this should simplify the process for prescribers.

With the introduction of electronic claiming, and the switch to pharmacy validation of scripts, the restrictions within the Schedule are also being reviewed. This will lead to the simplification and standardisation of some restrictions, as well as the elimination of others.

Prioritisation

PHARMAC has made good progress with the development of its cost utility analysis framework. We have consulted widely with interested parties both:

- on the framework within which we perform cost utility analyses; and
- how we do the analyses.

The result is that, on most issues, the PHARMAC approach is considered to be reasonable, but further debate has been stimulated on the issues of measuring quality of life and discounting. We are currently working through these. We note that while final resolution of these issues may be some time away, in particular in measuring quality of life, a pragmatic approach has been adopted which allow analysis to continue being done in the meantime.

We have also built a library of past analyses whose results are valuable comparators to on-going work in progress.

We feel that the companies are, in general, taking a wait and see approach to our adoption of cost utility analysis.

Demand Driven Expenditure

One of the major areas for attention this year will be demand driven expenditure. The former Minister of Health asked the HFA and PHARMAC to focus their attention on the management of demand driven expenditure. There are a number of actions that we will take this year, including:

Analysis of the risks

We have funded an analysis of the factors driving volume growth in pharmaceutical use. We hope to use this analysis to inform our interventions this year.

Demand side interventions

We are putting considerable effort and investment into counter marketing and other demand side interventions.

DTC advertising

During this year we will be continuing our efforts to restrict or at least monitor direct to consumer advertising of funded prescription medicines.

International Contacts

In late 1998 PHARMAC management met with senior staff from a number of countries who are involved in the management of the subsidisation of pharmaceuticals. It was useful to learn from other countries how they manage very similar issues to those faced in New Zealand, and we are sure they also learned from our experiences.

For example, the South African contingent were not aware that the pharmaceutical industry was so litigious, and had thought that it was unusual to be facing litigation. As Holland, Canada, and New Zealand had all faced similar litigation, we assured the South Africans that they were not alone.

Information Strategy

Goal

A productive and flexible work environment for PHARMAC staff, with easy access to all relevant information resources.

Data Warehouse

Management of the PharmHouse has been outsourced to the New Zealand Health Information Service (NZHIS) until September 2000. We will need to monitor trends in technology to determine whether savings can be made by adopting newer alternatives.

HFA

The HFA intended to install a single network and “common desktop” for all HFA staff, based on Compaq equipment and Microsoft applications, but this strategy posed substantial threats to our security and the flexibility of our working environment. Consequently we have agreed to upgrade our network to the HFA standard and connect to the rest of the HFA so that we can share Internet access etc, but remain secure against any access from outside PHARMAC.

To facilitate this process we have already adopted WindowsNT network operating system and Exchange e-mail system and now meet the HFA specifications except in the following areas:

- The server equipment rack and un-interruptable power supplies. Replacement costs are estimated at around \$10,000. These items would have no impact on users of the network, but would be necessary if we were to place our servers in shared space with the HFA.
- Our desktop PCs. The HFA specification of Pentium 333 MHz is already obsolete. Upgrading to Pentium 400MHz from our current mixture of 14 Pentium 133MHz and 7 Pentium MXX 166/233MHz would cost \$86,205 at current prices. Under our existing replacement policy we would only have considered upgrading some of the 14 Pentium 133 MHz PCs at a maximum cost of \$57,470.

Year 2000

We believe PHARMAC is in pretty good shape, but we will need to monitor the Year 2000 threats from business partners. We will also be allocating appropriate resources to comply with documentation and reporting demands of the State Services Commission.

Opportunities

Our recent network upgrade offers possibilities to enhance the work environment and reduce administration costs.

Datamart

A summary of the data in the data warehouse has been created on PHARMAC's own network. This provides data for most contract monitoring and business planning. Expansion of this service may eventually prove to be a cheap alternative to the PharmHouse.

Website

This has been recently re-vamped. It is proving very popular and there may yet be additional value to be obtained from further development.

CD library

PHARMAC now has a CD server for sharing information from the Cochrane database on systematic reviews and Department of Statistics Census data etc. Addition of further material is possible.

Schedule Database

Goal

A robust and efficient means of implementing Board decisions on pharmaceutical subsidies by disseminating timely and accurate information to claimants and HBL.

Database Software

Performance issues will be addressed by moving from the present Paradox based system to SQL-Server, a much more robust and efficient product. We are already using SQL-Server for our document management system, address database and a summary of our data warehouse. It is performing well and many features that required custom development in the Paradox system are provided by SQL-Server “straight out of the box”, so that the costs of the project should be minimal.

Schedule distribution in electronic media to all clients except HBL will immediately be simplified on migrating to SQL-Server. The distribution to HBL, however, is complicated by its reliance on custom developed software rather than “open systems”, which necessarily makes projects with their business partners difficult. Much of the cost of this project will fall in this area but HBL are keen to co-operate.

Drug Coding

The different coding systems used by PHARMAC, HBL and the industry continues to be a major source of ambiguity and a large drain on resources. The Pharmacy Guild’s Pharmacode system has recently gained acceptance by all parties in the pharmaceutical benefit area and has been incorporated in the HFA specifications for electronic claiming.

We intend to use Pharmacodes exclusively in the design of the new Schedule because we believe the need for a single system is of overriding importance.

Opportunities

Substantial opportunities exist to save on expenses such as typesetting and to streamline processes.

Database Publishing

Schedule distribution in print media direct from the Schedule database has been a longstanding goal of PHARMAC. We believe, however, that the redesign currently underway will make this achievable this year.

User Interface

Ideally the database should be able to read Board decisions, update all the relevant items and display the results for proofing. Although this ideal is probably unachievable, there is nevertheless scope for improvement over our existing system.

Restriction Review

A review of restrictions is currently underway. On completion, the results will be incorporated into the Schedule database in a manner that will permit them to be applied by HBL's electronic claiming system, and pharmacy software.

Environment

Physical environment

If a move to the HFA office occurs, our goal will be to minimise the disruption from the move. Our aim will be to replicate the features of the current office space (open plan, relaxed, good communication) that contribute to PHARMAC performing well.

Whether or not the move occurs we will aim to develop more effective links with the HFA. This process has already started with visits to the localities in March; being on-site will expand the potential for informal contact.

Organisational environment

Health Funding Authority

As noted above, generally this year we see a further development of the relationship between PHARMAC and the HFA, although PHARMAC remains a limited liability company, with all that this entails in terms of management and structure.

Health Benefits Ltd

Changes in pharmacy claiming mean a greater integration between PHARMAC and HBL, with PHARMAC now exporting the Schedule database directly to HBL. (Previously, HBL maintained its own Schedule database for pharmaceutical pricing.) There is a shared vision of how the Schedule database will be used and good communication from both sides. Maintaining an effective working relationship with HBL will be important during this year.

PharmHouse

The quality of data we get from the PharmHouse depends on two external parties. The New Zealand Health Information Service (NZHIS), that manages the operation of the PharmHouse, and Health Benefits Ltd (HBL), that supplies the data.

Currently NZHIS is, in our view, performing adequately. HBL is currently undergoing two revolutionary changes to the way it manages its core function, that of paying claims. First, it has adopted an entirely new pricing framework (the ProNet system) for pricing pharmaceutical claims. Second, it is moving from manual paper based claiming systems to an electronic claiming system.

We have proposed that PHARMAC and NZHIS take a more proactive role in reviewing the HBL processes in regard to storing and supplying data with a view to proposing and implementing specific solutions. This is currently underway.

Pharmaceutical Schedule

Goal

To provide a user friendly resource for use by health professionals, that provides up to date, correct prices and restrictions that may or may not be associated with subsidised pharmaceuticals.

The Pharmaceutical Schedule and Update are used by health professionals to source information on subsidised pharmaceuticals. It is therefore vital that the information contained within the Schedule is correct and that it can be easily and correctly interpreted. In order to facilitate this a major project is planned to review the update. The review will look at ways of improving the layout of the update so that changes occurring during the four month update cycle are readily identifiable. The review will also bring the update format into alignment with the Schedule format style. This will have two major benefits. First, users will be looking at the same format so all symbols, layout etc will be familiar and secondly it will save production time because the typesetter will not have to reformat the changes into the Schedule.

As noted previously, a major review of the restrictions associated with the Pharmaceutical Schedule is continuing throughout the year. This review has been undertaken to facilitate electronic claiming by pharmacists and will streamline the restrictions used in the Pharmaceutical Schedule.

Printing the Schedule and Update directly from the Schedule database is still planned for the end of the year and work is progressing on the database to facilitate this.

4. DELIVERING THIS YEAR

PHARMAC aiming to keep 1998/99 gains in the 1999/2000 year

We are currently forecasting the growth in pharmaceutical expenditure will be static over the 1999/2000 year. We expect the underlying growth from increasing volumes and interaction mix to continue. However, these will be offset by the out year impact of decisions currently being made, and new commercial opportunities coming on line.

Target setting for 1999/2000

We have advised the HFA IPA management staff, that our view for 1999/2000 is that expenditure growth will remain static.

Forecast Risks

How confident are we that we can create these savings?

There is less risk around the forecast savings this year than in previous years. In each of the major decisions, there is little or no new clinical debate involved, with the emphasis on commercial factors.

The debate and litigation over the application of PHARMAC's commercial tool-kit, has to a large extent been played out over the past six years, in PHARMAC's favour. For example, application of reference pricing, preferred supplier and tendering have all, in principle, been accepted within the marketplace.

Consequently, the major risk to the implementation of PHARMAC savings decisions, and their impact on the forecasts, will be slippage in the date of implementation.

Underlying growth stronger than forecast

The major risk for 1999/2000 will come from the size of the winter seasonal increase in prescription numbers. 1998/99 had an exceptionally low winter seasonal increase, reflecting the warm La Nina winter. A cold winter in 1999/2000 could see a volume increase of up to 7%.

The size of this risk, is estimated in the range of \$5 - \$10 million.

ACC unbundling

The current rush to unbundle ACC prescriptions from illness related prescription costs induces significant uncertainty into the forecasts for the 1999/2000 year.

Our expectation is that, if it goes ahead this year, \$10.2 million will be taken from the pharmaceuticals budget, but expenditure can be expected to drop by a lesser amount as prescriber based information systems will not be able to cope with the change, and the HFA will continue to fund most accident related prescriptions. We estimate, in the early years, that the size of this risk is anywhere between \$0 - \$10.2 million.

New atypical antipsychotics

PHARMAC has negotiated the Pharmaceutical Schedule listing of the atypical antipsychotic agents. We have not previously included the impact of these drugs on the forecasts as they are

to be funded from Mental Health funding rather than Personal Health funding. Consequently, when comparing expenditure outcomes with forecasts, these agents have been excluded.

In the near future, PHARMAC may be asked to accept responsibility for the atypical antipsychotic budget. This subject has already been broached in talks with the HFA's Mental Health staff.

Also, PHARMAC has agreed to fund new atypicals from the Personal Health budget, to the extent that savings from older antipsychotics can be identified.

Summary of risks

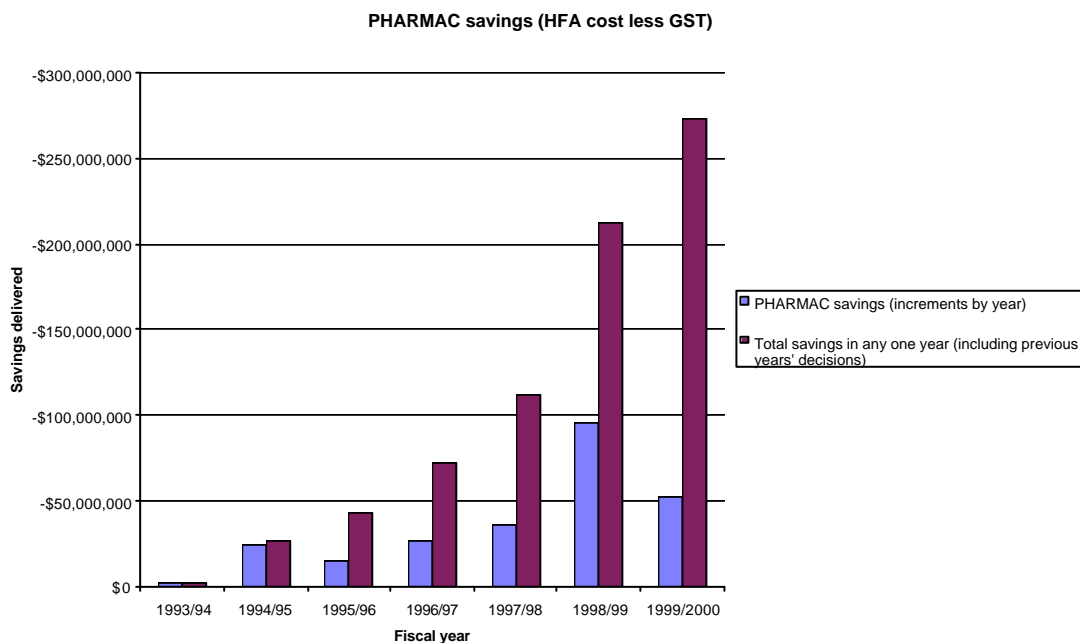
The risks can be classified as either external or administrative. External risks are to a large extent outside of PHARMAC control. Administrative risks we have some ability to influence.

External risks. These are dominated by volume growth risk and to some extent external reasons for implementation slippage.

Administrative risks. Of these internal reasons for implementation slippage and problems with ACC unbundling dominate. Funding of new antipsychotics should be manageable.

How does the forecast 1999/2000 year's effort compare to past PHARMAC performance

In terms of realised savings, the 1999/2000 year looks to be PHARMAC's second most successful year. The most successful year, is the current 1998/99 year, where PHARMAC interventions took an extra \$95 million (over and above savings accruing from previous years' decisions) from the market.



Pipeline

Although, the main focus of pharmaceutical companies world-wide remained that of increasing R&D productivity and therefore outputs of new chemical entities (NCE), the 1998 has been clearly a year of consolidation. Dominated by an unprecedented wave of mergers, pharmaceutical companies in 1998 appeared increasingly aware that current returns are insufficient to fund new product development and were therefore driven by the desire to achieve cost savings and synergies.

In fact, the total number of pharmaceuticals in active development rose by a modest 154 from the previous year to reach 6,444, and the number of projects evaluating these drugs across all therapeutic groups was down by 1.6%. However, selected groups like biotechnology, alimentary/metabolism and, to a lesser extent, cardiovascular and anticancer, offset this general trend ensuring that the research in this field remains strong. The ten leading companies declared a combined R&D budget of some US\$15.4 billion (up 6% from the previous year), that is, on average, about 16.9% of individual sales (up 1% over the previous year).

Undoubtedly, however, the industry seems to have focused increasingly more on lifestyle drugs and direct-to-consumer advertising, in order to maintain volume sales and counterbalance government interventions on pharmaceutical spending. New treatments for erectile dysfunction, obesity and male pattern baldness are the main examples of this new direction. Viagra, for example, was responsible for Pfizer rising from 7th to 3rd in the ranking of the top ten companies in prescription sales, the fastest growing pharmaceutical company world-wide in 1998.

It is also thanks to this new tendency that pharmaceutical sales in the 12 leading world markets in 1998 maintained the steady growth (5-6%) recorded in 1997 led, once again, by a strong performance in North America (+10%). Financial and economic crises in Asia and Latin America hit these markets hard (Japan -3%, Brazil -2%), while the patchy European market was able to register some consistent growth by the end of the year (6%), despite continued pressure on pricing and reimbursement. Pharmaceutical sales to retail pharmacies in Australia/New Zealand rose by 8%, (though subsidy expenditure in New Zealand alone fell by 4%).

However, although 1998 saw the lowest number of NCEs launched for the past five years (38), increasing R&D productivity remains a high priority objective for the entire industry and the benefits of the huge range of new technologies, such as genomics, proteomics, combinatorial chemistry, mass screening and rational drug design will soon have to materialise. It has been calculated that 12 of the leading companies have 241 NCEs in their R&D pipeline somewhere between Phase I and pre-registration. According to historical success rates, 94 of the 241 compounds could reach the market over the next 5 years effectively doubling their output from an average of 0.8 to 1.6 NCEs per annum.

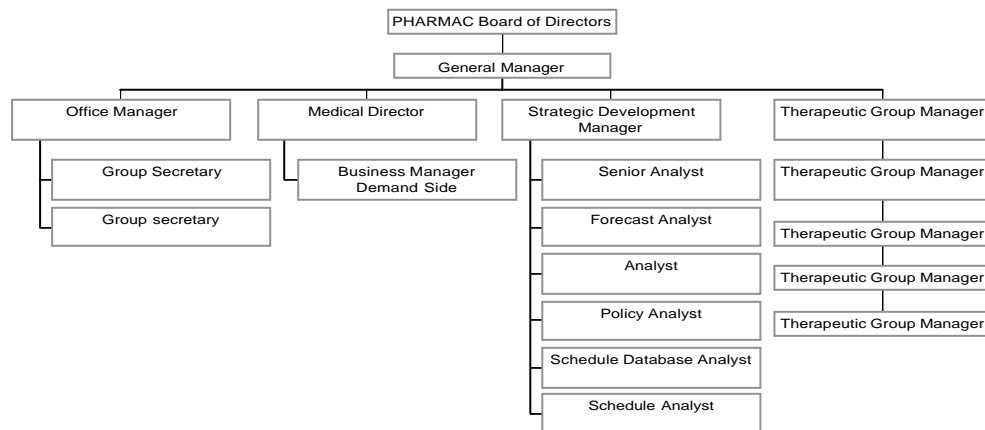
Projects

As well as delivering on the specific expenditure targets, PHARMAC aims to take tangible steps in a number of areas to further PHARMAC's work. We have therefore identified a series of projects that we aim to complete or substantially progress during the year. (These are separate from specific transactions which will be necessary to achieve the expenditure targets.)

Project	Priority	Action needed
Demand side management	High	Focus and resources
Refinement of preferred supplier: ensure more robust market mechanisms; clarify processes for substitution	High	Develop more sophisticated contracts with suppliers, build support of IPAs and pharmacy
Development of TGM processes: development of 3 year plans, integration of plans and pipeline, development of pro-active approach to management of health needs and expenditure	High	Focus
Development of PharmHouse: exploiting the information resources we are developing	High	Resources
Contract management: ensure that contracts are monitored and benefits gained	High	Focus and resources
Continued development of priority assessment: ensure that staff are adequately trained and progress is continued	High	Resources
Development of Schedule: compatibility with other parties and medium for publishing and targeting different readers	High	Resources
Development of research policy	Medium	Resources
Special Authority review	Medium	HBL decision and support
Review of industry self regulation, including constraints on direct advertising	Medium	Resources
Development of process for drug inclusive contracting, as a way of developing risk sharing mechanisms for specialised drugs	Medium	Resources. Cooperation of HFA
Development of pipeline analysis: identify system for reviewing and updating pipeline	Medium	Focus and resources.

Personnel issues

PHARMAC currently employs 16 full time staff, plus a number of staff on contract to undertake specific projects. The staffing structure is as shown below:



There have been a number of changes to PHARMAC's staffing structure in the past year, including a wholesale change in the management. We anticipate adding an additional staff member to complete the Demand Side team, subject to budget approval. Two new analysts have joined the team, however one of them has advised that he will be leaving early in 99/00.

Our major staffing issue at present is a lack of resource in the area of pharmacoeconomic analysis. Our major resource in this area is unavailable due to illness. We are attempting to cover until his return with existing resources, but may need to contract for the provision of some of the work.

Operating Budget

Following is a draft operating budget for PHARMAC for 99/00. The budget is decreased by approximately 6%, excluding the increase as a result of the increase in focus on Demand Side management. Including the Demand Side expenditure, the total operating budget is forecast to rise by 15%.

The Demand Side budget is also included in the operating and service budgets below. Much of the money included in the Demand Side budget is to assist in the implementation of transactions. Formerly these funds would have been requested from the HFA at the time of the transactions. We have chosen to include these in the budget to assist the HFA with its operation budget planning.

Increases in the operating budget relate largely to corrections to allow for actual spending over the past two years. There have also been significant increases in the cost of producing the Pharmaceutical Schedule, as this document has grown larger over time. We expect to review our production methods for the Schedule this year in an attempt to make the process more efficient.

The proposed staffing budget is below that for 98/99. Current full time staff now number 16. There is also one vacancy in the Demand Side team.

APPENDIX: Operational Plans and Strategy by Therapeutic Group

STRATEGIC OVERVIEW OF MUSCULOSKELETAL DRUGS March 1999

Therapeutic Group Manager: Luca Li Bassi

Current Expenditure (ex manufacturer, excl. GST)

BNF2 Groups	Expenditure (\$million)		Growth rate %
	1997/98	1998/99	
Drugs used in Rheumatic Diseases and Gout	14.6	13.3	(-8.5)
Drugs used in other Musculoskeletal Disorders	2.4	2.2	(-5.7)
TOTAL	16.9	15.5	(-8.2)

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Drugs Used In Rheumatic Diseases And Gout	-10%	-11%	4%	3%	-2%	-1%
Drugs Used In Other Musculoskeletal Disorders	-12%	0%	6%	5%	1%	1%

Contribution to health status

The main group of drugs in this therapeutic area is that of non-steroidal anti-inflammatory drugs (NSAID). These drugs are used widely in the management of arthritis and their main use centres around the reduction of pain and inflammation. There is considerable variation in response to these drugs between patients. However, about 60% of patients will respond to any single NSAID. On the other hand, about 10% of rheumatoid arthritis patients will not respond to any NSAID and will therefore have to switch to slow acting anti rheumatic agents (SAARD). The most commonly observed adverse effects of NSAIDs include gastric ulceration, renal failure, hepatic dysfunction and bleeding. It is important to note that it cannot be predicted which NSAID will best serve a particular patient and therefore a trial period should generally be given for anti-inflammatory effectiveness to be observed.

Reasons for Current Expenditure Trends

Drugs used in Rheumatic Diseases and Gout

The major driver of this group is the expenditure on non-steroidal anti-inflammatory drugs (NSAIDs), which accounts for around 80% of the total expenditure. However, although units sold are stable or slightly increasing, HFA expenditure on NSAIDs has been declining consistently over the past few years for two main reasons;

- a significant reduction in subsidy achieved through reference pricing, preferred supplier arrangements or no-tendering agreements;
- a switch to the use of low-dose products.

During the past year, PHARMAC has been able to considerably decrease expenditure and prices in the musculoskeletal therapeutic area. We plan to maintain an aggressive approach in both listing new generic products and ensuring that a sufficient number of brands remain fully subsidised.

The next year will also see the implementation of the tender winners for certain NSAIDs, which should contribute to achieving further important savings in this area while bringing the price of these products in line with international prices.

Long term analysis

The new generation of NSAIDs is represented by COX-2 inhibitors. Although the first representatives of this class are not fully selective on the COX-2 receptors but maintain some activity also on the COX-1 receptors, we are aware that further research in this field will soon make available more selective compounds. The clinical effectiveness and cost-utility of these products will have to be carefully considered against older NSAIDs to determine how much PHARMAC is prepared to pay for them.

STRATEGIC OVERVIEW OF GENITOURINARY SYSTEM March 1999

Therapeutic Group Manager: Luca Li Bassi

Current Expenditure (ex manufacturer, excl. GST)

BNF2 Groups	Expenditure (\$million)		Growth rate %
	1997/98	1998/99	
Contraceptives	11.6	11.9	2.3
Treatment of vaginal and vulval condition	1.2	1.1	(-9.4)
TOTAL	12.8	12.9	1.1

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Contraceptives	0%	0%	2%	1%	1%	0%
Treatment Of Vaginal And Vulval Conditions	-2%	0%	-8%	-8%	0%	0%

Contribution to health status

Contraceptives are an important preventative measure against unwanted pregnancies and to counteract the high abortion rate currently affecting the population. Last year, one-third of the abortions performed in New Zealand were for women who had already had two or more live births, thus suggesting that older women should also be targeted for contraception. Almost 90% of women under the age of 45 years use contraception and, of these, 42% use hormonal contraception (oral and injection).

Reasons for Current Expenditure Trends

Hormonal Contraceptives

There is steady growth in combined oral contraceptives (7.2%) and progestogen-only contraceptives (10.4%). There is a decline in the prescribing of the third generation oral contraceptives (-3.2%) due to the publicity that these agents may be associated with higher risk of venous thrombosis and the Ministry of Health advice to consider prescribing second generation agents. Total expenditure is expected to continue to grow at around 2% per annum. Two more fully subsidised brands were provided, bringing the total number of fully subsidised oral contraceptives to four, which may have lowered HFA expenditure to fund the Special Authority for low income women.

However, the Special Authority for oral contraceptives to waive the surcharge for low-income women still contributes significantly to the total expenditure in the area. In 1997, expenditure on the Special Authority was \$919,000.

Condoms

Due to new listings in bulk packs, the subsidy for condoms with spermicide has dropped by 6% and that of condoms without spermicide by 32% this year. We note that while the price of the latter is now competitive with international prices we should expect to achieve some

savings with the former. The volume of condoms sold appears to have stabilised in the last 2 years and total expenditure is currently just under \$2million.

Gynaecological anti-infectives

The listing of new generic products has prompted a decrease in the subsidy of gynaecological anti-infectives from \$960,000 in 1997 to \$450,000 in 1999. Therefore, we do not expect any substantial change in the expenditure for these products.

Pregnancy test kits

The listing of a new brand last year allowed for a considerable subsidy reduction of pregnancy tests, with savings of around \$400,000. We are now tendering these products, and expect further savings as a result.

Clinical and financial risks

Despite recent concerns about the safety of third-generation contraceptive pills, we consider it still appropriate to list these products on the Pharmaceutical Schedule. We note that the PTAC sub-committee continues to consider that access to these preparations for low income women should be maintained via the Special Authority.

A request to consider the listing of a brand of extra strength condoms, following delisting by the supplier of the only available brand on the Pharmaceutical Schedule, has been sent to us by The Director General of Health. We have already requested applications from different suppliers to list these products and we are currently awaiting responses.

Proposed PHARMAC actions

We are in negotiation with a major supplier of oral contraceptives for the provision of more fully funded preparations. In the near future, we expect to be able to list another one or two fully funded products.

PHARMAC needs to promote the best use of first- and second-generation oral contraceptives to prescribers and ensure that third-generation products are used only after at least one unsuccessful trial on an older preparation. The proportion of women in New Zealand on third-generation pills is amongst the highest of the western countries and it is quite logical to assume that a number of those women could tolerate first- or second-generation preparations, of which four brands are currently fully funded. This would also reduce the risks of serious side effects caused by third-generation pills.

For condoms, we plan to list a new brand in bulk packs at a lower price and subsidy, which would enable us to reduce the current high price differential between condoms with and without spermicide.

We will implement the tender for pregnancy tests.

STRATEGIC OVERVIEW OF HORMONE PREPARATIONS March 1999

Therapeutic Group Manager: Luca Li Bassi

Current Expenditure (ex manufacturer, excl. GST)

BNF2 Groups	Expenditure (\$million)		Growth rate %
	1997/98	1998/99	
Sex hormones	11.3	11.7	2.8
Thyroid and anti-thyroid drugs	0.5	0.6	9.6
Agents affecting bone metabolism	1.2	1.8	43
TOTAL	13.1	14.1	7.5

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Sex Hormones	-1%	0%	7%	5%	-2%	-1%
Thyroid And Antithyroid Drugs	0%	0%	8%	5%	1%	1%
Drugs Affecting Bone Metabolism	0%	0%	27%	18%	13%	8%

Contribution to health status

Hormone preparations are used for a variety of conditions but expenditure is mainly driven by hormone replacement therapy (HRT). HRT is aimed at improving the quality of life in post-menopausal women by reducing the symptoms associated with a lower production of endogenous hormones. In addition, there is evidence suggesting that HRT has a positive effect on bone protection, therefore reducing the risk of osteoporosis at a later stage. Recent clinical evidence has emerged suggesting that alendronate could be effective in preventing fractures in certain patients already affected by osteoporosis. For this limited group of patients, therapy with alendronate could reduce the risk of new fractures and therefore of hospital admission and surgery, effectively resulting in a favourable investment.

Reasons for Current Expenditure Trends

Growth in HRT is primarily due to increased volume and we expect this to continue given the ageing population and the increased awareness of the benefits of HRT.

At present, etidronate, pamidronate, and calcitonin are the main agents affecting bone metabolism. There is increasing use of these products, probably due to increased awareness of osteoporosis and Paget's disease, and also the increased awareness amongst prescribers of the benefits of bisphosphonates. The forecasts above include estimates if alendronate is listed in 1999/00. However, the estimates take into account some cost offset on expenditure for calcitriol.

Value for money

- We have been able to define the patient group that would most benefit from treatment of osteoporosis and Paget's disease with alendronate. Although this drug requires a

considerable investment, there seems to be enough evidence that in selected patients it has the potential to decrease total HFA expenditure in treating the severe consequences of osteoporosis, when all cost offsets are considered.

Clinical and financial risks

The potential market for osteoporosis is huge, potentially all post menopausal women. Volume growth will continue in HRT as there is increased evidence that HRT is beneficial for coronary heart disease, osteoporosis and Alzheimer when used long term. However, expenditure is currently contained by a low subsidy, which means that high part charges are being paid directly by patients.

Clinical and Financial Opportunities

Prevention and treatments for osteoporosis

We note that in HRT, compliance is a big issue, as increasing evidence shows that benefits in terms of reduced cardiovascular events and prevention of fractures will only occur after long-term use. However, on average 40% of women on HRT tablets discontinue treatment within one year because of side effects of oral formulations. The potential increase in total HRT expenditure is likely to be compensated by a reduced expenditure for additional subsidy through Special Authority, currently available to fully fund HRT patches to the level of the lowest priced brand.

Others

Budget holding of infertility agents is currently still in place. We plan in the short future to work closely with the HFA for these products to be transferred from the Pharmaceutical Schedule to drug inclusive infertility contracts. This could give savings of \$200,000 per annum and contain growth.

Proposed PHARMAC actions

- Implement budget holding for agents used in ovulation induction
- List alendronate with appropriate targeting restrictions and with accompanying restrictions on other products
- Development and promotion of clinical guidelines for the prevention and treatment of osteoporosis.

STRATEGIC OVERVIEW OF DERMATOLOGICAL PRODUCTS March 1999

Therapeutic Group Manager: Luca Li Bassi

Current Expenditure (ex manufacturer, excl. GST)

BNF2 Groups	Expenditure (\$million)		Growth rate %
	1997/98	1998/99	
Corticosteroids	9.0	8.8	(-1.4)
Anti-acne	8.9	8.7	(-2.1)
Psoriasis	2.6	2.8	8.4
Emollients and barrier preparations	1.3	0.9	(-36)
TOTAL	21.8	21.2	(-2.7)

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Corticosteroids endocrine	0%	0%	10%	7%	0%	0%
Topical Corticosteroids	-7%	0%	5%	3%	-2%	-2%
Preparations For Acne	-10%	0%	-9%	-12%	20%	16%
Preparations For Psoriasis And Eczema	0%	0%	9%	5%	0%	0%
Emollient And Barrier Preparations	-27%	0%	-2%	-10%	-1%	-2%

Contribution to health status

These drugs are used for the treatment of various skin conditions, especially inflammation (dermatitis), often of unknown aetiology, or infections, caused by fungus, bacteria, viruses or parasites. Skin infections are often treated successfully with a short topical therapy. This avoids more difficult-to-treat complications and is also important for public health reasons. On the other hand, dermatitis can last much longer, sometimes indefinitely, forcing patients on chronic treatments for long periods in order to contain the condition or at least control its symptoms.

Included in this area are also treatments for moderate and severe acne, which although medically not considered a major issue, deserve however some attention for the psychological implications that this condition has, especially for younger patients.

Reasons for Current Expenditure Trends

Total expenditure for this therapeutic group appears to be stable and is mainly represented by corticosteroids and anti-acne preparations. Topical antifungals have seen a considerable drop in the subsidy level, due to new listings of generic preparations. We have listed cyclosporin A as third line treatment for patients with severe atopic dermatitis.

Clinical and financial risks

There are very few new products coming through in dermatology. One product we are watching closely is cyclosporin A. In addition to the indication of psoriasis, we have now added to the Special Authority that of severe atopic dermatitis. We note that while the market

for these indications is not expected to be particularly big, there are quite a number of indications now listed and total expenditure is now growing considerably.

Clinical and Financial Opportunities

Corticosteroids

We are planning to work closely with suppliers and our demand side management team in order to develop clinical guidelines for the treatment of severe acne with isotretinoin that take into account the appropriateness of prescribing and the safety issues around this drug.

Proposed PHARMAC actions

- Development of clinical guidelines in cooperation with dermatologist for the treatment of severe acne with isotretinoin.
- Resolve issues of access to isotretinoin so that access is based on severity of acne, not ability to pay for a specialist.

STRATEGIC OVERVIEW OF CARDIOVASCULAR MARCH 1999

Therapeutic Group Manager: Martin Szuba

Current Expenditure

BNF2 groups	1997/98	1998/99	% growth
ACE inhibitors and alpha blockers	58.5	31.3	(46.5)
Anti-arrhythmics	3.6	4.0	11.1
Beta blockers	18.3	13.7	(25.1)
Calcium channel blockers and nitrates	35.0	31.3	(10.6)
Diuretics	2.9	2.7	(6.9)
Lipid modifying agents (LMAs)	14.3	19.9	39.1
Other	0.6	0.9	50.0
Total	133.2	103.6	(22.2)

Costs ex-manufacturer, GST excluded.

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Antihypertensive Drugs	-51%	0%	10%	7%	0%	0%
Anti-Arrhythmic Drugs	0%	0%	10%	7%	0%	0%
Beta-Adrenoceptor Blocking Drugs	-29%	-8%	6%	5%	0%	0%
Nitrates And Other Vasodilators, And Calcium Channel Blockers	-16%	-29%	5%	3%	2%	1%
Diuretics	-12%	0%	5%	4%	-3%	-2%
Drugs Used In The Treatment Of Hyperlipidaemia	-1%	0%	14%	11%	23%	13%

Contribution to Health Status

Cardiovascular disease is the most common cause of death in New Zealand. The buildup of atherosclerosis is the culprit behind almost all cardiovascular disease. At present there is no 'quick fix' to prevent atherosclerosis or any of its complications. Pharmaceuticals in this therapeutic group play a significant role in the management of various cardiovascular disease such as lipid disorders, raised blood pressure (hypertension), ischaemic heart disease (angina), congestive heart failure, cardiac arrhythmias, and others. Management of lipid disorders, hypertension and angina accounts for the major proportion of expenditure in this group, and contributes to the health status of the HFA's populations by providing symptomatic relief and preventing severe complications in some patients. Over the forecast period, the major expenditure will be on ACE inhibitors including in combination with diuretics, lipid modifying agents and to a lesser extent CCBs.

Reasons for current expenditure trends

There are three major areas of expenditure within the cardiovascular therapeutic group: ACE inhibitors, calcium channel blockers and lipid modifying agents.

There are over 130,000 patients currently being treated with ACE inhibitors. The main use for these drugs is in the treatment of raised blood pressure which accounts for 80% of ACE inhibitors use, with the other 20% being congestive heart failure, post myocardial infarction and diabetic nephropathy. The implementation of the Parke-Davis agreement had a substantial effect on the cost of ACE inhibitors during 1998/99. However, there is strong underlying growth in the use of ACE inhibitors, and we expect this to continue.

Calcium channel blockers are the next highest area of expenditure. Like ACE inhibitors they are promoted heavily for the treatment of raised blood pressure and angina. The implementation of the Astra and Bayer agreements is expected to have a substantial effect on the cost of CCBs in the following years.

Lipid modifying agents is the therapeutic subgroup with the highest growth rate. There is strong underlying volume growth in this market. Recently, the expenditure growth was boosted due to the shift towards more expensive agents.

Clinical & Financial Risks

- Strong underlying growth in the use of antihypertensives. While this is an expenditure risk, there are associated health benefits.
- Inappropriate use of antihypertensives – shift from cheaper diuretics and beta blockers to more expensive ACE inhibitors, CCBs and potentially the most expensive Angiotensin II antagonists (if listed).

Angiotensin II antagonists (AIIAs)

This is a new class of anti-hypertensive and heart failure drugs. Applications for listing have been received for a number of these agents. The current opinion of the cardiovascular subcommittee of PTAC is that these agents offer a negligible clinical benefit over ACE inhibitors for the treatment of hypertension. The therapeutic benefit for the treatment of congestive heart failure is questionable as well. This view has been reinforced by a recent, February 1999, issue of the Australian Adverse Drug Reactions Bulletin, which provides details of numerous adverse reactions associated with these drugs (like intractable cough, angioedema, hepatotoxicity and hyperglycaemia). Early expectations were that problems such as cough and angioedema associated with ACE inhibitors would be avoided with this new class of antihypertensive drugs. However, as the bulletin says, “this appears not to be so.”

A further drawback to the AIIAs is their price. At the moment they are significantly more expensive than ACE inhibitors.

For a small group of patients with CHF who cannot tolerate an ACE inhibitor due to intractable cough or angioedema AIIAs may be an option. The Cardiac Society recently expressed an opinion that the number of such patients is very small.

- Strong underlying growth in the use lipid modifying agents, especially given clinical pressures to widen the access.

Opportunities for managing expenditure

Lipid modifying agents

Expenditure on statins continues to grow. The desire for suppliers to have their statin fully funded should provide some opportunities for lowering prices. Raising the subsidy on

simvastatin may be cost-effective, both in the short term as it competes with atorvastatin, and longer term as it comes off patent in 2001.

ACE inhibitors

We will continue to review the need for funding of the surcharge for existing congestive heart failure patients during this year. At the moment, however, the available data suggest that the treatment of congestive heart failure with ACE inhibitors is relatively cost-effective, mainly due to the associated reduction in hospital admissions and death rates. We will continue to promote the use of the more appropriate thiazide diuretics for the management of raised blood pressure.

Calcium channel blockers

Treatment of raised blood pressure with CCBs as the first line agents remains questionable value for money especially as there is a lack of evidence for long term outcomes such as a reductions in mortality and morbidity. There is also some evidence that the use of CCBs actually increases the risk of cardiovascular mortality. Recently BMJ published a report of raised suicide rates among patients taking these drugs.

We expect further reductions in both the price and use of dihydropyridine calcium channel blockers in the coming year. We also expect further reductions in the prices for other calcium channel blockers (diltiazem) as new generic agents enter the market.

Nitrates

Due to the tendering of nitrate patches and substantial reductions in the price for oral nitrates in the past year, we consider that there is little need for further action in this area in the medium term. Action will be taken to ensure appropriate relativity between the subsidies of the once daily nitrates.

Beta blockers

Tendering in this market has resulted in substantial savings during the past year.

Cost savings

Major subsidy reductions have been achieved for the antihypertensive drugs, meaning that further price reductions may not be great in the short term. The most likely prospect is further reductions among the DHP CCBs. Despite these reductions, there is still a massive spread in what we are paying for some of the cardiovascular drugs.

Demand side actions

- PHARMAC is instituting a campaign involving the provision of the brochures and posters to patients and prescribers and subsidised doctor visits for patients switching from DHP CCBs that are no longer fully subsidised. Patients will be encouraged to switch from DHP CCBs to other fully subsidised anti-hypertensive and anti-anginal treatment.
- There is a need for a continuation of the education campaign aimed at prevention and treatment of ischaemic heart disease, a leading cause of death in NZ, with special focus on risk factors such as: lipid disorders, hypertension and cigarette smoking. The campaign should, in the first instance, stress the importance of non-pharmacological

measures such as diet modification (fat and salt restriction), excess weight reduction, exercise, smoking cessation and alcohol moderation.

- In co-operation with the National Heart Foundation, PHARMAC will provide prescribers with information on cost-effective prescribing of lipid modifying agents .

Three year analysis

- According to PhRMA (Pharmaceutical Research and Manufacturers of America) more than 104 different drugs are in development against heart disease. Some of these products may come to the market in the medium term. Gene therapy and genetic engineering are starting to play an important role in that development. The idea behind gene therapy is to correct a problem by delivering the genes that cause the growth of new blood vessels, which can act as a natural bypass to supply blood to blocked-off areas of the heart. Optionally, delivering a protein instead of genes can also stimulate angiogenesis. This approach, if successful, could make coronary artery bypass surgery obsolete. Patients with untreatable chest pain would literally grow their own coronary bypasses.

STRATEGIC OVERVIEW OF ANTI-INFECTIVE AGENTS
March 1999

Therapeutic Group Manager: Matthew Brougham

Current Expenditure (ex manufacturer)

Year ending 30 June	HFA cost (\$million)		Underlying growth (%)
	1998	1999	
Antivirals	11.960	8.710	13
Antibacterials	36.760	34.600	-2
Antifungals	4.200	4.600	10
Others	0.054	0.057	6
Group total	52.910	47.960	2

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Antiviral Drugs	-42%	-30%	15%	9%	-2%	0%
Antibacterial Drugs	-9%	-18%	6%	6%	-2%	-2%
Antifungal Drugs	0%	0%	-2%	-2%	12%	9%

Key information about the group

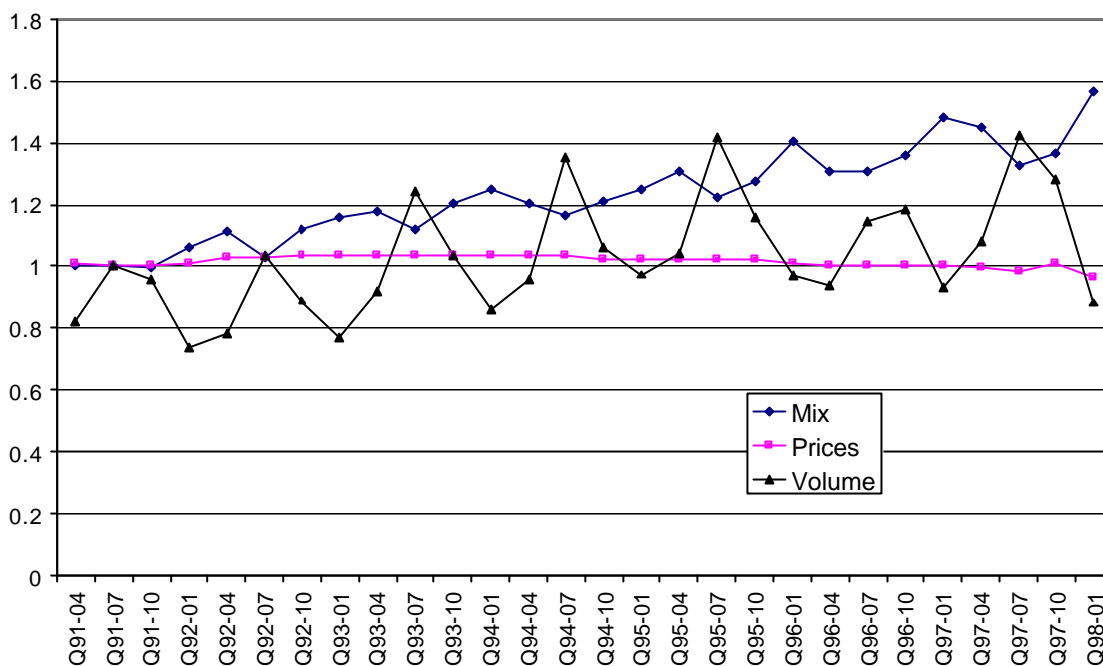
Anti-infectives account for about 8% of Pharmaceutical Schedule spending.

Contribution to health status

Anti-infectives treat infectious diseases as opposed to non-infectious diseases like heart disease and diabetes. Generally, anti-infectives are considered to have profound effects on the health status of the nation. Antibacterial and antifungal therapies tend to be short course therapies that cure infection (relieving pain, suffering and, in some cases, preventing death). Anti-retrovirals are used indefinitely to keep infections under control thereby relieving symptoms and preventing premature death. They are regarded as highly effective.

Reasons for Current Expenditure Growth

Price, Volume and Mix Analysis for anti-infectives group



Analysis of price, volume and mix indices indicates that, overall, mix is still playing a role in spending trends on anti-infectives. However, decomposition of the above data by the three key classes (antibiotics, antifungals, and antivirals) shows that mix explains growth only in antifungals while volume explains growth for antivirals. The decomposition also reveals that the lack of growth in antibacterials has occurred despite overall growth in volume and as a decline due to mix effects. The price index for all groups of drugs has remained relatively stable for 7 years, hence, the indices suggest that price reductions have yet to be fully utilised as a means of reducing spending on all anti-infectives.

Antibiotic use

The mix index for antibiotics indicates that overall, prescribers are beginning to switch to less expensive antibiotics.

Antivirals

Despite a 75% reduction in the subsidy for herpes treatments, underlying growth in herpes treatments remains at between 15 to 20 percent. Much of this has come from derestricting the suppressive treatment for genital herpes from 1 July 1997. The other key driver of expenditure is simply the widespread incidence of the disease (estimated at up to 20 percent of the population) and raised awareness among doctors of this treatment option.

Antiretrovirals

Growth in AIDS treatments is driven by their effectiveness at reducing viral load (and the observation that this coincides with improvements in HIV/AIDS patients survival curves) and the increasing replacement of dual therapy with triple therapy (which includes using a protease inhibitor).

Antifungals

Expenditure on antifungals grew at 10% a year. The reasons for this growth are unknown.

Top 20 presentations by number of prescriptions

The top 20 anti-infective presentations by number of prescriptions account for about 80% of all spending on anti-infectives. Another way of understanding what factors are underlying spending trends is to review changes in the number of scripts written for these presentations. Script growth was negative for almost all anti-infectives bar liquid presentations of antibiotics and norfloxacin. The negative growth is indicative of a warm winter and, hence, fewer opportunistic infections. The positive growth in oral liquids reflects the implementation of the under 6s policy. This growth was enough to offset the decline and, hence, volumes for antibiotics grew overall (as noted above). This is likely to be a one-off effect.

Clinical and Financial risks

AIDs drugs

As noted above, expenditure on AIDS therapies is forecast to increase significantly over the next few years, as more and more patients are treated with triple therapy and potentially for longer. We note that in the short term there will be some offset costs from fewer hospitalisations and fewer opportunistic infections.

We understand that the number of new cases of HIV looks set to grow over the next few years. Although data are not yet available, sexual health specialists report that due to a general relaxation in people's awareness of the disease, spread of sexually transmitted diseases is up again. In addition, there are no rules preventing or limiting immigration into New Zealand for HIV positive patients. Recent reports indicate that 80% of new infections over the last year were due to immigrants. We, therefore, expect that there will be an increase in patients being treated over the short term.

Antimicrobial resistance

The issue of antimicrobial resistance was recently considered by the PTAC antibiotics subcommittee. The committee appears likely to maintain a conservative stance on the listing of new antimicrobials. The committee identified the over-riding objective for the management of antimicrobials is to reduce consumption across all classes unless there are very good medical reasons for doing otherwise. Thus, the pressure created by antibiotic resistance is likely to act to reduce volumes and spending on antimicrobials.

Cystic fibrosis and dialysis antibiotics

A range of injectible antibiotics is listed on the schedule specifically for these indications.

Clinical and financial opportunities

Antimicrobials off-patent

Almost all heavily prescribed antibiotics listed on the schedule are off-patent.

Generic competition

World prices for anti-infectives are lower than New Zealand prices for many products. Amoxicillin prices are still high by world standards. We still do not have a fully funded phenoxymethyl penicillin yet international prices are a fraction of the New Zealand subsidy. Even after the price reductions on flucloxacillin, prices are still high. Augmentin comes off patent early in 1999. Enhancing price competition, therefore, appears to hold real promise for reducing the spending on anti-infectives.

The key barrier to generic competition bidding down prices in the anti-infectives market is gaining marketing approval. Many of the low priced overseas generics are old and have old registration dossiers. To bring these up to MoH accepted standards would be uneconomic for many of the suppliers given the size of the markets. Work on reducing the height of this hurdle is ongoing.

Prescriber education

Prescriber education is considered an essential component of managing anti-infective use. We consider that it is best handled by third parties, however, PHARMAC will aim to facilitate and assist the development of education programmes aimed at reducing inappropriate prescribing of antibiotics. Reducing prescribing of antibiotics through demand side actions forms one of the key goals of the demand side group.

Anti-microbial resistance

The PTAC antibiotics subcommittee considered information on optical immunoassay tests for strep and flu infections. The committee considered that these in-surgery rapid tests had the potential to reduce antimicrobial use and, therefore, help delay the onset of resistance. It recommended PHARMAC pilot test the technology to assess its effect on prescribing behaviour. Clearly, if such tests were funded through the Schedule, this technology could significantly increase expenditure for the Schedule although it would extend the benefit of antibiotics.

The committee also questioned whether or not the reduction in the use of antiseptics was based on changes in medical evidence or tastes. It suggested investigating the opportunity antiseptics might provide for reducing antimicrobial resistance.

Proposed PHARMAC actions

Next 12 months

- Consider proposals for the supply of amoxicillin clavulanate or tender it on expiry of its patent (a 50% price reduction would mean savings in excess of \$5.0 million a year).
- Evaluate current bids for sole supply of antibiotics included in the 1998 tender and implement winning bids.
- Review the listings of antibiotics for cystic fibrosis and dialysis and adjust as appropriate.
- Pilot test the usefulness of surgery-based microbiology tests (rapid tests) in influencing antibiotic prescribing decisions (also referred to in the demand side work programme).
- Review the appropriateness of prescribing antiseptics instead of antibiotics for skin infections and, depending on the outcomes, provide this information to the demand side team for appropriate promotion.
- Review applications for the listing of antimicrobials in accordance with PTAC's recently outlined management objectives for this class of drugs and process as appropriate.

(Note: other demand side actions covered by the demand side plans include promoting the appropriate use of antibiotics – particularly their non-use in the case of viral infections. This promotion is planned to assist IPA initiated efforts in the first instance.)

Long term

- Analyse the possible benefits or otherwise of funding bioavailability studies of generic antibiotics.

STRATEGIC OVERVIEW OF IMMUNOSUPPRESSION March 1999

Therapeutic Group Manager: Matthew Brougham

Current Expenditure (ex manufacturer)

Year ending 30 June	HFA cost (\$million)		Underlying growth (%)
	1998	1999	
Drugs affecting immune response	9.300	10.650	7
Group total	9.300	10.650	7

Key information about the group

Drugs affecting the immune response account for about 2% of Pharmaceutical Schedule spending.

Contribution to health status

Drugs affecting the immune response include immunosuppressants, immunostimulants, and interferons (an immune system enhancer). Immunosuppressants are used predominantly as long term therapy to prevent patients with transplanted organs from rejecting these transplants. Immunostimulants are used to enhance the body's natural response to fight infectious disease and cancers. Included among the immunosuppressants is cyclosporin. It has a wider range of applications including treatment of atopic dermatitis, psoriasis, and rheumatoid arthritis. Many different dosing schedules exist but generally, these products are considered essential medicines.

Reasons for expenditure growth

Price, volume and mix indices indicate that spending is growing as a consequence of volume growth alone. Small price reductions in cyclosporin and interferon have resulted in both the price and mix indices falling below unity but both these influences on reducing spending are significantly over-shadowed by volume growth. We believe that this volume growth is being driven by "indication creep". For example, over the last few years, subsidised access to cyclosporin A has been widened to include psoriasis, severe atopic dermatitis, and severe rheumatoid arthritis. Interferon use may have increased as awareness of the prevalence of hepatitis infections has grown.

Clinical and financial risks and opportunities

Hepatitis

The government's proposed screening programme for hepatitis B could result in significant additional use of the interferon alphas. This risk has not be included in the forecasts. Estimates put this spending risk as high as \$25 million a year (assumes 100% take-up). However, the risk should reduce over time as the effects of the vaccination programme are felt and the infected cohort decreases in size.

Renal failure

Growth rates for renal failure and, therefore, demand for dialysis and kidney transplantation remain high at around 8% a year. This is an international trend and no-one appears to know why. For now, the effect this has on demand for immunosuppressants is kept in check by the supply of organs which appears to remain constant.

Compulsory organ donation

There is a trend beginning internationally to make organ donation statutorily compulsory. If such laws were enacted in New Zealand, transplantations would increase dramatically with significant effects on health and health costs. (This risk is currently considered very speculative.)

STRATEGIC OVERVIEW OF BLOOD AND BLOOD-FORMING AGENTS March 1999

Therapeutic Group Manager: Matthew Brougham

Current Expenditure (ex manufacturer)

Year ending 30 June	HFA cost (\$million)		Underlying growth
	1998	1999	
Anaemia treatments	2.210	2.400	3%
Antiplatelets	0.700	0.900	9%
Anticoagulants	1.180	1.330	4%
Antifibrinolytics & haemostatics	0.220	0.320	10%
Group total	4.310	4.950	5%

Key information about the group

Blood and blood-forming agents account for less than 1% of Pharmaceutical Schedule spending.

Contribution to health status

Anaemia treatments include iron and folic acid supplements and erythropoietin. These all assist haemoglobin production and, consequently, improve exercise capacity. The cost effectiveness of erythropoietin (which is very expensive) is of considerable debate internationally. Antiplatelet therapy is used primarily to prevent thrombotic cerebrovascular events – primarily clots forming on the arterial side of the circulatory system. They are generally considered effective medicines. Anticoagulant therapy is used to control clot formation on the venous side of the circulatory system. Anti-fibrinolytics and haemostatics are used to control bleeding.

Reasons for expenditure growth

Growth in antiplatelet therapies has been driven by the widening of the access restrictions on dipyridamole to include dipyridamole monotherapy in patients who are intolerant of aspirin. The growth in antifibrinolytics and haemostatics is being driven solely by volume; the reasons for this growth are unknown.

Proposed PHARMAC actions

- PHARMAC will also work with the HFA to determine how to manage access to the low molecular weight heparins (this management forms part of a broader strategy on out-patient versus in-patient delivery of particular services).
- PHARMAC will review the health benefits and subsidy levels for oral iron supplements.

STRATEGIC OVERVIEW OF ONCOLOGY DRUGS March 1999

Therapeutic Group Manager: Matthew Brougham

Current Expenditure (ex manufacturer)

Year ending 30 June	HFA cost (\$million)		Underlying growth
	1998	1999	
Cytotoxic drugs	1.090	1.210	7%
Hormones and antagonists	5.910	5.380	6%
Group total	7.000	6.590	6%

Key information about the group

Oncology drugs account for about 1.5% of Pharmaceutical Schedule spending.

Contribution to health status

Cytotoxic drugs are used to kill cancerous cells. They can also kill normal cells. They are used in a variety of ways: to attempt a cure, to prolong life, palliatively, as neo-adjuvant treatment (to shrink tumors prior to surgery or radiotherapy), and as adjuvant treatment (after surgery or radiotherapy when the risk of sub-clinical metastatic disease is known to be high). Hormones and hormone antagonists are used in a similar way to treat cancers that are hormone responsive. Because of the profound side-effects of many of these drugs, their contribution to health status can be considered a bit of a mixed bag.

Reasons for expenditure growth

Past expenditure growth in both groups has been driven primarily by volumes. The reasons for this are unknown (one could postulate that the number of cancer's receiving treatment is increasing faster than growth in the population or that the prevalence of treatable cancers has remained unchanged but that patients are being treated with larger combinations of therapy). However, substantial drops in the prices of flutamide and tamoxifen resulted in recent reductions in spending.

Clinical and financial risks and opportunities

Pipeline

The pipeline for anti-cancer drugs is substantial (there are reports of up to 300 new drugs currently under trial worldwide). These spending risks are not included in the forecasts.

Geographical equity

There are geographical disparities in access to cancer drugs that will lead to pressure to fund more oncology drugs through the Pharmaceutical Schedule.

Proposed PHARMAC actions

- PHARMAC will continue to take advantage of price reduction opportunities as they arise. However, such opportunities are likely to occur relatively rarely from here on.
- PHARMAC intends to work with the HFA to determine how best to manage the inherent spending risk oncology agents create for the HFA.

STRATEGIC OVERVIEW OF ALIMENTARY TRACT AND METABOLISM - DIABETES March 1999

Therapeutic Group Manager: Dilky Rasiah

Current Expenditure

BNF2 groups with sales greater than \$3 million	HFA Cost (\$m, excl GST)		Growth Rate % 98/99
	1997/98	98/99*	
Insulin & Oral hypoglycaemics**	16.4	18.2	14%
Testing strips	11.2	12.7	18%
Group Total	27.6	30.9	

Contribution to Health Status

This therapeutic group includes people with diabetes mellitus. Although incidence may not be increasing (not known for sure) diagnosis and degree of intervention is increasing. Traditionally insulin and the oral hypoglycaemics have been the mainstays of treatment (following diet and weight reduction) and variations of these products are expected in the next 2 years. Further down the track appear to be treatments such as gene manipulation (to decrease risk of obesity) and modulation of insulin resistance at a cellular level.

Reasons for Current Expenditure trends

Context

Diabetes is divided into two major types:

- Insulin dependent diabetes mellitus (Type I or IDDM)
- Non insulin dependent diabetes mellitus (Type II or NIDDM)

The cost of complications in diabetes is high, and inevitable if good quality treatment is not provided. Diabetic nephropathy, retinopathy, and neuropathy are the major long-term complications, with the possible result of renal failure (dialysis/transplant); blindness; and amputation of limbs.

Diabetic patients also often have other conditions such as hypertension and hypercholesterolaemia which also have significant treatment cost implications.

The Ministry of Health in its September 1997 document, 'Diabetes: Prevention and Control' estimated that in 1992-93 82,000 people had diagnosed diabetes, of whom 12,000 were Maori and 3,000 Pacific Island people. By 2006 it estimated that this would increase by 30% to 106,600 diagnosed, due to an ageing population, but a 47% increase for Maori and 70% increase for Pacific Island people. This means a prevalence of known diabetes as 2.0% for NZers of European origin and others, 4.8% for Maori and 3.6% for Pacific Island people.

Currently it is estimated that many diabetic patients (although it is difficult to find estimates of numbers) do not receive treatment, and only a proportion of those who do are treated with the most effective regimen. A landmark trial in 1993 (DCCT) clearly indicated that aggressive treatment of IDDM patients with insulin decreases some of the medium and long-term complications of this condition. Heightened awareness, at least amongst prescribers following the release of the first results from the UKPDS study is likely to be reflected in slightly increased expenditure in all diabetes products.

Insulin

Growth is increasing, at 14% per annum and may increase. Reasons for increased growth include improved diagnosis and more aggressive treatment, a continued switch away from the less expensive insulin vials to the more expensive insulin cartridges and little competition in the market.

Oral Hypoglycaemics

These products are growing at 15% per annum. In the 1997/98 financial year significant subsidy reductions on metformin had little effect on expenditure because of the underlying volume growth.

Diabetes management agents

Blood glucose test strips continue to increase in expenditure but at an increased rate, 18%, compared with the previous 15%, as expected. The reasons are as already discussed.

Clinical and Financial Risks

Developments by the Ministry of Health, diabetes specialists, diabetes interest groups, and pharmaceutical suppliers will all result in increased diagnosis and treatment of diabetes, with resulting increase in pharmaceutical expenditure.

Diabetes management agents

Currently there is little opportunity for savings in the area of test strip subsidies given the issue of patient access to meters.

Insulin Pumps

We are starting to have requests by patients to fund insulin pumps (at a cost of several thousand dollars for pump and maintenance equipment). The diabetes subcommittee of PTAC has previously recognised its use in the small "brittle" patient group but so far has not recommended PHARMAC subsidise them. Currently there appear to be various ways patients access pumps, for instance hiring them from hospitals. Anecdotally we are aware that manufacturers are starting to promote pumps for wider use than just brittle diabetics.

Opportunities for Managing Expenditure

New Investments

During 1999/00 we propose to rationalise the test strips and look at funding one or more meters. PTAC in 1996 noted that some of the currently subsidised test strips were for meters that did not perform adequately. The proposal is to phase these test strips out. The subcommittee has recommended a 2 to 3 year phase out of the less effective meters. At the same time it suggested funding one or more meters. We expect such funding to be cost neutral as by offering greater market share we expect suppliers to be more competitive.

Cost Savings

The sulphonylureas (glibenclamide, glipizide and gliclazide) are being tendered. Once the tender bids have been analysed we will decide how to implement price reductions.

Demand Side actions

It is important to consider diabetes in terms of the whole disease state management. Avoiding the long-term complications is one of the main aims of diabetes management, as those have significant health and cost implications.

The HFA has contracted with Diabetes NZ to provide the listed blood glucose test strips. Encouraging use of this scheme while previously providing small savings to the HFA, may now be a small additional cost because of the nature of the new pharmacy contracts. We propose considering the value of this scheme at the same time as rationalising the currently listed test strips.

Diabetes nurses have approached PHARMAC in the interest of working together on improving GP use of diabetes nurse educators. Such work has the potential of improving testing (less wastage) and is being considered by the Demand Side Team.

**STRATEGIC OVERVIEW OF RESPIRATORY SYSTEM AND ALLERGIES
THERAPEUTIC GROUP
March 1999**

Therapeutic Group Manager: Dilky Rasiah

BNF2 groups with sales greater than \$3 million	HFA Cost (\$million, excl GST)		growth rate % 97/98
	1997/98	1998/99*	
Allergic disorders	2.1	2.3	0%
Inhaled Corticosteroids**	43.6	40.0	6%
Bronchodilators	26.0	22.0	1%
Prophylaxis of asthma	5.8	6.4	5%
Drugs acting on the nose	6.3	5.4	-1%
Total of above groups	83.8	76.1	

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Allergic Disorders	0%	0%	15%	7%	-6%	-6%
Corticosteroids asthma	-15%	-7%	9%	7%	-1%	-1%
Bronchodilators	-18%	0%	3%	2%	1%	1%
Prophylaxis Of Asthma	0%	0%	-7%	-7%	17%	12%
Drugs Acting On The Nose	-13%	0%	-4%	-7%	5%	4%

Contribution to Health Status

The main conditions treated in this therapeutic area are asthma and chronic obstructive respiratory disease (CORD). We already subsidise a large number of useful pharmaceutical therapies for asthma and CORD, however as the incidence of these conditions appears to be growing, any new therapy in this area is likely to be enthusiastically received by patients/public.

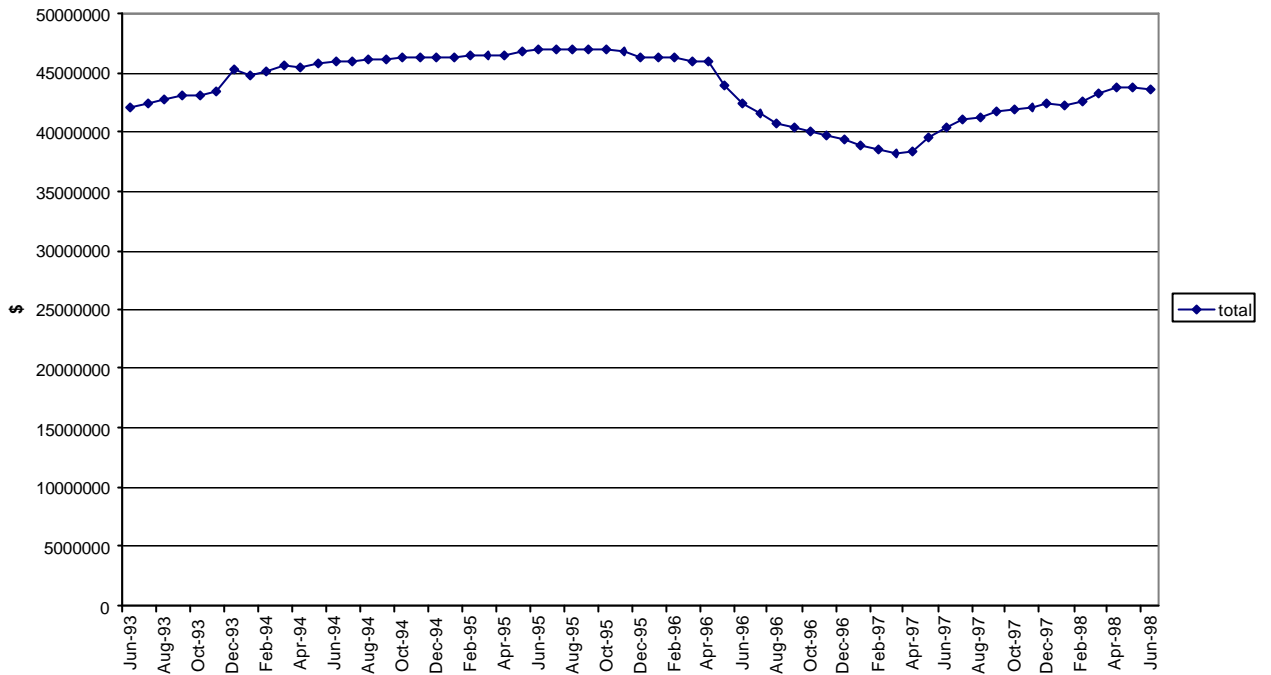
There are also a range of treatments available for allergic conditions (antihistamines, nasal corticosteroids). These conditions may not be increasing in incidence, however, they are growing in prominence and the pressure is increasing to provide fully subsidised care for some patients.

Current Expenditure Trends

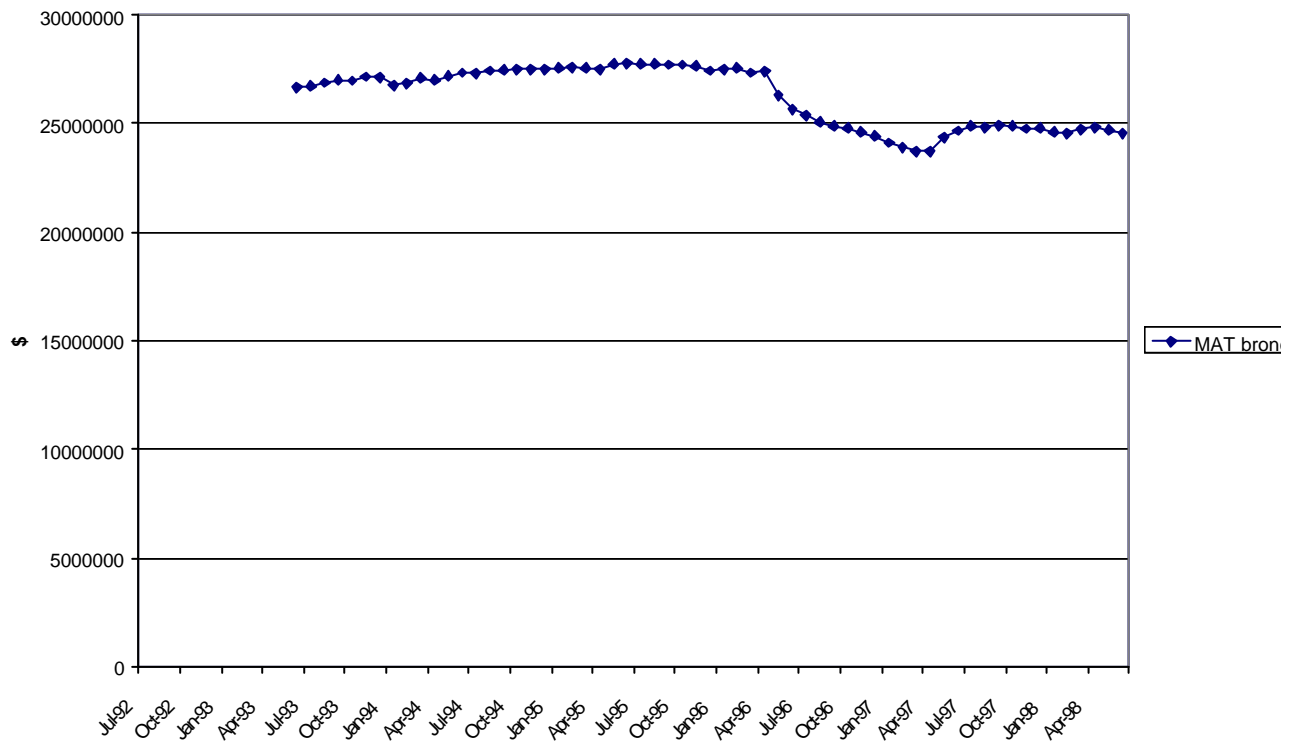
Inhaled Corticosteroids/bronchodilators

These are displayed in the graphs below.

MAT HFA expenditure (ex manufacturer) inhaled corticosteroids



MAT HFA ex manufacturer expenditure on bronchodilators



There is also growth in a number of areas of minor expenditure. These include peak flow meters, spacers for children and ipratropium bromide. We expect volume growth to continue, partly offset by the subsidy reduction from tendering of ipratropium bromide. Growth in these areas is again a result of increased incidence, diagnosis and aggressive treatment of asthma/CORD.

Cystic Fibrosis

Pulmozyme (dornase alfa) for the management of cystic fibrosis was listed on the Pharmaceutical Schedule in April 1997. Its use is being restricted via strict guidelines and applications being approved through a selected panel of clinicians.

Antihistamines

There is no growth in this area mainly as a significant proportion of antihistamines are purchased over the counter and price increases by suppliers have not been accompanied by subsidy increases.

Nasal Sprays

Expenditure in the steroid nasal sprays shows no growth as a result of previous price reductions.

The previous rationalising of the respiratory market in particular delisting of lower health gain products was completed this year.

Clinical and Financial Risks

Expenditure in respiratory has been over \$90 million per annum. The largest area is asthma. This expenditure reflects the high prevalence of asthma in NZ, which appears to be growing, the lack of generic competition, the relatively high prices compared with overseas, the patent protection for breath activated devices and the strong hold that the few companies in the market have on market share through presence/promotion. This has been the case for a number of years.

The Montreal protocol to phase out CFC products is a significant disincentive to introducing generic MDI products. We face mounting pressure from companies to list their CFC product versions at a higher subsidy level. This has been compounded by Australia's recent decision to subsidy CFC free products at a higher level than their non-CFC counter parts.

An unresolved issue is spacers for adults. Although some suppliers already supply spacers free, this has the potential to cost the HFA up to \$500,000. This may be offset by savings from substitution for expensive dry powder devices and nebuliser solutions.

Antihistamines

Major issues continue to be that most products have premiums, a lack of rational pricing and the fact there is no fully subsidised non-sedating antihistamine. However, there have been safety concerns with the use of many of the non-sedating antihistamines. Towards the end of 1997 we consulted on delisting antihistamines or rationalising them in some other way. There was very little support for delisting, but some support for having available at least one fully subsidised non-sedating and one sedating antihistamine. This would probably entail extra expenditure.

Clinical and Financial Opportunities

New Investments

Asthma

Over the next 2 years we expect to receive applications from suppliers for combination products, in particular ICS and inhaled long acting beta agonists, although no price indications have been given as yet.

Cost Savings

Asthma

The forecast fall in ICS expenditure from 99/00 is due to subsidy reductions following an RFP on beclomethasone MDIs.

Depending on the restrictions accepted to achieve the RFP reductions there may be an opportunity for further reductions on these drugs.

Nasal Corticosteroids

As a result of a RFP on these products, prices were reduced but an embargo on tendering exists until the end of 1999.

Demand Side

Major gains could be made by more efficient and cost effective prescribing. BPAC carried out a back titration campaign last year but the results of this are not known. The use of MDIs with spacers instead of BADs or nebulisers would result in very significant savings.

We have signed a national asthma plan contract with the Asthma Foundation.

STRATEGIC OVERVIEW OF THE NERVOUS SYSTEM THERAPEUTIC GROUP MARCH 1999

Therapeutic Group Managers: Dilky Rasiah (anti-depressants)
Cristine Della Barca (everything else)

Current Expenditure

BNF2 Groups	HFA Cost (\$ million, excl GST)		Growth rate
	1997/98	1998/99	%
Antidepressants	33.2	31.0	9.0%
Analgesics	18.1	19.6	8%
Antipsychotics	4.3	17.5	307%
Anticonvulsants	11.8	13.7	16%
Antiparkinson	6.2	5.8	-6%
Anxiolytics	2.1	2.1	5%
CNS Stimulants	1.7	2.0	18%
Other	3.6	3.6	0%
Speculatives	-	-	-
TOTAL	81.0	95.3	18%

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Antidepressant Drugs	-15%	-20%	7%	5%	3%	2%
Analgesics	-2%	0%	10%	7%	0%	1%
Drugs Used In Psychoses And Related Disorders	0%	0%	13%	3%	156%	109%
Antiepileptics	0%	0%	11%	8%	5%	4%
Drugs Used In Parkinsonism And Related Disorders	-13%	-3%	3%	2%	3%	2%
Hypnotics And Anxiolytics	0%	0%	0%	0%	1%	1%
Central Nervous Stimulants	0%	0%	22%	14%	-1%	-1%

Key information about the group

Pharmaceuticals listed under the "Nervous System" section of the Schedule (excluding anti-depressants) accounts for about 9% of HFA spending via the Pharmaceutical Schedule (13% including anti-depressants).

Contribution to Health Status

Anti-depressants – Depression has a high profile and increasing acceptance as a disease state. One estimate is that 5 to 10% of the NZ population is suffering from depression at any one time. This would be about 175,000 to 350,000 people. Although efficacy is similar between therapies, tolerance has varied leaving the way open for more and more antidepressants (with slightly different side effect profiles) to be developed.

Analgesics – analgesics are an important component of the management of many diseases and, in some cases, the only treatment option. Some analgesics (opioids) are addictive and can be abused.

Antipsychotics – pharmaceuticals are among the most effective treatments for Schizophrenia and other psychoses and play an important role in patient management especially when access to other services are limited.

Anticonvulsants – epilepsy affects up to 1% of the population. While anti-convulsants are not always 100% effective in controlling the debilitating effects of the disease, they can contribute greatly to improved quality of life.

Anti-Parkinson's drugs – Parkinson's disease affects a mainly elderly population. The effects of the disease often necessitate intensive home help or eventual institutionalisation. Antiparkinson's drugs are beneficial in controlling the symptoms of disease, in many cases to the point where dependence on assistance is reduced or, for a time at least, avoided.

Anxiolytics – the benefit of these drugs is questionable. They are addictive when used long-term but may be useful for short periods in certain instances.

CNS Stimulants (methylphenidate and dexamphetamine) - appear to have benefit in the treatment of attention deficit and hyperactivity disorder (ADHD) (in addition to narcolepsy). Given the current lack of access to child and adolescent psychiatrists in parts of New Zealand, they may be for some patients, the only treatment option available. They are, however, also abused and have black market value.

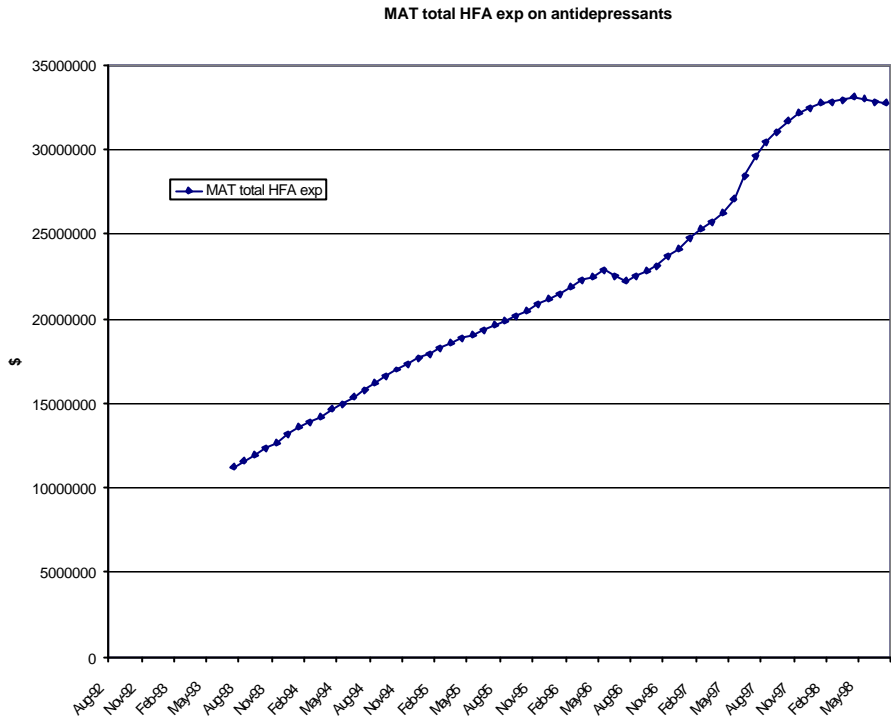
Other (methadone) – methadone is used mainly in alcohol and drug (A&D) clinics where it can be legally prescribed for the treatment of opioid dependence. However, a small amount is also used in the treatment of pain because methadone has a longer half life than morphine. Treatment of opioid addiction is based around the “harm reduction” model. Programmes based on oral methadone replacement of opioid drugs (oral and injected) aim to reduce a patient's requirements but not necessarily withdraw the drug altogether.

Speculatives – the health benefit of beta interferon for Multiple Sclerosis is small (cost utility likely to be marginal at best). There is too little data on new drugs for the treatment of Alzheimer's Disease to ascertain health benefit at this stage.

Reasons for current expenditure trends

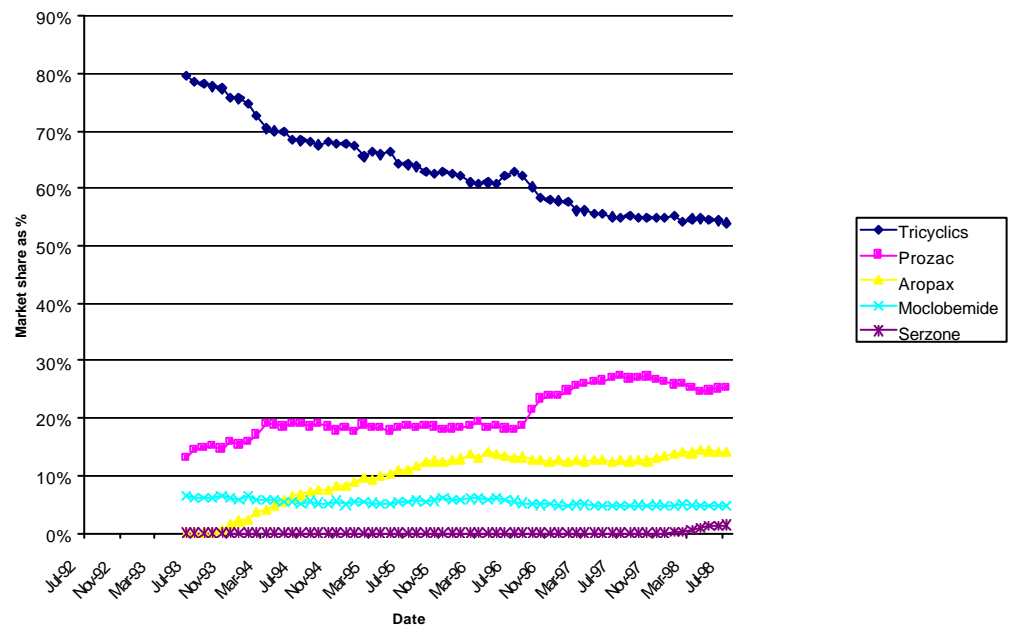
Anti-depressants - volumes of antidepressants continue to increase, as does the mix factor. The newer antidepressants are being more widely prescribed and are being used as first line treatment for depression. Part of the demand is consumer driven, but also general practitioners are now more familiar with the newer antidepressants, and are reluctant to prescribe tricyclic antidepressants.

However as shown in the two graphs below growth in antidepressant expenditure is now slowing down to 9% compared with over 20% in the past few years. The reason for this change is unclear but may reflect a maturing market, decreased marketing by suppliers and/or an increased understanding amongst prescribers that management of depression should be multifactorial, not only pharmaceutically based.



Prescribing of the older agents although always higher than the newer agents had been falling rapidly. It now appears to have stabilised at just over 50% of prescriptions as shown below.

Antidepressants - market share by number of written prescriptions (all of HFA excluding North Health)



Analgesics – despite subsidy reductions as a result of preferred and sole supplier arrangements for a number of analgesics in the last year, expenditure in this therapeutic group continues to grow. This growth appears to be mostly due to volume growth of long-acting

morphine sulphate preparations. Illicit use of opioid analgesics may also be increasing. The free health for under 6's policy has increased use of liquid paracetamol. Anti-migraine preparations (sumatriptan) have also contributed to the growth in this area also.

Antipsychotics – the recent “increase” in expenditure for these agents is due to the listing of risperidone, clozapine and olanzapine on the Schedule. These agents were already being funded via the HFA and continue to be funded from the Mental Health operating group budget. However, there is a trend away from first line use of the older, less expensive agents which is expected to increase expenditure over the next 5 years.

Anticonvulsants – growth in this area is almost exclusively due to increased use of the New Anti-convulsant drugs.

Anti-Parkinson's drugs – this market is declining because of price reductions on some agents and listing of at least one newer agent (tolcopone) under a cost neutral arrangement.

Anxiolytics - while this declining market (HFA expenditure around \$600,000) is not a high cost area, there are issues around access to these agents.

CNS Stimulants – most of the growth in this area is due to increased awareness of and diagnosis rate for ADHD and concomitant increase in the use of methylphenidate (Ritalin).

Other - HFA expenditure for methadone has been increasing steadily for the last few years (annual expenditure (cost to the HFA) for year ending 30 September 1998 was about \$6 million). The numbers of patients being treated via A&D clinics is reported to be increasing by 15% per year.

Clinical & Financial Risks and Opportunities

Anti-depressants

This market gears up to become a generic one after Prozac comes off patent in January 2000. Subsidy reductions will be available but with the issues around switching we would need to carefully consider the timeframes around implementation.

Newer SSRIs with claims of additional benefit over current SSRIs have arrived with more on the horizon. PTAC's approach so far has been to not subgroup these products separately but recommend that they be targeted to those patients who would benefit in particular (for example venlafaxine for treatment-resistant depression).

Prozac comes off patent in January 2000. This will provide a significant opportunity to shift the cost of SSRIs down.

It is not obvious that other suppliers will match subsidy reductions. Therefore we would face patient switching. We will need to consider the timeframes around the implementation of any reference pricing change.

Tricyclic antidepressants (TCA) generally cost less in Australia. For instance amitriptylline 50mg is almost half the NZ price. A number of TCA's are part of the current tender round. Over the next year we will implement the results of the tender

We will need to monitor this market closely to see whether the recent slowdown both in prescription volumes and in switching from TCAs to SSRIs is maintained. If previous trends reassert themselves we will need to consider ways of changing prescriber behaviour with appropriate messages to practitioners and patients. It may be appropriate to send the message to practitioners that for mild depression it is relevant to consider whether non-drug therapy is

appropriate. The potential risks of conveying this message to patients needs to be carefully considered.

Antipsychotics

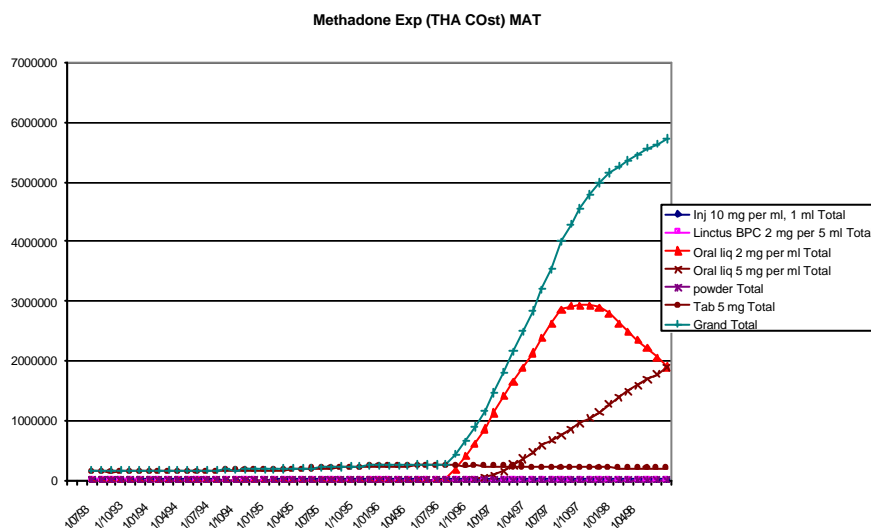
Wider access to atypical anti-psychotic agents as facilitated by the Schedule listings carries financial risk since it is expected that demand for the agents will exceed the amount that the HFA is able to provide funding for within the existing budget. However, there is still immediate financial risk associated with demand for olanzapine (this demand is expected to reduce as a result of the removal of the Special Authority from clozapine). It is still possible that additional funding for olanzapine might have to be allocated by the HFA especially given that evidence supporting olanzapine over clozapine may be emerging. The risk is likely to increase rather than decrease with the introduction of other atypical antipsychotic agents.

Analgesics

Volume growth of long-acting morphine sulphate preparations is of concern. These preparations now account for a significant proportion of expenditure on analgesics. Price reductions associated with the most recent new listings in this market had some downward effect on expenditure but expenditure has recently begun to increase again.

Methadone

The listing of commercially prepared methadone mixtures was expected to reduce the costs of treatment which, until that time, were based around mixtures compounded extemporaneously from morphine powder and tablets. The 2mg/ml strength was the first proprietary mixture on the Schedule. The 5 mg per ml was later introduced at a lower price/subsidy per mg.

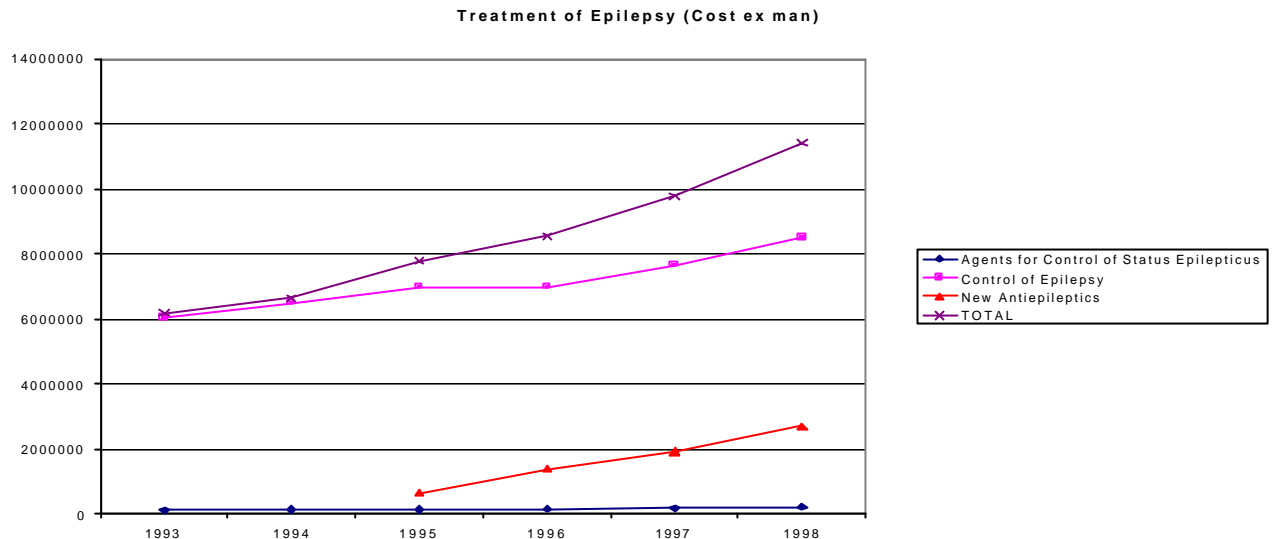


Antimigraine

The HFA is now able to fund a range of acute migraine treatments (injections and tablets) for an unlimited number of patients at little more than the expected cost of funding Imigran injection that was already listed.

Anticonvulsants

Since 1994, new anti-convulsant drugs (NADs) have been funded from the Pharmaceutical budget under arrangements that were intended to contain expenditure within budgets administered at an RHA level. Interestingly, increased growth in use of NADs also appears to have been associated with increased expenditure for conventional agents:



A 1998 survey of prescribers highlighted the following issues with the current funding arrangements:

- Access is managed differently in each region (for example, in some areas GPs are allowed to prescribe for stable patients but not in others).
- Most prescribers are happy with the current prescribing guidelines.
- Appropriateness of treatment with NADs is monitored regularly in most areas (using seizure frequency as an index) but quality of life is not always monitored and in some areas, few patients are exiting the trials (creating restrictions for new patients entering).
- Prescribers want access to a wider range of NADs.
- Prescribers feel that they do not get enough feedback on their current budgetary constraints.
- Prescribers dislike the administration required under the current system.

PHARMAC has identified the following potential solutions and is consulting on their viability:

1. Amend the existing system.

This is likely to involve:

- a. resetting the budget or introducing a national budget, to be managed by either the HFA or PHARMAC, to take account of growth;
- b. clarifying guidelines to prevent future budget blowouts;
- c. improving patient response monitoring so that trials are discontinued when patients do not respond adequately;
- d. standardising prescribing authority (i.e. specialists vs GPs) nationally.

2. Replace the existing system with a Special Authority system.

This would involve replacing the existing guidelines with Special Authority criteria. Defined prescribers would then apply to Health Benefits Limited (HBL) for approval for funding. Expenditure on NADs could be controlled at HBL by limiting the number of Special Authorities that can be issued to fit within a new national budget.

3. Negotiate a commercial solution.

If the HFA's financial risk in respect of NADs could be shared or reduced by entering into a commercial arrangement or arrangements with a supplier or suppliers then PHARMAC might consider removing the budget holding arrangements altogether. The scope for using certain commercial solutions may be limited by issues specific to these drugs, for instance application of reference pricing resulting in manufacturer's surcharges on some products might be unacceptable if it disrupted a patient's epilepsy control. However, commercial options that are potentially viable include:

- a. the introduction of a market cap (either for NADs or for all anti-convulsant drugs) managed by one supplier or shared by more than one supplier;
- b. the introduction of an expenditure cap on one product or more than one product; or
- c. significant price reductions either on NADs or in some other market in consideration of access to NADs.

Anti-Parkinsons drugs

A review of anti-Parkinson's agents was initiated this year but is yet to be completed. There may be some opportunity for savings from reference pricing (at least the dopamine agonists and related compounds and anto-cholinergics). The potential savings from the application of reference pricing are yet to be determined. A fuller review of the therapeutic group will assist this process. Meanwhile, PHARMAC is relying on price reductions on individual agents to continue reducing costs in this area.

Anxiolytics

The one month restriction that currently applies to these drugs is sometimes criticised for being unnecessarily restrictive. On the other hand, its removal may not be applauded because of abuse issues. The Ministry of Health has recently reclassified these medicines as Controlled Drugs. This is mainly so that laws concerning prescription for addiction can be applied to them. The reclassification does not alter the availability (CD forms not required, storage and recording requirements are unchanged and, by law, three months supply can be prescribed rather than the usual 10 days-1 month for other CDs). It is doubtful whether it is PHARMAC's role to impose subsidy restrictions for the purposes of reducing misuse of drugs. However, the fact remains that these drugs can be abused and have a black market value. Demand side activity could be a more appropriate focus as well as any restriction that would help to reduce illicit use. Furthermore, with the advent of electronic claiming, it is doubtful whether the one month subsidy restriction can practically be enforced.

Central nervous system stimulants

Expenditure continues to increase in this area. Most of the increase is due to methylphenidate (Ritalin), which had been growing at over 100% per year. While the new Special Authority to be implemented this year is likely to go some way towards ensuring appropriate use of these medicines (by necessitating a diagnosis according to strict and recognised criteria), it is unlikely to significantly reduce or curb expenditure.

Furthermore, due the shortage of paediatric psychiatrists the recommendations of the sub-committee, which were based on what it considered to be optimal practice for diagnosis and treatment of ADHD, have been compromised to some extent.

Multiple Sclerosis

There are a number of new therapies for multiple sclerosis-the Interferon betas 1b (Betaferon, Schering) and 1 alpha (Avonex, CSL). PHARMAC is in receipt of applications for both Betaferon and Avonex. Both applications have been considered by the neurology subcommittee. Further indications (for secondary progressive MS) are emerging. Listing of Betaferon and/or Avonex is dependent upon the availability of the funding required to subsidise these medicines, the identification of a mechanism to target their use appropriately and/or a viable commercial proposal. Furthermore, indications are that, because of the small and uncertain benefit of these drugs, they are unlikely to be as cost-effective as other investments the PHARMAC Board may consider. Preliminary cost-utility work based on that conducted in two separate locations in the UK indicate the cost per QALY may be in the millions of dollars.

Proposed PHARMAC Actions

Over the next 12 months

- Anti-depressants - establish informally before Prozac comes off patent what companies plan to offer as well as finding out what applications are in the pipeline at Medsafe.
- Anti-psychotics - negotiate further commercial solutions (or, as a last resort, an increased budget) to provide access to quetiapine and/or olanzapine.
- Analgesics - investigate commercial arrangements to reduce expenditure in the morphine sulphate market (especially long-acting) and, if appropriate, initiate an RFP. Demand side activity to increase awareness of illicit use may be considered appropriate.
- Methadone - seek comment from A&D clinic and pharmacy groups about the possibility of reference pricing and/or tendering this market
- Anti-convulsants drugs - consult with Neurology sub-committee of PTAC regarding submissions in response to consultation (specifically examine the viability of using reference pricing and/or introducing generics), negotiate with suppliers/issue RFP, and implement new arrangements (require addressing budget, special authority and potentially generic competition issues).
- Anti-Parkinsons drugs - complete review of anti-Parkinson's drugs (PTAC sub-committee advice, consultation and implementation of any outcomes).
- Multiple Sclerosis - undertake a cost-utility analysis for Betaferon and Avonex, seek a preliminary view from the PHARMAC Board regarding whether investment in these agents would be seriously considered and, if so, the size of the investment the Board would be prepared to make and under what conditions, and, if the Board's recommendation is positive, negotiate with suppliers and consult with neurologists about targeting.

In the long term

- Anti-depressants - underlying growth in new antidepressant expenditure will continue to be a risk. However, we will start to gain some pricing levers, especially as Prozac comes off patent.

- Anxiolytics - consult with alcohol and drug addiction clinics (and other interested parties including the medical council) on issues and option. Consider removing or replacing the one month restriction.
- Methadone - consider and consult on other options such as budget holding arrangements with A&D clinics.

STRATEGIC OVERVIEW OF ALIMENTARY TRACT AND METABOLISM JUNE 1999

Therapeutic Group Manager: Cristine Della Barca

Current Expenditure

<i>BNF2 Groups</i>	HFA cost (\$ m, GST excl.)		Current Growth rate %*
	1997/98	1998/99	
Anti-ulcerants	32.4	23.8	-27%
Treatment of chronic diarrhoeas	5.6	7.0	18%
Vitamins & Minerals	5.1	5.7	12%
<i>Laxatives</i>	4.1	3.7	-10%
Antacids & Alginates	1.2	0.6	-47%
Ceredase	0.8	0.8	0%
Other	5.2	5.4	4%
TOTAL	54.5	46.8	

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Ulcer-Healing Drugs	-39%	-31%	12%	9%	10%	8%
Treatment Of Chronic Diarrhoeas	0%	0%	10%	7%	7%	5%
Vitamins	0%	0%	10%	7%	6%	4%
Minerals	-2%	0%	8%	6%	-1%	-1%
Laxatives	-5%	0%	-1%	0%	-5%	-4%
Antacids	-40%	0%	-13%	-15%	4%	4%

Contribution to health status

Anti-ulcerants – pharmaceutical therapy is the mainstay of treatment for ulcer and reflux disease. Surgical intervention is rarely used. The advent of triple therapy has meant that pharmaceutical treatment can cure ulcer disease as opposed to simply treating the symptoms.

Treatment of chronic diarrhoeas – the pharmaceutical therapies used in diseases that cause chronic diarrhoeas offer symptomatic relief of these conditions and may control the disease to the point where radical surgery, the other main treatment option, can be avoided.

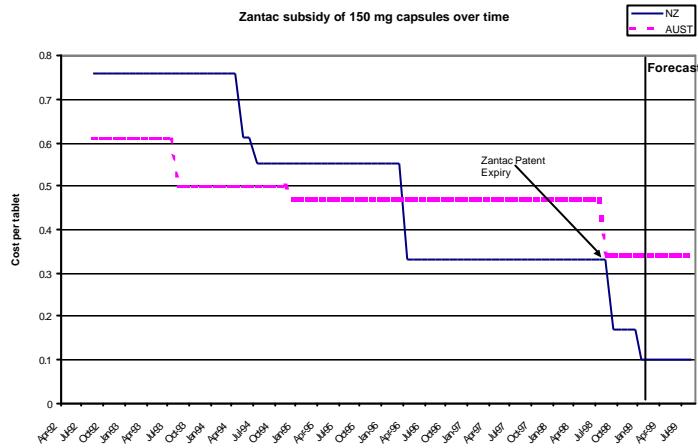
Vitamins & Minerals – most of the products listed in this area are used for the prophylaxis of osteoporosis or to stimulant faster healing from fractures. Osteoporosis and complication of the disease can cause severe disability requiring hospitalisation and/or home support.

Antacids & Alginates – provide symptomatic relief from ulcer and reflux disease. They may not be as effective as H2 antagonists or PPIs but are quite inexpensive and may suffice for some patients.

Ceredase – the health benefit of this product is debatable and arguably, dose dependent. It may be of little use in patients with severe bony disease (of which there is a large proportion in NZ), at least at the doses subsidised in NZ. Other treatment options are various surgical interventions.

Reasons for current expenditure trends

Anti-ulcerants – expenditure has been falling due to the introduction of expenditure caps and price reductions on the H2 antagonists. Prices and subsidies for the H2 antagonists have fallen dramatically, particularly over the last year as shown in the graph below which compared the Australian and New Zealand subsidies for ranitidine over time (NB reference pricing applies to other H2 antagonists):



Treatment of chronic diarrhoeas – expenditure has been increasing by about \$1 million per year for the last 3 years. This is due to increased use of the new oral rectal and colonic anti-inflammatory drugs over the older, less expensive ones.

Vitamins & Minerals – most of the cost that the HFA spends on vitamins and minerals is attributable to the Vitamin D derivative - Rocaltrol. Expenditure for this agent fell in the second half of 1997 as a result of a price reduction from the supplier (Roche) offered as part of a multi-product agreement. Indications are that use is growing again. A further \$1-2 million per year is spent on calcium supplements (also mainly used in the prevention of osteoporosis) although the recent tender of calcium carbonate should reduce this significantly. There has also been significant growth within the remainder of the vitamin market – namely in the use of vitamin B and multi-vitamins.

Antacids & Alginates – expenditure has decreased due to a review of this therapeutic group which saw reference pricing applied and subsequent savings.

Ceredase – expenditure continues to be managed within a set budget.

Clinical & financial risks and opportunities

Ulcer healing drugs

Litigation over the derestriction of pantoprazole is on-going.

The large falls in H2 antagonist prices have mean that, despite concurrent falls in PPI prices, there is still a large disparity between the average daily cost (ADC) of H2 antagonist therapy vs PPI therapy.

ADC PPI (assume 20mg omeprazole)	= \$1.00
ADC H2A (assume 150mg ranitidine bd)	= \$0.20

Demand side activity focused on promoting trial of the less expense H2 antagonists before resorting to PPI is therefore one of the key activities planned this year to address the underlying growth in use of PPIs. Incorporated into this programme could be the promotion of H.pylori eradication to eliminate the need for on-going treatment.

There is now a range of triple therapy H.pylori eradication packs listed on the Schedule (an omeprazole/amoxicillin/clarithromycin (OAC) is also currently being considered for listing). While these are more expensive than the individual components dispensed separately, the convenience of the pack is considered to have the potential to increase the uptake of the agents and thus decrease demand for long-term ulcer therapy.

Treatments for chronic diarrhoeas

PHARMAC has initiated a review of the area with a view to sub-grouping the agents in some way to achieve savings and curb expenditure. However, the potential savings from reference pricing may be limited because of the different indications and side effect profiles of the agents involved.

A new agent (budesonide), for use in patients with chronic diarrhoea who cannot tolerate steroids, has been listed on the Schedule under a Special Authority. This drug is only indicated for the treatment of acute exacerbations of inflammatory bowel disease (and the Special Authority restricts its use as such).

Vitamins and minerals

The role of Rocaltrol in the treatment and prevention of osteoporosis has been questioned by clinicians and supporters of the bisphosphate alendronate. PHARMAC will review access to Rocaltrol as it progresses the application to list alendronate.

There has been significant growth within the remainder of the vitamin market – namely in the use of vitamin B and multi-vitamins.

Growth in the use of Vitamin B is mainly due to increased use of hydroxycobalamine (indicated for pernicious anaemia but becoming popular for treating chronic fatigue syndrome) which has tailed off since the supplier increased its price by about 200% but the subsidy remained unchanged. The supplier has requested a subsidy increase.

Antacids & Alginates

As a result of the review of these drugs last year, there is only one fully subsidised antacid listed on the Schedule. There are no calcium free or liquid antacids that receive full subsidy. This is likely to generate a switch to H2 antagonists or PPI. H2 antagonists are now likely to be less expensive than antacids (assuming antacids are used as prescribed). However, a switch to PPI would increase the costs of treatment of ulcers/dyspepsia significantly. Furthermore, antacids are sometimes used in addition to rather than instead of H2 antagonists. These issues need to be incorporated in the demand side activity proposed for the ulcer/reflux market.

Drugs for Biliary Cirrhosis

PHARMAC has agreed to list ursodeoxycholic acid (Actigall) on the Schedule in 1999. This drug represents the first effective pharmaceutical treatment for primary biliary cirrhosis (PBC).

Ceredase

The annual costs of the Ceredase Treatment programme are likely to increase with pressure from clinicians to increase the dose for patients who have not responded to the very low dose regimen and a request for a subsidy increase from Genzyme. Production of Ceredase is likely to cease by June 1999 leaving PHARMAC with little choice but to subsidise the recombinant version, Cerezyme at a higher level.

Other

Laxatives – since 1997, HFA expenditure on laxatives has fallen. This is mainly due to price reductions for bulk forming laxatives and lactulose which now comprise about 60% of the market.

Digestives including Enzymes - small savings might be made from listing Panzytrat 10,000 as it is a low dose and could reduce wastage as well.

Mouth & Throat - oropharyngeal anti-infectives accounted for \$700,000 of expenditure in the past year.

Proposed PHARMAC actions

Over the next 12 months

- Anti-ulcerants: - plan, prepare and undertake demand side activity, list an OAC triple therapy pack and fight Astra PPI litigation.

- Treatments for chronic diarrhoeas - consult more extensively with the New Zealand Society of Gastroenterologists on the issue of reference pricing, consult on options and implement reference pricing.
- Vitamins and minerals - ascertain reason for increased expenditure on multi-vitamins and address if necessary.
- Ceredase - undertake a cost utility analysis, explore potential for concurrent use of bisphosphonates, discontinuation of Ceredase (negotiation with supplier on Cerezyme).
- Digestives including enzymes - obtain specialist input regarding the potential for tendering this market.

In the long term

- Anti-ulcerants – management of volume growth via promotion of appropriate prescribing/treatment, promotion of H.pylori eradication to reduce demand for long-term treatment and possible further decreases in H2 antagonist prices.

**STRATEGIC OVERVIEW OF SENSORY ORGANS THERAPEUTIC GROUP
JUNE 1999**

Therapeutic Group Manager: Cristine Della Barca

Current Expenditure

BNF2 Groups	HFA Cost (\$million)		Growth rate %
	1997/98	1998/99	
Glaucoma	3.7	3.8	3%
Other	2.1	2.3	10%
TOTAL	5.8	6.1	5%

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Treatment Of Glaucoma	0%	0%	3%	2%	1%	1%

Key information about the group

Sensory products account for less than 1% of the Pharmaceutical Schedule spending.

Contribution to Health status

Glaucoma treatments represent long-term therapy to treat both acute phases of glaucoma and to prevent or delay the onset of blindness and/or need for surgery as a result of the disease. Preparations for tear deficiency and other eye preparations are long-term treatments for chronic eye conditions. Most of the other products listed in this section of the Schedule are short-term treatments (i.e. anti-infectives or anti-inflammatories) for acute problems.

Reasons for current expenditure trends

Glaucoma affects mostly older people. Expenditure for glaucoma preparations is expected to increase as the population ages. Growth is expected to be slow because the rate of detection/diagnosis of glaucoma is low compared with the theoretical incidence.

Growth in expenditure for “other” eye and ear preparations remains unexplained. Anti-infective use may be increasing because of resistance issues (i.e. higher incidence of first line failure).

Clinical and financial risks and Opportunities

Glaucoma

Since the listing of dorzolamide under a Special Authority, PHARMAC has been under pressure to widen access to patients who have glaucoma but normal intraocular pressure. Latanoprost is twice as expensive as dorzolamide and brimonidine, which in turn cost more than the older beta blocker eyedrops. Ophthalmologists have described the three agents as essentially similar and their approach to treatment as trial and error with each agent until intraocular pressure (IOP) is controlled. This would indicate that the most desirable outcome would be one where clinicians could choose any one of the three new agents for a trial in order to ascertain which best or adequately controls the patient’s IOP. We also note that with price differentials between first line products and newer agents and also between the newer

agents themselves, it is important that the funding mechanism encourages appropriate prescribing (i.e. first line use of the cheaper agents and monotherapy where appropriate).

The availability of the newer agents (and widened access for dorzolamide) will require additional HFA expenditure. The amount would depend on the number of eligible patients and the mechanism by which access is controlled. There are a number of funding options to address the issues associate with access and subsidies for these products.

The potential to gain savings from betablockers for glaucoma is limited by an agreement with Pacific Pharmaceuticals not to tender the market for sole or preferred supply arrangements. However, there may be opportunities for straight price reductions.

Proposed PHARMAC Actions:

Over next 12 months:

- Address issues of access to new products in Glaucoma market.
- Implement result of tender for other eye products.
- Tidy up restrictions on ear preparations for electronic claiming.

In the long term

- Rationalise range of low priority products available

**STRATEGIC OVERVIEW OF SPECIAL FOODS THERAPEUTIC GROUP
JUNE 1999**

Therapeutic Group Manager: Cristine Della Barca

Current Expenditure

BNF2 Groups	HFA Cost (\$million)		Growth rate %
	1997/98	1998/99	
Special Foods	4.3	5.0	16%

Underlying Price, Volume and Mix

	Price Growth Rate %		Volume Growth Rate %		Mix Growth Rate %	
	1998/99	1999/00	1998/99	1999/00	1998/99	1999/00
Foods For Special Diets And Nutritional Support	-23%	-86%	40%	22%	-14%	-3%

Key information about the group

Special Foods account for less than 1% of the Pharmaceutical Schedule spending.

Contribution to health status

Special Foods are essential to life for patients who are unable to consume standard food and for a large proportion of patients whose food intake is severely restricted. Used as supplements, special foods can assist in recovery/healing from trauma or surgery and in the management of certain illnesses.

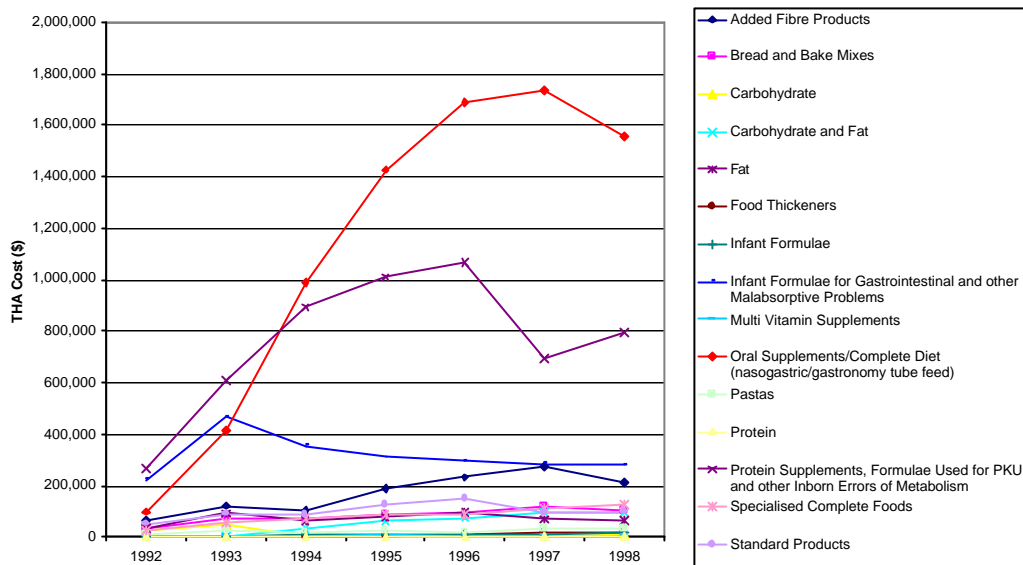
Reasons for current expenditure Trends

The major growth in this market is being driven by two main features:

- the trend towards earlier discharge and patient management in the community; and
- increasing use of protein supplements in older patients.

HFA expenditure trends are shown below (note: North Health data missing):

HFA Expenditure (MAT) on Special Foods



The largest portion of expenditure on Special Foods is for oral supplement/complete diets. This area of the market is dominated by three products. There has also been growth in a smaller niche market of fibre added products.

The HFA also currently spends about \$1 million (cost ex manufacturer, GST exclusive) per year on phenyl free foods and protein supplements etc for PKU and other inborn errors of metabolism and use is steadily increasing (though not at the rate of oral supplements and complete diets).

Expenditure on infant formulae appears to be falling. The reasons for this fall are unclear but may be related to the various charges (manufacturer's surcharges, co-payments and part-charges) associated with these products.

Clinical & Financial Risks and Opportunities

Oral Supplements

Further growth in use of oral supplement/complete diets and in fibre added products. At its last meeting, the PTAC sub-committee also recommended that access to oral supplements and complete diet foods for children be widened to include children up to 10 yrs of age (they are currently only available for children up to 6 yrs of age).

Phenyl free foods and protein supplements etc for PKU and other inborn errors of metabolism

Use of these products is steadily increasing (though not at the rate of oral supplements and complete diets). This is potentially an area that could be managed separately under a fixed budget. Identification of an appropriate group to manage this access appears to be the biggest barrier to introducing this mechanism. Gluten free foods could also potentially be managed via such a mechanism although expenditure on these products is quite small (less than \$200,000 per year) so it unlikely that this option would be viable alone.

Infant formulae

Expenditure in this area is falling. The reasons for this fall are unclear but may be related to the various charges (manufacturer's surcharges, co-payments and part-charges) associated

with these products. In order to obtain a subsidy for these products, patients are required to have a Special Authority number and a prescription. The prescription is required for subsidy purposes only since these products are not medicines and can be bought over the counter. Dispensings are subject to the usual co-payment requirements (although, in most cases patients would not pay any co-payment because of the exemption for patients under 6 years of age). In addition to any manufacturer's surcharge, patients are required to pay a part-charge which was originally introduced to bring the cost to patients into line with the costs of normal milk formula. These charges may now be out of step with retail prices. PHARMAC staff need to ascertain what the prices of infant formulae, (whether there are surcharges, and what the cost is to the patient) in order to decide whether the part-charge policy needs to be revised.

This area may be another that could potentially be managed under a fixed budget.

Retail Pharmacy Dispensing

A major issue that needs to be addressed before the end of May 1999 is the transition from hospital pharmacy only dispensing to retail pharmacies. Under HFA contracts, this has occurred in some areas for most hospital pharmacy only products from 1 January 1999. However, the transfer of Special Foods was deferred because, without products prices (these are currently not indicated in the Schedule and not provided by the suppliers) it is impossible to tell what effect retail pharmacy mark-ups on manufacturer's surcharges would have on the direct costs to users. Prices have been requested from suppliers (under the ultimatum that if they do not provide prices, products could be delisted). The transition should therefore be able to take place within the required timeframe. However, once this transition takes place, it is almost certain that HFA costs associated with Special Foods will increase because hospital pharmacies are able to purchase stocks of Special Foods at prices lower (because of bulk discount) than retail pharmacies are likely to be able to via pharmacy wholesalers.

Distribution

Several suppliers have indicated an interest in direct to patient distribution that is already underway in the South Island. It may be appropriate to expand this system nationally. Savings may be possible.

Actions to be taken

Over the next 12 months

- Complete stage one of the current review (including listing prices for all special foods).
- Initiate second part of Special Foods with a view to finding intermediate and/or long-term solutions to issues associated with the management of funding for Special Foods.

In the long term

- Seek alternative funding arrangements for at least some Special Foods that would help to manage expenditure and/or allow them to be removed from the Schedule.

STRATEGIC OVERVIEW OF THE DEMAND SIDE 1999/2000 FEBRUARY 1999

Demand Side Manager: Ruth Casalvolone

Background

The year 1998/1999 was focused on implementation and development of the PHARMAC Demand Side structure based on the management structure and strategy model approved at the 25 September 1998 Board meeting. To this end a number of initiatives were put into place. One of the first objectives was to develop a business plan and a Demand Side team.

Although various activities were implemented, many of these were not treated as Demand Side activities as such and were added to the larger PHARMAC process. The focus of the Demand Side programme is to manage the continued volume and mix growth within pharmaceutical expenditure.

Projects that have been implemented include:

- specific marketing plans to support PHARMAC transactions (e.g. the ACE inhibitors and the DHP Calcium Channel Blockers);
- more generalised projects (e.g. the appropriate use of antibiotics); and
- support of conferences, publications (e.g. Healthy Scepticism), website and other ongoing PHARMAC activities.

Proposed Activities

Where appropriate, potential high expenditure areas will be targeted in terms of prescriber awareness and patient education, and savings will be re-allocated to priority areas. These activities include providing support to key PHARMAC transactions, in conjunction with Therapeutic Group Managers, as a means of reducing financial risk, maximising transaction outcomes and encouraging buy-in by key stakeholders.

Cardiovascular Drugs

Key Issues and Assumptions

The cardiovascular therapeutic group remains the largest expenditure group. Major cardiovascular transactions have occurred over the past year with changes to the funding of the ACE inhibitors, lipid modifying agents, beta blockers and the dihydropyridine calcium channel blockers.

It is necessary to ensure that statin expenditure is controlled and that patients most likely to benefit from treatment are reached through appropriate targeting.

Proposed Activities

- The DHP CCB project needs to be completed in 1999/2000. This project began in February 1999 to support the changes taking place to funding on 1 June 1999. Although the marketing will be completed by the start of the new financial year, the project will continue to run until 18 October and will be followed by an evaluation of the outcomes.
- An education campaign, piggy-backing on existing programmes, aimed at prevention and treatment of ischaemic heart disease, a leading cause of death in New Zealand, with special focus on risk factors such as lipid disorders, hypertension and cigarette smoking.

Benefits

These include the gains from changes to funding decisions. Also of note are the gains that will accrue from changes to prescribing patterns and adoption of best practice methods.

Asthma Drugs

Key Issues and Assumptions

- New Zealand has one of the highest incidences of asthma in the world. The incidence of asthma appears to be increasing.
- More efficient and cost-effective prescribing could make gains in both healthcare and financial terms.

Financial Risks

The growth in spending on asthma drugs was around 6% in 1997/1998. Patients may be taking higher doses than necessary to control their asthma. Initiatives to reduce expenditure should be aimed at encouraging prescribers to prescribe the lowest effective dose in an appropriate dosage form.

Proposed Activities

PHARMAC, under the National Asthma Plan contract where applicable, could support the:

- promotion of the use of MDIs and spacers instead of nebulisers and dry powders;
- back titration of inhaled corticosteroids to the minimum effective dose when asthma is controlled;
- Asthma and Respiratory Foundation, HFA and other groups interested in the control of asthma; and/or
- entry of new suppliers into the market, smoothing the way for resultant price reductions and/or the introduction of generics.

Benefits

According to the Asthma Foundation's Plan, improved asthma management could result in annual savings of \$7.5 million to the HFA through a 25% reduction in hospital admissions.

Antibiotics

Key Issues and Assumptions

The most frequently prescribed antibiotics are broad spectrum, increasing the risk of resistance and the demand for innovative, potentially more expensive agents. The need to move away from prescribing antibiotics for non-bacterial infections, as well as the appropriate use of antibiotics generally, will be the focus of a project this year.

Financial Risks

Although Augmentin comes off patent this year (with an associated price reduction of up to 50%), switching to more expensive broad-spectrum antibiotics could limit these gains.

Proposed Activities

- PHARMAC will support IPAs in their activities to promote appropriate use of antibiotics and will aim to assist IPAs with the development and promotion of guidelines.
- PHARMAC will increase IPA exposure by working on a national level to educate consumers using support material for distribution through the health sector. This could follow the UK strategy - Campaign on Antibiotic Treatment (CAT) and National Advice to the Public (NAP).
- Media exposure through "piggy backing" will be sought.
- PHARMAC will encourage other healthcare professionals to adopt this programme.
- PHARMAC intends to launch the programme before June 1999 and run it through the winter months.
- A pilot study on "rapid tests" will be considered.

Benefits

The appropriate use of antibiotics will result in decreased spending and less resistance, prolonging the period of use of current antibiotics and staving off the purchasing of innovative more expensive drugs. There will be health gain and economic benefits.

Key Outcome Measures

A measurable reduction in total consumption across all classes of antimicrobials and a change in broad-spectrum/narrow-spectrum mix.

Generics

Key Issues and Assumptions

Generics make up less than 20% of the NZ prescription market compared to 43% in the USA, 45% in the UK, 37% in Canada and 60% in Denmark. PHARMAC estimates that savings of at least \$50 million per year could be achieved if the barriers to entry of new generic suppliers were lowered. The myths regarding safety and efficacy of generics need to be allayed.

Financial Risks

Any progress PHARMAC can make in improving the environment for the prescribing of generics will add weight to its attempts to increase price competition in the market, through, for example, tendering or preferred supplier arrangements.

Proposed Activities

Educational and promotional activities aimed at healthcare professionals through journal articles, publications and professional promotional material. The aim will be to provide information on the cost-effectiveness and benefits of prescribing generics.

Benefits

- savings through increased use of generics; and
- opening the market to generics through changing perceptions.

Other Initiatives

Other risk areas identified include:

- Diabetes - The volume of transactions is rising, pushing up overall expenditure. This is a concern as a minority of those suffering from diabetes have been diagnosed and are being treated. Uncontrolled diabetes leads to complications requiring additional intervention. While we can expect the volume of transactions to rise due to the large unmet need, we can manage this increase by ensuring the appropriate use of medicines.
- Ulcer healing agents - Volumes continue to grow. Agents and the conditions for which they are being used need to be identified. Best practice targeting may be useful with the PPIs and H2 antagonists to manage volume growth.
- Antidepressants - This is an area of growing expenditure. A review of patient therapies and dosages would be desirable.
- Compliance - There needs to be ongoing promotion and education on the correct use of medicines by patients and methods of increasing compliance for prescribers so as to limit wastage and increase savings.
- Waste Management - This is a major factor in the prescribing (or over-prescribing) of pharmaceuticals. The message to use medicines wisely needs to be conveyed. This can be tied in with compliance.
- Polypharmacy - A public awareness programme with regard to the dangers of mixing medicines needs to be implemented. Over 15% of elderly patients are admitted to hospitals because of polypharmacy.
- Medicalisation - Many conditions (e.g. obesity) can be managed through lifestyle modification rather than medicine.

These projects will be considered in light of the availability of staff and financial resources.

Ongoing Demand Side Activities

The following need to be incorporated into the Demand Side programme:

Website

This would include updating PHARMAC information and matters of relevance to the healthcare industry. If managed properly, this site could be used as a valuable marketing mechanism for PHARMAC's aims and activities and could provide users with educational material and information.

Publications/Articles

PHARMAC supports the publications *Healthy Scepticism* and, through the HFA contract, *PreMec Medicines Information Bulletins*.

It is important that PHARMAC use all available opportunities to contribute articles/advertorials to journals and industry publications, directly or through contracted authors. It is intended to feature regular articles in the NZNO, RNZCGP, NZMA and other organisational publications and electronic media.

Support

PHARMAC is approached by a large number of organisations requiring financial support for congresses, workshops, tradeshow and lectures. It would be in PHARMAC's interest to consider sponsorship of those activities from which it would gain the largest exposure. In the

case of conferences, it would be good to negotiate conference fees for those attending, the presentation of a paper and promotional space.

In 1999, PHARMAC is sponsoring the speaking tour of Dr Peter Mansfield (MaLAM). It would further PHARMAC's aims to invite and contribute towards the costs of other such tour in the future.

Promotion

PHARMAC has no corporate promotional material, except for a stand and its Annual Review. The Demand Side team will compile a package of materials relating to PHARMAC, what we do, how we do it and why we do it. Give-aways should be available as well as handouts/pamphlets on current and ongoing PHARMAC activities.