

# Pharmac and pharmaceutical issues

## Executive Summary

**Pharmac** was established as a subsidiary of the four Regional Health Authorities in 1993 as a response to major growth in pharmaceuticals growth in the early 1980s and 1990s. Ownership of Pharmac was later transferred to the Health Funding Authority and in 2000 Pharmac was re-established as an independent Crown entity under s.46 of the New Zealand Public Health and Disability (NZPHD) Act 2000. The Minister of Health is the Minister responsible for Pharmac.

Pharmac engages with District Health Boards (DHBs) to develop a proposed community pharmaceutical budget which is then approved by the Minister of Health. Pharmac manages community pharmaceutical expenditure on behalf of the DHBs.

Pharmac continues to be highly successful in slowing the growth of pharmaceuticals expenditure, improving competition within the industry, influencing prescriber behaviour, and administering the Pharmaceutical Schedule.

- In the period, June 1993 to June 2002, estimated average movements in the main drivers of expenditure were: volume — 4.5 percent per year, mix<sup>1</sup> — 5.0 percent per year, and cost — only 2.5 percent per year. However, some increase in cost growth is now expected.
- Pharmac's operations resulted in savings estimated at \$1.9 billion in the period 1993–2002 that have been reinvested in pharmaceutical and other health expenditure. Savings of a further \$702 million are forecast by Pharmac for 2002/03.
- While the pharmaceutical manufacturing sector activity has declined recently, the overall industry, the last few years excepted, has experienced growth.
- Pharmac has undertaken, or is in the process of undertaking, a number of major initiatives to address the promotion of appropriate prescribing behaviour including: the development of a Māori Responsiveness Strategy and running national and regional campaigns promoting the responsible use of medicine.
- In the eight years to 2001: 630 new or enhanced products were listed and access was widened for a further 137 products.

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<sup>1</sup> The 'mix' factor occurs as a result of the entry or exit of medicines or when the proportions of medicines prescribed change over a period of time. Increases in expenditure due to mix changes occur when doctors increase the proportion of less expensive prescriptions with more expensive (generally newer) substitutes.

## **Key issues for the Government and Pharmac**

### **Management of the new DHB environment**

The most significant risks for Pharmac involve managing issues related to the new DHB environment particularly those concerned with devolution of the pharmaceutical budget to DHBs, maintaining a nationally consistent pharmaceutical schedule and the shortage of consistent and robust data upon which Pharmac relies to undertake its analysis of health needs, outcomes and benefits.

- *Community pharmaceuticals* – As responsibility for pharmaceuticals has been devolved to DHBs they will seek to take more responsibility to meet the specific needs of the populations they serve. This may have consequences for their overall spending on pharmaceuticals.
- *Hospital pharmaceutical procurement* – Pharmac has been authorised to manage hospital drug purchases on behalf of DHBs. The Ministry of Health supports the overall direction of the strategy, and has identified a number of risk minimisation approaches that should be undertaken by Pharmac to smooth the implementation of the strategy. Various issues are in the process of being finalised.
- *Relationships and co-operative* working practices are evolving between Pharmac and DHBs.

### **Growth and innovation framework and biotechnology strategy**

The biotechnology sector includes the pharmaceutical sector, both pharmaceutical companies and the biomedical research sector. This link has led to increased pressure from pharmaceutical companies for the Government to review its purchasing framework for drugs. The proposition is that the potential contribution that the pharmaceutical sector could make to growth and innovation activities outweighs the benefits that the health system receives through the Pharmac model. From a health perspective, the critical point is to ensure that the sector's potential to provide at least the same amount of overall health services to New Zealanders is not adversely affected by any initiatives undertaken to support the Government's growth and innovation objectives.

The Biotechnology Strategy identifies a number of other health sector issues that require the input of a Minister of Health including:

- the work underway to address legislative gaps on the management of human tissues and assisted human reproduction; and
- on the system for supporting and managing clinical trials.

### **Budgetary issues**

- *Should the pharmaceutical budget be larger?* – There is a growing debate that additional spending on pharmaceuticals may be more cost effective than spending elsewhere in the health and disability sector. The Ministry of Health, in association with DHBs, DHBNZ and the Treasury, has embarked on a process to develop a more robust funding prioritisation methodology for implementation across the whole health and disability sector.

- *Multi-year funding* – Pharmac’s operations involve decisions that have fiscal impacts for the outyears. The provision of multi-year funding would give it more certainty in planning.
- *Annual adjustment mechanism to the pharmaceutical budget* – The current annual adjustment mechanism, the Forecast Funding Track,<sup>2</sup> does not allow for price growth in pharmaceuticals. Nor does it address expenditure growth caused by ‘mix’ pressures.

The review of the three year Health Funding Package and prioritisation project will address these budgetary issues.

### **Pharmaceutical lobby**

The industry is likely to offset a reduction in litigation with greater lobbying effort directed at government, consumer groups and the sector, and through direct-to-consumer advertising.

### **Direct-to-consumer advertising**

Without the early implementation of tighter regulations the industry is likely to continue to push the advertising boundaries and will take advantage of any delays in their implementation. Policy development on appropriate regulatory constraints for direct-to-consumer advertising is underway, but it is not expected that a new regulatory approach will take effect before the end of 2002.

### **Consumer groups**

There is evidence of growing lobbying pressure on Pharmac from consumer groups advocating the extension of subsidies for drugs to cover the treatment of specific illnesses suffered by their constituencies. Ongoing pressure from consumer groups can be expected.

### **Parallel importing of pharmaceuticals**

The Crown has an exemption from restrictions that may restrict parallel importing and so could potentially parallel import pharmaceuticals. Any delegation of Government’s exemption to Pharmac, or any other agency, other than in cases of continuity of supply<sup>3</sup>, would need to be carefully considered.

### **Costs and subsidies**

The only cost a patient should incur for a fully subsidised medicine is the standard government prescription charge, or the cost of the medicine, whichever is less. Through the normal subsidisation process plus the Special Authority and Exceptional Circumstances arrangements the needs of the vast majority of patients’ are met. There are, nevertheless, a small proportion of patients (ie, those who have side-effects to a subsidised pharmaceutical or require access to

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<sup>2</sup> This mechanism is used to adjust Vote Health by an amount sufficient to fund price and technology growth net of efficiency,

<sup>3</sup> Even continuity of supply cases may prove contentious.

a drug that is not subsidised) who are concerned that they must still bear the full cost of their medicines.

### **Extension of prescribing by health professionals**

[The Medicines Act 1981](#) was amended in 1999 to enable the making of regulations to allow registered health practitioners, such as nurse practitioners or Pharmacists, to prescribe a limited list of medicines under a particular scope of practice. In 2001, Cabinet approved regulations covering nurse practitioners working in aged care and child family health, although currently there is only one nurse practitioner (who does not have prescribing authority). The New Prescribers Advisory Committee is currently assessing applications to grant optometrists, and nurse practitioners working in sexual and reproductive health limited independent prescribing authority. Strong resistance from some sector interest groups remains.

## **Pharmaceutical Management Agency (Pharmac)**

Pharmac's origins were a response to the burgeoning pharmaceuticals budget in the early 1980s and early 1990s. The agency was established in 1993 to improve the management of pharmaceuticals by supervising the drug tariff, encouraging competition, expanding consumer choice and influencing prescriber behaviour.

A not-for-profit subsidiary of the former Health Funding Authority (HFA), Pharmac was re-established during the recent health reforms as a stand-alone, independent Crown entity under s.46 of the New Zealand Public Health and Disability (NZPHD) Act 2000 and is directly accountable to the Minister of Health.

Pharmac's central role is to manage the government's expenditure on pharmaceutical subsidies. This role includes activities relating to the supply of pharmaceuticals (eg, negotiating with pharmaceutical companies over the subsidisation of their products) and activities influencing the demand for pharmaceuticals (eg, promoting appropriate prescribing and best practice initiatives). Pharmac establishes the pharmaceutical budget<sup>4</sup> with DHBs and manages it on their behalf.

As part of this role, Pharmac manages the [Pharmaceutical Schedule \(Schedule\)](#). The Schedule is a list of more than 3,000 medicines and related products, subsidised by the government and mostly<sup>5</sup> available to all eligible people within New Zealand on prescription by a medical doctor. The process that Pharmac usually follows in listing pharmaceuticals on the Schedule is given in Appendix I.

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<sup>4</sup> This activity was limited to the community Pharmaceutical budget up till September 2001 when Pharmac's role was extended to also cover hospital Pharmaceuticals. Consultations are nearing an end on the procedures and protocols that will govern relating the establishment and management of the hospital Pharmaceutical budget.

<sup>5</sup> Some medicines are listed with guidelines or conditions such as 'only to be prescribed by specialists' or 'only dispensed by hospital Pharmacies', to ensure that medicines are used by those people who are most likely to benefit from them. Pharmaceuticals provided to patients for use while in hospital are not covered by the Schedule.

[Pharmac's Board](#) consists of up to six members appointed by the Minister of Health. All the decisions relating to Pharmac's operations are made by or under the authority of the Board. In particular, the Board decides on the strategic direction of Pharmac and decides which pharmaceuticals should be subsidised and at what levels, and whether or not special conditions or guidelines should apply.

Pharmac is provided with independent technical advice on pharmaceutical products by the [Pharmacology and Therapeutics Advisory Committee \(PTAC\)](#) and its subcommittees. PTAC's membership includes medical practitioners with broad general experience and a particular interest in pharmaceuticals and their therapeutic properties.

## **Pharmac's Operating Policies and Procedures**

### **Review of Operating Policies and Procedures (OPP)**

[Pharmac's Operating Policies and Procedures \(OPPs\)](#) were reviewed in the 18 months prior to 1 January 2001 when the revised OPPs became effective. They are the result of extensive public consultation and the need to be consistent with the NZPHD Act 2000. They also take account of the recommendations of the former HFA's independent reviewers Hon. David Caygill and Dr Joel Lexchin, whose main recommendations for change included:

- separating Pharmac's OPPs from supply contracts
- setting Pharmac's budget in context with funding in the wider health sector
- improving Pharmac's relationships with all stakeholders (through improving its consultation process, regular meetings with major stakeholders, ensuring objective and unbiased advice from PTAC and the establishment of a consumer advisory committee).

### **Main elements of Operating Policies and Procedures (OPPs)**

The main elements of Pharmac's revised OPPs: its objective, statutory functions, strategic priorities, decision criteria and strategies are outlined below.

#### *Pharmac's objective*

Pharmac's overall objective, as outlined in s.47 of the NZPHD Act, is to secure for all eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment from within available funding.

#### *Pharmac's statutory functions*

Within the funding available to Pharmac, its functions under s.48 of the NZPHD Act are:

- to maintain and manage a Pharmaceutical Schedule that applies consistently throughout New Zealand, including determining eligibility and criteria for the provision of subsidies

- to manage incidental matters arising out of managing and maintaining the schedule including, in exceptional circumstances, providing for subsidies for the supply of pharmaceuticals not on the pharmaceuticals schedule
- to engage as it sees fit, but within its operational budget, in research to meet the objectives set out in s.47(a) of the NZPHD Act
- to promote the responsible use of pharmaceuticals
- 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.

In September 2001 Pharmac was given a new function which authorises it to manage the purchasing of any or all pharmaceuticals used both inside and outside hospitals on behalf of DHBs. Pharmac is in the process of reviewing its OPPs to reflect this responsibility.

### *Strategic priorities*

According to the Crown Funding Agreement between the Minister of Health and Pharmac, Pharmac is required to focus on the government's priorities as outlined in the New Zealand Health and Disability strategies and related strategies

### *Pharmac's decision criteria*

Pharmac updates the Schedule at regular intervals to notify prescribers, Pharmacists and patients of changes to drug subsidies. In making decisions about amendments to the Schedule, Pharmac is guided by its OPPs. Reflecting its OPPs, Pharmac takes into account the following criteria when making decisions:

- the health needs of all eligible people within New Zealand; (eligible defined by the government's then current rules of eligibility)
- the particular health needs of Māori 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 Schedule
- the direct cost to health service users
- the government's priorities for health funding, as set out in any objectives notified by the Crown to Pharmac, or in Pharmac's Funding Agreement, or elsewhere
- such other criteria as Pharmac thinks fit. Pharmac will carry out appropriate consultation when it intends to take any such 'other criteria' into account.

### *Pharmac's strategies*

Pharmac adopts a range of supply and demand side strategies in order to achieve its overall objective.

#### (a) Supply side strategies

These focus on negotiating the best price that achieves its set expenditure goals. Example include:

- reference pricing: reference pricing means that all pharmaceuticals in any given therapeutic subgroup to which Pharmac decides to apply reference pricing are subsidised at the level of the lowest priced pharmaceutical in that sub-group
- capped expenditure contracts
- rebate arrangements
- package deals and
- various tendering arrangements for sole and preferred supply.

#### (b) Demand side strategies

These focus on influencing clinicians and patient behaviour to promote cost effective and responsible use of pharmaceutical. Examples<sup>6</sup> are:

- developing IT tools for clinicians
- running prescribing information campaigns
- issuing a request for proposals for services for promoting the responsible use of pharmaceuticals
- responding to direct-to-consumer advertising.

## **Regulation**

[Medsafe](#), a business unit of the Ministry Of Health, is the authority responsible for the regulation of therapeutic products in New Zealand. Medsafe administers the Medicines Act 1981 and Medicines Regulations 1984, and parts of the Misuse of Drugs Act 1975 and Medicine Regulations 1977.

## **How successful has Pharmac been?**

Pharmac has been highly successful in:

- slowing the growth of pharmaceuticals expenditure
- improving competition within the industry
- influencing prescriber behaviour and
- administering the Schedule, including managing the listing of products based on evidence and ensuring expenditure on products provides good health gains.

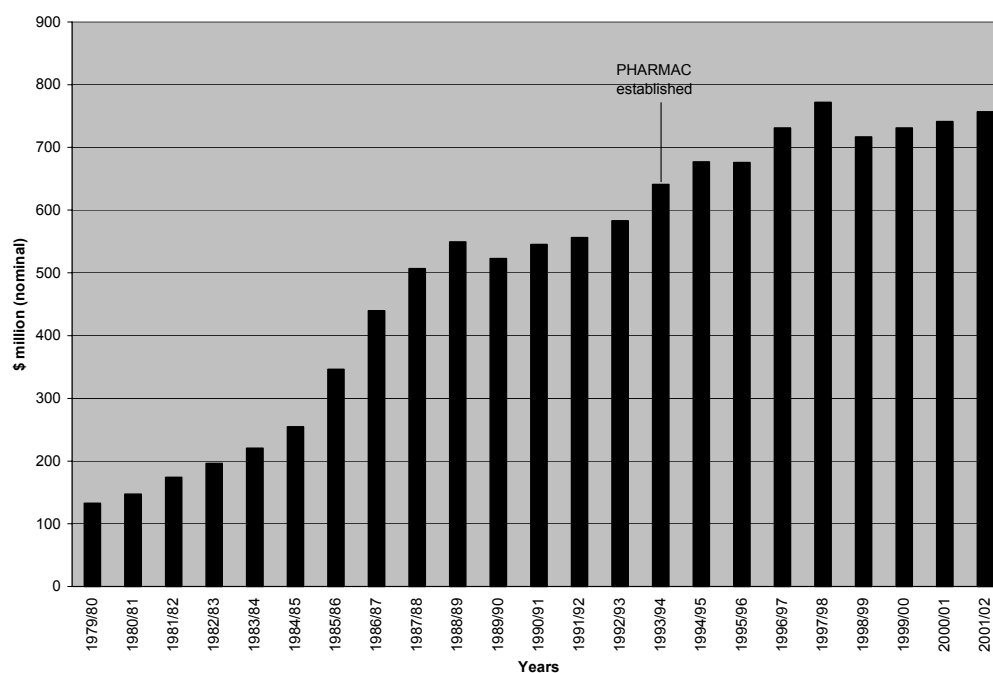
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<sup>6</sup> Also see section of influencing prescriber behaviour below.

## Slowing the growth of pharmaceuticals expenditure

Pharmac has been extremely effective in slowing the rate of growth in pharmaceuticals expenditure. According to its 2001 Annual review Pharmac:

*...held the growth of pharmaceutical expenditure (after rebates) at around 2 percent – without its intervention growth would have been 9 percent. This is consistent with its performance over the last eight years and demonstrates Pharmac’s effectiveness.<sup>7</sup>*



**Figure 2: Publicly funded pharmaceuticals expenditure, 1979–2002**

Figure 2 shows the trend in total publicly funded pharmaceuticals expenditure for the period 1980–2000. Between 1979/80 and 1997/98 (the highpoint for the period), expenditure grew at an average growth rate of 10.1 percent per year. The change in recent years, between 1997/98 and 2001/02, averaged a decline of 0.5 percent per year. For the future, it is believed that the most significant and readily implemented opportunities to achieve falls in prices have already been made and some quickening in the rate of growth of overall expenditure is now to be expected.

Figure 3 (below) gives movements in Pharmac’s indices for volume, mix and subsidy and the resulting cost. In the period, mid-1993 to June 2002, estimated average movements in these indices have been as follows:

- Volume – 4.5 percent per year
- Mix – 5.0 percent per year
- Subsidy – 6.5 percent per year
- Cost – 2.5 percent per year

<sup>7</sup> Pharmac. Annual Review for the year ended 30 June 2001. p.4.

**Figure 3: Volume, mix, subsidy and cost changes**

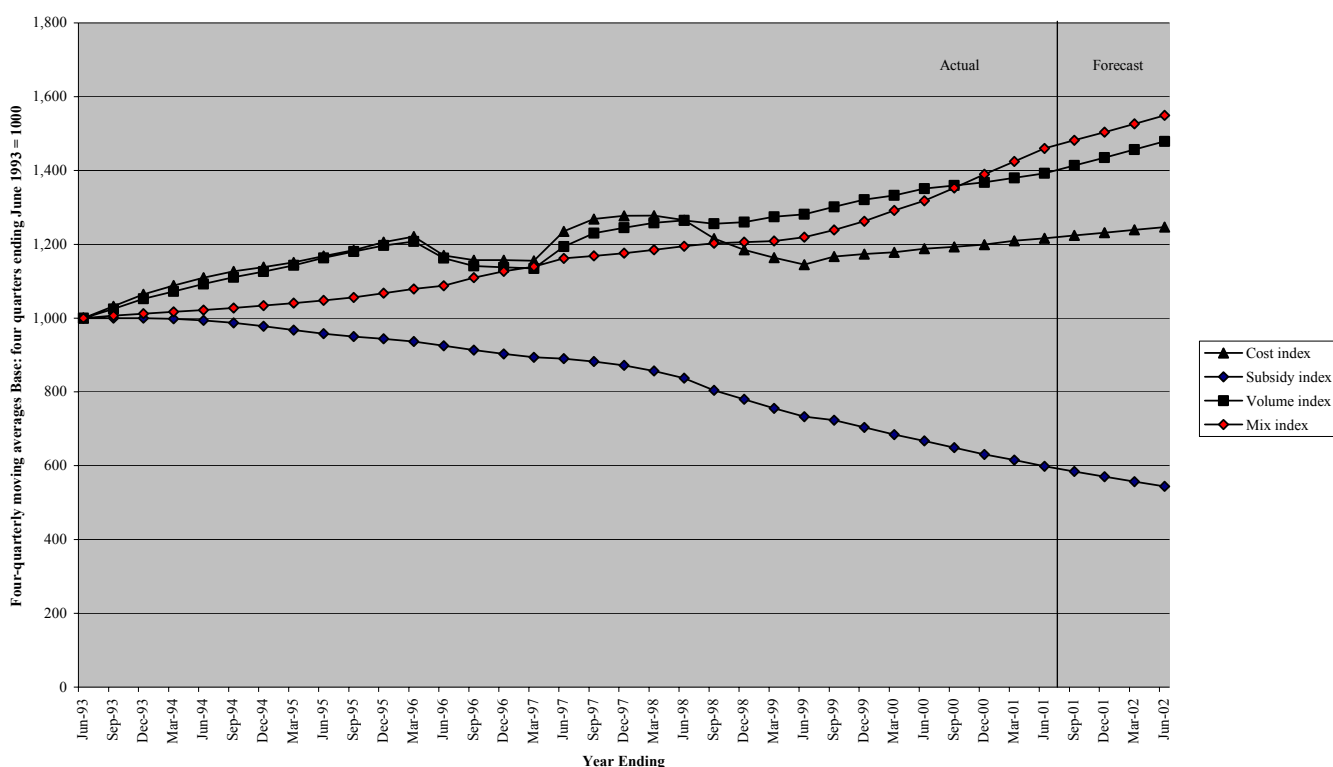


Table 1 reinforces this view. It shows that Pharmac’s operations have resulted in savings estimated at \$1.9 billion in the period 1993–2002 that have been reinvested in pharmaceutical and other health expenditure. Cumulative savings of \$702 million are forecast by Pharmac for 2002/03.

**Table 1: Cumulative estimated and forecast savings from Pharmac’s operations (GST exclusive)**

1996/97	1997/98	1998/99	1999/00	2000/01	2001/02	2002/03*
\$88 m	\$141 m	\$251 m	\$328 m	\$478 m	\$551 m	\$702 m

Source: Pharmac. 2001. *Annual Review for the year ended 30 June 2001*, p8, plus communication from Pharmac re savings in 2001/02 .

### Improving competition within the industry

Pharmac has also improved the level of competition in the pharmaceutical industry. Its success in containing costs (Figure 3) without affecting supply illustrates this.

Also, while the number of pharmaceutical manufacturing facilities in New Zealand is declining this is perhaps not as significant as has been claimed by industry advocates.

As Table 2 shows, for the period 1989–1999, the number of employees in New Zealand’s pharmaceutical manufacturing companies fell by around 13 percent – 1038 in 1989 and 907 in 1999.

**Table 2: Numbers of employees and companies**

Year	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999
Employees	1038	1017	867	991	947	683	990	923	998	990	907
Companies	28	28	21	28	27	22	21	21	19	22	17

Source: NZIER. 2002. *Bio-pharmaceuticals — A Pathway to Economic Growth. Report to the Researched Medicines Industry (RMI)*. p. 19.

The number of companies has declined significantly from 28 to 17, a decline of 39 percent mainly through merger and take-over activity.<sup>8</sup> Only one company no longer has an office in New Zealand, but its products are still available here. At the same time the overall industry, the last few years excepted, has experienced growth (see Figure 2).

## Influencing prescriber behaviour

Pharmac had budgeted to influence prescribers through a mix of demand side strategies during 2002/03. It is co-ordinating with DHBs which have incentives for primary providers to ensure the strategies apply in a co-ordinated way. Pharmac works collaboratively with clinical groups in implementing demand side activities.

Pharmac has undertaken, or is in the process of undertaking, a number of major initiatives to address the promotion of best practice prescribing behaviour including:

- the development of a Māori Responsiveness strategy;
- running national and regional campaigns promoting the responsible use of medicines (eg Pharmac has funded and coordinated the ‘Wise Use of Antibiotics’ campaign for four years, and has initiated an education campaign on managing the risks of cardiovascular disease in conjunction with key stakeholders, National Heart Foundation and Sport and Recreation New Zealand.
- the E-schedule project – this involves integrating the Schedule into Practice Management Software including prescribing information
- issuing a request for proposal for services promoting the responsible use of pharmaceuticals.

<sup>8</sup> The NZIER report a drop in medicinal and Pharmaceutical product manufacturing activity of 36.2 percent between 1997 and 1999. NZIER. 2002. *Bio-Pharmaceuticals – A Pathway to Economic Growth. Report to the Researched Medicines Industry (RMI)*. p.15.

## Administering the Schedule

The ongoing success of Pharmac's operations illustrates its achievements in its core business of administering the Schedule. Table 3 illustrates one example of this success. In the eight years to 2001 Pharmac improved market access to pharmaceuticals by listing 630 new or enhanced products, access was widened for a further 137 products, access for 36 products was limited, while 668 products were de-listed. (De-listings were inflated partly due to sole supply arrangements and the completion of the review of products mixed/prepared in Pharmacies<sup>9</sup> in 2000.)

**Table 3: Listing changes to the Pharmaceutical Schedule**

	2001	2000	1999	1998	1997	Total 1994-2001
New chemical entities listed	20	18	32	14	11	121
New presentations listed	13	21	40	33	24	195
New products listed	28	39	56	53	20	314
<i>Total new listings</i>	<i>61</i>	<i>78</i>	<i>128</i>	<i>100</i>	<i>55</i>	<i>630</i>
Derestrictions or expanded access	19	17	34	14	10	137
Changes that restrict or limit access	6	6	3	7	6	36
<i>De-listing</i>	<i>135</i>	<i>362</i>	<i>51</i>	<i>106</i>	<i>14</i>	<i>668</i>

Source: Pharmac. 2001. Annual Review for the year ended 30 June 2001. p 23.

During 2001, the Pharmac Board considered 93 applications for subsidy and listed 61 of these an acceptance rate of 66 percent.

A further measure of Pharmac's operational success can be gauged by the Government's decision to extend its operations to cover the purchase of pharmaceuticals for the hospital sector a market that is in the region of \$110–\$140 million a year.

## Key Issues

### Management of the new DHB environment

The most significant issues for Pharmac involve managing within the new DHB environment, particularly given the devolution of the pharmaceutical budget to DHBs, maintaining a nationally consistent pharmaceutical schedule and the shortage of consistent and robust data upon which Pharmac relies to undertake its analysis of health needs, outcomes and benefits.

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<sup>9</sup> Extemporaneously Compounded Products review.

## **Relationships between Pharmac and DHBs and others**

The importance of relationship management in the new environment is critical. Pharmac has developed a strategic priority for working with DHBs that states:

*Pharmac will work with DHBs to build an understanding of their needs and develop a two-way flow of information and have processes in place for working on joint projects.<sup>10</sup>*

To assist it in meeting this objective, Pharmac has developed a set of protocols – *Relationship Agreement between District Health Boards and Pharmac* – which it is in the process of agreeing with individual DHBs.

Pharmac is also developing a closer relationship with the pharmaceutical industry through biannual meetings with the Researched Medicines Industry Association of New Zealand (RMI).

## **Community pharmaceuticals**

Pharmac is responsible for managing the pharmaceuticals budget that is held by DHBs. As more responsibility is devolved to DHBs, they will seek to take more responsibility to meet the specific needs of the populations they serve. This may have consequences for their overall spending on pharmaceuticals.

## **Hospital pharmaceutical procurement**

Pharmac has been authorised to manage hospital drug purchases on behalf of DHBs. Pharmac, together with the Hospitals Pharmaceuticals Advisory Committee, developed a [procurement strategy](#) and submitted it to the Minister of Health in February 2002. Modest savings are expected from this initiative, particularly in the early years.

Initiatives to reduce price and manage the costs/utilisation of pharmaceuticals used in hospitals are already in place in most DHBs, particularly the larger DHBs. The strategy will build on those initiatives.

A number of issues are still outstanding including the tender arrangements with suppliers, the product list and Pharmac's OPPs as they relate to the hospital purchasing strategy. These consultations are due to be resolved by the end of July 2002.

## **Pharmaceutical sector's relationship to Government's growth and innovation framework and biotechnology strategy**

The growth and innovation framework ([Growing an innovative New Zealand](#), 2002) and the biotechnology component raise pharmaceutical related policy issues. The biotechnology sector includes the pharmaceutical sector, both pharmaceutical companies and the biomedical research sector.

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<sup>10</sup> Pharmac. 2002. *Relationship Agreement between District Health Boards and Pharmac*. p.4.

This link has led to increased pressure from pharmaceutical companies for the Government to review its purchasing framework for drugs. The proposition is that the potential contribution that pharmaceutical sector could make to economic growth and innovation activities outweighs the benefits that the health system receives through the Pharmac purchasing model. While a number of OECD governments appear to be competing with each other to develop their pharmaceutical research and development sector, the evidence on the net national benefit to New Zealand from participating in this type of competition with other governments is not clear. From a health perspective, the critical point is to ensure that the level of overall health services provided to New Zealanders is not adversely affected by any initiatives undertaken to support the government's growth and innovation objectives.

The Ministry for Research, Science and Technology is working on a New Zealand Biotechnology Strategy. Cabinet is expected to consider a public discussion document on the components of a strategy early in the new parliamentary term.

The strategy would set out a vision and goals for the use and development of biotechnology in New Zealand. This process is likely to identify various mechanisms to support the biomedical research sector. While the strategy identifies growth as an objective, a Biotechnology Sector Taskforce, has been established to identify specific actions to support this objective.

Having a biomedical research sector benefits the health sector by encouraging the retention of highly skilled individuals in New Zealand and providing capability for understanding and accessing new developments. While the focus has been on public good and fundamental research, rather than on commercially oriented research, the New Zealand biomedical sector has had some entrepreneurial successes. As biomedical research findings are often ultimately utilised through new drugs, developing linkages with pharmaceutical companies who have the resources required to progress development of a drug is important where researchers wish to move beyond fundamental research.

The Biotechnology Strategy also identifies a number of other health sector issues that require the input of a Minister of Health including:

- the work underway to address legislative gaps on the management of human tissues and assisted human reproduction; and
- on the system for supporting and managing clinical trials.

## **Budgetary issues**

The breakdown of the pharmaceutical budget is given in Table 4 for 2000/01.<sup>11</sup> Pharmac's share of the overall publicly funded pharmaceutical budget is the residual of the total cost to government after crediting co-payments and rebates<sup>12</sup> and deducting dispensing fees and mark-ups paid to pharmacies.

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<sup>11</sup> Note this is the target Pharmaceutical budget. The actual budget outcome could differ from this amount, normally within a range of  $\pm 2$  percent, depending on the timing of expenditure.

<sup>12</sup> Rebates result from contracts Pharmac negotiates with some Pharmaceutical companies. They are earned when volume/spend thresholds are passed and are therefore in the nature of discounts. Rebates are not shown in Table 4.

**Table 4: Subsidised pharmaceutical budget breakdown 2001/02**

	\$ million (excluding GST)	\$ million (including GST)
Pharmaceutical budget costs to Government	673	757
Less dispensing costs	213	240
<i>Sub-total</i>	<i>460</i>	<i>518</i>
Plus patient contribution	68	77
Pharmac's budget	528	594

Source: Ministry of Health.

### **Should the Pharmac's pharmaceutical budget be larger?**

There is a growing debate that additional spending on pharmaceuticals may be more cost effective than spending elsewhere in the health and disability sector. Pharmac has been criticised by the pharmaceutical industry, in particular, for not taking into consideration in its operations the wider health benefits, and for not increasing its budget to take advantage of these benefits. Pharmac, however, has as noted, wider-ranging decision criteria than previously and uses them. It also has a fixed budget, which it holds on behalf of DHBs, which it has no ability to alter and within which it prioritises.

The trade-off decision between pharmaceuticals and health and disability services taken by the Ministry of Health and DHBs is largely historically based and is a structural problem for the whole sector. The solution lies in a re-evaluation of the current ring-fenced funding streams and the possible implementation of a prioritisation process that allocates funding across the whole health and disability sector according to cost effectiveness and other relevant principles.

The Ministry of Health, in association with DHBs, DHBNZ and the Treasury, has embarked on a process to develop a more robust prioritisation methodology for implementation across the whole health and disability sector. It is recommended that this work be extended to include consideration of the elimination of ringfences and other institutional barriers to purchasing the most cost effective services and products. Any work in this area will clearly need to take into account the needs of those that are met by the current ringfence funding structure.

### **Multi-year funding**

Pharmac's operations involve decisions that have fiscal impacts for the outyears. The provision of multi-year funding would give it more certainty in planning.

### **Annual adjustment mechanism to the pharmaceutical budget**

The current annual adjustment mechanism – the Forecast Funding Track (FFT) – that is used to adjust Vote Health by an amount sufficient to fund price and technology growth net of efficiency, does not allow for cost growth in pharmaceuticals. The rationale for this decision was that price growth for

pharmaceuticals in recent years has been negative for pharmaceuticals. This situation is changing and, over time, some price growth is expected for pharmaceuticals. The present FFT also does not address expenditure growth caused by 'mix' pressures (as noted these are estimated to have risen by an average rate of 5.0 percent per year in the period June 1993 to June 2002).

The review of the three year Health Funding Package and prioritisation project will address these budgetary issues.

## Pharmaceuticals lobby

The pharmaceutical industry continues to be concerned at Pharmac's success and its effects on their profit margins in New Zealand. In order to counteract Pharmac's success, the industry and RMI have put considerable effort into seeking to minimise the effectiveness of Pharmac's operations. In the past this has included significant litigation activity, extensive lobbying of ministers and members of parliament, direct-to-consumer advertising (DTCA), and applying international government pressure where possible.

More recently, litigation activity has fallen. It appears that the industry in New Zealand, as elsewhere, has adopted a strategy to avoid legal recourse in response to a perception that this is damaging to the industry's image. In Pharmac's 2001 Annual report makes reference to:

*...a pronounced shift in dealings between Pharmac and the pharmaceutical industry. For the first year since 1994, no new litigation was brought against Pharmac by suppliers, and Pharmac has not had to take legal action against any supplier. In fact the pendulum appears to have swung in the opposite direction. Now despite the fact that we will always have opposing agendas, there is mutual recognition of the pressures and challenges each other face. There is greater acceptance on the part of the industry that Pharmac must work within a limited budget, and Pharmac shares some of the industry's concerns about future access to pharmaceuticals in a constrained financial environment.<sup>13</sup>*

While it is hoped that Pharmac's 2001 sentiments transpire, it is likely that the industry will offset litigation<sup>14</sup> through engaging in a greater lobbying effort directed at government, consumer groups and the sector and through DTCA.

## Direct-to-consumer advertising (DTCA)

There has been significant growth in direct-to-consumer advertising (DTCA) by drug companies in recent years. Expenditure in New Zealand on prescription and over-the-counter DTCA was estimated to be \$48 million during 2000, up 41.7 percent on 1999. DTCA on prescription drugs was up 23.6 percent in 2000 to around \$17.9 million. The growth in DTCA is largely a response by the industry to the more competitive market created by Pharmac. Pharmac is concerned that this is creating consumer demand for expensive drugs when often a much lower cost, clinically appropriate alternative is available.

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<sup>13</sup> Pharmac. *Annual Review for the year ended 30 June 2001*. p.4

<sup>14</sup> There has been some reoccurrence of litigation in the recent past.

A Ministry of Health discussion paper in 2000 canvassed opinion on DTCA in New Zealand. The Minister of Health's subsequent decision was to require advertising regulations to be tightened. This work is being carried out by the Ministry (through Medsafe).

Without the implementation of tighter regulations the industry is likely to continue to push the advertising boundaries and will take advantage of any delays in their implementation. Early strengthening of controls is proposed rather than delaying the process to fit with legislation that would be administered through the proposed joint trans-Tasman therapeutic products agency. Policy development by Medsafe on appropriate constraints for DTCA is underway, but a new regulatory approach is unlikely before the end of 2002.

## Consumer Groups

There is evidence of growing lobbying pressure from consumer groups advocating the extension of subsidies for drugs to cover the treatment of specific illnesses suffered by their members or constituencies. A recent example is the Leukaemia and Blood Foundation's public campaign to have Pharmac extend subsidised coverage of Glivec for the treatment of chronic myeloid leukaemia.<sup>15</sup> Despite information campaigns outlining prioritisation and other criteria that Pharmac brings to bear on such issues, ongoing pressure of this kind can be expected from consumer groups.

## Parallel importing of pharmaceuticals

The Copyright (Removal of Prohibition on Parallel Importing) Amendment Act 1998 removed previous Copyright Act restrictions on the parallel importing of all goods, including pharmaceuticals. However, it did not alter the various restrictions in other Acts which may restrict parallel importing, including the [Medicines Act 1981](#).

These provisions apply to Pharmac as well as to individuals. The Crown has an exemption from these requirements, and so could potentially parallel import pharmaceuticals. The benefit of allowing parallel importing is that it allows purchasing of goods from any supplier in the world. This enables buyers to shop for the best price, rather than having to accept the price offered by an exclusive New Zealand supplier.

Any delegation of Government's exemption to Pharmac, or any other agency, other than in cases of continuity of supply, would need to be carefully considered.

## Costs and subsidies

Most of the cost of a subsidised pharmaceutical is met by the government. The government pays a subsidy for the medicine and a fee covering distribution and Pharmacy dispensing services. The subsidy does not necessarily represent the final cost to the government. This depends on the nature of Pharmac's contractual arrangements with the supplier.

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<sup>15</sup> Pharmac is currently consulting with interested parties on Glivec access criteria.

The only cost a patient should incur for a fully subsidised medicine is the standard government prescription charge, or the cost of the medicine, whichever is less. The government prescription charge for a three month course of a particular medicine ranges up to \$15 and represents the patient's contribution to the cost of the medicine. The government pays the rest of the cost.

Pharmac operates<sup>16</sup> two other arrangements that allow it to be more flexible in setting subsidies:

- *Special Authority* – a Special Authority provides subsidised access to patients where prescribing is restricted to specialists and/or where expensive drugs are restricted to patients who most need a certain drug.
- *Exceptional Circumstances* – The Exceptional Circumstances provision is used to meet the requirements of patients who have rare medical conditions or whose needs are not otherwise met by the Schedule.

While these funding arrangements cover the vast majority of patients' needs there is, nevertheless, a small proportion of patients – ie, those who have side-effects to a subsidised pharmaceutical or require access to a drug that is not subsidised – who are concerned that they must bear the full cost of their medicines.

## **Extension of prescribing by health professionals**

The more efficient and effective delivery of services that extended prescribing by health professionals would bring also imposes risks to safety and expenditure growth. While there is support for changes that build on the evolving practice nurse/GP relationship in a way that enhances teamwork and partnership, there is strong resistance from some sector interest groups.

The Medicines Act 1981 was amended in 1999 to enable the making of regulations to allow registered health practitioners, such as nurse practitioners or Pharmacists, to prescribe a limited list of medicines under a particular scope of practice. In 2001, Cabinet approved regulations covering nurse practitioners working in aged care and child family health. The New Prescribers Advisory Committee is currently assessing applications to grant optometrists, and nurse practitioners working in sexual and reproductive health limited independent prescribing authority.

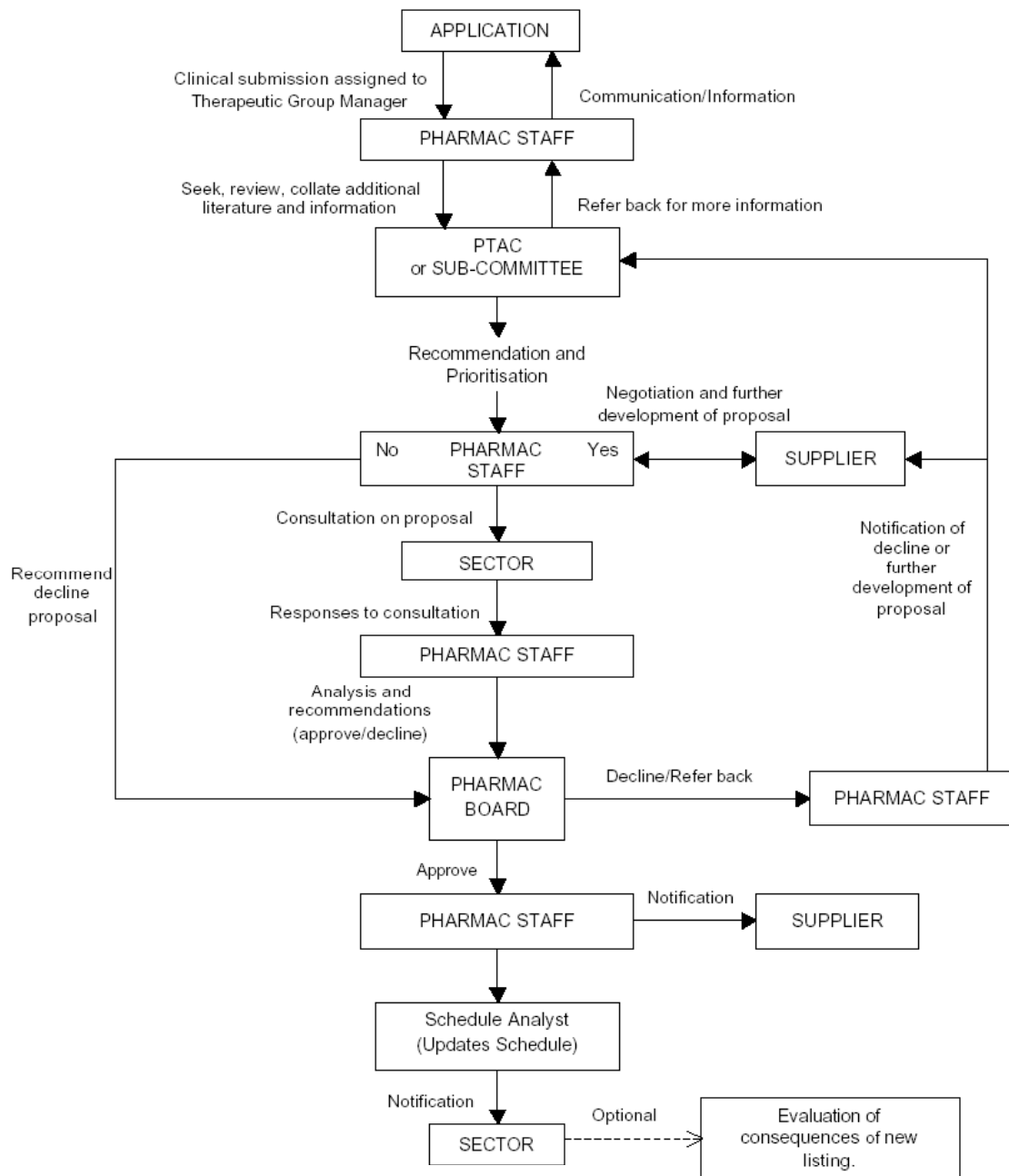
A review of extended prescribing will be undertaken over a three year period. The costs and benefits will be assessed with Pharmac monitoring the impact on the pharmaceutical budget.

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<sup>16</sup> The Exceptional Circumstances provision was previously managed by the HFA.

# Appendix One

## Procedure for listing a pharmaceutical on the Pharmaceutical Schedule



Source: Pharmac. 2001. Operating Policies and Procedures. p.12.

NOTE: This diagram provides a simplified, indicative guide to the process that Pharmac will usually follow when listing a pharmaceutical on the Schedule. Pharmac is not bound to follow the process set out in the diagram and may vary this process or adopt a different process where appropriate.