

**Pharmaceutical Management Agency
(PHARMAC)**

Statement of Intent

1 July 2004 to 30 June 2005

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FOREWORD

The Pharmaceutical Management Agency (PHARMAC) has prepared this Statement of Intent (SOI) to meet the requirements of section 67(1) of the New Zealand Public Health and Disability Act 2000 (NZPHD Act).

The SOI outlines for Parliament the performance we have agreed with the Minister of Health (the Minister) to deliver for the year commencing 1 July 2004 to 30 June 2005.

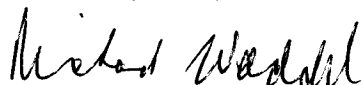
In particular, this document specifies:

- the performance that PHARMAC will seek to achieve from 1 July 2004 to 30 June 2005;
- the ownership performance PHARMAC will aim to achieve during this time; and
- financial forecasts.

This specification of performance will be used as a basis for comparison against our actual performance when our annual report is prepared at the end of the year.

The community pharmaceutical budget for 2004/05 was confirmed in June 2004 and has been reflected in the completion of a Crown Funding Agreement which will be signed in July 2004.

Should PHARMAC's purchasing intentions change significantly, PHARMAC will exercise its discretion under section 41H of the Public Finance Act 1989 (the PF Act) and produce a revised SOI.



Richard Waddel
Chairperson
PHARMAC

June 2004

PART 1 PHARMAC'S OBJECTIVES AND STRATEGIC PRIORITIES

PHARMAC's objectives, as outlined in section 47 of the NZPHD Act, are to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided.

PHARMAC's Statutory Functions

In accordance with section 48 of the NZPHD Act, the functions of PHARMAC are to perform the following within the amount of funding provided to it and in accordance with its annual plan and any directions given to it under section 65 of the NZPHD Act:

- a) to maintain and manage a Pharmaceutical Schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies;
- b) to manage incidental matters arising out of (a) including, in exceptional circumstances, providing for subsidies for the supply of pharmaceuticals not on the Pharmaceutical Schedule;
- c) to engage as it sees fit, but within its operational budget, in research to meet the objectives set out in section 47(a) of the NZPHD Act;
- d) to promote the responsible use of pharmaceuticals; and
- e) any other functions it is for the time being given by or under any enactment, or authorised to perform by the Minister by written notice to the Board of PHARMAC after consultation with it.

As a result of an authorisation from the Minister in September 2001, under section 48(e) of the NZPHD Act, PHARMAC is authorised to manage the purchasing of any or all pharmaceuticals, whether used either in a hospital or outside it, on behalf of District Health Boards (DHBs).

Strategic Priorities

In preparing this SOI, PHARMAC has undertaken a review of the Strategic Priorities which will guide its business activities over the following three-year period. As a result of this review, PHARMAC has revised its Strategic Priorities. While the new priorities are consistent with those PHARMAC has relied on in the past, they now better reflect the development of PHARMAC's core activities and its planned future direction.

PHARMAC's Strategic Priorities for 2004/05 and the following two years are outlined below. The first two priorities reflect PHARMAC's core statutory functions. Priorities 3, 4, 5 and 6 are important to enable PHARMAC to meet its core statutory functions. Finally, Strategic Priority 7 reflects new initiatives which are a short term priority but which are ultimately expected to either form part of PHARMAC's core activities or to fall away. PHARMAC expects that

this priority will change annually over the three-year period covered by this SOI.

Strategic Priority 1: Comprehensive management of pharmaceutical expenditure and use

PHARMAC will ensure that the Pharmaceutical Schedule is managed in a manner that ensures that treatments are appropriately prioritised and listed, and that maximises health outcomes from within the funding available. PHARMAC will also engage in strategies to promote the cost effective, responsible use and prescribing of pharmaceuticals.

PHARMAC is known for its ability to meet challenging targets and its primary focus will continue to be managing pharmaceutical expenditure on behalf of DHBs. However, an important part of PHARMAC's focus is programmes aimed at promoting the responsible use of pharmaceuticals. This priority integrates PHARMAC's Supply Side and Demand Side activities to reflect the need for a holistic approach to managing pharmaceutical expenditure both by PHARMAC and across the sector.

PHARMAC will engage in activities with the aim of ensuring that patients have access to a wide range of subsidised pharmaceuticals and that patients and prescribers are aware of the appropriate use of those pharmaceuticals. PHARMAC Demand Side campaigns will work in partnership with local DHB initiatives to promote the responsible use of pharmaceuticals.

Strategic Priority 2: National Hospital Pharmaceutical Strategy

Following the successful implementation and review of the National Hospital Pharmaceutical Strategy, PHARMAC will further develop and implement the Strategy to assist DHBs with the management of expenditure on hospital pharmaceuticals.

During the 2003/04 year, PHARMAC conducted a two year review of the National Hospital Pharmaceutical Strategy and received feedback from various levels within DHBs on the success of the strategy against its stated goals. The review indicated that savings of approximately \$10 million per annum have been achieved. More than 40% of hospital pharmaceutical expenditure is now under PHARMAC national contracts. Continued contracting is likely to result in both an increase in savings and an increase in the percentage of expenditure under national contracts.

In pursuing this priority, PHARMAC will progress initiatives to ensure DHB Hospitals can purchase key pharmaceuticals at the best possible prices and will continue its on-going assessment of the cost-effectiveness of new pharmaceuticals proposed to be used in DHB Hospitals. During 2004/05 PHARMAC will focus on the continuation and monitoring of the discretionary community supply provisions in the Pharmaceutical Schedule. PHARMAC will also assess its future role in the development and implementation of a quality use of medicines strategy for DHB Hospitals.

Strategic Priority 3: Working with DHBs

Building on the closer co-operation which has been achieved between PHARMAC and DHBs, PHARMAC will focus on improving information sharing and risk management and on developing and implementing specific initiatives that benefit DHBs.

Strategic Priority 4: Ensuring all New Zealanders have similar access to subsidised pharmaceuticals

PHARMAC will engage in initiatives to promote the appropriate use of pharmaceuticals by disadvantaged populations, including Maori, to improve health outcomes and health status and ensure utilisation is similar across all groups of New Zealanders.

Strategic Priority 5: Improving relationships with stakeholders

PHARMAC will develop its relationships with stakeholders through regular meetings and a clear communications strategy aimed at achieving a better understanding of PHARMAC's objectives in the wider public arena. Key relationships include the Minister, the Ministry of Health, all politicians, other government agencies, clinicians, pharmacists, patients and their representative groups, Maori, and the pharmaceutical industry.

Strategic Priority 6: Developing PHARMAC's internal capacity

PHARMAC will ensure that it has the capability to meet its business objectives through the recruitment of staff with appropriate skills, experience and knowledge, the provision of an attractive working environment and through demonstrating the value it places on staff.

Strategic Priority 7: New initiatives to assist DHBs

PHARMAC will extend its operational activity to include new initiatives that assist DHBs. In 2004/05, PHARMAC will procure the influenza vaccine and will assume responsibility for the management of the pharmaceutical cancer treatments budget (the "Cancer Basket"). PHARMAC will also develop further initiatives, in conjunction with DHBs.

PHARMAC staff have begun a process of seeking information on the current purchasing activities of DHBs in relation to a selected list of medically related products and services. PHARMAC anticipates that it could bring an evidence-based evaluation and decision-making approach to procurement of medical products which could deliver value to DHBs. The initial indications are that there is wide variation amongst DHBs in how these purchasing activities are conducted. This may lead to regional rather than national initiatives.

While an expansion of PHARMAC's functions beyond the terms set out under section 65 of the NZPHD Act would require authorisation from the Minister, the new DHB approved initiatives that PHARMAC is currently working on (being the influenza vaccine and the management of the funding of pharmaceutical cancer treatments as discussed below) remain within the terms of PHARMAC's mandate. PHARMAC has taken legal advice to ensure that it stays within the scope of the NZPHD Act and will continue to seek legal advice in implementing this Strategic Priority in order to ensure that it continues to operate within the law.

Two initiatives that PHARMAC will be focussing on during 2004/05 are the procurement of the influenza vaccine and the management of the Cancer Basket. These initiatives were proposed by the DHBs and PHARMAC has undertaken to work on the initiatives following consultation with the Ministry of Health (Ministry). PHARMAC will continue to work with DHBs and the Ministry in progressing these initiatives.

PHARMAC will undertake the procurement of the influenza vaccine on behalf of the DHBs for the 2005 winter campaign. PHARMAC was approached by the Ministry to undertake this role and this was approved by the PHARMAC Board in September 2003 and by the DHB CEOs in May 2004. The budget for the influenza vaccine and the immunisation benefit will remain with the DHBs. The system for purchase, claiming and criteria for eligible patients will remain unchanged. PHARMAC proposes to issue a Request for Proposals and award a contract before December 2004 for the start of the campaign in April 2005.

It is also proposed that the management of funding for all pharmaceutical cancer treatments be transferred to PHARMAC during the 2004/05 year. All pharmaceutical cancer treatments would be listed in the Pharmaceutical Schedule with associated subsidies. DHB Hospitals would continue to purchase and pay for these cancer treatments as they currently do but would be required to claim for reimbursement via HealthPAC. PHARMAC's indicative community pharmaceutical budget would be increased to reflect current spending on pharmaceutical cancer treatments. PHARMAC will be establishing a high level steering group with multi-agency representation to assess this proposal.

As well as the key strategies outlined above, PHARMAC's future direction will focus on developing strategic alliances with others in the sector and maximising core competencies such as analysis and assessment tools which could be used as a blueprint for other areas of the health sector. These activities will ensure that PHARMAC continues to achieve excellent results in managing New Zealand's community pharmaceutical budget while building relationships across the sector and offering its expertise to improve health and fiscal outcomes for New Zealand.

PHARMAC's aim in 2004/05

PHARMAC's aim in 2004/05 is to focus on:

- continuing to manage the Pharmaceutical Schedule effectively by listing products that will help achieve the objectives outlined in the New Zealand Health Strategy (Strategic Priority 1);
- improving PHARMAC's work in promoting the responsible use of pharmaceuticals by focussing on projects with measurable outputs and/or outcomes over the medium term (Strategic Priority 1);
- developing a mechanism with DHBs for on-going funding for Demand Side campaigns (Strategic Priority 1);
- continuing to seek ongoing benefits through nation-wide hospital pharmaceutical purchasing and looking for synergies between the community and hospital pharmaceutical sectors (Strategic Priority 2);
- developing increasingly closer working relationships with DHBs through improved information sharing and risk management (Strategic Priority 3);
- contributing to improvements in the health status of all New Zealanders by helping to ensure that all New Zealanders have similar access to subsidised pharmaceuticals (Strategic Priority 4);
- working to identify representative groups which will be impacted by PHARMAC's activities and decisions and, where possible, communicating with those groups prior to significant decisions (Strategic Priority 5);
- reviewing internal structures and skill sets to ensure that PHARMAC is best placed to achieve its aims in promoting the responsible use of pharmaceuticals (Strategic Priority 6);
- taking steps to procure the influenza vaccine for use in the community and progressing the consideration of the transfer to PHARMAC of management of the Cancer Basket (Strategic Priority 7); and
- developing further new initiatives with DHBs to support them in achieving their objectives (Strategic Priority 7).

PHARMAC's plans for each of these strategic priority areas are set out in more detail below and in section 3 of PHARMAC's Annual Plan. In planning for these strategic priorities, PHARMAC has made a distinction between those priorities which encompass funding responsibilities (Strategic Priorities 1 and 2) and those priorities which are intended to enable PHARMAC's performance of its core statutory function (Strategic Priorities 3, 4, 5 and 6). Strategic Priority 7 of this SOI is more closely aligned with PHARMAC's funding responsibilities. However, this could change depending on the nature of initiatives which PHARMAC and DHBs decide to work together on. For the purposes of this SOI, PHARMAC has dealt with Strategic Priority 7 as a funding responsibility.

This distinction has also been used by PHARMAC in setting its performance targets for the year. Strategic priorities 1, 2 and 7 relate to purchase objectives which are set out in Section A of Part 2 of this Statement of Intent. Strategic priorities 3, 4, 5 and 6 relate to ownership performance objectives which are set out in Section B of Part 2 of this Statement of Intent.

Key Activities

➤ Managing pharmaceutical expenditure

PHARMAC's success in managing the community pharmaceutical budget has been predominantly as the result of Supply Side initiatives managing price and, to some degree, the volume and mix components of pharmaceutical expenditure. Volume growth has been affected by targeting tools such as the Special Authority mechanism and mix growth has been affected by reference pricing and tendering. PHARMAC's activities in promoting the responsible use of pharmaceuticals are also a key tool in managing the pharmaceutical budget.

The key strategic approaches that PHARMAC will continue to use to manage the supply aspects of the pharmaceutical budget are:

- exploiting market opportunities to reduce the unit cost of pharmaceuticals, so that DHBs obtain better value on existing medicines and so that new investments can be funded;
- listing pharmaceuticals that are assessed as offering value for money within the budget that is available, so that health outcomes for the New Zealand population are improved;
- monitoring and managing our supplier contracts, so that DHBs receive the full benefit of our supply agreements;
- managing and enhancing our relationships with all our stakeholders, so that our stakeholders perceive PHARMAC as an effective and valuable organisation; and
- contracting for services to promote the responsible use of pharmaceuticals.

For the first time PHARMAC has a three-year community pharmaceutical funding path including a provision for new investments. Year one is set by the Minister of Health and years two and three are indicative only. This will allow both PHARMAC and suppliers to plan investments into the future with more confidence. Suppliers have been asking for this signal as part of the Government's commitment to the pharmaceutical industry. It also links into the three-year funding path for DHBs.

While there is a commitment to new investments, the extent of the investment is dependent on:

- the available budget; and

- the success of our negotiation strategies in managing the existing budget.

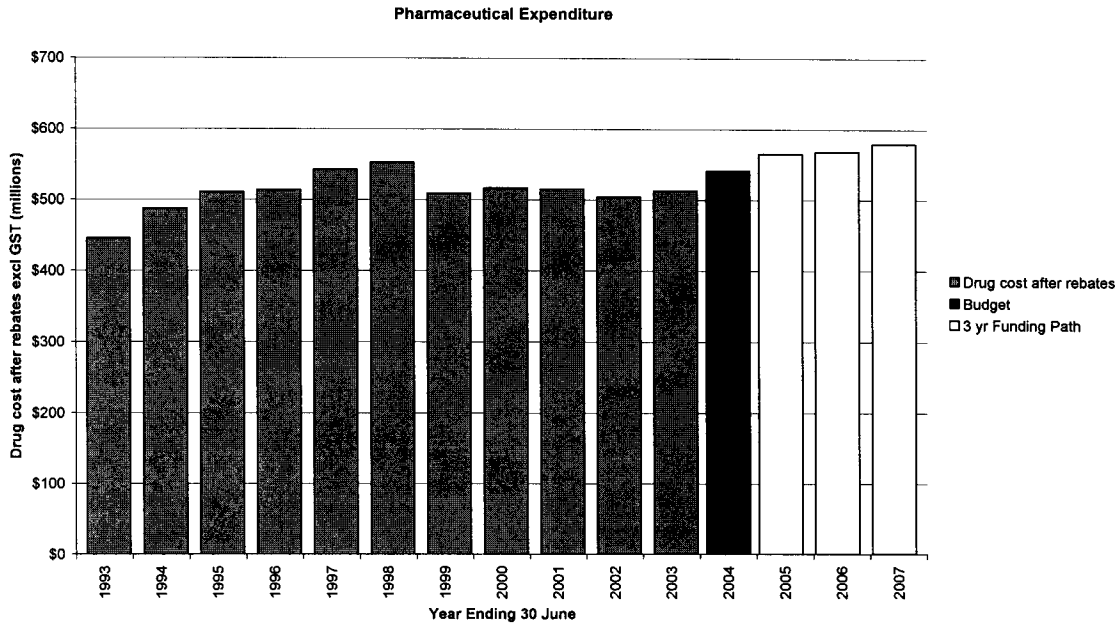
The investment opportunities that we have identified for 2004/05 fall within the following therapeutic groups:

- Respiratory
- Oncology and Immunosuppression
- Analgesia
- Mental Health
- Infections
- Diabetes
- Blood and blood forming
- Dermatology
- Musculoskeletal

PHARMAC is focusing on obtaining the most value from the tender for 2004/05. In particular, when key products in therapeutic groups come off patent, we will be looking to ensure maximum value by reviewing opportunities to apply reference pricing or to use other aspects of PHARMAC's negotiation strategies in an effort to get the best value for DHBs' investment in medicines.

The drug cost portion of pharmaceutical expenditure, after rebates, is budgeted to be \$565 million (excluding GST) during 2004/05. This represents about 4% growth from projected actual expenditure in 2003/04. The underlying growth results from using newer more expensive medicines and volumes are forecast to continue trending upward. These increases will, to some extent, continue to be offset by savings and rebates.

The following graph shows actual expenditure for the past 10 years, the projected out-turn 2004, the budget for the current year, and forecast expenditure for the following two years.



The focus of Supply Side transactions (PHARMAC defines transactions as agreements with suppliers to reduce prices or manage expenditure of individual or groups of pharmaceuticals) is to improve the value of the Government's expenditure on pharmaceutical subsidies. This is achieved by improving value for money by lowering subsidies and improving the quality of expenditure by investing in superior medicines.

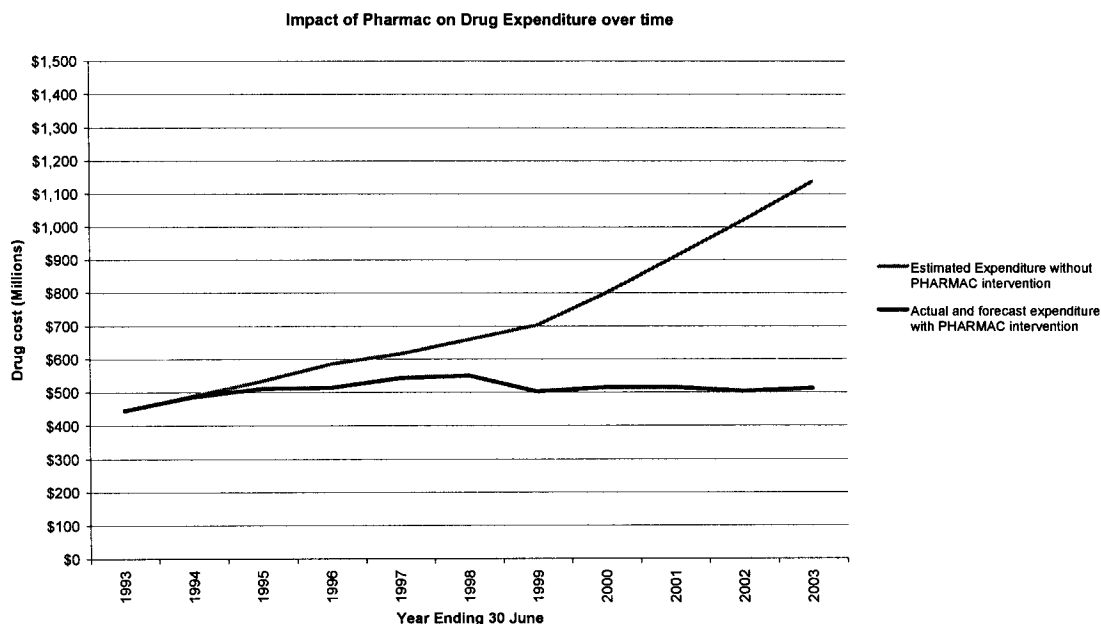
This year PHARMAC will again apply rigorous attention to management of new investments and savings with a view to managing expenditure within target. This activity allows us to lower subsidies, counteracting the 9% underlying growth in the market due to increasing volumes and a shift from the use of cheaper to more expensive drugs.

New pharmaceuticals will continue to be evaluated using our pharmacoeconomic tools. Priorities for funding will be established based on the projected cost-quality adjusted life year (QALY) ratio, with low ratio products having higher priority. We will also consider the other features of the products, such as how well they meet PHARMAC's Decision Criteria.

Rebates are an increasingly important part of PHARMAC's financial performance increasing from \$20.1 million in 2000/2001 to a projected \$81 million in 2003/04. Rebates are forecast to be about \$100 million in 2004/2005. This represents an increase on rebates for 2003/04 as a consequence of continued use of the rebate mechanism by pharmaceutical companies.

The following chart shows the impact of the successful implementation of a range of savings transactions. The line showing estimated expenditure without PHARMAC intervention highlights the strong underlying growth, of 9% per annum, that exists for pharmaceuticals. This line is calculated by assuming that without PHARMAC's intervention, subsidies would have

remained at the same level as those applying in 1993. It, therefore, does not show the effect PHARMAC has had on expenditure as a result of exercising control of new listings.



➤ Demand Side activities

PHARMAC's Demand Side team undertakes activities to address PHARMAC's legislative function to promote the responsible use of pharmaceuticals. The activities of this team, in conjunction with the activities of the Supply Side team, enable PHARMAC to meet its strategic priority to comprehensively manage pharmaceutical expenditure and use.

During the term of this SOI, PHARMAC will continue with Demand Side initiatives which are aligned with the New Zealand Health Strategy and other key health strategies. Campaigns which will be run in 2004/05 include:

- a continuation of the very successful annual "Wise Use of Antibiotics" Campaign;
- the cardiovascular risk management campaign "One Heart Many Lives" which is being further rolled out in 2005 following successful pilot roll-outs in Gisborne and Porirua in 2003/04;
- a campaign to promote the appropriate use of diabetes test strips which is intended to commence in the second half of 2004 following research and consultation with interested parties; and
- a campaign to promote the cost effective utilisation of Atypical Antipsychotic medicines. This campaign is expected to commence in 2004/05 after consultation with interested parties.

PHARMAC also contracts for referred service activities which promote the responsible use of pharmaceuticals. These include the Green Prescription Programme and activities undertaken by the Best Practice Advocacy Centre New Zealand. PHARMAC ensures that, wherever possible, the contracted services are aligned with activities undertaken by DHBs in their contracting with Independent Practitioners Associations (IPAs) and Primary Health Organisations (PHOs). An example of this was the asthma campaign launched in February 2003 which was co-ordinated by PHARMAC, funded with the support of the DHBs and supported by a broad cross section of the medical community including general practitioners, asthma educators, nurses and pharmacists. PHARMAC is also working on the National DHBNZ/Ministry of Health Referred Services Management Project to ensure that external agencies contracted to undertake pharmaceutical demand services are aligned with proposed clinical and quality indicators.

Where possible, PHARMAC will work in collaboration with key stakeholders. Examples of campaign collaboration include involving pharmacy groups, general practice organisations, the NZ Guidelines Group and Diabetes New Zealand for the diabetes campaign; and involving the National Heart Foundation and Sport and Recreation NZ (SPARC) in the "One Heart Many Lives" campaign. PHARMAC will act upon requests from clinicians and communities for clinical resources; assist in the implementation of PHARMAC Supply Side contracting initiatives; and assist in implementation of PHARMAC's Maori Responsiveness Strategy through the development of culturally appropriate resources.

PHARMAC recognises the developing role of PHOs and the growing role of various health professionals, such as nurse prescribers, in the prescribing continuum. To this end, PHARMAC is working closely with the Ministry and DHBs to ensure that PHARMAC Demand Side management and the pharmaceutical referred services component of PHO contracts are aligned.

The addition of nurse practitioners to the prescribers defined in the Pharmaceutical Schedule has had minimal impact to date on prescribing as only one nurse has completed the Nursing Council's requirements for prescribing. However, it is expected that the number of nurse prescribers will increase slowly over the next few years and that other health professionals such as optometrists will become increasingly involved in the provision of pharmaceuticals.

Changing attitudes, expectations and behaviour of individuals and agencies takes time. PHARMAC continues to use recognised techniques to elicit behavioural change in health professionals and social marketing techniques to elicit behavioural change in patient groups. During 2004/05 PHARMAC aims to improve its work in this area by focussing on projects that have measurable outputs and/or outcomes over the medium term. PHARMAC will be reviewing internal structures and skill sets to ensure that it is best placed to achieve this.

In 2004/05 PHARMAC plans to fund approximately \$1.7 million of Demand Side activities from Crown reserves. To ensure the sustainability of a similar level of Demand Side activities in 2005/06 (once the Crown equity has been consumed) PHARMAC will work with DHBs in 2004/05 to obtain a commitment from DHBs to financially support PHARMAC's Demand Side programme in 2005/06. As Demand Side activities help to control DHB pharmaceuticals expenditure, it is appropriate that DHBs contribute to the funding of this programme.

➤ **Hospital pharmaceutical purchasing**

In the time since the Minister's approval of the National Hospital Pharmaceutical Strategy in September 2001, PHARMAC has implemented national procurement contracts for DHB Hospitals that are expected to produce savings of about \$10 million per year (of an estimated \$140 to \$150 million total spend on hospital pharmaceuticals).

Total expenditure by DHBs on pharmaceuticals is difficult to quantify. PHARMAC is only provided with purchase volume data from all DHB Hospital Pharmacies. Expenditure can be calculated from this information only when the price of the product is known. PHARMAC only has access to price information for products that are subject to a National Pharmaceutical Contract. Given these limitations, it is difficult to forecast national expenditure on hospital pharmaceuticals.

During 2004 PHARMAC conducted a review of the National Hospital Pharmaceutical Strategy (NHPS). The aims of the review were to assess:

- savings achieved through national contracting as implemented under the NHPS;
- costs to PHARMAC of additional resourcing as a result of the NHPS;
- effect of NHPS national contracts on access to pharmaceuticals;
- influence on formularies and attitudes through the New Hospital Pharmaceutical Assessment Process (NHPAP) and an assessment of the goals proposed by this process and whether these have been achieved;
- any change in the competencies of PHARMAC and DHB staff as a result of undertaking the NHPS;
- where possible a comparison between PHARMAC contracts and previous contracts entered into by individual DHBs;
- the changes in contracting terms between the first hospital contracts implemented by PHARMAC and the more recent contracts;
- the difference between hospital contracts and those entered into for community pharmaceuticals, how these changes have evolved and the motivation for the changes; and
- an assessment of the relationships with key stakeholders affected by the NHPS, in particular those that previously had little to do with

PHARMAC and how these relationships have changed through the implementation of the Strategy.

During the review of the NHPS, feedback was received from DHBs on the success of the Strategy against its stated goals. The review indicated that more than 40% of hospital pharmaceutical expenditure is now under PHARMAC national contracts. It is expected that through continued focus on this strategy there are likely to be further increases in savings and an increase in the percentage of expenditure which is under national contacts.

At its May 2004 meeting the PHARMAC Board resolved that the Hospital Strategy would continue in its current form. The Board also directed that:

- further consideration of PHARMAC's future involvement in the Quality and Safe Use of Medicines Strategy be conducted and presented to the PHARMAC Board in July 2004;
- further consideration of the future of the Hospital Pharmaceuticals Advisory Committee (HPAC) be presented to the PHARMAC Board in July 2004;
- further consideration of the options for commercial contracting for hospital supply be presented to the PHARMAC Board in July 2004;
- with DHBs agreement the Hospital Strategy be extended to include radiological contrast media, bulk intravenous fluids and recombinant blood products and the processes proposed in relation to these areas be submitted to the DHB CEOs; and
- the New Hospital Pharmaceutical Assessment Process continue in its current form until further independent review of the process is completed and that PHARMAC staff present a paper to the PHARMAC Board following the independent review of the NHPAP, outlining a proposal for the future of the NHPAP.

PHARMAC has established processes for assessing the cost-effectiveness of pharmaceuticals that DHB Hospitals are considering adding to their formularies. DHB Hospitals are not obliged to follow any recommendations made by PHARMAC. However, the processes are aimed at improving DHB Hospitals' own assessments, encouraging debate about the relative merits and disadvantages of new pharmaceuticals, and enhancing overall decision-making. This aspect was included in the two year review and an independent analyst has been contracted to conduct a further detailed analysis of the processes. During 2004/05 consideration will be given as to the future of these processes.

In order to collate national hospital pharmaceutical utilisation data without imposing onerous IT or data coding requirements on DHB Hospitals, PHARMAC has been working on a reporting system, which enables DHB Hospital pharmacy sites to report their monthly usage of pharmaceuticals to PHARMAC. A data co-ordinator within PHARMAC will then manipulate the data received into a common data format and compile it into a single database. The project has been significantly progressed and the database

includes all products which are under national contracts so monitoring of DHB compliance and allocation of appropriate rebates is achieved. All DHB Hospitals sites are now regularly reporting usage to PHARMAC. Although the quality of the data received is not as high as PHARMAC would like, limiting the potential for other uses of the data collected. No further input is likely to be required of DHBs, other than the on-going provision of monthly reports (for which programmes have been written and installed to automate the process) and some validation work.

During 2004/05 PHARMAC will consider further development of the National Hospital Pharmaceutical Strategy as a result of the two year review undertaken in early 2004 as outlined above. PHARMAC will also consider other areas of DHB hospital procurement (in pharmaceutical and related areas) where PHARMAC's expertise and experience may benefit the DHBs and result in national savings. This initiative to search for other ways in which PHARMAC can assist DHBs has been recognised as a priority by the addition of Strategic Priority 7 above.

(a) Discretionary Community Supply provisions

In the past, DHB Hospitals have dispensed a number of pharmaceuticals for use in the community that were not listed on the Pharmaceutical Schedule. This practice was inconsistent with the NZPHD Act which requires that DHBs comply with the Pharmaceutical Schedule. PHARMAC recognised that there were some pharmaceuticals not listed on the Pharmaceutical Schedule the use of which in the community by hospital out-patients was justifiable on the grounds of cost-effectiveness (whether generally or in individual cases). To cover these cases, PHARMAC's Board approved two new provisions of the Pharmaceutical Schedule for implementation on 1 July 2003. The provisions, which are detailed in Section H of the Pharmaceutical Schedule, are known as "Discretionary Community Supply (DCS)" and "Hospital Exceptional Circumstances (Hospital EC)." Feedback on these provisions was received from DHBs as part of the review of the National Hospital Pharmaceutical Strategy. PHARMAC will be reviewing this feedback and will be undertaking a specific review of the effectiveness of these provisions before the end of 2004.

(b) Quality Use of Medicines Strategy

PHARMAC, in conjunction with HPAC, developed and consulted on a Quality Use of Medicines Strategy (QUM Strategy) which focused largely on the secondary care sector with a more limited focus on the primary/secondary care interface. This Strategy was approved by the PHARMAC Board in February 2002 and PHARMAC staff subsequently sought nominations for positions on the QUM Advisory Committee.

In 2003, a Safe Use of Medicines Group was formed as part of the DHBNZ Chief Executives' initiatives. This group contained many of the individuals nominated for the PHARMAC QUM Advisory Committee.

Further, it was identified that there was a significant degree of crossover between the two initiatives.

In 2003, a decision was made for two representatives of PHARMAC to be invited to all the Safe Use of Medicines Group meetings. Since that time PHARMAC has played an active role in the Group including assisting with the organisation of the Safe and Quality Use of Medicines Conference held in May 2004.

As outlined above, PHARMAC will further review the future options for the QUM Strategy in 2004.

➤ **Exceptional Circumstances**

PHARMAC has responsibility for the management of exceptional circumstances (EC) which enables the approval of treatment for patients who have a high need for pharmaceuticals that are not otherwise subsidised and who meet certain criteria.

As noted above, during 2003/04 new Discretionary Community Supply (DCS) and Hospital Exceptional Circumstances (Hospital EC) provisions were implemented recognising that there are some pharmaceuticals not currently listed on the Pharmaceutical Schedule the use of which in the community by hospital out-patients is justifiable on grounds of cost-effectiveness (whether generally or in individual cases). Following the implementation of these provisions, the numbers of applications made under the provisions of Hospital EC was such that an additional staff member was assigned solely to process these applications.

The EC Panel have historically met two weekly by teleconference to deal with Community Exceptional Circumstances applications. With the introduction of Hospital EC the Panel members now assess applications on a daily basis, as the turn-around time for Hospital EC applications is 48 hours. The number of Hospital EC applications currently stands at around 250 a month. Where a number of DHBs are applying for a particular pharmaceutical on cost effective grounds under Hospital EC provisions, the Panel has recommended a DCS listing. Such a listing would decrease the numbers of Hospital EC applications, and hence lower the Panel workload.

➤ **Building Relationships**

DHBs

PHARMAC and DHBs have been developing a co-operative relationship since their inception in 2000. During 2002/03 PHARMAC extended its working relationship with DHBs to examining new opportunities as part of the Budget negotiation. In setting the 2003/04 pharmaceutical budget, a new level of co-operation was agreed with the inclusion of disease state management and efficiency related activities in our shared work programme. This level of co-operation was built on in setting the 2004/05 budget.

PHARMAC has a Relationship Agreement with each DHB which was entered into in January 2002. During 2003/04 PHARMAC began work on formalising processes for the management of rebates with DHBs. During 2004/05 PHARMAC will continue to work with DHBs on completing an updated Relationship Agreement reflecting new initiatives and the increasing amount of interaction between PHARMAC and DHBs.

During 2003/04 PHARMAC worked with DHBs on the implementation of changes to Section F of the Pharmaceutical Schedule, to allow the increased use of 'stat' or all-at-once dispensing. This initiative has allowed DHBs to reprioritise spending. It has also enabled DHBs to increase the amount of money available for subsidising pharmaceuticals. PHARMAC will be reviewing all-at-once dispensing by 1 October 2004 as agreed when the policy was implemented.

Relationship building with the DHBs remains a priority area for PHARMAC. Following the success of PHARMAC's efforts to meet with all DHB Board Chairs during 2002/03, PHARMAC visited all DHB Boards during 2003/04 to discuss ways in which PHARMAC can add value to their businesses.

During 2004/05, PHARMAC intends to work with DHBs and the Ministry to scope new areas where PHARMAC might be able to provide assistance to DHBs either regionally or nationally. Such areas include PHARMAC assisting with overall health management such as by taking responsibility for vaccine purchasing and negotiating the purchase of other hospital consumables, such as recombinant blood products and recombinant factor products. This area has been recognised as a priority area by PHARMAC in setting Strategic Priority 7 above.

PHARMAC will also continue to work with DHBs in connection with the pharmaceutical budget, including forecast expenditure, new investments and management of rebates; management of the Exceptional Circumstances Scheme; provision of information; joint initiatives; and hospital pharmaceutical purchasing. It is expected that DHBs will also work with PHARMAC on initiatives to promote the responsible use of pharmaceuticals as appropriate.

Patients and Consumers

Both the Supply Side and Demand Side teams conduct their relationships with patients via communication and interaction with representative groups. During 2003/04 the Supply Side team has focussed particularly on identifying representative groups most likely to be affected by activities during the year ahead and communicating with those groups prior to significant developments. This work will continue in 2004/05. PHARMAC also recognises the value in maintaining regular contact with representative groups beyond the processes triggered by particular developments.

PHARMAC continues to expect underlying growth from the use of newer more expensive drugs rather than older less expensive alternatives.

PHARMAC is committed to influencing the volume and mix of drugs prescribed. That is, ensuring that New Zealanders have access to medicines listed on the Pharmaceutical Schedule and they are taken appropriately.

The continued implementation of a Maori Responsiveness Strategy and the ongoing work of the Consumer Advisory Committee (CAC) are tangible mechanisms through which PHARMAC will seek further community engagement and analyse issues.

The CAC provides input to the PHARMAC Board from a patient or consumer perspective and is expected to focus primarily on issues around PHARMAC's Demand Side activities. A review of the work of the CAC was undertaken during 2003/04. As a result, there were slight amendments made to the terms of reference, but overall the review concluded that the CAC was performing well.

Ministry of Health

PHARMAC also has a very important relationship with the Ministry. The Ministry acts as the agent of the Minister in negotiating, communicating and clarifying the Minister's expectations and in monitoring PHARMAC's performance against the Annual Plan and the Crown Funding Agreement. PHARMAC works closely with HealthPAC and NZHIS (which are divisions of the Ministry) in carrying out its statutory objectives.

PHARMAC's performance in a number of areas is dependent upon receiving data from HealthPAC and upon HealthPAC's assistance in implementing new initiatives. PHARMAC and HealthPAC will continue to improve the sharing of information to assist HealthPAC meeting agreed deliverables in a timely manner. Data received from HealthPAC is stored on PHARMAC's behalf within the Pharmhouse data warehouse by NZHIS. PHARMAC's continued timely access to this data and involvement in the processes surrounding the structure and governance of the data warehouses are critical to PHARMAC's ongoing performance.

PHARMAC is developing a Memorandum of Understanding with the Ministry regarding the relationship between PHARMAC, HealthPAC and NZHIS. This document will replace the service level agreements which PHARMAC had with each party and will set out the expectations of each party in dealing with the other.

The Ministry of Health has indicated its intention to charge PHARMAC for the costs of implementing proposals that necessitate changes to HealthPAC's systems. PHARMAC and the Ministry of Health are working together to identify an appropriate charging regime. Until this work is complete, PHARMAC is not able to accurately estimate HealthPAC's charges in advance. These costs have not been provided for in PHARMAC's operating budget for 2004/05. To the extent that PHARMAC and the Ministry agree that PHARMAC should bear the costs of system changes, PHARMAC and the Ministry will also need to agree on how these costs will be funded

PHARMAC's Contribution to the Health Sector

PHARMAC continues to have a critical role in acting as an agent of DHBs to manage pharmaceutical expenditure. This relationship will continue through the ongoing implementation of the National Hospital Pharmaceutical Strategy; PHARMAC's management of the EC Scheme; and joint projects with DHBs aimed at improving health outcomes through the appropriate use of pharmaceuticals. Timely availability of expenditure data is vital to PHARMAC's management of pharmaceutical expenditure.

As noted above, as part of its role in managing hospital pharmaceuticals, PHARMAC is assisting in the implementation of a QUM Strategy that aims for a better co-ordinated approach to the quality use of pharmaceuticals in hospitals. The aim of the QUM Strategy is to ensure that patients have access to the highest standard of care and best possible health outcomes from pharmaceuticals used in hospitals.

During 2004 PHARMAC played an active role in the Safe Use of Medicines Group which was formed as part of the DHBNZ Chief Executives initiatives. This group organised the Safe and Quality Use of Medicines Conference in May 2004. During 2004/05 PHARMAC expects to review the QUM Strategy including the role that PHARMAC should play in implementing that strategy in the future. Longer term the Strategy could be integrated with similar strategies in the primary care sector and with initiatives in the community already developed by PHARMAC as part of its role to promote the responsible use of pharmaceuticals.

PHARMAC continues to implement the Maori Responsiveness Strategy as part of its objective to improve access to subsidised medicines for all New Zealanders. Two key areas of the Strategy are: improving business planning processes by establishing Maori health priorities and ensuring focus on those priorities; and increasing PHARMAC's responsiveness to Maori health issues by improving data collection processes to explicitly address Maori issues and by improving consultation processes so that the expertise of more Maori providers and health professionals is included. PHARMAC staff are investigating options and models that can be used to improve the use of current ethnicity data. PHARMAC intends to seek advice from external experts in addressing this area.

PHARMAC has ensured representation of Maori across the organisation, with the appointment of a Maori Board Member, a Maori member of PTAC, several Maori members of the CAC and the appointment during 2003/04 of a Maori Health Manager to the PHARMAC staff.

PHARMAC will continue to look for opportunities to improve the delivery and responsiveness to all New Zealanders in the provision of pharmaceuticals and quality health advice.

During 2004/05 PHARMAC will continue to develop its relationships with its key stakeholders. PHARMAC is working with DHBs to ensure increased efficiency in the sector, particularly in the delivery of medicines, and with disease state management activities. PHARMAC has worked with DHBs to implement all-at-once dispensing to address dispensing volumes and dispensing volume growth and improve the quality of the service patients receive. All-at-once dispensing was a positive initiative that allowed DHBs to invest in other health services and increased the amount of funding available to subsidise medicines.

Consistent with Strategic Priority 7, in 2005 PHARMAC intends to assist DHBs in procuring the influenza vaccine for community use. PHARMAC also intends to work with DHBs to transfer the responsibility for managing the funding of all pharmaceutical cancer treatments from DHB Hospitals to include the costs of these medicines within the Community Pharmaceutical Budget. PHARMAC and DHBs are working together to ensure the appropriate budget is transferred.

With the use of expenditure data provided by HealthPAC, PHARMAC will continue to provide regular reports on pharmaceutical expenditure to DHBs and continue to assess the form and content of these reports in response to feedback from DHBs. PHARMAC will also continue to meet regularly with its stakeholders in order to achieve a close working relationship and ensure that the sector works co-operatively on shared goals and priorities. Part of this co-operation has been ensuring that increased sector efficiency is recognised in an improved pharmaceutical budget. This will ensure that access to needed medicines will continue to improve.

PHARMAC will continue to develop its capability and seek to advance health improvement by sharing its knowledge base with other parts of the health sector and through learning from others in the health sector. PHARMAC will focus on developing strategic alliances with others in the sector and maximising core competencies, such as analysis and assessment tools, which could be used as a blueprint for other areas of the health sector.

Role of the Minister on Behalf of the Crown

The Minister is accountable to Parliament for the overall performance of PHARMAC.

As set out in the PHARMAC Crown Funding Agreement for 2004/05, the role of the Minister in relation to the performance of PHARMAC is to:

- indicate to PHARMAC priority areas for Government through various strategy documents such as the New Zealand Health Strategy, the New Zealand Disability Strategy and related strategies;
- obtain Parliamentary appropriations with which to fund PHARMAC;
- set expectations that inform and guide PHARMAC's high level planning as part of the process of preparing, and agreeing to, any Annual Plan

- and Crown Funding Agreement and commenting on any Statement of Intent;
- agree to the performance measures contained in the Crown Funding Agreement;
 - monitor the performance of PHARMAC against the Crown Funding Agreement;
 - appoint members of the Board;
 - hold the Board accountable for its performance;
 - require compliance by DHBs with legislative requirements and with other obligations specified in their Crown Funding Agreements with respect to the Pharmaceutical Schedule; and
 - undertake the duties and exercise the powers of a Responsible Minister as set out in the PF Act.

The Minister is not responsible for the day-to-day activities of PHARMAC. That is the responsibility of the Board.

The Ministry acts as the Minister's agent in the Minister's relationship with PHARMAC, with respect to negotiating, communicating and clarifying the Minister's expectations and in negotiating the Annual Plan and Crown Funding Agreement and commenting on the Statement of Intent. The Ministry also acts as the Minister's agent in monitoring PHARMAC's performance against these documents, including the management of risk.

The Minister has expressed the expectations of the Crown as owner of PHARMAC within the Crown's Statement of Ownership Expectations (SOE), dated 12 September 2003. Those expectations are consistent with the terms of this Crown Funding Agreement. However, to the extent of any inconsistency the terms of the SOE will override.

Board of PHARMAC on behalf of PHARMAC

The Board is accountable to the Minister for the performance of PHARMAC.

All decisions relating to the operation of PHARMAC are made by or under the authority of the Board. The Board has all powers necessary for the governance and management of PHARMAC. The Board is to ensure that PHARMAC delivers its Output, achieves the financial performance and provides the reports specified in its Crown Funding Agreement and complies with all other requirements associated with its objectives, powers, obligations and functions under the NZPHD Act. The Board is responsible for agreeing PHARMAC's accountability documents with the Minister.

The Board will comply with the duties and requirements placed on it by the PF Act.

The Board remains accountable for the delivery of any part of the Output or any part of its operations that has been subcontracted to a third party.

Ownership Performance

The Crown, as owner of PHARMAC, has the following expectations with respect to how PHARMAC will carry out its functions and the development of its organisational capability.

PHARMAC will focus on Government priorities as outlined in the New Zealand Health Strategy, the New Zealand Disability Strategy and other related strategies. The seven principles outlined in the New Zealand Health Strategy are:

- acknowledging the special relationship between Maori and the Crown under the Treaty of Waitangi;
- good health and well-being for all New Zealanders throughout their lives;
- an improvement in health status of those currently disadvantaged;
- collaborative health promotion and disease and injury prevention by all sectors;
- timely and equitable access for all New Zealanders to a comprehensive range of health and disability services, regardless of ability to pay;
- a high-performing system in which people have confidence; and
- active involvement of consumers and communities at all levels.

PHARMAC's activities contribute to these Government priorities in a number of ways:

- consulting and collaborating with Maori as Treaty partners with the Crown to address issues relating to pharmaceuticals that affect Maori as outlined in PHARMAC's Maori Responsiveness Strategy;
- pharmaceuticals are instrumental in improving the health and well-being of New Zealanders throughout their lives;
- access to subsidised pharmaceuticals is part of ensuring equitable access for all New Zealanders to a comprehensive range of health services, regardless of ability to pay;
- PHARMAC's evaluation of new drug technologies and investment in superior technologies contributes to a high-performing system;
- PHARMAC's efforts to obtain the optimum value from pharmaceutical funding assist with the process of meeting need within the funds available;
- consulting with PHARMAC's Consumer Advisory Committee as representatives of patients and to provide input from health consumers' points of view on PHARMAC's processes;
- PHARMAC's encouragement of the responsible and cost-effective use of pharmaceuticals through its activities to promote the responsible use of pharmaceuticals, contributes to the health of New Zealanders and enhances the quality of healthcare provided; and

- PHARMAC's hospital strategy encourages co-operative purchasing arrangements amongst DHBs.

PHARMAC has been particularly successful at managing growth in expenditure on pharmaceuticals. This success has been achieved through Supply Side initiatives (negotiations with pharmaceutical companies on the listing of pharmaceuticals and subsidy levels) and through programmes aimed at promoting the responsible use of pharmaceuticals.

Over the next three years PHARMAC will contribute further to improving outcomes in priority areas for Government.

PHARMAC's business has significant links with, and implications for, DHBs and PHARMAC will work on developing its relationships with DHBs to ensure that any gains from working together are achieved. PHARMAC will ensure that appropriate discussion and consideration of the impact of PHARMAC decisions on DHBs takes place.

Governance: The PHARMAC Board will provide high quality and effective governance of PHARMAC.

Integrity: PHARMAC will meet the standards of accountability, conduct and behaviour that are appropriate for a public entity. This includes compliance with the Public Service Code of Conduct and the Board Appointment and Induction Guidelines produced by the State Services Commission.

Financial Management and Financial Performance: PHARMAC will comply with the PF Act and the NZPHD Act and meet all of the financial management and financial performance requirements set out in the Crown Funding Agreement and the NZPHD Act. This includes ensuring the prudent and wise use of financial resources.

Risk Management: PHARMAC will manage financial and non-financial risks effectively, and keep the Minister informed of such risks. PHARMAC will:

- continue to manage risks by maintaining effective and timely risk management strategies and processes within the constraints set by the Crown, including budget and financial operating constraints, and which are consistent with recognised standards;
- continue to maintain a risk register; and
- fully inform the Minister and the Ministry, as early as possible, of significant financial and non-financial risks facing PHARMAC and how it intends to manage those risks.

Capability: PHARMAC will function effectively in terms of human resources, organisational systems and processes, and responsiveness. PHARMAC will ensure that it has the capability to:

- ensure the performance specified in the Crown Funding Agreement is delivered as specified;

- ensure that all of PHARMAC's statutory, legislative, and other regulatory functions and obligations are met.

Relationships: PHARMAC will take reasonable steps to maintain constructive relationships with all stakeholders. DHBs are critical stakeholders for PHARMAC. PHARMAC will further develop its relationships and standard business practices to link more closely with DHBs. Input from DHBs will inform PHARMAC's decision processes. This is particularly so in the areas of:

- responsible use of pharmaceuticals;
- hospital pharmaceuticals; and
- setting of pharmaceutical expenditure targets.

As it considers appropriate PHARMAC will also consult, inform or work with any organisations, sections of the public, groups or individuals that, in the view of PHARMAC, may be affected by any of PHARMAC's wider activities, including those involved in the delivery of the outputs in the Crown Funding Agreement. According to the circumstances, this may include DHBs, the Ministry, pharmaceutical suppliers, the Pharmacology and Therapeutic Advisory Committee (PTAC), health professionals, CAC, community or patient groups, Maori, Pacific peoples and other groups.

PART 2 STATEMENT OF PLANNED PERFORMANCE

A PURCHASE OBJECTIVES – OUTPUT: MANAGEMENT OF PHARMACEUTICAL EXPENDITURE

As set out in the Crown Funding Agreement, PHARMAC has one output class “securing the best achievable health outcomes from pharmaceutical treatment, within the funding provided”. There are five business activities within this one output class.

The five business activities include, but are not limited to:

- 1) Management of Community Pharmaceutical Expenditure, including:
 - management of community pharmaceutical expenditure on behalf of DHBs;
 - management of the Pharmaceutical Schedule to determine eligibility for access to subsidised pharmaceuticals;
 - operation of the Exceptional Circumstances Scheme; and
 - management of national programmes for High Cost Pharmaceuticals.

This activity contributes to Strategic Priority 1.

- 2) Promotion of the Responsible Use of Pharmaceuticals, including:
 - Demand Side projects;
 - referred services contracts; and
 - support of the Consumer Advisory Committee.

This activity contributes to Strategic Priority 1.

- 3) Management of Hospital Pharmaceutical Purchasing, including:
 - negotiating supply contracts for some hospital pharmaceuticals on behalf of DHBs;
 - establishing an elective national process for assessing applications to fund new pharmaceuticals in hospitals; and
 - developing a Quality Use of Medicines Strategy for hospital pharmaceuticals in consultation with DHBs.

This activity contributes to Strategic Priority 2.

- 4) Research Fund:
 - establish a mechanism with the Health Research Council and DHBs to fund pharmaceutical related research.

This activity contributes to Strategic Priority 3.

- 5) Assist DHBs on New Initiatives:
 - procure the influenza vaccine for 2005; and
 - assume responsibility for the management of expenditure for pharmaceutical cancer treatments.

This activity contributes to Strategic Priority 7.

PHARMAC has sole responsibility for maintaining and managing the Pharmaceutical Schedule, which applies consistently throughout New Zealand.

Activity One: Management of Community Pharmaceutical Expenditure

PHARMAC manages community pharmaceutical expenditure on behalf of DHBs and uses the Pharmaceutical Schedule to determine eligibility for access to subsidised pharmaceuticals. PHARMAC's management of the Pharmaceutical Schedule involves assessing the clinical benefits and economic impacts of listing particular drugs, undertaking reviews of currently listed pharmaceuticals, negotiating with drug companies and producing the Pharmaceutical Schedule.

In determining whether or not a drug should be listed on the Pharmaceutical Schedule PHARMAC will follow the Decision Criteria in PHARMAC's Operating Policies and Procedures, as amended from time to time. This requires the following factors to be considered:

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

PHARMAC will support its decisions by the following strategies, which aim to improve the value of pharmaceutical expenditure:

- independent advice from PTAC to PHARMAC on pharmaceuticals and their benefits;
- information received from PHARMAC's Consumer Advisory Committee;
- assessment of significant new investments, using the principles outlined in PHARMAC's Prescription for Pharmaco-Economic Analysis, as updated from time to time;

- cost utility analysis, used to assess some current investments of poor value, with subsequent dis-investment, where appropriate;
- consulting on matters that relate to the management of pharmaceutical expenditure with any sections of the public, groups, or individuals that, in the view of PHARMAC, may be affected by decisions on those matters, (which may according to the circumstances include DHBs, pharmaceutical suppliers, PTAC, health professionals, CAC, community or patient groups, Maori, Pacific Peoples and other groups); and
- take measures to inform the public, groups and individuals of PHARMAC's decisions concerning the Pharmaceutical Schedule.

PHARMAC will use a number of strategies for negotiating with drug companies to achieve the set pharmaceutical expenditure goals, including:

- reference pricing;
- capped expenditure contracts;
- rebate arrangements;
- price/volume arrangements;
- package deals; and
- tendering for sole supply.

The 'Management of Community Pharmaceutical Expenditure' business activity also includes:

- **Operation of the Exceptional Circumstances Scheme**

PHARMAC will manage the operation of the Exceptional Circumstances Scheme (EC Scheme) consistent with section 48(b) of the NZPHD Act "in exceptional circumstances providing for subsidies for the supply of pharmaceuticals not on the Pharmaceutical Schedule".

The purpose of the EC Scheme is to provide funding for outpatient medication in circumstances where the provision of a funded medication is appropriate, but the funding is not able to be provided through the Pharmaceutical Schedule. Consistent with the Medicines Act 1981 and the eligibility criteria for the EC Scheme, EC is also used to fund medications that have not received MedSafe approval, for example, where supplies are brought into New Zealand under section 29 of the Medicines Act or where a patient is treated for an indication which was not a specified indication in the MedSafe approval.

The EC Panel will make decisions based on criteria which may be changed from time to time following consultation.

- **National Programmes for High Cost Medicines**

As part of managing pharmaceutical expenditure, PHARMAC will establish, maintain and/or manage national programmes and expert panels that encourage the cost effective use of particular high cost pharmaceuticals. These programmes involve targeting the provision of subsidies for certain pharmaceuticals (currently dornase alpha - Pulmozyme, beta-interferon, imiglucerase – Cerezyme, human growth hormone and imatinib - Glivec) to patients meeting defined entry and exit criteria.

Decisions on funding are based on published access criteria and are taken by panels of expert clinicians involved in the various areas of treatment.

Exceptional Circumstances has received a number of applications for funding of several high cost pharmaceuticals used in the treatment of pulmonary hypertension (e.g. iloprost, bosentan). The numbers of patients with pulmonary hypertension nationally may exceed the limit for approval of funding through Exceptional Circumstances. In addition, as the pharmaceutical costs are high for each patient (up to \$150,000 annually) PHARMAC considers that the establishment of a Pulmonary Hypertension Panel may be effective in ensuring the cost effective use of these high cost pharmaceuticals. PHARMAC will be assessing the need for the establishment of a Pulmonary Hypertension Panel during the course of the year and will take steps to establish such a panel if it considers it necessary.

Activity One: Management of Community Pharmaceutical Expenditure

	Expectation	Deliverable	Target Date
1.1	PHARMAC will manage expenditure on community pharmaceuticals within the levels agreed in the Crown Funding Agreement.	<p>Subject to deliverable 1.2 below, PHARMAC will maintain expenditure on subsidised community pharmaceuticals for the year ending 30 June 2005 within \$565 million (excl GST), after deduction of rebates from pharmaceutical suppliers.</p> <p>Subject to deliverable 1.2 below, quarterly pharmaceutical expenditure targets on a cumulative basis, (excluding GST) before the deduction of rebates are:</p> <p>Quarter One \$164 million Quarter Two \$333 million Quarter Three \$494 million Quarter Four \$664 million</p>	<p>30 September 2004 31 December 2004 31 March 2005 30 June 2005</p>
1.2	PHARMAC will review the expenditure target for the following quarters on a quarterly basis.	<p>PHARMAC will review the quarterly pharmaceutical expenditure targets phasing set out in deliverable 1.1 above and if appropriate propose amendments to those deliverables to DHBs and the Ministry.</p> <p>PHARMAC in discussion with DHBs, will review the spend target mid way through the year, and recommend any adjustments to the Minister</p>	<p>30 September 2004 31 December 2004 31 March 2005 31 December 2004</p>
1.3	PHARMAC will forecast pharmaceutical expenditure.	PHARMAC will provide the Ministry of Health with a 1-3 year forecast of pharmaceutical expenditure.	31 December 2004
1.4	PHARMAC will monitor pharmaceutical expenditure in the community against forecast.	Any potential deviation from the forecasts will be promptly notified to the Ministry.	Identified in monthly reports if required.

Activity Two: Promoting the Responsible Use of Pharmaceuticals

As noted above, this requires the development of relationships with key stakeholders and strategies to ensure appropriate prescribing behaviour and usage of pharmaceuticals.

	Expectation	Deliverable	Target date
2.1	PHARMAC will promote the responsible use of pharmaceuticals by aiming to influence the volume and mix of medicines prescribed.	<p>An evaluation report on the Cardiovascular Management Campaign to be provided to the Ministry.</p> <p>PHARMAC will undertake the "Wise Use of Antibiotics" campaign during the winter of 2004. A report evaluating the campaign to be provided to the Ministry.</p> <p>PHARMAC will provide Pharmhouse data to the Ministry demonstrating the results of the Diabetes Test Strip Project.</p> <p>PHARMAC will provide Pharmhouse data to the Ministry demonstrating the results of the Atypical Antipsychotics project.</p>	<p>28 February 2005</p> <p>31 December 2005</p> <p>30 April 2005</p> <p>30 June 2005</p>
2.2	PHARMAC will contract with external parties which promote the responsible use of pharmaceuticals.	<p>PHARMAC will contract with BPAC New Zealand to deliver services in 2004/05. Quarterly reports will be provided to PHARMAC by the partnership by the 20th of the month following each quarter, detailing whether it has met the output and outcome targets agreed to in the contract and service plan.</p> <p>PHARMAC will contract for the delivery of the Green Prescription programme in 2004/05. Quarterly reports will be provided to PHARMAC by SPARC by the 20th of the month following each quarter detailing whether the programme has met agreed targets in the contract.</p>	BPAC and SPARC to meet quarterly performance targets specified in funding contracts with PHARMAC.
2.3	PHARMAC will promote the responsible use of pharmaceuticals by making the Pharmaceutical Schedule readily available to GPs.	PHARMAC will undertake an evaluation of a pilot of the Schedule on CD.	The evaluation will be completed by 30 June 2005.

Activity Three: Management of Hospital Pharmaceutical Purchasing

PHARMAC has been authorised to manage the purchasing of hospital pharmaceuticals on behalf of DHBs. In carrying out the Hospital Purchasing function PHARMAC either has, or will, address at the appropriate time, at a minimum, the following factors:

- (a) maintenance and updating of the hospital pharmaceutical strategy as required;
- (b) consulting and communicating with DHBs and other interested parties as PHARMAC considers appropriate;
- (c) amending PHARMAC planning, funding and policy documents to the extent appropriate;
- (d) compiling and analysing information from DHBs on pharmaceutical volumes, expenditure, and contractual arrangements;
- (e) adjusting the Pharmaceutical Schedule as necessary;
- (f) carrying out purchasing on behalf of DHBs;
- (g) calculation and payment to DHB Hospitals of rebates and/or financial compensation payable under national contracts for hospital pharmaceuticals;
- (h) ensuring the hospital pharmaceutical database is maintained and appropriate updates are made and using this data to assist in making future decisions regarding hospital pharmaceutical purchasing;
- (i) monitoring DHB compliance with restricted brand contracts containing Hospital Supply Status (HSS) provisions for hospital pharmaceuticals annually; and
- (j) operating the discretionary community supply (DCS) and Hospital exceptional circumstances (EC) schemes. These two programmes ensure that patients who are discharged into the community can continue on the treatments that were commenced whilst they were inpatients.

The performance measures for this activity in 2004/05 are given in the following table.

	Expectation	Deliverable	Target Date
3.1	PHARMAC will collect hospital pharmaceutical utilisation data to monitor national contracts.	Provide a report about DHB compliance with restricted brand contracts to DHBs and the supplier annually and complete any actions required to be taken.	By 1 November 2004
		Rebates under hospital pharmaceutical contracts calculated and distributed to DHBs.	Within six months of the end of each rebate period whether quarterly, six-monthly or annually.

	Expectation	Deliverable	Target Date
3.2	Ensure that the Discretionary Community Supply System is effective.	Review the Hospital DCS system.	31 December 2004
3.3	PHARMAC will promote and further develop processes for assessing new pharmaceutical technology in hospitals.	6-8 Cost Utility Analyses completed and shared with DHBs.	Three by 31 December 2004. Four to six by 30 June 2005.
3.4	PHARMAC will consider its future involvement in the promotion of the Quality Use of Medicines and Safe Use of Medicines in the hospital setting.	The Board will decide the role PHARMAC will play in the Quality Use of Medicines and Safe Use of Medicines in the hospital setting.	30 September 2004.
3.5	As part of the Hospital Strategy, PHARMAC will examine options to include radiological contrast media.	PHARMAC will provide information to DHB CEOs that identifies option(s) for establishing a competitive process, contracting system and inclusion in the Pharmaceutical Schedule. If agreed, PHARMAC will develop a process for DHB data provision to ensure compliance with any resulting agreement. Implementation of agreed process.	Consultation on option(s) will be complete by 31 October 2004. 31 May 2005 Commencing by 31 May 2005.
3.6	As part of the Hospital Strategy, PHARMAC will examine options to include bulk intravenous fluids.	PHARMAC will provide information to DHB CEOs that identifies option(s) for establishing a competitive process, contracting system and inclusion in the Pharmaceutical Schedule. If agreed, PHARMAC will develop a process for DHB data provision to ensure compliance with any resulting agreement. Implementation of agreed process.	Consultation on option(s) will be complete by 31 October 2004. 31 May 2005. Commencing by 31 May 2005
3.7	PHARMAC will extend the Hospital Strategy to include recombinant blood products	PHARMAC will work with the New Zealand Blood Service (NZBS), the Ministry of Health, DHBNZ and the DHB Working group on the strategy and future contracting for supply of recombinant blood products. PHARMAC will present an options paper to the PHARMAC Board subject to an outcome being agreed by NZBS, MOH and DHBNZ.	31 December 2004

	Expectation	Deliverable	Target Date
3.8	Review of the Hospital Pharmaceutical Advisory Committee (HPAC).	Review the structure and function of HPAC.	31 December 2004

Activity Four: Research Fund

PHARMAC has been authorised to establish a fund that will allow the Crown to fund independent pharmaceutical related health research.

The performance measures for this activity in 2004/05 are given in the following table.

	Expectation	Deliverable	Target Date
4.1	PHARMAC will develop a fund that will be used to fund independent health research in partnership with the Health Research Council.	Work with DHBs to establish a fund and get DHBs' approval for a research budget. PHARMAC will present a budget proposal to the Minister of Health.	31 December 2004 31 May 2005

Activity Five: Assist DHBs on New Initiatives

PHARMAC has been authorised to procure the influenza vaccine on behalf of District Health Boards, and over time assume responsibility for the management of both community and hospital cancer treatments.

The performance measures for this activity in 2004/05 are given in the following table.

	Expectation	Deliverable	Target Date
5.1	PHARMAC will assist DHBs by procuring the influenza vaccine.	<p>Issue a Request for Proposals.</p> <p>Evaluating proposals, negotiating with submitter(s) of one or more preferred proposals.</p> <p>Consulting on a provisional agreement and PHARMAC's Board or Chief Executive considering this provisional agreement.</p> <p>Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is October/November 2004 for the March 2005 campaign.</p>	<p>31 July 2004</p> <p>31 August 2004</p> <p>30 September 2004</p>
5.2	PHARMAC will assist DHBs by managing the expenditure of Pharmaceutical Cancer Treatments.	<p>Review Oncology basket, develop and consult on Pharmaceutical Schedule Rules.</p> <p>Develop Budget setting process.</p> <p>Consult with suppliers and publish new rules.</p> <p>Implementation.</p>	<p>31 October 2004</p> <p>30 November 2004</p> <p>31 March 2005</p> <p>1 July 2005</p>

B OWNERSHIP PERFORMANCE

PHARMAC will deliver the ownership performance in Section Three of its Funding Agreement and in particular will meet the following performance measures.

	Expectation	Deliverable	Target Date
6.1	PHARMAC works effectively with DHBs	<p>Complete strategic initiatives to assist DHBs, and develop appropriate reporting mechanisms. Six monthly reporting to DHB representatives.</p> <p>Relates to initiatives 3.5 - 3.7 and 5.1 – 5.2.</p> <p>Review the implementation of all-at-once dispensing, as agreed when the policy was implemented.</p>	By 1 October 2004
6.2	<p>PHARMAC will ensure that all New Zealanders have similar access to subsidised pharmaceuticals by implementing its Maori Responsiveness Strategy.</p> <p>Report to the PHARMAC Board quarterly on progress against implementation of initiatives.</p>	<p>PROJECT I Develop patient and whanau education resources dealing with the use of medications – (linked to project II train the trainer hui).</p> <p>PROJECT II Train the trainer hui to be held for:</p> <ul style="list-style-type: none"> ▪ Maori Disease State Management Nurses; ▪ Maori Community Health Workers; and ▪ Maori Community Nurses. <p>PROJECT III</p> <ul style="list-style-type: none"> ▪ Maori provider and stakeholder hui to build relationships and understanding of PHARMAC and subsidised medicines and the demand side campaigns <p>Analyse options and report to PHARMAC Board on the capture and use of information that will assist in ensuring consistent access to subsidised medicines for all New Zealanders. Specifically looking at:</p> <ul style="list-style-type: none"> ▪ Nationwide surveillance ▪ Sentinel surveillance ▪ Discrete epidemiological cross sectional surveys 	<p>Project I 30 March 2005</p> <p>Project II 31 May 2005</p> <p>Project III 30 June 2005</p>

	Expectation	Deliverable	Target Date
6.3	PHARMAC will consider input from a consumer or patient point of view.	PHARMAC with the assistance of the Consumer Advisory Committee will undertake a project to update the lists of groups, parties and individuals that PHARMAC consults with.	31 March 2005
6.4	PHARMAC will develop with DHBs an ongoing mechanism for funding of Demand Side activity.	Develop, consult and get agreement for the on-going funding of Demand Side Initiatives with DHBs. DHB financial support for Demand Side in 2005/06 agreed with DHBs.	Signal this to DHBs in July 2004 Consult on process 30 November 2004 31 March 2005

PART 3 FINANCIAL AND OWNERSHIP INFORMATION

A Statement of accounting policies

(a) Reporting entity

PHARMAC is a body corporate owned by the Crown with perpetual succession and is responsible for securing for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided. It has sole responsibility for managing the Pharmaceutical Schedule.

Forecast financial statements in this document have been prepared in accordance with section 67(1) of the NZPHD Act 2000 and the PF Act.

(b) Measurement system

The general accounting policies, recognised as appropriate for the measurement and reporting of financial performance and position on a historical cost basis, have been followed in the preparation of the projected financial statements.

(c) Accounting policies

The following particular accounting policies, which materially affect the measurement of results and financial position, have been applied.

➤ Valuation of assets

(i) Fixed Assets

Fixed assets are valued at cost less accumulated depreciation.

(ii) Accounts Receivable

Accounts receivable are valued at net realisable value.

➤ Depreciation

Depreciation of fixed assets is calculated using the straight line method to allocate the historical cost over the estimated useful life of each asset.

Major depreciation periods are:

Office equipment	2.5 - 5 years
EDP equipment	2.5 years
Furniture and fittings	5 years
Leasehold improvements	5 years

➤ **Revenue recognition**

Revenue received from the Crown to cover operating costs is recognised as the revenue falls due.

➤ **Goods and Services Tax (GST)**

All amounts shown are exclusive of goods and services tax, with the exception of debtors and creditors, which are shown GST inclusive.

➤ **Taxation**

For the purposes of the Inland Revenue Acts, PHARMAC is a “public authority” as stated in clause 32(1) of Schedule 6 of the NZPHD Act 2000.

➤ **Financial instruments**

There are no financial instruments that expose PHARMAC to foreign exchange risk or off balance sheet risks, although PHARMAC has entered into contracts with pharmaceutical suppliers that provide for limited variations in price according to exchange rate fluctuations.

All financial instruments, including bank accounts, accounts receivable and accounts payable are disclosed at their fair value. Revenue and expenses, in relation to the financial instruments, are recognised in the Statement of Financial Performance.

➤ **Employment entitlements**

PHARMAC’s liability for annual leave has been provided for and has been calculated on an entitlement basis at current rates of pay.

➤ **Budgeted figures**

The 2004/05 budget figures, and 2005/06 and 2006/07 forecast figures have been prepared in accordance with generally accepted accounting policies adopted by the Board.

➤ **Leases**

PHARMAC leases office premises. As all the risks of ownership are retained by the lessor, these leases are classified as operating leases. Operating leases are expensed in the period in which they are incurred.

➤ **Changes in accounting policies**

There are no changes in accounting policies. All accounting policies have been applied on a consistent basis.

B FINANCIAL STATEMENTS

Projected Statement of Financial Performance

	For the period of 1 July 2004 to 30 June 2005 \$000 (GST excl)	For the period of 1 July 2005 to 30 June 2006 \$000 (GST excl)	For the period of 1 July 2006 to 30 June 2007 \$000 (GST excl)
Revenue			
Crown:			
Operating ^{1 2}	8,060	8,690	9,128
Responsible use of pharmaceuticals	2,895	3,040	3,192
Interest received	190	190	190
Total Revenue	11,145	11,920	12,510
Operating Expenditure			
Operating costs	3,617	3,797	4,013
Salaries and related costs	3,572	3,751	3,938
Audit fees	15	17	19
Directors fees	121	121	121
Depreciation	280	280	280
Rentals and leases	288	288	288
High cost medicines	412	433	454
Responsible use of pharmaceuticals	4,570	3,040	3,192
Total Expenditure	12,875	11,727	12,305
Net surplus/(deficit)	(1,730)³	193	205

Note: The above statement should be read in conjunction with the accounting policies on page 39.

¹ As noted in Part 1 – Key Activities above, the Ministry of Health has indicated its intention to charge PHARMAC for the costs of implementing proposals that necessitate changes to HealthPAC's systems. PHARMAC and the Ministry of Health are working together to identify an appropriate charging regime. Until this work is complete, PHARMAC is not able to accurately estimate HealthPAC's charges in advance. These costs have not been provided for in PHARMAC's operating budget for 2004/05. To the extent that PHARMAC and the Ministry agree that PHARMAC should bear the costs of system changes, PHARMAC and the Ministry will also need to agree on how these costs will be funded.

² PHARMAC is funded for High Cost Medicines within its operating budget.

³ PHARMAC has forecast a deficit of \$1,730,000 (excluding GST) for the 2004/05 year. This deficit will be funded by PHARMAC from equity reserves. This will reduce PHARMAC's equity reserves to an appropriate level and contribute to managing financial pressures in the health sector.

Projected Statement of Financial Position

	At 30 June 2005 \$000 (GST excl)	At 30 June 2006 \$000 (GST excl)	At 30 June 2007 \$000 (GST excl)
PUBLIC EQUITY			
Retained Earnings & Reserves	7,406	7,599	7,804
TOTAL PUBLIC EQUITY	7,406	7,599	7,804
Represented by:			
Current Assets			
Cash and bank	10,373	10,373	10,373
Receivables and prepayments	181	139	242
Total current assets	10,554	10,512	10,615
Non-current assets			
Fixed assets	400	400	400
Total non-current assets	400	400	400
Total assets	10,954	10,912	11,015
Current liabilities			
Payables	3,548	3,313	3,211
Total current liabilities	3,548	3,313	3,211
NET ASSETS	7,406	7,599	7,804

Note: The above statement should be read in conjunction with the accounting policies on page 39.

Projected Cash Flow Statement

	For the period of 1 July 2004 to 30 June 2005 \$000 (GST incl)	For the period of 1 July 2005 to 30 June 2006 \$000 (GST incl)	For the period of 1 July 2006 to 30 June 2007 \$000 (GST incl)
Cash flows – Operating activities			
Cash was provided from:			
- Ministry of Health	12,324	12,941	13,588
- Interest	190	190	190
	12,514	13,131	13,778
Cash was disbursed to:			
- Cash outflow to suppliers and employees	(13,600)	(12,470)	(13,117)
- Net GST	(364)	(381)	(381)
	(13,964)	(12,851)	(13,498)
Net cash flow from operating activities	(1,450)	280	280
Cash flows – Investing activities			
Cash was disbursed to:			
- Purchase of fixed assets	(280)	(280)	(280)
Net cash flow from investing activities	(280)	(280)	(280)
Cash flows – Financing activities			
Net cash flow from financing activities	0	0	0
Net increase/(decrease) in cash held	(1,730)	0	0
Add opening cash brought forward	12,103	10,373	10,373
Closing cash balance	10,373	10,373	10,373

Note: The above statement should be read in conjunction with the accounting policies on page 39.

Projected Movement in Equity

	2004 / 2005 \$000 (GST excl)	2005 / 2006 \$000 (GST excl)	2006 / 2007 \$000 (GST excl)
Public equity at the beginning of the period	9,136	7,406	7,599
Net surplus/(deficit)	(1,730)	193	203
Public equity as at the end of the period	7,406	7,599	7,804

Note: The above statement should be read in conjunction with the accounting policies on page 39.

Reconciliation of Net Surplus to Cash Flow from Operating Activities

	2004 / 2005 \$000 (GST excl)	2005 / 2006 \$000 (GST excl)	2006 / 2007 \$000 (GST excl)
Net operating surplus (deficit)	(1,730)	193	205
<i>Add non-cash items:</i>			
Depreciation	280	280	280
Total non-cash items	280	280	280
<i>Add/(less) working capital movements:</i>			
Decrease (increase) in receivables	(56)	42	(103)
Increase (decrease) in payables	140	(235)	(102)
Working Capital Movement – net	84	(193)	(205)
Net cash flow from operating activities	(1,366)	280	280

Note: The above statement should be read in conjunction with the accounting policies on page 39.

Key Assumptions

- The operating budget has been based upon the continuation of PHARMAC's existing level of activity, provision for new activities, future work plans and estimated costs.
- Demand Side budget is based on estimated future activity.

Actual results may differ from Forecast

This summarised financial information is forward looking and based on prudent assumptions which may or may not eventuate. The financial forecasts are dependent on the outcome of funding negotiations for the out-years. Accordingly, the actual financial performance, financial position and cash flows are likely to vary from the projected information presented.

PART 4 OTHER MATTERS

Formal Monthly Reports

PHARMAC will provide the Minister and the Director-General of Health with a monthly report by the 20th working day of the following month covering, at a minimum:

- (a) pharmaceutical subsidy expenditure and rebates compared with budget and revised forecasts of expenditure and rebates when appropriate;
- (b) major Schedule decisions;
- (c) significant issues or developments that the Minister or Ministry should be aware of;
- (d) any potential non-performance against the Crown Funding Agreement;
- (e) PHARMAC's operational financial performance showing:
 - (i) Year to date: actual, budget, variance (\$), variance (%), with commentary to explain significant variances;
 - (ii) Year to date financial performance;
 - (iii) Year to date financial position;
 - (iv) Year end forecast; and
 - (v) Year end budget.

Formal Quarterly Reports

PHARMAC will provide a quarterly report to the Ministry of Health comprising:

- (a) PHARMAC's performance against all performance measures contained in Schedule B of this Agreement that fell due in the previous month. PHARMAC may also outline progress made towards achievement of significant milestones due in later months;
- (b) an update on price, volume, mix and expenditure indices;
- (c) a statement of cashflows for the immediately preceding quarter; and
- (d) PHARMAC's use of the Legal Risk Fund, including: litigation expenditure; confirmation that PHARMAC has used the monies in the Fund in accordance with the model set out in the Ministers letter of 6 November 2003 and, following the end of each financial year, identification of any unspent operating litigation budget added to the Fund.

Informal Reports

In addition to the formal reports the Board, will, at any time necessary:

- alert the Minister and the Ministry to any emerging factors that PHARMAC is aware of that could preclude the achievement of any expectation set out in the Crown Funding Agreement; and

- inform the Minister and the Ministry of any issue likely to be of significance to the Minister.

Reports to Parliament

PHARMAC will prepare a Statement of Intent for 2005/06 and Annual Report for the year July 2003 to June 2004.

The content and timing of the production of these documents shall comply with the requirements of the NZPHD Act and the PF Act.

Information for Ministers

On request, PHARMAC will provide:

- the Ministry with information that will enable the Ministry to prepare Ministerial briefings and draft speech notes in writing and, where practicable, in agreed form;
- the Ministry will information (in writing and in an agreed form) that will enable the relevant Minister to, in a timely manner:
 - (i) respond to Parliamentary questions;
 - (ii) deal with routine Ministerial correspondence; and
 - (iii) deal with select committee inquiries; and
- the Ministry with information relating to its activities that enables the Ministry to conduct special reviews and audits on its activities, which may be carried out as often as the Crown reasonably believes those reviews and audits are necessary.