PHARMAC

BUSINESS PLAN

2000-01

July 2000

PHARMAC BUSINESSPLAN 2000-01

EXECUTIVE SUMMARY

The theme for 2000-01 is the further development of the supply side tools for the management of expenditure and the development of the Demand Side. These initiatives will continue to support PHARMAC's goal of optimising the Government's expenditure on pharmaceutical subsidies. This means we want to strike the right balance between pharmaceutical subsidies and other forms of healthcare, and with pharmaceuticals.

These initiatives will require balancing commercial objectives with responsiveness to doctors' concerns about the impact on patients. It will involve further development of PHARMAC's relationships with external parties.

We are forecasting moderate growth in pharmaceutical expenditure of 2-3% in 2000-01. The outcome will be influenced by:

- the negotiation of subsidy reductions, particularly in relation to a range of significant products about to come off patent;
- the level of underlying growth and whether there is a mild or severe winter;
- Government policy and whether we are directed to fund certain drugs;
- the effectiveness of demand side activities at restraining growth.

Important developments that it is anticipated will occur in 2000-01 include:

- completion of the OPPs review and implementation of a revised set of OPPs;
- encouraging the Government to review, and preferably restrict, direct to consumer advertising;
- implementation of a co-ordinated demand side strategy focused on major expenditure risk areas – especially those where we lack pricing or contracting tools to manage expenditure;
- continued emphasis on using cost-utility analyses to inform decisions on new investment;
- development of an integrated information strategy;
- assessment of current arrangements and potentially implementing new arrangements for access to pharmaceutical subsidy data;
- implementation of a new system for special authority applications and authorisations.

These developments will take place within a health sector that will be subject to significant change. PHARMAC will need to be attentive to the restructuring occurring within the HFA and Ministry of Health to ensure that:

- PHARMAC maintains its exemption from the Commerce Act;
- the optimal structure with appropriate accountabilities is put in place for PHARMAC;
- relationships with other organisations and functions – pharmacy claims processing, pharmacy contracting, GP contracting – are maintained and strengthened.

PHARMAC BUSINESSPLAN 2000-01

Introduction

The theme for the 1999/00 PHARMAC Business Plan was the changing environment, with a discussion of the consequent changes in PHARMAC's operations. This year the Business Plan focuses on the further development of the tools for managing pharmaceutical expenditure, with a particular focus on prioritisation of new investments and on the Demand Side (ie tools for influencing the demand for pharmaceuticals).

PHARMAC had another successful year in 1999/00. It was able to implement a number of transactions, thereby increasing the efficiency of the Government's investment in pharmaceuticals.

It is vital that PHARMAC is able to continue to apply existing strategies as well as to develop new strategies free of disruptions if the Government and New Zealand taxpayers and patients are to continue to see the benefits.

Contents

The report is divided into five parts:

1. The outcome of the 1999/00 year: a description of the expenditure outcome for 1999/00.
2. Pharmaceutical Expenditure in 2000/01: our forecast.
3. Strategic direction: where are we going?
4. Operational development: more detail on our operations.
5. Delivering in 2000/01: Savings and investments.

Appendix: Overview of Operational Plans by Therapeutic Group.

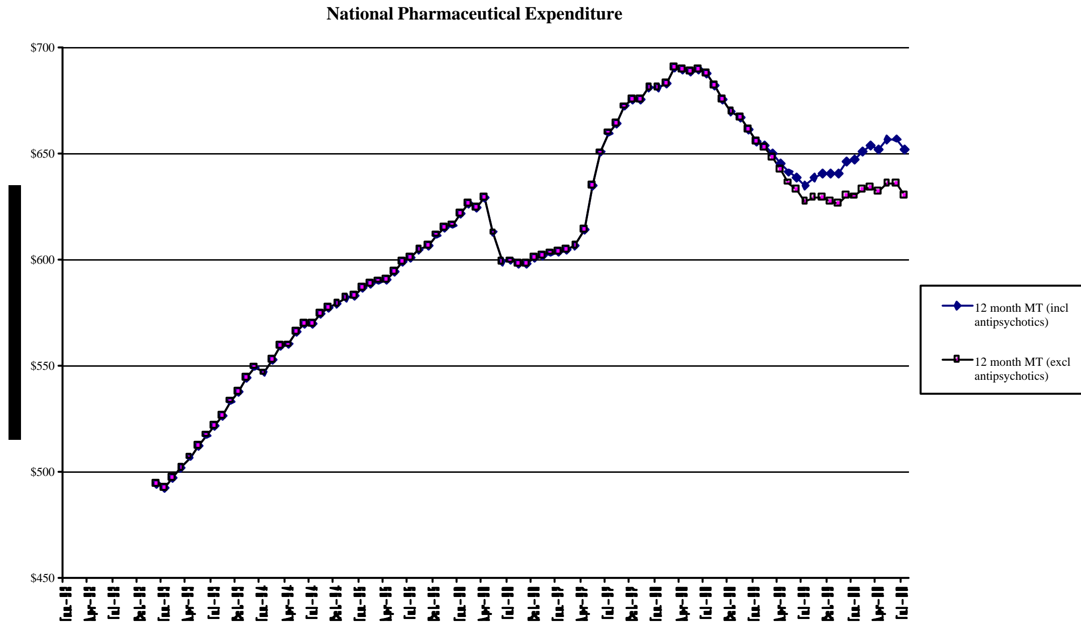
1. PHARMACEUTICAL EXPENDITURE IN 1999-00

Commentary

Pharmaceutical expenditure in the 1999/00 year increased due to the addition of new expenditure on anti-psychotics out of the Personal Health budget. Excluding the new anti-psychotics, expenditure was flat compared with the previous year.

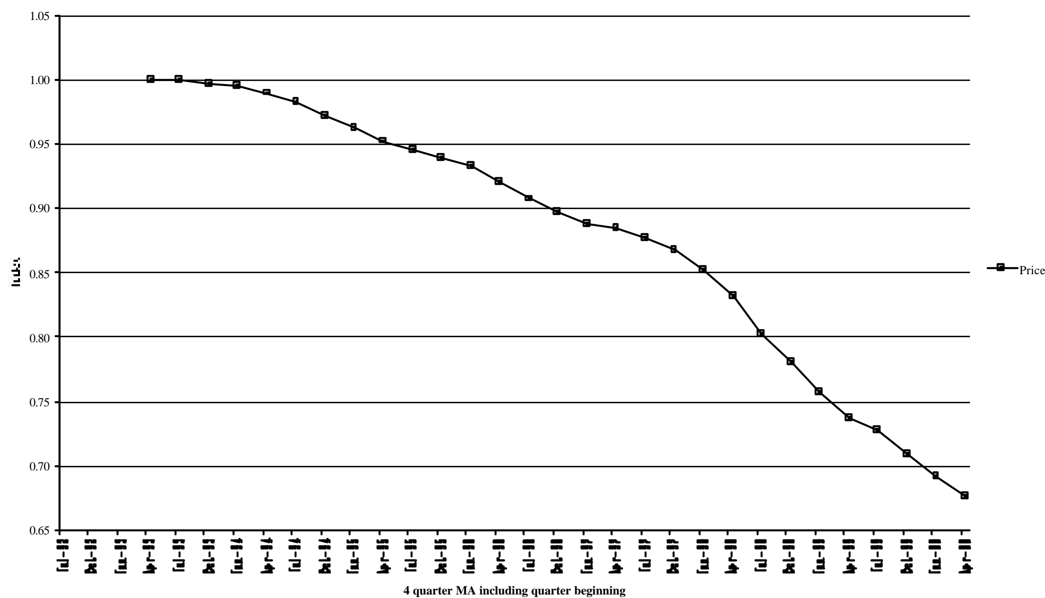
As a result of the addition of new anti-psychotics to the Personal Health budget and the consequent transfer of funds from Mental Health to Personal Health, the Funding Agreement target was revised to $657.25 million. It should be noted that the Personal Health target was set at $649.25 million and included an allowance for $2 million worth of new investments. However due to an increase in the amount of savings and a better estimate of the amount of potential rebates, new investments were funded within the current target.

The annual impact of savings in the 1999/00 year is estimated at $45 million.

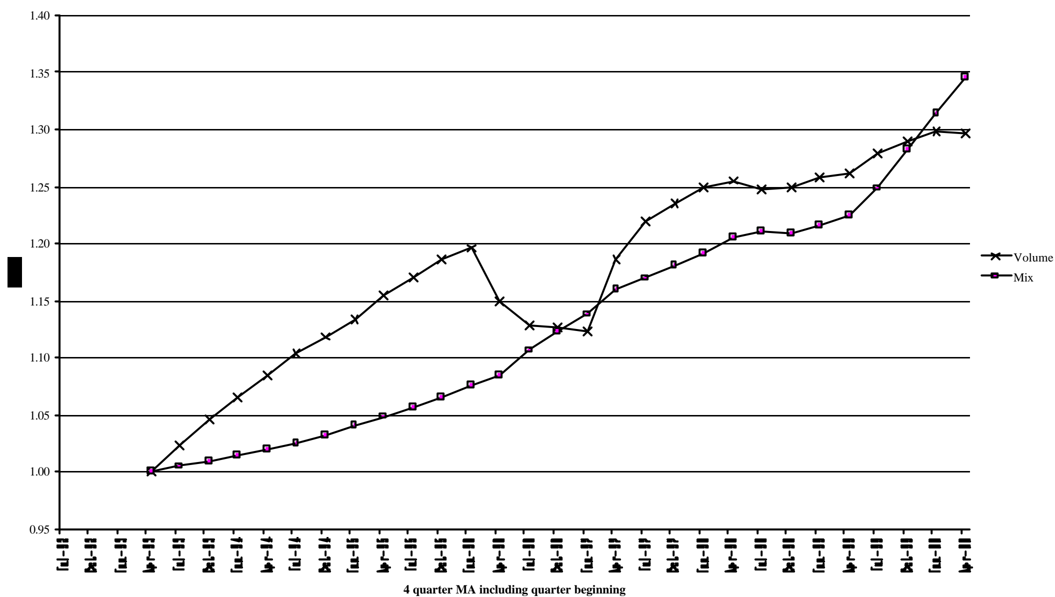


PHARMAC's performance is in line with its performance targets for the 1999/00 year, which were to assist the HFA in meeting a target annual budget of $649.25 million.

The main factor enabling PHARMAC to meet this target was continued price reductions. This is reflected in the price index, which clearly shows a strong downward trend.



Mix continues to be the main driving force of pharmaceutical expenditure. This is particularly evident in the markets for anti-psychotics and statins, where there has been a substantial shift to the newer more expensive agents.



Volume, on the other hand, appears to have been static over the last year. This could be attributable to the mild winter or the effect of tendering on subsidy levels (ie reducing subsidies so that the charge on prescriptions falls below $15 with the result that a large number of claims go unrecorded since there is no cost to be paid by the HFA). We will undertake further analysis the coming year to assess the causes and longer-term implications of these reductions in volumes.

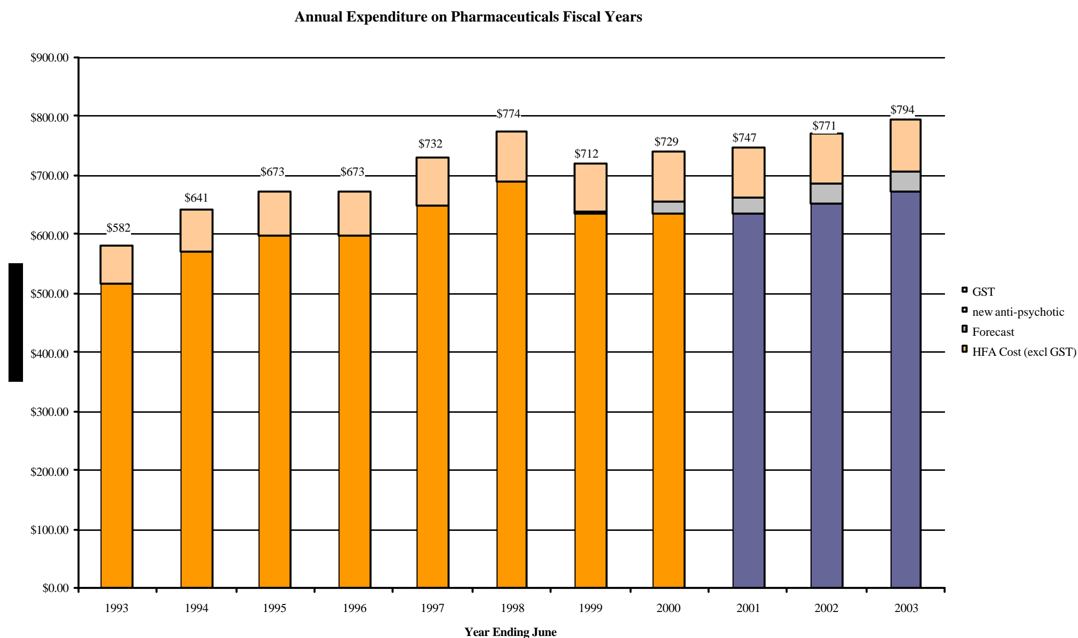
It is expected that the mild winters will not continue and that volumes are, therefore, likely to rise in the following years, which will then place pressure on PHARMAC to continue to lower subsidies.

2. PHARMACEUTICAL EXPENDITURE IN 00/01

PHARMAC aims to continue to lower subsidies through price competition initiatives

In 2000/01, we expect the underlying growth resulting from increasing mix interaction to continue. Volumes are expected to increase as normal winters resume, although the increase may be less than expected due to the continuing effects of tendering on subsidy levels and prescription charges, ie reducing prescriptions to under the $15 threshold.

The graph below shows the expected expenditure over the next 3 years. The forecasts shown in the graph were developed at a high level. When making these forecasts we tried to account for the cumulative impact of new investments and of savings and rebates in the later years. It is difficult to derive accurate figures for the later years because many investment decisions beyond 1999/00 will be made in relation to drugs for which we have not yet received applications and which we only know about from our study of the drug pipeline.



Target setting for 2000/2001

We have advised the Ministry of Health and the HFA of our view that base expenditure for 2000/01 will increase by about 2.5% after accounting for new anti-psychotics. Without new anti-psychotics expenditure is expected to remain flat over 2001.

Forecast Risks

Underlying growth

We anticipate a return to previous volume growth rates compared with the lower figure of 0-2% in 1998/99, which resulted from a milder winter and possibly other factors such as slower

population growth and more prescriptions falling below the $15 co-payment level. The major risk for 2000/2001 is the size of the winter seasonal increase in prescription numbers. A cold winter in 2000/2001 could see a volume increase of up to 7%.

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

Demand side activities

PHARMAC's continuing focus on demand side activities should help control volume and mix in the later years. The positive impact of these activities has yet to be quantified.

Summary of risks

The risks can be classified as either external or administrative. External risks are to a large extent outside of PHARMAC's control. We do, however, have some ability to influence administrative risks.

Administrative risks are dominated by internally generated implementation slippage. The development of high level forecasts also creates some risk. However, we also plan to develop forecasts from low level indices and it is thought that these will give a firmer idea of what to expect in later years.

How does the forecast 2000/2001 year's effort compare to past PHARMAC performance?

In terms of realised savings, the 2000/2001 year looks to be full of savings opportunities. Although expenditure will begin to increase, PHARMAC's activities should keep this to manageable levels.

3. STRATEGIC DIRECTION

Defining PHARMAC

PHARMAC's goal is to optimise the government's expenditure on pharmaceutical subsidies. This means we want to strike the right balance between pharmaceutical subsidies and other forms of healthcare, and also between different pharmaceuticals.

PHARMAC has been effective. We have expanded the range of subsidised pharmaceutical therapies while maintaining the growth in NZ pharmaceutical expenditure to a level that is below that of other countries. However, PHARMAC is perceived by some as being concerned solely with cost cutting, not health care. In addition, PHARMAC is sometimes blamed for increasing doctors' administrative workload, especially where additional paperwork is associated with strategies for managing pharmaceutical expenditure.

A number of doctors support PHARMAC's commercially pro-active approach to the drug companies. Where doctors do have concerns it is usually in relation to the impact of PHARMAC's strategies on patients, on their workloads and on their incomes, as well as the range of treatments that are available to them to offer to their patients. PHARMAC takes doctors' concerns into account in the course of its decision-making, particularly so over the last 2-3 years.

Areas that we need to continue to focus on are:

- integrating demand side activities focussing on the effective use of pharmaceuticals into PHARMAC supply-side programmes;
- implementing savings decisions (potentially foregoing some short term savings);
- planning transactions over the medium term to avoid frequent and repeated disruptions to patients' treatment;
- simplifying the administrative demands on doctors with respect to determining eligibility for subsidies (such as the Special Authority system); and
- demonstrating that we are listening to doctors by either acting on their suggestions and consultation responses or by explaining why we have chosen not to do so.

We also need to promote the same messages as we have done in the past about the way in which we use cost utility analysis to identify high value items and then take away funding from low value items in order to fund those high value items. We also need to stress that savings are not valued in their own right, but for the opportunity that they give us to fund other healthcare – as our ability to fund new treatments is dependent on making savings on other drugs.

Changes to the way in which PHARMAC operates have implications for internalprocesses such as the weight we give external opinions, the way transactions are planned and processed, and how we prioritise different projects. It is important that any solutions we put in place, especially in terms of improving communication with the medical profession, are not overly burdensome on staff time. The goal is to construct a PHARMAC that is comfortable within itself and also comfortable within its external environment.

Changes in the Health Sector

The new Government's health policies are emerging as a significant influence on PHARMAC's operating environment. During the 2000/01 year, the HFA will be dissolved and replaced by an expanded Ministry of Health and a number of District Health Boards (DHBs). It appears increasingly likely that a substantial amount of the responsibility for funding healthcare will be devolved to the DHBs.

It appears to be widely accepted that PHARMAC's role and functions, including management of the Pharmaceutical Schedule, should remain centrally and nationally organised. However, it is likely that PHARMAC will end up operating as an agent of the DHBs. PHARMAC's goal will be to manage the relationship with the DHBs in such a way that we can clearly demonstrate that PHARMAC is able to manage national pharmaceutical expenditure effectively and efficiently.

Review of the Operating Policies and Procedures

The 2000/01 year will see the completion of PHARMAC's review of its OPPs and will be the time to put these new procedures into place. We anticipate that the new OPPs (currently yet to be finalised) will give new players in the sector a better understanding of PHARMAC's roles and functions and thus will contribute to a greater clarity in the market place.

Maori and Pacific Peoples' Health Needs

The coming year will see the development of strategic policies and practices to document how PHARMAC intends to respond to Maori and Pacific peoples' health needs through the making available of pharmaceuticals. We started the ball rolling at the beginning of 2000 by incorporating an additional criterion into the new OPPs requiring PHARMAC to take "the particular health needs of Maori and Pacific peoples" into account when making decisions. The new OPPs also include a provision that states that PHARMAC is committed to the principles of the Treaty of Waitangi. These statements now need to be supported by specific policies at a strategic level. We intend to carry out consultation during the year on the development of these policies. It is likely that this consultation will also include:

- ways of providing better access to pharmaceuticals;
- the development of strategies to monitor whether Maori and Pacific peoples' health needs are being met by pharmaceuticals;
- the development of staff education and training programmes about the health needs, cultural values and protocols of Maori and Pacific Island societies;
- recruitment of Maori within PHARMAC staff; and
- establishment of Maori and Pacific peoples advisory groups.

PTAC

The Ministry of Health has completed its review of the process for appointing PTAC members. As a result, PTAC members are now appointed following a process of advertising for nominations according to a job description and person specification. The PHARMAC Board will continue to make the final appointment decision.

In order to make the processes around PTAC operations more transparent, a draft PTAC Manual has been prepared. The Manual describes step by step how meetings are organised and managed. Once the draft Manual is complete, we intend to consult and make it public, hoping that the industry and medical sectors and other interested parties will come to a better understanding of PTAC's role and functions and its relationship with PHARMAC.

Media

PHARMAC continues to see the media as the major means of raising awareness of resource allocation issues. Advising patients of the health service provided by the government is an important part of PHARMAC's role. PHARMAC plans to continue the approach of publicising not just the decisions that result in large savings but also those that on their own result in distinct health gains.

We are working to improve and increase our public relationship with prescribers. This is being achieved by regularly liaising with them on media issues and releases and also by dealing directly in the first instance with doctors who regularly comment publicly. The PHARMAC Demand Side team has also helped to improve the way in which PHARMAC is perceived by some sections of the medical profession.

Management of Political Information

Our use of Viewpoint Communications has enabled us to take a proactive stance so far as keeping Members of Parliament informed is concerned. PHARMAC has made a concerted effort to keep all politicians in touch with key developments and to develop clear, two way communication channels.

This approach has benefited both PHARMAC and politicians – many of whom have commented positively on the information flow.

Demand driven expenditure / direct to consumer advertising

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

In the past year we have seen the pharmaceutical industry shift its emphasis from calls for, and an expectation of, endless growth in Government funding of pharmaceuticals to targeting private funds. There has been a significant growth in direct to patient advertising, and this growth is continuing. This marketing is often based on emotion rather than information, using fear or vanity to encourage people to pay for a medicine, when a fully funded and much cheaper alternative may be available.

In some cases this advertising is used to promote the use of funded medicines, to encourage the use of a particular brand or just to grow the market in a particular area. The one thing that we can be sure of is that the pharmaceutical industry regards the goal of increasing health gain as being subservient to growing profits[1].

We do not consider the public advertising of prescription medicines to be at all 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;
- unnecessary concern amongst 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); and
- undermining public confidence in the state funded health care system.

PHARMAC attempted to use the complaints procedures administered by the RMI and the Advertising Standards Complaints Board to remedy breaches by direct to consumer advertisers and other advertisers of the relevant industry codes. Ultimately, however, the minimal sanctions provided for by these codes render them relatively ineffectual as a deterrent.

We will continue to take action where appropriate to control the industry's activities. This will include ongoing work with Medsafe to ensure that the current Medicines Act and Regulations are appropriately enforced.

Demand Side

The PHARMAC demand side team's strategy for the coming year is to build on the successes of the current year, identify new opportunities and target key therapeutic areas requiring demand side activities – all in an effort to maximise savings while at the same time remaining focussed on improved health outcomes.

The coming year will see the demand side team undertaking a number of projects that it is anticipated will produce measurable gains in controlling the rate of expenditure on pharmaceuticals. The projects will focus on key high expenditure areas in terms of volume and mix. A systematic evaluation of the risk areas has been undertaken and a number of specific projects are being planned for implementation. The demand side strategy has been developed to

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[1] Highlighted this year by the behaviour of Lundbeck, a company that chose to withdraw its antipsychotic drugs as a lever in a contract dispute.

ensure that activities target areas where gains can be made in savings through creating a shift in volume and/or mix, while promoting best practice initiatives.

Activities targeting specific therapeutic areas will be agreed by the demand side team and the relevant Therapeutic Group Managers. This will ensure that any demand side activities are developed with an understanding of the issues relating to the targeted therapeutic group as a whole. This will minimise risk and ensure that demand side activities are integrated into the general PHARMAC programme.

In addition, the team will continue to support supply side transactions and undertake implementation programmes as they arise.

As well as developing and implementing projects in high-risk areas and supporting supply side initiatives, the demand side team will continue to manage referred services contracts.

Responsibility for the management of referred services contracts was transferred from the HFA to the PHARMAC demand side team in 1999. The demand side team currently manages the Preferred Medicines Centre (PreMeC) contract and the Best Practice Advocacy Centre (BPAC) contract on behalf of the HFA. Then in July 2000 the demand side team took over responsibility for contracting with the referred services providers – as well as managing the PreMeC and BPAC contracts. A review of referred services management is to be completed prior to entering the 2000/2001 contracting round, however. The findings of the review will impact on the services contracted for in 2000/2001.

The demand side team also works proactively with other groups offering referred services management, such as Primary Care Organisations (PCOs). Building relationships with groups within the health sector, such as PCO pharmacy facilitators, representative medical and pharmacy groups and other interest groups has been, and will continue to be, a key focus for the demand side team. It is important to work with these groups to ensure the smooth implementation of projects and buy-in of key messages. Whenever possible, and without compromising its own independence, the PHARMAC demand side team endeavours to collaborate with these and other organisations to maximise results.

Evaluation is a key component of any activity undertaken by the demand side team. Work was undertaken over the first 6 months of 2000 to develop robust evaluation tools to measure the results of those demand side activities that are outlined later in this Plan. This focus will be a continuing one - adequate concurrent monitoring must occur in order to ensure that trends can be analysed and the effectiveness of the team's activities monitored.

Cost Utility Analysis

Background

Cost effectiveness analysis is key to justifying additional spending on the Pharmaceutical Schedule. Such spending can be the result of listing new chemical entities or of widening access criteria to drugs already listed on the Schedule. Before deciding to list new chemicals or expanding access to drugs, PHARMAC almost always considers the cost effectiveness of such a decision.

Cost effectiveness analyses are most useful when they use a common denominator of health benefit. Increasingly, health benefit is being measured through estimating the changes in the

Quality Adjusted Life Years (QALYs) created by an intervention. QALYs estimate the effect of an intervention on quantity of life adjusted for its quality or the relative utility an individual gains from it (relative to perfect health). Studies that calculate the cost per QALY gained from an intervention are, therefore, frequently called cost utility analyses. Using a common denominator of health (while potentially limiting its sensitivity to measuring changes in health outcomes) enables different interventions to be compared. By selecting those interventions with the lowest cost per QALY, the greatest gain in health benefit can be obtained for any given budget.

As budgets become tighter relative to the costs of new interventions, the quality of decision making is expected to improve. As such decision making relies heavily on cost effectiveness analyses, the quality of the analysis demanded steadily rises. This demand is generally met through making the analyses more detailed (i.e. through greater disaggregation of the data) rather than through gaining access to more accurate and complete information. The modeling, therefore, takes more time but the underlying accuracy may not be enhanced.

Also, as budgets become tighter, access to new drugs is further and further restricted to those patients considered likely to benefit the most. Cost utility analyses are, therefore, becoming key to determining targeting criteria, again, through greater and greater call upon disaggregated analysis.

Issues

PHARMAC has a small resource devoted to cost utility analysis. Further, the capacity for TGMs to do their own analyses diminishes as the value of rough analyses diminishes and the value of detailed analyses increases. Outsourcing analyses is also unlikely to help for the following reasons:

- the work is required for policy purposes not research purposes – it therefore needs less effort devoted to presentation and more devoted to detailing results (this makes the work less attractive to those available for hire);

- PHARMAC is likely to require repeat analyses on a "drop everything and do it now" basis – a requirement that contractors are seldom able to meet;

- specifying such a service agreement would be difficult and is likely to be very costly, particularly if sought from a research house / consultancy group in which PHARMAC could have confidence in the results.

Possible responses

To meet the challenges, PHARMAC will need to ensure that its small cost utility analysis resource is applied as efficiently as possible and is as efficient as possible. This could be effected through the following actions:

- making PHARMAC's indicative assessment process more objective and systematic to ensure that the highest valued proposals are worked on first;

- since much of the indicative assessment relies on appraisal of trial data, PHARMAC could achieve efficiencies in this process by improving its in-house critical appraisal skills;

- its specialist modelers should devote time to learning how to model as efficiently as possible and all knowledge gained in this area should be transferred both within this team and to all PHARMAC staff required to produce quantitative analyses.

Proposed PHARMAC actions

Next 18 months

- systematise the indicative assessment process;
- run quarterly critical appraisal workshops;
- reassess work priorities;
- complete assessments according to the work priorities list; and
- complete an assessment of Treeage (at the level of Markov modeling for a cohort of patients) and disseminate gains made in this area.

International Contacts

In late 1998 PHARMAC management met with senior staff from a number of countries 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. Beyond these immediate benefits, there may emerge benefits from a more co-ordinated sharing of data (or even a more co-ordinated approach to purchasing or subsidising pharmaceuticals), though we consider this is some way off.

For example, the South African contingent was 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.

There has been no further development of this concept. A promised follow up meeting in the Netherlands in 1999 never eventuated. However, we hope to make further contact with other purchasers this year.

Information Strategy

The theme for the 2000/01 year is consolidation. Some recent redevelopments have yet to reach their full potential, so the focus needs to be on the detail rather than the structure. There may be less expenditure on hardware and systems, but there will be an ongoing need for contract workers to tidy up data to make that data fit for publication and analysis.

PHARMAC's goal is to adopt a coherent strategy covering how we supply, use and receive information. The focus of this strategy is to be on: effectiveness – information being an effective tool to support PHARMAC's key business activities; efficiency – PHARMAC using information at least financial and resource (particularly staff time) cost; timeliness – information being supplied to or by PHARMAC at the time that it is required.

In order to implement this strategy we will need to improve coordination of the information we are providing (primarily the Schedule) and the information we are receiving (Pharmhouse). As a result, issues that will need to be dealt with during the 2000/01 year will include:

- resolution of issues surrounding organisation of data and databases vis-a-vis Schedule and PharmHouse use;
- development of the Schedule – including the role of the Schedule within pharmacy electronic claiming and printing from the database;
- development of PharmHouse – including assessing the implications of the dissolution of the HFA, preparing for contract renewal in September and assessing the implications of any restructuring of HBL in terms of its ability to continue to supply data;
- development of a service-level agreement with HBL that sets out the responsibilities and obligations of PHARMAC in relation to the Pharmaceutical Schedule and of HBL in relation to the supply of data to the Pharmhouse; and
- the need to heed the lessons contained in the Auditor General's Report on electronic claiming, especially the need to develop a project plan and to have thorough project management where any information related project is concerned.

Local network

Goal

A productive work environment for PHARMAC staff that is flexible yet secure, independent and robust.

Current position

Generally local services are performing satisfactorily, although some degradation in performance occurred with the upgrade to WindowsNT without a simultaneous hardware upgrade. There were also some lingering issues that arose as a result of the relocation, but these now appear to have been resolved.

Opportunities

The relocation of Matthew Brougham to Hamilton necessitated the provision of remote access. The experience gained from this may enable a more flexible work environment to be provided for other staff.

We now have limited access to HFA resources such as the Intranet.

Website

Use of this media to promote PHARMAC's objectives could be developed further. The "Interactive Schedule" is already quite popular and may become a viable alternative to the printed Schedule for many subscribers.

Pharmaceutical Subsidy Database

Goal

A robust and efficient means of recording pharmaceutical subsidies and dissemination of timely and accurate data to:

- pharmacy electronic claiming systems;
- data analysts;
- prescribers; and
- patients.

Risks

The Pharmaceutical Subsidy Database is now used directly for electronic claiming and will soon become the authoritative version of the Pharmaceutical Schedule. Any problems will, therefore, directly affect pharmacy claiming systems.

Risks identified in last years Business Plan, namely poor database software and multiple coding systems, have been addressed successfully, and effort is now being focused on improving data quality. A considerable amount of data proofing has been undertaken and as a result the number of reported errors has decreased substantially.

PHARMAC has produced a Quality Management Plan covering data entry and editing and we are now have a lot of confidence in the ongoing accuracy of the database. This Plan and our adherence to it will be subject to an independent audit.

Even when the database is 100% correct for electronic claiming purposes, further work will be necessary to clean up descriptive data and make it more consistent with other systems such as the British National Formulary and legacy HBL data.

Opportunities

The following opportunities were identified last year:

- publication of the Pharmaceutical Schedule direct from the Pharmaceutical Subsidy Database;
- adoption of a more efficient user interface to the Database; and
- encodement of restrictions to permit more thorough checking under electronic claiming.

The priority for this financial year will be consolidation of these systems to ensure stability. Other systems such as Pronet and pharmacy claimants will be encouraged to use the database directly.

Tighter integration with other PHARMAC systems such as the contract monitoring database will be pursued once the subsidy database has been sufficiently stabilised.

Special Authority System

The current Special Authority system requires applications to be evaluated by clerical staff against a set of text based rules - an expensive and cumbersome process. If the rules were expressed in Extensible markup language (XML) the application process could be automated and PHARMAC would gain greater control over this process.

PHARMAC, in conjunction with HBL, the HFA and various medical groups, will investigate alternative approaches to the current special authority regime.

4. OPERATIONAL DEVELOPMENT

Environment

Organisational and political environment

Minister of Health

PHARMAC will keep the Minister fully briefed on all significant matters during this year. Based on our early experience, the Minister and the new Government are supportive of PHARMAC's approach to management of the Pharmaceutical Schedule.

Health Funding Authority/Ministry of Health

Changes during this year will affect PHARMAC's operations. At this stage it remains unclear exactly how much these changes will affect PHARMAC's day-to-day business, however we can expect that some of the following issues will require attention during the year ahead:

- Structural development: The New Zealand Public Health and Disability Bill establishes PHARMAC as a stand-alone crown entity. It will be important to ensure that PHARMAC forges close links with the appropriate staff within the Ministry of Health and the new DHBs.

- Budget setting: PHARMAC will need to work with the Ministry of Health to develop the process for the setting of the pharmaceutical budget. We will aim to establish, amongst other things, clear budget targets (preferably three year targets); clear mechanisms to shift funds between pharmaceuticals and other health care as appropriate; and clear prioritisation methods that reduce the risk of cost shifting between sectors.

Health Benefits Ltd

Changes in pharmacy claiming means that PHARMAC and HBL's activities are becoming more and more integrated - with PHARMAC now exporting the Schedule database directly to HBL. (Previously, HBL maintained its own Schedule database for pharmaceutical pricing.) These changes create challenges. Fortunately, there is a shared vision of how the Schedule database will be used and good communication between both sides. Maintaining an effective working relationship with HBL will be important during the 2000/01 year.

We aim to formalise the arrangements between HBL and PHARMAC, so that there are no misunderstandings between the two organisations over their respective roles and responsibilities.

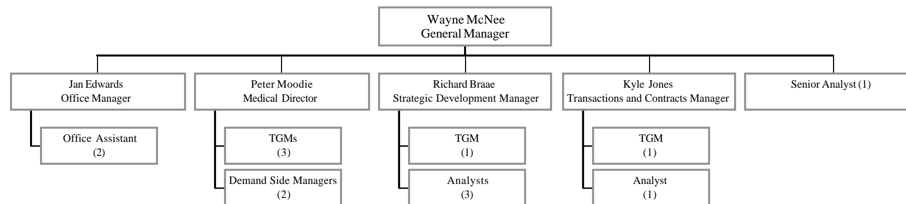
Physical environment

During this year, PHARMAC will either remain in the Old Bank building (with significant further development work being undertaken to improve the space), or will move to an alternative office.

At this stage, management would prefer to move to purpose-built office space.

Personnel issues

PHARMAC currently employs 19 full time staff, plus a number of staff on contract to undertake specific projects. The staffing structure is as shown below:



PHARMAC Team Development

This year will provide us with an opportunity to rebuild the PHARMAC team after a period of intense pressure and change. We propose to review our medium to long term strategy this year, taking a close look at both the supply and demand side of pharmaceutical management. As part of this review we will be assessing the skill mix of the team, and undertaking any necessary skill development.

PHARMAC's therapeutic group management structure has been one of its major successes. The embryonic "integrated care" model that it creates has resulted in significant leverage for PHARMAC. TGMs are well placed when negotiating with suppliers because of the level of their knowledge of the therapeutic area in which they are working.

Risk Management

We will continue with the same process of risk management as currently used. This involves reviewing all risks on a monthly basis and passing this report through to the Board. Risk management processes, such as the business continuity plan, will be reviewed as necessary.

5. DELIVERING IN 2000/01 – SAVINGS AND INVESTMENTS

Price competition initiatives

Overview on initiatives to date

New Zealand has historically had high prices for off-patent pharmaceuticals. Since 1997, PHARMAC has undertaken a series of initiatives to lower prices in these markets. The principal techniques used have been preferred brand arrangements, sole supply and tender protection contracts (where incumbent suppliers have reduced prices of certain products in return for PHARMAC agreement not to tender products).

The results of these initiatives are summarised below. Figures are approximate and include the effects of reference pricing.

Year	*Contract type*	*Annualised savings ($m)*
1997/98	Tender protection contracts (after 97/98 tender consultation) – includes around 20 products from Pacific	$18 million
	Preferred brand – tenoxicam, naproxen, paracetamol liquid, codeine, permethrin, pholcodeine, timolol maleate)	$2 million
	Sole supply 97/98 tender – 15 tenders accepted	$7 million
1998/99	Tender protection contracts after 98/99 tender consultation – contracts with RPR, Novartis, Boehringer Ingelheim and Roche	$7 million
	Preferred brand – atenolol, acyclovir, H2 antagonists loperamide, azathioprine	$15 million
	Sole supply 98/99 multi—product tender	$14 million
	Sole supply contract, RFP – Augmentin	$5 million
1999/00	Tender protection contracts (after 99/00 tender consultation) – Roche, PSM	$1 million
	Sole supply (99/00 tender)	$21 million
Total		$90 million

Future direction

The tender process is likely to become more fragmented with individual tenders or RFPs for large products (as has occurred with Augmentin). Multi-product tenders will, however, probably still take place.

We expect total savings using the price competition tool kit to be similar in the next three years to the levels achieved in the past year. However, more forecasting work still needs to be done in order to verify this expectation, eg the likely prices of products to come off patent in the next three years and timing and sources of supply for these products.

Savings are more likely to be driven by large products that have recently come off-patent, and by the re-tendering of smaller products resulting in diminishing returns..

Price competition initiatives expected for 2000/01

We expect savings from price competition initiatives in the 2000/01 year to probably exceed $20 million. Possible candidates would be:

- products protected until July 2001 (or earlier) from price changes that are due to tendering;
- large products recently or soon to come off patent;
- small products not included in tenders/ RFPs so far;
- products that were tendered in 97/98 and that can now be re-tendered, in particular, cefaclor.

Pipeline

Undoubtedly, the industry is becoming increasingly focused 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. (Although the most-prescribed drug ever in the US is currently the new COX-2 inhibitor, celecoxib).

It is partly thanks to this new direction that pharmaceutical sales in the 12 leading world markets in 1999 maintained a good growth (around 6-8%) led, once again, by a strong performance in North America (over 10%). Financial and economic crises in Asia and Latin America hit those markets hard, while the patchy European market was able to register some consistent growth by the end of the year (around 6%), despite continued pressure on pricing and reimbursement. Pharmaceutical sales to retail pharmacies in Australia/New Zealand rose by around 7% (all of which was accounted for by Australia).

Increasing R&D productivity remains a high priority for the entire industry. It is expected that the benefits of the huge range of new technologies, such as genomics, proteomics, combinatorial chemistry, mass screening and rational drug design will soon materialise in the form of new products that have reached the end stage of development. 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. Oncology in particular represents an area of intensive research, with reports of up to 300 new drugs currently under trial world-wide.

Some of the areas in which we may see applications for new products in the near future are outlined below.

Cardiovascular

According to PhRMA (Pharmaceutical Research and Manufacturers of America) more than 104 different drugs were in development against heart disease in 1999. Some of these drugs could come to the market in the medium term.

Gene therapy and genetic engineering are starting to play an important role in the development of therapies for ischaemic heart disease. The research focusing on angiogenesis is of particular

interest although it is too early to say if this approach would be successful in the near term. If approved, such therapies could make coronary artery bypass surgery obsolete as patients with untreatable chest pain could possibly grow their own coronary bypasses. Other therapies that might change the way coronary artery disease is treated include: ranalozine, oral glycoprotein IIb/IIIa inhibitors or the most recently approved by the FDA single bolus tenecteplase - thrombolytic agent for MI. Interesting new treatments for heart failure include: b-type natriuretic peptide for acute CHF or new generation of beta blockers for chronic CHF. For hypertension it appears that the most important development may be the new vasopeptidase inhibitor omapatrilat although there is still some controversy around the higher risk of developing angio-edema.

Antibacterial

For some time R&D in this area has been relatively quiet. However, with the increasing concerns of antibacterial resistance, companies are refocusing on new therapeutic agents. Sparfloxacin (Zagam) and grepafloxacin (Raxar) are both third-generation quinolones developed by Rhone Poulenc Rorer and Glaxo Wellcome, respectively, to address this problem of antibacterial resistance.

Musculoskeletal

The first drug ever indicated for delaying structural damage in rheumatoid arthritis, leflunomide (Arava), has been introduced in the US market, although reaction to its effectiveness has been mixed. For patients who have failed on disease modifying agents, the novel mechanism of action of a new product against rheumatoid arthritis, etanercept (Enbrel), could soon become a powerful, although expensive alternative. COX-2 inhibitors for the management of arthritis pain are also being introduced to the NZ market.

Osteoporosis

Lilly's raloxifene (Evista) is the first selective oestrogen receptor modulator (SERM) to reach the market and has been developed as an alternative to hormone replacement therapies for preventing bone loss in post-menopausal women. Risedronate (Actonel) has been just launched in US as a bone formation stimulant for the treatment of Paget's disease.

Diabetes

Glitazones are the type of products that may have great growth potential in this market and we expect them to reach NZ soon. Troglitazone, before being withdrawn, became one of the fastest growing products in the US market with annual sales of US$500 million. We expect that as a result of the troglitazone withdrawal there will be some caution initially among doctors when prescribing rosiglitazone.

Neurology

For the treatment of Alzheimer disease, tacrine is expected to reach the market in the short term. Carbegoline is an anti-Parkinson drug being developed by Pharmacia & Upjohn, for which marketing approval is now being sought in some countries.

Psychiatry

What initially appeared as promising drugs for the treatment of schizophrenia, sertindole and ziprasidone, received a setback in 1998 when serious side effects were identified.

Respiratory drugs

A second leukotriene antagonist, zafirlukast, is expected to reach the NZ market soon. At this stage it is difficult to predict if leukotrine antagonists will be more widely used for the treatment of asthma.

A humanized anti-IgE (E25) monoclonal antibody Xolair is probably the single most important development that may change the way allergic asthma and allergic rhinitis are treated. The product has successfully completed Phase III clinical trials in both allergic asthma and seasonal allergic rhinitis. FDA and European registration for both indications is expected to come by mid-2001. If approved, E25 will be administered by subcutaneous injections once or twice per month. It is expected that a use of E25 would reduce the demand for inhaled short acting beta agonists and inhaled steroids and improve the quality of life of asthma and allergic rhinitis patients.

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 must be completed in order to achieve the expenditure targets.)

Project	Priority	Action needed
Demand side management	High	Focus and resources
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.

PHARMAC

2000/01 Business Plan

Annex: Detailed Analysis

STRATEGIC OVERVIEW OF THE NERVOUS SYSTEM THERAPEUTIC GROUP

Current Expenditure

TG level 1 name	HFA Cost ($ million, excl. GST)			Growth rate
	1997/98	1998/99	1999/00	
Analgesics	21.9	21.5	23.7	10%
Anti-convulsants	13.3	15.4	17.4	13%
Anti-depressants	39.3	37.0	32.8	-11%
Anti-migraine preparations	4.8	7.2	8.5	18%
Anti-nausea/vertigo	2.3	2.5	2.6	4%
Anti-Parkinson	7.6	6.8	6.4	-6%
Anti-psychotics	6.3	11.8	26.0	120%
Other CNS agents	1.7	2.3	2.6	13%
Other Beta-interferon	3.3	3.5	3.6 0.5	3%
Total	**100.5**	**108.0**	**124.1**	**15%**

Key information about the group

Pharmaceuticals listed under the "Nervous System" section of the Schedule accounts for about 18% of HFA spending via the Pharmaceutical Schedule.

Contribution to Health Status

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. 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.

Anti-convulsants – 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-depressants – Depression has a high profile and increasing acceptance as a disease state. One estimate is that 5 to 10% of the NZ population (around 5% for women, 10% for men) is suffering from depression at any one time. This would be about 175,000 to 350,000 people (although the mental health subcommittee has recently indicated that the higher estimate is probably too high). 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.

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.

Anti-psychotics – 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 is limited.

CNS Stimulants - 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.

Speculatives – there is too little data on new drugs for the treatment of Alzheimer's Disease to ascertain health benefit at this stage.

Main suppliers

Newer antidepressants - Eli Lilly, SmithKline Beecham, Roche, Bristol-Myers Squibb, Douglas, Lundbeck, Pacific.
Analgesics – Douglas Pharmaceuticals and other generic suppliers, GlaxoWellcome, PSM, Warner Lambert, Pharmacia & Upjohn, Eli Lilly.
Anti-psychotics – Janssen Cilag, AstraZeneca, Novartis, Eli Lilly.
Anti-convulsants – GlaxoWellcome, Reckitt and Coleman, Hoechst Marion Rousell, Janssen Cilag, Novartis, Roche.
Anti-Parkinson drugs – Novartis, Roche.
Anxiolytics – Roche, Pharmacia & Upjohn, generic suppliers.
CNS Stimulants – Novartis, PSM.
Beta-interferon - Schering, CSL.

Reasons for current expenditure trends

Analgesics – subsidy reductions resulting from preferred and sole supplier arrangements for a number of analgesics appear to have reversed the expenditure growth in this therapeutic group. However, despite an expectation of further savings in some areas from the next round of tendering (and agreements not to tender some markets) some renewed growth is expected. This is likely to stem mostly from methadone and long-acting morphine sulphate preparations. Between August 1998 and August 1999, expenditure on long-acting morphine preparations grew by 15%. HFA expenditure for methadone has been steady for the last two years following a considerable increase between July 1996 and 1997. However, numbers of patients being treated via A&D clinics is likely to increase which is expected to lead to renewed growth.

Anti-convulsants – growth in this area is largely due to increased use of the new anti-convulsant drugs (NADs) although use of sodium valproate also appears to be increasing significantly. Over the last year, it has become apparent that the restriction on access to subsidies for NADs (which consists of a distinct budget, limited prescribing rights and eligibility criteria) is being overridden by prescribers. Expenditure for NADs is now in excess of $3.6 million per year.

NADs account for 23% of expenditure for epilepsy in parts of the UK. In New Zealand, they already account for more than 27% of expenditure on epilepsy.

Anti-migraine preparations (mostly sumatriptan) have historically also contributed to the growth in this area. Total HFA expenditure in this area is, likely to be limited to that growth allowed for within the agreed caps. Real growth, however, is expected to exceed those limits.

Anti-Parkinson's drugs – this market is declining despite the listing of a new, more expensive agent, tolcapone in 1998. This is partly because it was listed under a cost neutral agreement but also because there have been safety concerns raised about tolcapone which has limited its use. Price reductions on older agents have also contributed to an overall decline in expenditure for this market.

Anti-psychotics – the sudden increase in expenditure on these agents over the last years and expected rise in subsequent years is partly due to the listing of risperidone, clozapine and olanzapine on the Schedule in February 1999. The initial increase over 1998/99 and much of the apparent increase in subsequent years can be explained by the transfer of the HFA budget for these drugs to the pharmaceutical budget. However, additional investment of $55 million over the next 5 years will be required in order to meet demand for the atypical agents despite commercial arrangements which provide for significant rebates.

Anti-depressants - total expenditure on antidepressants in 1999/00 was about $33 million. 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 may be reluctant to prescribe tricyclic antidepressants. Growth in expenditure on antidepressants has already started to decline and is expected to decline further over the next few years due to generic fluoxetine and paroxetine entering the market. The reason for the initial slowing down of growth 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.

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). We estimate that this growth will continue.

Clinical & Financial Risks and Opportunities

Analgesics

PHARMAC intends to expand on a survey of A&D clinics conducted in 1999 to ascertain patient needs and preferences. Depending on the results of that survey, it may be possible to include methadone in a sole/preferred supplier tender. Alternatively, PSM has offered a straight price reduction in return for listing. Several of these products have increased in price recently, apparantly as a result of increases in costs of raw materials.

Anti-convulsants

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 by the RHAs. The original national budget was $950,000 but since 1994 this amount has been increased three times by the PHARMAC Board because RHA expenditure on NADs consistently exceeded the set budgets. Interestingly, increased growth in use of NADs also appears to have been associated with increased expenditure for conventional agents (mainly sodium valproate):

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 (specifically topiramate and gabapentin).
- Prescriber feel that they do not get enough feedback on their current budgetary constraints.
- Prescribers dislike the administration required under the current system.

During 1998, PHARMAC consulted on replacing the existing funding management systems for NADs with a Special Authority system. At the same time, we invited proposals from suppliers with a view to potentially attracting bids from each supplier that would avoid the need for a Special Authority. It is possible that additional expenditure is required and that Cost Utility Analysis will be necessary to justify this. We also have anecdotal advice that used of NADs is escalating as awareness that the current access criteria are not being enforced grows.

Expenditure on NADs is likely to grow as the focus of the review by the neurological sub-committee of PTAC has been to increase access to these drugs and make available a wider range of options.

Anti-migraine

The HFA is currently funding a range of acute migraine treatments (injections and tablets) under an arrangement with GlaxoWellcome.

Anti-Parkinsons drugs

A review of anti-Parkinson's agents was initiated last year but is yet to be implemented. There may be some opportunity for small savings from reference pricing (at least the dopamine agonists and related compounds and anti-cholinergics).

Anti-psychotics

The recent acceptance of a proposal to widen Special Authority access to olanzapine (and associated additional funding allocated) is expected to enable the provision sufficient access to atypical anti-psychotic agents to meet most of the current demand. However, the new arrangements may also increase the risk of disproportionate use of olanzapine over risperidone and may necessitate demand side initiatives to avoid additional financial risk.

Options for controlling growth are limited due to the nature of this market. This area is likely to be a risk long term (once current cap arrangements expire) because of the inherent difficulties and risks associated with patients switching therapies and related limitations in terms of the application of reference pricing.

Multiple Sclerosis

Applications for the listing of beta-interferon 1 alpha (Avonex) and beta-interferon 1 beta (Betaferon) have recently been approved for funding. Processes and systems have been put in place for selecting appropriate patients to receive treatment and monitoring their progress on the drug. The major focus this year will be on assessing how well these systems are working.

Anti-depressants

This market is in the course of becoming a generic one - given that Prozac came off patent in January 2000. A series of price reductions have been achieved; the major issue now is the implementation of reference pricing within SSRIs therapeutic group.

Newer SSRIs with claims of additional benefit over current SSRIs have arrived and more are on the horizon. We will face the question of the efficacy of these products and the related question of whether the newer serotonin and noradrenaline reuptake inhibitors should be subgrouped separately from the SSRIs.

A number of TCAs were part of the last tender round and resulted in 30-50% reductions on subsidies for these chemicals. A few TCAs were not included (smaller market, only one listed supplier) and may be included in the next tender round.

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 whether we should try to change 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. We could suggest to prescribers, especially budget-holding GPs, that they trial patients first on TCAs then SSRIs with caps before using other SSRIs. Demand side propose a depression project next year.

Central nervous system stimulants

Expenditure continues to increase in this area. Most of the increase is due to methylphenidate, which has been growing rapidly. While the new Special Authority (implemented in February 2000) 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. Note that initially this Special Authority was to have been implemented in April 1999 but was delayed, as a result of administrative and Y2K issues, until February 2000.

Furthermore, due to 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.

Price reductions, via tendering or market cap arrangements, are more likely to be effective in controlling expenditure.

Proposed PHARMAC Actions

Over the next 12 months, proposed actions include:

- Anti-psychotics – initiate activities to promote appropriate use of olanzapine, especially in conjunction with use of risperidone.
- 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 – undertake CUA analysis, conclude negotiations with suppliers, if appropriate consult on and implement new arrangements.
- Anti-Parkinsons drugs – process new applications.
- Multiple Sclerosis – implement Minister of Health's directive to fund beta-interferon.
- CNS Stimulants – consider whether to list long acting methylphenidate.

STRATEGIC OVERVIEW OF ALIMENTARY TRACT AND METABOLISM

Current Expenditure

TG level 1 name	HFA Cost ($ million, excl GST)			Growth rate
	1997/98	1998/99	1999/00	
Anti-ulcerants	36.9	33.5	37.0	10%
Treatment Of Chronic Diarrhoeas	8.0	8.5	8.7	2%
Vitamins and Minerals	6.7	7.0	5.7	-19%
Other	7.6	6.8	6.8	0%
Laxatives	5.9	5.8	5.5	-5%
Cerezyme	0.6	0.7	0.7	0%
Total Alimentary	65.7	62.3	64.4	3%

Main suppliers

Anti-ulcerants – AstraZeneca, Pharmacia & Upjohn, GlaxoWellcome, Wyeth plus key generic suppliers (H2 antagonists).
Treatment of chronic diarrhoeas – Baxter, Pharmaco, Pharmacia & Upjohn.
Vitamins & Minerals – Roche.
Antacids & Alginates – Reckitt & Coleman.
Cerezyme – Genzyme.

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.

Cerezyme – the health benefit of this product is debatable and arguably, dose dependent. Other treatment options are various surgical interventions.

Reasons for current expenditure trends

Antacids & Anti-flatulants – the decline of this market is probably due in part to the increasing popularity of PPI and H2 antagonists and the surcharges on most antacids.

Anti-ulcerants – expenditure has continued to rise, limited to some extent by expenditure caps, despite price reductions on the H2 antagonists and Proton Pump Inhibitors (PPI).

Treatment of chronic diarrhoeas – expenditure has been increasing by $0.5-$1 million per year for the last 3-4 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 HFA expenditure on vitamins and minerals is attributable to the Vitamin D derivative – calcitriol (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. To some extent, the effect of that price reduction was recovered by the supplier through market expansion. 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.

Cerezyme – expenditure has increased due to a price increase associated with the replacement of Ceredase with Cerezyme but continues to be managed within the set budget.

Clinical & financial risks and opportunities

Ulcer healing drugs

The large falls in H2 antagonist prices have meant 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

There is now a range of triple therapy H.pylori eradication packs listed on the Schedule (omeprazole/amoxycillin/clarithromycin (OAC) and omeprazole/amoxycillin/metronidazole (OAM)). 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 this area with a view to sub-grouping the agents in a way that achieves savings and curbs expenditure. PTAC has recommended the use of a Special Authority to target use of the most expensive agents more appropriately. Development of the Special Authority criteria will require consultation with gastroenterologists.

A new agent (budesonide), for use by 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). However, prescribers are keen to use the drug more widely. Since its listing, we have come under constant pressure to widen access.

Vitamins and minerals

Growth in the use of calcitriol has been of concern for some time. The role of calcitriol in the treatment and prevention of osteoporosis has been questioned by clinicians and supporters of the bisphosphate alendronate. While expenditure on calcitriol is likely to fall significantly as a result of a new agreement there is still considerable pressure on PHARMAC to restrict access to this agent in favour of increased access to the bisphosphonates. PHARMAC has sought clinicians' advice on the matter and is in the process of putting in place changes to promote the appropriate use of both calcitriol and etidronate.

There has been significant growth within the remainder of the vitamin market – namely in the use of vitamin B and multi-vitamins. It is hoped that tendering will limit the effect of that growth on expenditure to some extent.

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). An issue to resolve is whether to increase the subsidy to the level of its price.

Antacids & Alginates

As a result of the review of these drugs implemented at the beginning of 1998, there is only one fully subsidised antacid listed on the Schedule. There are no calcium free or liquid antacids that receive full subsidy. Tendering some of the antacid market may result in an increase in fully subsidised options.

Drugs for Biliary Cirrhosis

PHARMAC agreed to list ursodeoxycholic acid (Actigall) on the Schedule in 1999. This drug represents the first effective pharmaceutical treatment for primary billiary cirrhosis (PBC) and represents new expenditure of approximately $1 million per year.

Cerezyme

Expenditure on Ceredase for the year ending 30 June 2000 is expected to be about $700,000 – an increase over the previous year due to the price increase associated with Cerezyme which replaced Ceredase in 1999. Following a recommendation not to increase the maximum dose of Ceredase/Cerezyme funded under the Gauchers Treatment Programme, PHARMAC initiated an exercise aimed at assessing the health benefits that have been gained from the current programme.

Laxatives

Underlying volume growth in this market has offset price reductions, keeping expenditure at around $6 million per year. Tendering of lactulose, glycerol suppositories and sodium citrate with sodium lauryl sulphoacetate enemas is expected to yield further savings, with total expenditure possibly falling.

Other

Anti-haemorrhoidals – an RFP for one agent could result in savings of around $500,00 per year.

Cisapride – use of this agent, particularly the paediatric presentation, continues to grow steadily despite the fact that there are some safety risks associated with its use by certain groups of

patients. Adult presentations now represent over $850,000 expenditure per year (compared with around $630,000 3 years ago). Use of the paediatric product has almost doubled in that time. Options for managing expenditure in this area will be explored.

Proposed PHARMAC actions

Over the next 12 months, proposed actions include:

- Treatments for chronic diarrhoeas - consult with the New Zealand Society of Gastroenterologists on the issue of targeting access to the more expensive agents and promote price competition.
- Vitamins and minerals – demandside activities for calcitriol, review subsidy for hydroxycobalamine (possible targeting mechanism).
- Cerezyme - undertake assessment of programme.
- Digestives including enzymes - obtain specialist input regarding the potential for tendering this market.
- Anti-ulcerants – management of volume growth via promotion of appropriate prescribing/treatment and promotion of H.pylori eradication.

STRATEGIC OVERVIEW OF SENSORY ORGANS THERAPEUTIC GROUP

Current Expenditure

TG level 1 name	HFA Cost ($ million, excl. GST)			Growth
	1997/98	1998/99	1999/00	
Ear preparations	0.3	0.4	0.4	0%
Eye Preparations	8.4	7.8	8.2	5%
Total	8.7	8.2	8.6	5%

Key information about the group

Sensory products account for about 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.

Main suppliers

Merck Sharp & Dohme, Allergan, Alcon, Ciba Vision and Pacific.

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. Costs of older agents are falling but new anti-glaucoma agents, at higher prices, are negating this effect to some extent. While we are currently forecasting net savings in these markets, it is possible that expenditure on the newer agents could exceed savings on older agents.

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. Demand for other agents has been addressed, to some extent, by the listing of latanoprost and bromonidine. However, issues still remain with respect to patient access to the treatments.

Proposed PHARMAC Actions:

Over next 12 months:

- Address remaining issues of access to new products in Glaucoma market.

In the long term

- Rationalise range of low priority products available

STRATEGIC OVERVIEW OF SPECIAL FOODS THERAPEUTIC GROUP

Current Expenditure

TG level 1 name	HFA Cost ($ million, excl. GST)			Growth rate %
	1997/98	1998/99	1999/00	
Food thickeners	0.02	0.03	0.03	0
Gluten Free Foods	0.14	0.09	0.09	0
Infant Formulae	0.33	0.43	0.46	7
Multi Vitamin Supplements	0.00	0.01	0.01	0
Oral Supplements	0.03	0.05	0.05	0
Oral Supplements/Complete Foods	2.02	2.96	3.16	7
Phenyl Free Foods	0.02	0.03	0.03	0
Protein Supplements used for PKU and other in born errors of metabolism	0.78	1.29	1.36	5
Total	3.34	4.89	5.19	6

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.

Main suppliers

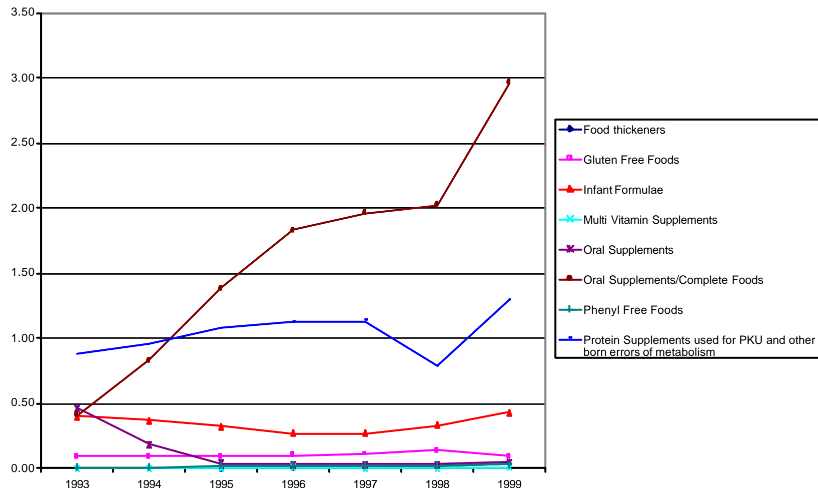
Abbott Laboratories, Nutricia Limited, Mead Johnson (SmithKline Beecham), Novartis Nutrition.

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:



The largest portion (about $3 million (cost ex manufacturer, GST exclusive)) of expenditure on Special Foods is for oral supplement/complete diets. This area of the market is dominated by three products (Ensure Plus and Pediasure (supplied by Abbott) and Fortisip (supplied by Nutricia)). There has also been growth in a smaller niche market of fibre added products.

The HFA also currently spends about $1.3 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 also appears to be growing. The effect of revised charges on these products in 1999 is not yet clear.

Clinical & Financial Risks and Opportunities

Oral Supplements

Further growth in use of oral supplement/complete diets and in fibre added products is expected. In the past, PHARMAC has been able to manage the effect of volume growth via incremental subsidy reductions leveraged from new entrants to the market or product changes.

A good range of fully subsidised options has been maintained following the last round of subsidy reductions. However, unless there is interest from further new entrants, it is unlikely that further gains from straight price reductions will be forthcoming. This may mean that the main mechanism used to control expenditure in this area in the past may be less effective in the future.

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 could be investigated.

Infant formulae

Charges on Infant formulae were reviewed and updated in 1998 and subsidy changes were implemented in 1999. The effect of these changes will be unclear until further data becomes available.

Gluten Free Foods

Expenditure on gluten free foods, which has been growing over the last few years, fell in the last year. This may have been due to subsidy changes implemented in 1999 although we expect that it is too soon to see the full effect of these changes.

The new subsidies in each case were set to bring the costs of these foods into line with non-gluten free foods. In other words, each product has been assigned partial subsidy only. The changes have met with some opposition. The special foods sub-committee of PTAC has reviewed the basis of the subsidies in this market and was satisfied that it is a fair one. PHARMAC will continue to review the effect of co-payment on this market.

Distribution

Another possible option for management of most, if not all, Special Foods is sub-contracting the responsibility for purchasing and distributing the products to another organisation. PHARMAC has been experiencing difficulties in obtaining the information we require in order to analyse the costs and benefits of this approach. However, it remains an option that PHARMAC may explore further.

Actions to be taken

Over the next 12 months include:

- review gluten free foods subsidies;

- prepare comprehensive forecasts for some or all of the Special Foods market that can be used to assess proposals relating to purchase and distribution arrangements.

STRATEGIC OVERVIEW OF CARDIOVASCULAR

Current Expenditure (ex-manufacturer, excl. GST)

	Cost ($ million, excl. GST)			**Growth rate**
	1997/98	1998/99	1999/00	
Agents affecting the renin-angiotensin system	61.44	32.07	35.27	10%
Alpha blockers	5.67	6.17	6.79	10%
Anti-arrhythmics	5.48	5.81	5.87	1%
Beta-blockers (including in combination with diuretics)	21.69	14.74	13.93	-5%
Calcium channel blockers (DHP CCBs and others)	33.28	29.29	14.80	-49%
Diuretics	5.40	5.65	6.22	10%
Nitrates	8.99	6.27	5.93	-5%
Lipid modifying agents (LMAs)	15.49	24.43	26.38	8%
Others	0.99	0.80	0.84	5%
Total	**158.43**	**125.23**	**116.02**	**-7%**

Main suppliers

Pfizer (Parke-Davis), Roche, AstraZeneca, Aventis, Bayer, Novartis, Merck Sharp and Dohme, Bristol Myers Squibb, Apotex, Pacific, Global and Douglas.

Contribution to Health Status

Cardiovascular disease remains one of the most common causes of death in New Zealand. The build up of atherosclerosis is often the culprit. At present there is no ‘quick fix’ to prevent atherosclerosis or any of its complications. Pharmaceuticals play a significant role in the management of various cardiovascular risk factors such as lipid disorders, raised blood pressure, etc. Pharmaceuticals also play an important role in the management of ischaemic heart disease (angina), congestive heart failure, cardiac arrythmias, and others. Management of lipid disorders, raised blood pressure and angina accounts for the major proportion of expenditure in this therapeutic 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 agents affecting the renin-angiotensin system (ACE inhibitors, ACE inhibitors in combination with diuretics and angiotensin II antagonists), lipid modifying agents (mainly statins and fibrates) and, to a lesser extent, calcium channel blockers.

Reasons for current expenditure trends

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

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 mainly 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 were, until the end of 1999, the next highest area of expenditure. Like ACE inhibitors they are promoted for the treatment of raised blood pressure and angina. Recent price and subsidy reductions have, however, substantially reduced expenditure ion this area.

Lipid modifying agents is the therapeutic subgroup with the highest growth rate. There is strong underlying volume growth in this market. The expenditure growth is expected to increase until the time when simvastatin (Zocor) comes off patent i.e. March 2001. There is an underlying shift from cheaper, poorly promoted fibrates to more expensive statins.

Clinical & Financial Risks

- Strong underlying growth in the use 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 Angiotensin II antagonists.

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

Opportunities for managing expenditure

Lipid modifying agents

Over the past year the expenditure on statins has grown by 30-40%. The risk of over-expenditure has now been reduced mainly because of atorvastatin expenditure caps and a new agreement regarding simvastatin. Simvastatin patent expiry is due in March 2001 and should provide some opportunities for savings in the statins therapeutic subgroup. This could also provide some opportunities to make savings in other therapeutic areas as some suppliers may be prepared to enter into cross-deal agreements.

Patents on all drugs belonging to the fibrate therapeutic subgroup have already expired. Recent tender decisions will further reduce expenditure in this therapeutic subgroup in the short term.

ACE inhibitors

We expect to continue funding the surcharge for existing congestive heart failure patients on ACE inhibitors (other than quinapril or cilazapril) as we are concerned about the potential risks that are associated with shifting unstable patients from their existing treatments. We will continue to promote the use of more appropriate thiazide diuretics and beta blockers for the management of raised blood pressure. The WADC of treatment with ACE inhibitors is expected to fall from the current level of about $0.36 by the end of 2001.

Angiotensin II antagonists (AIIAs)

At this stage the available data suggest that the use of AIIAs to treat heart failure may be limited to those patients who are unable to tolerate ACE inhibitors. At present there are two AIIAs listed on the schedule i.e. losartan (for certain CHF patients) and candesartan (for certain patients with 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 lack of evidence of long term positive outcomes, eg a reduction in mortality and morbidity. There is also some evidence that the use of CCBs actually increases the risk of cardiovascular mortality, especially in patients with impaired glucose tolerance.

As a result of the agreements with Bayer and AstraZeneca, expenditure on DHP CCBs has been reduced considerably. We expect further reductions in both the price (the entrance of generic felodipine) and the use of DHP CCBs. We may also see some reductions in the prices for other, non-DHP calcium channel blockers i.e. diltiazem and verapamil 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 low value area in the medium term.

Beta-blockers

Tendering in this market has resulted in substantial savings during the past year. Over the coming year we propose to complete the tender programme.

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 i.e. 2000. The most likely prospect for bigger price reductions would come in 2001 when enalapril, captopril and simvastatin would come off patent. In the meantime the spread in what we are paying for some of the cardiovascular drugs will continue ($0.03 for thiazides diuretics, $0.08–0.25 for beta blockers, $0.28 for DHP CCBs, $0.36 for ACE inhibitors and about $0.50 for diltiazem). This creates opportunities for savings if prescribers can be encouraged to use the cheaper agents more intensively.

Demand side actions

CHD risk assessment

In conjunction with the HFA/MoH, National Heart Foundation, Cardiac Society, cardiologists, GPs and other interested parties PHARMAC will promote the idea of multiple risk factor assessment to help GPs identify patients at risk of coronary artery disease and help those patients reduce that risk before a coronary event occurs. Such an assessment should be a major aim of routine medical evaluation of all patients, including diabetics and the elderly. GPs should be provided with tools allowing them to assess that risk as well as with suggestions as to what sort of

therapeutic or preventive actions should be taken in order to minimise that risk. Recently, the American Heart Association and the American College of Cardiology issued a scientific statement relating to this issue. PHARMAC could take a similar type of action in the future. Risk assessment should be followed by direct recommendations (lifestyle and cost-effective pharmacological interventions) addressing various components of the overall risk. By promoting certain cost-effective interventions (e.g. beta blockers and diuretics first line agents for raised blood pressure, long acting bezafibrate or generic simvastatin for lipid disorders etc), PHARMAC may be able to encourage the use of more appropriate medicines.

Primary prevention of CHD

There is a need for a public education campaign aimed at primary prevention of coronary heart disease among the general public. A possible campaign could involve the Hilary Commission and should, in the first instance, address the importance of non-pharmacological measures such as diet modification (fat and salt restriction), excess weight reduction, exercise, smoking cessation and alcohol moderation.

Other possible actions

Other types of demand side actions could be taken that are aimed at promoting the wider use of ACE inhibitors and spironolactone in CHF patients and beta-blockers following myocardial infarction. While numerous studies have been completed that demonstrate the efficacy of these drugs in reducing mortality, they appear, however, to be underused at present.

Longer term analysis – new products in the pipeline

According to PhRMA (Pharmaceutical Research and Manufacturers of America) more than 104 different drugs were in development against heart disease in 1999. Some of these drugs could come to the market in the medium term.

Gene therapy and genetic engineering are starting to play an important role in the development of therapies for ischaemic heart disease. The research focusing on angiogenesis is of particular interest although it is too early to say if this approach would be successful in the near term. If approved, such therapies could make coronary artery bypass surgery obsolete as patients with untreatable chest pain could possibly grow their own coronary bypasses.

Some examples of cardiovascular drugs currently in the pipeline:

- New statin drug with a potency equivalent to atorvastatin. AstraZeneca completed phase II trials of this statin preliminary named "superstatin". According to Scrip the product was well tolerated and is expected to reach the markets in 2001.
- Anti-hypertension drug omapatrilat developed by BMS. This is a novel vasopeptidase inhibitor that may possibly be used for treating raised blood pressure and heart failure. It simultaneously inhibits neutral endopeptidase (NEP) and angiotensin-converting enzyme (ACE), two key enzymes that work together to regulate blood pressure and heart function. Omapatrilat is in the stage III clinical trials (OVERTURE - The Omapatrilat Versus Enalapril Randomised Trial of Utility in Reducing Events).

- B-type natriuretic peptide (hBNP) – nesiritide may have some use in the management of acute CHF. BNP is a naturally occurring cardiac human hormone, which is secreted as part of the body's natural response to a failing heart. The product is currently in phase III trials.
- There is also some new evidence that a new anti-arthritic drug etanercept (Enebrel) reduces symptoms of CHF as well as improves mortality and morbidity. Phase II/III trials for that indication are underway.
- Ranolazine is presently being investigated in phase III trials by CV Therapeutics. This product represents a new class of drugs called pFox inhibitors that may potentially be used for the treatment of angina. Current therapies - beta blockers, calcium channel blockers and nitrates - all treat angina by reducing the work that the heart has to do by lowering heart rate, blood pressure and/or the pumping force of the heart muscle itself. Because most angina patients take more than one of these drugs, their additive effects can result in unacceptable decreases in heart rate and blood pressure. In early studies ranolazine increased exercise parameters compared to placebo without reducing blood pressure or heart rate. pFOX inhibitors have an entirely different mechanism of action to potentially relieve angina. Unlike the current anti-anginal drugs, which reduce the work of the heart in order to reduce its demand for oxygen, pFOX inhibitors may reduce the heart's requirement for oxygen by altering the heart's metabolism.
- Aggrastat (tirofiban) is a new treatment for the management of unstable angina and has received the market approval in Canada in September 1999. Aggrastat belongs to the new class of drugs called glycoprotein (GP) IIb/IIIa receptor inhibitors which prevent the formation of blood clots. Aggrastat is the only treatment in its class indicated to reduce the rate of deaths, of new heart attacks and of refractory ischaemia (continuous severe chest pain despite medical intervention) in patients with unstable angina.

Key actions for 2000/01

1. Design strategies for when captopril, enalapril and lisinopril come off patent.
2. Development of appropriate strategy for the alpha blockers market.
3. Development of appropriate strategy for the diltiazem market.
4. Cost utility analysis of NRT products.
5. Possible review of access criteria to statins.

STRATEGIC OVERVIEW OF BLOOD & BLOOD FORMING ORGANS

Current Expenditure (ex-manufacturer, excl. GST)

	Cost ($million, excl. GST)			Growth rate
	1997/98	1998/99	1999/00	
Antianaemics	2.50	3.47	3.57	3%
Antifibrinolytics, haemostatics and local sclerosants	0.21	0.33	0.35	6%
Antithrombotic agents	4.36	5.21	5.73	10%
Fluids and electrolytes	3.50	3.67	3.85	5%
Total	**10.57**	**12.68**	**13.5**	**6%**

Key information about the group

Blood and blood-forming agents (excluding lipid modifying agents) account for about 1-2% of the Pharmaceutical Schedule spending.

Contribution to health status

Anaemia treatments include iron and folic acid supplements and erythropoietin. These all assist haemaglobin production and, consequently, improve exercise capacity. Antiplatelet therapy is used primarily to prevent thrombotic cerebrovascular events (strokes and transient ischaemic attacks) – 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.

Main suppliers

Roche, Aventis, Baxter, Boehringer Ingelheim, Abbott, Pharmacia & Upjohn, Novartis, PSM, AstraZeneca, Apotex, Pacific, Janssen-Cilag and Douglas.

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.

Clinical and financial risks and opportunities

Dipyridamole

There will be an opportunity to run a tender for sole supply of dipyridamole in 2001.

Heparin

There is pressure on the HFA to fund the use of low molecular weight heparins (LMWH) through the Pharmaceutical Schedule to address geographical disparities in access to these agents in the treatment of venous thromboembolism and to enable more treatment to occur in the community. Such a listing may result in shift of costs from hospitals to the Schedule. PHARMAC proposes to work through the budget implications of such a listing with the HFA. At this stage we consider LMWH to be a hospital type of medicine. In the coming months we don't propose to undertake any action relating to this issue.

New products in the pipeline

Oral formulation of heparin (currently in phase III) may potentially expand existing markets for heparin. Currently the most common indications for heparin therapy are the deep venous thrombosis (DVT), prevention of venous clots following surgery, especially orthopedic, pelvic, abdominal, trauma, angioplasty or heart surgery. If the oral formulation gets approval it may also be used for other indications such as inflammatory disease and cancer.

Key actions for 2000/01

1. PHARMAC intends to investigate further the cost effectiveness of treatment with erythropoietin and, subsequently, the pros and cons of budget holding for erythropoietin as means of managing the expenditure risk in this group (this work will be piggy-backed on a broader review of the place of budget holding in managing access to subsidies for pharmaceuticals).

2. PHARMAC will seek further price reductions for dipyridamole (an anti-platelet). At the same time we will consider listing of a combination of dipyridamole and aspirin for the secondary prevention of stroke and transient ischaemic attacks.

STRATEGIC OVERVIEW OF MUSCULOSKELETAL DRUGS

Current Expenditure (ex-manufacturer, excl. GST)

BNF2 Groups	Expenditure ($million)		Growth rate %
	1998/99	**1999/00**	
Drugs used in Rheumatic Diseases and Gout	12.9	11.1	-14.0
Drugs used in other Musculoskeletal Disorders	2.6	2.4	-7.0
TOTAL	**15.6**	**13.5**	**-13.5**

Main Suppliers

Novartis, Rhone-Poulenc Rorer, Roche, MSD, Syntex, Knoll, Pacific, Douglas, Pharmacia & Upjohn

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 mainly to reduce 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 1999/2000 we achieved significant subsidy reductions on NSAIDs, mainly from the listing of a range of generic diclofenac formulations and the tendering of ibuprofen and indomethacin. However, we expect to achieve further savings in 2000/2001 from the tendering of high strength ibuprofen, flurbiprofen, mefenamic acid, sulindac and tiaprofenic acid.

Clinical and financial risks

COX-2 inhibitors are indicated for the treatment of osteoarthritis, rheumatoid arthritis and the management of pain. Some products have already been registered in New Zealand and we expect that other similar compounds will be registered during 2000/01.

The claimed advantage of these new agents is that they have fewer gastro-intestinal side effects. Considerable interest in COX-2 inhibitors from doctors and patients has already been demonstrated publicly. However, contradictory evidence of this has emerged from countries in which their use has already been approved.

COX-2 inhibitors can be up to 6 times more expensive than the currently used agents. However, we need to take into account that NSAIDs are in many cases prescribed in association with other products to try and prevent damage at gastric level. A cost utility analysis will be required to translate the claimed advantages into the cost effectiveness of using these products compared to NSAIDs.

Potentially, the listing of COX-2 inhibitors could expose the HFA to a significant increase in expenditure in this area. A careful targeting of patients most likely to benefit from the improved safety profile of COX-2 inhibitors would be a key factor in determining our ability to fund these products, which have the potential to offset costs in other health budgets.

Other Anti-Rheumatic Drugs

There are a number of new products that have the potential to increase total expenditure in this area.

Synvisc (Bayer) is a new treatment for people with osteoarthritis of the knee. It is an elastoviscous supplement, injected directly into the knee joint, where it acts as a shock absorber and lubricant. It is used for patients who do not obtain adequate relief from simple painkillers or from exercise and physical therapy. Synvisc is considered a device, not strictly a drug, and is designed to replace the diseased synovial fluid found in osteoarthritic knees.

Leflunomide (Arava - Aventis) is a disease modifying agent for the treatment of active rheumatoid arthritis as an alternative to metothrexate.

Etanercept (Enbrel - Immunex Corporation and Wyeth-Ayerst Pharmaceuticals) is used to treat moderately to severely active rheumatoid arthritis in people who have not adequately responded to disease-modifying medicines.

Opportunities and PHARMAC actions

Although significant cost reductions have been achieved in the last 2 years, further gains are possible through tendering.

Currently, there is no limit on the number of NSAIDs tablets that can be prescribed and patients often receive a month’s supply per dispensing. However, given the high rate of patient intolerance, many patients collect one month’s supply but take only one or two tablets. Prescribers need to be encouraged, through appropriate guidelines, to prescribe 3-6 days therapy to start with and repeats only if the patient is responsive to therapy and tolerates it well. We are planning to work closely with our demand side to achieve this outcome.

Another important area of improvement on the demand-side, is the use of NSAIDs as analgesic for soft-tissue injuries. Recent surveys conducted in the Auckland region show that most doctors (around 70%) still rank NSAIDs more effective than paracetamol for this indication. NSAIDs were the most prescribed single analgesic agents, which is not supported by the available evidence and can potentially expose patients to an increased risk of re-injury by delaying healing.

Contribution to Goal of Managing Expenditure

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

Demand side actions

- Raise issues of over prescribing on NSAIDs and use in soft tissue injury.
- Promote the use of paracetamol in the treatment of osteoarthritis rather than NSAIDs where appropriate.

Long term analysis

The new generation of NSAIDs is represented by COX-2 inhibitors. Although the first representatives of this class do not seem to be 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, and to which patients their use should be targeted.

STRATEGIC OVERVIEW OF GENITOURINARY SYSTEM

Current Expenditure (ex-manufacturer, excl. GST)

BNF2 Groups	Expenditure ($million)		Growth rate %
	1998/99	1999/00	
Contraceptives - hormonal	11.6	11.4	-2.0
- non hormonal	2.2	2.0	-10.0
Treatment of vaginal and vulval condition	1.1	1.1	0
TOTAL	**14.9**	**14.5**	**-2.5**

Main Suppliers

Schering, Wyeth, Pharmacia & Upjohn, Searle, Ebos, Douglas, Janssen Cilag.

Contribution to health status

Contraceptives are an important preventative measure against unwanted pregnancies as well as counteracting the high abortion rate currently affecting the population. In 1998, 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

Until the beginning of 1999, there was a steady growth in combined oral contraceptives (7.2%) and progestogen-only contraceptives (10.4%). However, a significant decline in the prescribing of the third generation oral contraceptives (up to 45%) has followed the recent publicity that these agents may be associated with higher risk of venous thrombosis. The Ministry of Health's advice to consider prescribing second generation agents combined with an increasing awareness of the risk associated with third generation preparations is responsible for an increased usage of the second generation ones. Consequently, total expenditure is expected to decrease by around 2% during the 1999-00 year, in contrast to last year's prediction of 5% growth. Three more fully subsidised brands were provided this year, bringing the total number of fully subsidised oral contraceptives to seven, which has also lowered HFA expenditure on the Special Authority for low income women (estimated now at $550,000 per annum).

However, the Special Authority for oral contraceptives for low-income women has been recently reviewed and will now apply only to the third generation products for women who are unable to tolerate one of the fully funded preparations. Since all existing Special Authorities will continue to be valid until they expiry, we estimate that savings of around $240,000 per annum will not occur for another two or three years.

Condoms

Due to new listings in bulk packs, the subsidy for condoms with spermicide dropped by 6% and for condoms without spermicide by 32% last year. We note that while the price of the latter is now competitive with international prices we still expect to achieve some savings in relation to the former. The volume of condoms being 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 for gynaecological anti-infectives from $960,000 in 1997 to $450,000 in 1999. PHARMAC then maintained the subsidy at a fixed level for all of 1999. Therefore, we do not expect any substantial change in the level of expenditure on these products. However, some suppliers have showed an interest in participating in a tender for the sole supply of these preparations, which could serve to reduce current expenditure.

Pregnancy test kits

The tender of pregnancy tests (with both cassette type and dipstick type available at the same price) will provide savings of around $400,000 per year. We note that the subsidy for these products has dropped from $2.47 in 1998 to $1.10.

PHARMAC actions

For low income women, 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 seven brands are currently fully funded. In addition to reducing expenditure, this would also reduce the risks of side effects caused by third generation pills.

We shall continue seeking fully subsidised hormonal contraceptives.

STRATEGIC OVERVIEW OF HORMONE PREPARATIONS

Current Expenditure (ex-manufacturer, excl. GST)

BNF2 Groups	Expenditure ($million)		Growth rate %
	1998/99	**1999/00**	
Sex hormones	12.1	12.4	2.8
Thyroid and anti-thyroid drugs	1.5	1.7	12.0
Agents affecting bone metabolism	1.9	2.5	43
TOTAL	**15.5**	**16.6**	**7.0**

Main Suppliers

Schering, Wyeth, Pharmacia & Upjohn, Novo Nordisk, 3M, MSD, Novartis.

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 is effective in preventing fractures in certain patients already affected by severe osteoporosis. For this limited group of patients, therapy with alendronate can 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 calcitriol 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 of the listing of alendronate for severe osteoporosis. However, the estimates do not take into account the effective price reduction of calcitriol, which is included in the Strategic Overview of the Alimentary Tract and Metabolism therapeutic area.

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

- In addition, we are now in the process of tendering for etidronate, for which estimated expenditure is around $1.2million but increasing at around 50% in the last year. This is mainly due to an increasing number of osteoporotic patients being treated with this bisphosphonate. It currently represents the most effective alternative for women not able to tolerate HRT and also a cheaper option to the more potent alendronate. We expect the cost of etidronate to drop significantly after the implementation of the tender.

Clinical and financial risks

The listing of alendronate (Fosamax) for osteoporosis is going to increase expenditure in this area. However, the cost-utility analysis has enabled us to target the product to those patients who most benefit from this treatment, which will also mean significant cost offsets for the HFA.

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

Tendering of etidronate will help contain the exceptionally fast growing expenditure for this product. We have received indications from potential suppliers of generic etidronate that its price could effectively be halved as a result of tendering. However, considering the potential size of this market, we are also considering the possibility of developing some restrictions aimed at targeting patients most likely to benefit from this therapy.

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 possible listing of a new patch of HRT with reduced part charge should contribute to increased compliance. The potential increase in total HRT expenditure is likely to be compensated for by a reduction in expenditure on additional subsidies through Special Authorities, which are currently available to fully fund HRT patches to the level of the lowest priced brand.

Infertility Agents

Budget holding of infertility agents is currently still in place. We are now actively working with the HFA to have these products transferred from the Pharmaceutical Schedule to drug inclusive infertility contracts, which would give the HFA full control on these services. The HFA has indicated that this project could be completed in the near future.

Proposed PHARMAC actions

- Tendering for the sole supply of etidronate for the treatment of post-menopausal osteoporosis.
- Investigating tendering for the sole supply of growth hormone for the entire market or only for new patients

- Transfer budget holding for agents used in ovulation induction.
- Development and promotion of clinical guidelines for the prevention and treatment of osteoporosis.

STRATEGIC OVERVIEW OF DERMATOLOGICAL PRODUCTS

Current Expenditure (ex-manufacturer, excl. GST)

BNF2 Groups	Expenditure ($million)		Growth rate %
	1998/99	**1999/00**	
Corticosteroids	8.1	8.0	-1
Anti-acne	8.6	7.9	-8
Psoriasis	2.9	3.0	3
Emollients and barrier preparations	1.4	1.5	7
TOTAL	**21.0**	**20.4**	**-3**

Main Suppliers

GlaxoWellcome, Schering Plough, Roche, Schering, CSL, 3M, Wyeth, Douglas, Pacific, Pharmacia & Upjohn, ICI, Aventis, Bayer, Novartis, SmithKline Beecham, BMS.

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 fungi, 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 relatively 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. The listing of cyclosporin A as third line treatment for patients with severe atopic dermatitis is estimated to have increased expenditure by around $400,000 per annum.

Anti-acne preparations

In last year's Business Plan we had forecast expenditure for this area to grow to $9.9 million in 1999/2000 year. However, the listing of the first generic isotretinoin from Douglas Pharmaceuticals (Oratane) at a price 35% less than Roaccutane has helped to contain total expenditure growth.

Psoriasis and eczema preparations

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 a number of indications now listed and total expenditure is now growing considerably.

New products in the pipeline

There are only a few new products coming through in dermatology. None of them is expected to reach the market in the near term future.

Proposed PHARMAC actions

Possible actions for PHARMAC during 2000/01 include:

- Investigate tendering of topical antifungals.
- Request for proposal for the sole supply of isotretinoin and development of clinical guidelines in cooperation with dermatologists for the treatment of severe acne.
- Resolve issues of access to isotretinoin so that it is based on severity of acne, not ability to pay for a specialist visit.
- Complete a cost-utility analysis on the listing of imiquimod cream (Aldara) for the treatment of topical warts.

STRATEGIC OVERVIEW OF ANTI-INFECTIVE AGENTS

Current Expenditure (ex-manufacturer, excl. GST)

BNF2 Groups	Expenditure ($million)		Growth rate %
	1998/99	**1999/00**	
Antivirals	8.7	6.5	-25.0
Antibacterials	34.6	29.5	-14.7
Antifungals	4.6	4.9	6.5
TOTAL	**47.9**	**40.9**	**-14.6**

Assumptions in forecasts

- Volume growth in antibiotics will remain unchanged
- Decreased growth due to mix effects is also assumed to continue

Main Suppliers

SmithKline Beecham, Bayer, Abbott, Eli Lilly, GlaxoWellcome, Roche, Douglas and Pacific.

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. Herpes treatments are targeted at relieving symptoms when used as short term therapy and suppressing repeat episodes of acute symptoms when used in long term therapy.

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 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 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

Spending in this area has reduced due to tendering and demand side activities.

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 6.5% a year. The reasons for this growth are unknown.

Clinical and Financial risks

AIDS drugs

As noted above, expenditure on AIDS therapies has the potential to increase significantly over the next few years, if quadruple therapy is funded. 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. Recent reports indicate that 80% of new infections over the last year were due to immigrants. The recently proposed rules preventing or limiting immigration into New Zealand for HIV positive patients would have a significant impact on the number of patients being treated for this condition. Pressure will also mount to increase the number of drugs that can be used in combination therapy as well as the type of combinations.

Antimicrobial resistance

The issue of antimicrobial resistance was recently considered by the PTAC antibiotics subcommittee. 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. The recent campaigns on the correct use of antibiotics to prescribers and the general public could also have a favourable impact on antibiotic prescribing over the next winter.

Cystic fibrosis and dialysis antibiotics

A range of injectable antibiotics is listed on the schedule specifically for these indications. In general, suppliers consider these orphan products. PHARMAC will need to assess whether the current range should be maintained and what actions may be necessary to achieve this.

Clinical and financial opportunities

Antimicrobials off-patent

Almost all heavily prescribed antibiotics listed on the schedule are off patent. Those with significant sales that remain patent protected include the following:

Chemical entity
Ciprofloxacin
Clarithromycin
Fluconazole
Itraconazole
Terbinafine
Anti-retrovirals

Generic competition

World prices for anti-infectives are lower than New Zealand prices for many products. 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. A mechanism for PHARMAC to consider is the direct funding of bioavailability studies for important brands of antibiotic.

Prescriber education

Prescriber education is considered an essential component of managing anti-infective use. PHARMAC will aim to facilitate and assist the development of education programmes aimed at reducing inappropriate prescribing of antibiotics.

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 anti-microbial 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

Proposed PHARMAC actions over the next 12 months include:

- Evaluate current bids for sole supply of antibiotics included in the 2000 tender and implement winning bids.

- 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.

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

- Tender for aciclovir.

STRATEGIC OVERVIEW OF RESPIRATORY SYSTEM AND ALLERGIES THERAPEUTIC GROUP

Current Expenditure (ex-manufacturer, excl. GST)

TG2 groups	HFA Cost ($million)		Growth rate %
	1998/99	**1999/00***	
Allergic disorders	3.1	3.2	3.2
Inhaled Corticosteroids	44.4	37.0	-16.7
Bronchodilators	25.6	23.4	-8.6
Prophylaxis of asthma	3.2	3.3	3.1
Drugs acting on the nose	5.1	4.3	-15.6
Other**	3.3	4.2	27.2
Total of above groups	**84.7**	**75.4**	**-10.9**

Main Suppliers

Asthma market: GlaxoWellcome, AstraZeneca, 3M, Aventis, Novartis and Boehringer Ingelheim. Douglas and Pacific supply small volumes of generics.

Oral antihistamine market: Janssen Cilag, Aventis, Schering-Plough, Douglas, Bayer and Novartis.

Steroid nasal spray market: GlaxoWellcome, AstraZeneca, Douglas, Pacific, Roche and Schering Plough. Aventis, Janssen Cilag and Boehringer Ingelheim supply non-steroidal nasal sprays.

Contribution to Health Status

The main conditions treated in this therapeutic area are asthma and chronic obstructive pulmonary disease (COPD) followed by symptomatic treatment of upper respiratory tract conditions. We already subsidise a large number of pharmaceutical therapies for asthma and COPD, however as the incidence of these conditions, in particular asthma, appears to be growing, any new therapy in this area is likely to be enthusiastically received by patients/public/clinicians. This has been illustrated with the reception the montelukast supplier campaign received in mid 1999.

There is 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 antihistamines for some patients.

Reasons for Current Expenditure Trends

Inhaled Corticosteroids/bronchodilators

The current trend is decreasing expenditure for steroids and some growth with the inhaled bronchodilators. Steroid unit use is constant or in some cases declining in all but fluticasone (MDIs and BADs). Most fluticasone products are growing in use. The decrease in steroid

expenditure is due to price reduction agreements firstly in the steroids BADs, in 1998 and steroid MDIs in 1999. The respiratory market is driven by inhaled corticosteroids (ICS) and bronchodilators. We now have evidence that the message regarding the 2:1 dosing relativities of Flixotide versus the other ICS has not been well understood. This is particularly of concern if fluticasone unit use is increasing at the expense of older steroids.

Cystic Fibrosis

Pulmozyme (dornase alfa) for the management of cystic fibrosis was listed on the Pharmaceutical Schedule in April 1997. Its use is being managed via guidelines and applications being approved, according to set criteria, by a panel.

Antihistamines

Although expenditure has been declining over the past few years, from 2001 we assume some growth due to a PTAC recommendation that at least some antihistamines be fully funded for particular patient groups (those with chronic, severe disease). The previous decline would have been due to increased OTC use, less prescription use.

Nasal Sprays

Expenditure in the steroid nasal sprays has declined and is predicted to continue to decline due to a number of previous price reductions and a price reduction in 2000 following the tender.

Clinical and Financial Risks

Expenditure in respiratory is $84.7 million for the year ending June 1999 (HFA cost, excl GST). The largest area is asthma. This expenditure reflects the high prevalence of asthma in NZ, which appears to be growing, the still limited generic competition, 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. Interestingly, recent savings have not come from direct generic competition but from branded products trying to protect their markets. However, the possibility of generic competition was pivotal in achieving those agreements. Expenditure is expected to stabilise from 2000/01 on.

There is a range of generic inhalers available overseas but until recently only Douglas and Pacific had been successful in registering these and only in the bronchodilator market. Although we are starting to receive applications from generic suppliers for listing their products (for MDIs initially, then BADs in about 2 years) the reticence of clinical buy-in together with the branded suppliers ultimately providing the better financial proposal has meant that none of these newer generic products has been listed on the Schedule yet.

The Montreal protocol to phase out CFC products is a significant disincentive to introducing generic MDI products. There is some pressure from companies to list their CFC free product versions at a higher subsidy level, in part because of Australia's decision to subsidise CFC free products at a higher level than their non-CFC counter parts. We are in communication with the Ministry of Commerce and the Ministry for the Environment who are accepting PHARMAC's current approach regarding CFC-free new listings.

GlaxoWellcome and AstraZeneca followed by 3M hold the majority of the market share for asthma relievers and preventers. It is difficult for other players, especially generics, to enter the breath activated device market as patents protect most delivery devices.

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. Pressure for funding of adult spacers is also mounting in particular as demand side messages regarding use of MDI and spacer increase.

Interest in competition in the BADs ICS market has again increased following a relative lull in late 1998/99 (when the competition centered around the ICS MDI market).

Cystic Fibrosis

A review of the procedure around access by the panel has occurred and the recommendations have been considered by PTAC. The first (non-financial) part of the panel's recommendations have been accepted by the PHARMAC Board.

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. Previously 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. We have initiated a PTAC review of this area.

Clinical and Financial Opportunities

New Investments

Asthma

The PTAC respiratory sub-committee has asked for increased access to inhaled long acting beta agonists. The additional expenditure this would entail is likely to be significant. Suppliers have expressed interest and we have held an RFP, the outcome of which should be announced shortly.

Over the next 2 years we expect to receive applications from suppliers for combination products, in particular inhaled steroids and long acting beta agonists.

The old off-patent smaller use/expenditure areas are not only appropriate for tendering but also provide an avenue through which suppliers can provide savings for use on their new chemical entity listings. A recent example was the savings Pharmacia & Upjohn provided on Respax (nebulised salbutamol) in return for listing of its anti-glaucoma medication Xalatan.

Leukotriene antagonists (LTRAs)

Singulair (montelukast sodium) has been launched by MSD with a one-month free supply to patient campaign. This campaign has led to pressure to subsidise this product as discussed earlier.

AstraZeneca also has a leukotriene antagonist called Accolate (zafirlukast), although Medsafe has not approved this product yet. Accolate, already approved by the FDA, is expected to be available for supply in New Zealand within the next 2 years.

Cost Savings

The forecast decrease in ICS expenditure is due to agreements in the market in 1998 and 1999. It seems unlikely that there will be further savings in the next year or so in this area. The greater area of future cost saving opportunity is in the BADs.

Reference pricing of asthma ICS, perhaps based on a weighted average daily dose basis compared with the current cost per microgram method, may be examined.

A new tender for spacers for children may decrease expenditure and there are indications of further competition in the peak flow market.

Disease State Management

Asthma is one of 3 key areas named in the HFA/MOH funding agreement to be targeted for a disease state management approach. PHARMAC proposes to be closely involved in this HFA work, initially via being consulted by the relevant HFA people on draft documents/liaison and also through being represented on the working party.

Key Actions proposed for 2000/01

- Contract and implement ICS BAD savings proposal(s).
- Antihistamine review.
- Implement LABA increase in access (subjects to funding available)
- Assess the combination steroid and LABA products.
- Further assessment of leukotriene receptor antagonists.
- Pursue bronchodilator competition.

STRATEGIC OVERVIEW OF ALIMENTARY TRACT AND METABOLISM - DIABETES

Current Expenditure

BNF2 groups	HFA Cost ($m, excl GST)		Growth Rate (%)
	1998/99	99/00	
Insulin & Oral hypoglycaemics	20.3 (59.5%)	23.0 (60.8%)	11.7%
Testing strips	13.5 (39.6%)	14.5 (38.4%)	6.9%
Syringes/pen needles	0.3 (1%)	0.3 (1%)	0%
Group Total	**34.1**	**37.8**	**9.8%**

Main Suppliers

Apotex, Bayer, Roche, Pacific, Eli Lilly, Novo Nordisk, Servier, Pharmacia & Upjohn, Medica Pacifica, NZMS, Aventis, 3M, Douglas, Becton Dickinson.

Contribution to Health Status

This therapeutic group includes people with diabetes mellitus. Although incidence may not be increasing, diagnosis and degree of intervention is increasing. Traditionally ins ulin and the oral hypoglycaemics have been the mainstays of treatment (following diet and weight reduction) and variations of these products (i.e. insulin analogues, other classes of oral hypoglycaemics) 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

Diabetes mellitus (referred to from now on as 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 heart disease, hypertension lipid abnormalities, 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 Diabetes Control and Complications Trial (DCCT) clearly indicated that aggressive treatment of IDDM patients with insulin decreases some of the medium and long-term complications of this condition believed to be mediated by high levels of glucose.

More recent evidence from the UK Prospective Diabetes Study (UKPDS) shows that intensive therapy to reduce hyperglycaemia reduces the risk of complications. Therefore improved glucose control is now strongly linked to improved long-term complication rates.

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

Insulin

Insulin expenditure is growing rapidly, it was $12.3 million for the year ending June 1999 and is expected to reach $17.7 million by the end of the year ending 2003.

Oral Hypoglycaemics

These products are growing at 10% per year, however expenditure is estimated to markedly reduce as a result of significant price reductions on almost all products following tender.

Glucagen Hypokit

Growth is likely to be due to an increased incidence of hypoglycaemia in line with improved diabetes control.

Diabetes management agents

Blood glucose test strips expenditure is growing, and forms a significant proportion of total diabetes expenditure.

Syringes and needles are a very small part of expenditure and are expected to continue to be so, growing very slowly, as we do not plan to actively increase funding in this area in the next few years.

Insulin Pumps

We have received requests by patients to fund insulin pumps. 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. The subcommittee has considered the issue and expressed an interest in considering it further but gave

it a low priority compared to other diabetes areas and asked that before it consider it further, the funding stream (HFA directly or PHARMAC) be clarified.

Other

Sildenfil (Viagra) is now registered and available on prescription.

Cost Savings

Disease State Management

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.

Diabetes is one of 3 key areas named in the HFA/MOH funding agreement to be targeted for a disease state management approach. PHARMAC proposes to be closely involved in this HFA work via being consulted on draft documents and liaising with the relevant HFA people and being represented on the working party. Of the 3 areas progress seems greatest in diabetes.

The HFA has set up a Diabetes National Advisory group.

Proposed Key Actions for 2000/01

- Assess new products - analogues and repaglinide in particular. Listings may result.
- Assess impotence treatments.
- Participate in HFA Disease State Management programme.

STRATEGIC OVERVIEW OF IMMUNOSUPPRESSION

Current Expenditure

BNF2 groups	HFA Cost ($m, excl GST)		Growth
	1998/99	**1999/00**	
Drugs affecting immune response	11.5	12.3	7%
Group Total	**11.5**	**12.3**	**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.

Main suppliers

Novartis, Roche, Janssen-Cilag, Glaxo-Wellcome, Schering-Plough

Reasons for expenditure growth

The recent large jump in spending in this group – increase over 1998 spending of 34% - is accounted for primarily by the new listings of tacrolimus, mycophenolate mofetil, and expansion in access to cyclosporin for severe atopic dermatitis. Together, these drugs account for 80% of the increase. Both tacrolimus and mycophenolate mofetil spending is running roughly according to forecasts made at the time of their listing. Cyclosporin growth appears much larger than anticipated but is likely to have been driven by the change in access. Thus spending can be summarised as being driven by volume and mix effects.

Clinical and financial risks and opportunities

Ribavirin

Ribavirin is a relatively old drug but is finding new application in combined therapy with interferon for the treatment of hepatitis C. As a consequence, its listing – at a cost itself - would also increase the use of interferon.

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 roughly constant. Recent additions to the immunosuppressant armory have been funded. However, there is a desire to expand access to some of them with additional financial consequences (e.g. mycophenolate mofetil for those in whom azathioprine is contraindicated).

Budget holding and/or national dosing schedules

It could be argued that budget holding would increase physicians' incentives to back titrate and otherwise closely examine immunosuppression dosing regimes. However, counter-arguments may be raised that such incentives exist already given the potential side effects experienced by patients in this area. Further, dosing schedules in New Zealand in this area of treatment are currently thought to be standardised nationally by the NZ Nephrology Group. Opportunities to improve the efficiency of the way in which these medicines are used may be low.

Proposed PHARMAC actions

Next 12 months

- Review the listing of interferon alpha monotherapy for hepatitis C in light of new evidence concerning combination therapy.

- Identify if there are any ways of introducing price competition for cyclosporin and interferon.

STRATEGIC OVERVIEW OF ONCOLOGY DRUGS

Current Expenditure

BNF2 groups	HFA Cost ($m, excl GST)		Growth
	1998/99	99/00	
Cytotoxic drugs	1.3	1.4	7.7%
Hormones and antagonists	4.6	3.6	22%
Group Total	**5.8**	**5.0**	**5.2%**

Key information about the group

Oncology drugs account for about 1% 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 tumours 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 has both positive and negative effects.

Main suppliers

Pharmacia and Upjohn, Baxter, Pacific, AstraZeneca, Novartis, GlaxoWellcome

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 cancers 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 on hormones and hormone antagonists.

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).

Geographical equity

There are geographical disparities in access to cancer drugs (notably Taxol) that are resulting in calls to fund more oncology drugs through the Pharmaceutical Schedule.

Budget holding

Oncologists consider that they have been put at a disadvantage, relative to other specialties, through oncology drugs being managed by budget holding. They note that given the very low price of the older drugs, they are unable to make sufficient efficiency gains to fund new drugs within existing budgets. Further, they note that funds for surgery and radiation are not held within the oncology budget. Consequently, they consider that if the new pharmaceutical technology is to be accessible, additional funding needs to be allocated to oncology.

Proposed PHARMAC actions

Next 12 months

- 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. In particular, PHARMAC will consider if budget holding by hospitals or at a national level might improve access to oncology agents and at the same time, assist the management of future spending risks. Review and re-development of the policy on funding oncology agents will occur before PHARMAC considers any more listing applications for such agents.

- Applications to list new oncology agents are anticipated very shortly. These are very likely to require detailed cost utility analyses.

STRATEGIC OVERVIEW OF THE DEMAND SIDE

Background

The past year has seen the implementation and development of the Demand Side initiatives based on the initial strategy for the Demand Side and subsequent business plan.

Projects which have been undertaken to date include:

Project Type	Project	Period
Supporting Supply Side	ACE inhibitor implementation	June 1998 to December 1999
	DHP CCB implementation	April 1999 to January 2000
	Lispro Special Authority	June 1999
High Priority Areas	Antibiotics pilot	Winter 1998
	Antibiotics campaign	May – October 1999
	Asthma	September 1999 – Feb 2000
	Generic prescribing	September 1999 -
	Cardiovascular	March 2000 -
	Diabetes	May 2000 -
Ongoing Activities	Conference support	Various
	Publications	Journal articles
	Website	February 1999 revamp

Other activities included the shift in management of the referred services contracts, i.e. BPAC and PreMeC to PHARMAC from the Health Funding Authority. As far as possible, without compromising independence, PHARMAC has endeavoured to collaborate with these and other organisations (such as interest groups and healthcare professionals) to maximise results.

Proposed Activities

The key high expenditure areas in terms of mix and volume will be targeted. The most recent data is being used to identify key areas. Activities planned in these areas will be agreed upon by the Demand Side team and the Therapeutic Group Managers involved. Input will be sought from interest groups, the Health Funding Authority and healthcare professionals and representative bodies so as to ensure added value and a co-ordinated approach rather than a duplication of effort. In line with HFA and PHARMAC overall strategies, Maori health aspects will be considered in each case.

Anti-psychotics

Key Issues and Assumptions

This is an area of growing expenditure. The CNS therapeutic group is the second highest in terms of the mix component of pharmaceutical expenditure, the fourth highest in terms of the volume component, and the highest group in terms of overall expenditure on pharmaceuticals.

The growth is mainly due to the shift by prescribers to the newer, more expensive therapies - risperidone, clozapine and olanzapine that were listed on the Schedule in February 1999, as a result of a transfer from the mental health budget to the pharmaceutical budget.

Financial Risks

Funding of olanzapine has provided access to atypical anti-psychotic agents to meet most of the current demand. However, the new arrangements may also increase the risk of disproportionate use of olanzapine over risperidone and may necessitate demand side initiatives to avoid additional financial risk.

Proposed Activities

Demand side initiatives need to focus on the mix component of anti-psychotic expenditure. Activities should be designed to encourage the appropriate use of olanzapine vs risperidone, and should be targeted at psychiatrists. Key messages could include the promotion of risperidone as a first line agent, as the price is much lower than olanzapine and clinical trials indicate that both drugs are similar in efficacy and side effects.

Gastrointestinal

Key Issues and Assumptions

Alimentary Tract and Metabolism is second highest in terms of overall pharmaceutical expenditure, first in terms of volume and fifth in terms of the mix component of pharmaceutical expenditure. One of the reasons for the growth in expenditure is due to an increase in the volume of ulcer healing agents, despite price reductions on the H2 antagonists and Proton Pump Inhibitors (PPI). This has been limited to some extent by expenditure caps. 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/mix growth.

Financial Risks

H2 antagonists are significantly cheaper than PPIs. There is underlying growth in use of PPIs. There is now a range of triple therapy H.pylori eradication packs listed on the Schedule (omeprazole/amoxycillin/clarithromycin (OAC) and omeprazole/amoxycillin/metronidazole (OAM)). 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.

Proposed Activities

Demand side activities will address dose and treatment choice issues. Activities could include promotion of a trial of the less expense H2 antagonists before treating with PPIs. Incorporated into this programme could be the promotion of H.pylori eradication to eliminate the need for on-going treatment.

Benefits

As the triple therapy H.pylori eradication packs can cure ulcer disease as opposed to just treating symptoms, promotion of these packs should lead to a decrease in the demand for long-term ulcer therapy.

Promotion of the H2 antagonists ahead of PPIs should address the issue of underlying growth in PPIs.

Anti-infectives

Key Issues and Assumptions

More specific targeting in terms of shifting the mix should be attempted, as anti-infectives are currently third highest in terms of the mix component of pharmaceutical expenditure and the fifth highest group in terms of total overall pharmaceutical expenditure. This area should continue to be targeted as reinforcement of the previous years' messages. Mix continues to be problematic. There needs to be a shift to narrow spectrum antibiotics to reduce costs and the development of resistance.

Financial Risks

Switching from cheaper to more expensive broad-spectrum antibiotics could limit gains.

Proposed Activities

IPAs and other healthcare providers should be supported in the third year of the campaign to address the appropriate use of antibiotics. Messages should be designed to reinforce last year's key message of not treating viral "colds and flu" with antibiotics, while the use of broad vs narrow-spectrum antibiotics should be a key message for this years campaign.

Cardiovascular

Key Issues and Assumptions

Cardiovascular is the third highest pharmaceutical expenditure therapeutic group. It is also a major cost to the HFA in terms of other healthcare funding. Prevention is a key component in managing cardiovascular disease. Sharing initiatives with other groups within the sector, as well as interest groups, would be useful.

Financial Risks

There are three major areas of expenditure within the cardiovascular therapeutic group: ACE Inhibitors, lipid modifying agents and calcium channel blockers. There is strong underlying growth in the area of ACE Inhibitors, with over 130,000 patients currently being treated by them. Lipid modifying agents are the area with the highest growth within the cardiovascular therapeutic group, with an underlying shift from cheaper not promoted fibrates towards more expensive statins.

Proposed Activities

PHARMAC should add value to activities that reduce total cardiovascular risk, such as lifestyle modification programmes. A joint effort by PHARMAC and the HFA / Ministry of Health in part funding Green Prescriptions organised by the Hillary Commission will be addressed.

The National Heart Foundation and Rod Jackson also have activities in which PHARMAC could play a role in the pharmaceutical expenditure area, for example, programmes such as PREDICT, are designed to enable doctors to identify overall cardiovascular risk.

Other demand side actions could relate to the promotion of wider use of ACE inhibitor drugs and spironolactone in CHF patients and beta-blockers following myocardial infarction. Despite numerous studies demonstrating efficacy of these drugs in reducing mortality they seem to be underused at present. This campaign could focus on working with other organisations such as BPAC, PreMeC and IPAs to ensure this message is promoted through bulletins and case studies. These would not carry any direct cost to PHARMAC.

Benefits

Health gains – promotion of a healthy lifestyle could positively contribute towards savings in pharmaceutical expenditure through the non-issue of pharmaceutical prescriptions in favour of "green" prescriptions and may impact on other therapeutic areas too, e.g. diabetes.

Osteoporosis

Key Issues and Assumptions

The key agents used in the treatment of osteoporosis are HRT, etidronate, calcitriol and alendronate. The role of calcitriol in the treatment and prevention of osteoporosis has been questioned by some clinicians and supporters of the bisphosphonate alendronate, and continued growth in the use of calcitriol has been of concern for some time. Calcitriol and etidronate are both currently available with a Specialist Recommendation. Alendronate has been available since 1 April 2000, and is subsidised for the treatment of severe osteoporosis for patients meeting Special Authority criteria.

Financial risk

While expenditure on calcitriol is likely to fall significantly as a result of a new agreement there is still considerable pressure on PHARMAC to restrict access to this agent in favour of increased access to the bisphosphonates.

Proposed activities

Demand side initiatives could include supporting the development of clinical guidelines for the treatment and prevention of osteoporosis. It is anticipated that the guidelines would support a shift from calcitriol to etidronate. Any activity would need to involve working with key stakeholders to ensure that the guidelines are accepted by, and promoted to, both specialists and GPs. Activities should link with referred management service providers such as PreMeC, to ensure complementary promotion of key messages through tools such as bulletins.

Benefits

The shift of patients from calcitriol to etidronate would be cost neutral at this stage. Any promotion encouraging a shift from calcitriol to etidronate is based on clinical not financial outcomes.

Other initiatives

Some of the initiatives could be combined with specific projects. Resource dependent, the following will be investigated:

- ***Asthma***

An asthma management campaign in 1999/2000 targeted both patients and health professionals. Any additional Demand Side work would be around supporting organisations with the implementation of local asthma management strategies, and the further distribution of existing promotional material.

- ***Diabetes***

Diabetes was targeted in the 1999/2000 business plan. Any Demand Side activity in 2000/2001 will be linked with the activities undertaken in 1999/2000.

Currently it is estimated that many diabetic patients do not receive treatment, and only a proportion of those who do are treated with the most effective regimen. Demand Side activities could include the development of treatment guidelines, and support for educational programmes.

Diabetic patients also often have other conditions such as hypertension and lipid abnormalities which also have significant treatment cost implications. There are also benefits for diabetes resulting from the cardiovascular activities outlined above.

- ***NSAIDs***

Small volumes should be dispensed for the first issue, reducing waste due to compliance and intolerability issues.

- ***Compliance***

Ongoing education and promotion on the correct use of medicines should be undertaken, focusing on methods to increase compliance.

- ***Waste Management***

This should focus on the wise use of medicine.

- ***Polypharmacy***

A project on the dangers associated with mixing medicines could be undertaken.

- ***Medicalisation***

A look at changing lifestyle as a first option rather than medicines should be looked at.

- ***Drug Information***

The Demand Side will have a role to play in development of a drug information source and/or formulary should the Medical Director pursue this objective.

The Demand Side team will also support other PHARMAC projects when required, and provide resource where available and appropriate. Such projects could include:

- a review of the Special Authority mechanism;
- a project to review the feasibility of incorporating additional information into the Schedule to develop a BNF style publication.

Ongoing Demand Side Activities

Website

The site should be maintained as a key PHARMAC communications tool. Its use should be encouraged by updating with interesting articles and news items.

Publications/Articles

Articles on PHARMAC, the Demand Side and projects should be contributed to industry journals and lay media to increase knowledge of PHARMAC and the transparency of its operations.

Support

Industry conferences, workshops and lectures should be supported. PHARMAC should endeavour to obtain promotional space and speaker privileges for its contribution. Advantage should be taken of public speaking opportunities.

Promotion

Opportunities for promotion of PHARMAC should be increased. The use and usefulness of promotional tools should be monitored.

Referred Services Contracts

Contracts with referred services organisations will be managed based on the evaluation of referred services management in 1999.

Sector Liaison / Relationship Building

It is important to work with other groups with the sector to ensure the smooth implementation of campaigns and buy-in of key messages. The Demand Side team intend to meet with key stakeholders and representative bodies on a quarterly basis.