

PHARMACEUTICAL BENEFITS

PRICING AUTHORITY

ANNUAL REPORT

For the year ended 30 June 2004





PHARMACEUTICAL

BENEFITS

PRICING

AUTHORITY

Annual Report

For the year ended 30 June 2004

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Minister The Hon Tony Abbott MP
Minister for Health and Ageing
Parliament House
CANBERRA ACT 2600

Dear Mr Abbott

I present herewith the seventeenth annual report of the Pharmaceutical Benefits Pricing Authority on the operations of the PBPA, and on the PBPA's interpretation of its operating guidelines for the year ended 30 June 2004.

This report is made in accordance with the requirement of subsection 34C(2) of the *Acts Interpretation Act 1901*, that in the absence of specific requirements to the contrary, an annual report shall be furnished to you as soon as practicable after the end of the reporting period.

Yours sincerely



Graham Glenn

Chairman

2004

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PREFACE

This is the seventeenth annual report of the Pharmaceutical Benefits Pricing Authority covering the operations of the PBPA for the year ended 30 June 2004.

Tabling requirements

It is a requirement of sub section 34C(3) of the *Acts Interpretation Act 1901*, that in the absence of specific requirements to the contrary, the annual report shall be laid before each House of the Parliament within 15 sitting days of that House after the day on which the Minister receives the report.

Structure of report

The report is divided into four chapters:

- chapter 1 provides basic information about the PBPA's genesis, membership and financial arrangements;
- chapter 2 addresses the factors considered by the PBPA for pricing of pharmaceutical benefits made available under the Government's Pharmaceutical Benefits Scheme administered by the Department of Health and Ageing;
- chapter 3 deals with activities under the Government's Pharmaceutical Industry Investment Program, administered by the Department of Industry, Tourism and Resources; and
- chapter 4 contains related tables and figures.

CHAPTER 1

Pharmaceutical Benefits Pricing Authority

The Pharmaceutical Benefits Pricing Authority (PBPA) is an independent non-statutory body established in 1988 which is required to:

- review the prices of products supplied under the Pharmaceutical Benefits Scheme (PBS);
- recommend prices for new items that are recommended for listing on the PBS; and
- administer companies' participation in the Pharmaceutical Industry Investment Program (PIIP) until the end of June 2004.

Membership

The PBPA's membership for the 2003–2004 financial year was:

Chairman	Mr Graham Glenn — appointed with effect from 1 June 1992.
Industry nominee	Mr Kieran Schneemann — appointed with effect from 18 March 2003, as the nominee of Medicines Australia.
Consumer nominee	Ms Jo Watson — appointed with effect from 25 February 2002, as the nominee of the Consumers' Health Forum.
Department of Health and Ageing representative	Ms Joan Corbett — appointed with effect from 4 March 2003.
Department of Industry, Tourism and Resources representative	Mr Craig Pennifold — appointed with effect from 15 December 1999.

Secretariat Support

The PBPA is serviced by two secretariats, viz:

- | | |
|---|--|
| <ul style="list-style-type: none">• PBS pricing matters | <ul style="list-style-type: none">• Industry development matters |
| Ms Sue Campion | Mr Nicholas Dowie |
| Secretary | Executive Officer |
| Pharmaceutical Benefits Pricing Authority | Pharmaceutical Industry Investment Program |
| GPO Box 9848 | Pharmaceutical Benefits Pricing Authority |
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The PBPA supports best management practice in communicating with suppliers and other interested parties to make the PBPA's decisions and decision making processes as transparent as possible, subject to the confidences in which certain commercially sensitive information must be held.

Consultation with respective secretariat staff on the interpretation of the PBPA's guidelines, practices and procedures is encouraged to ensure that all interested parties gain a clear understanding of those matters and have the maximum opportunity to make their views known to the PBPA.

Technical support

Technical advice to assist the PBPA in its deliberations is provided by the Pharmaceutical Benefits Advisory Committee (PBAC).

Co-ordination to achieve timely outcomes

Pricing Authority meetings are coordinated with meetings of the PBAC, so that PBAC outcomes can be dealt with as soon as possible consistent with the need to collect pricing information.

Financial arrangements

The Department of Health and Ageing budget, in addition to financing the PBS, provides funds for:

- the fees and expenses incurred by the Chairman, industry and consumer nominees, in accordance with determinations made from time to time by the Remuneration Tribunal;
- the day to day operations of dealing with pricing matters under the Scheme; and
- the costs of associated meetings, seminars and other related expenses.

The Department of Industry, Tourism and Resources budget, in addition to financing the PIIP, provides funds for running costs associated with the Program.

For the year ended 30 June 2004 the PBPA operating costs were:

<i>PBPA operating costs 2003–2004</i>	<i>Health portfolio \$</i>	<i>Industry portfolio \$</i>	<i>Total costs \$</i>
Direct costs including Chairman's, industry and consumer nominees' expenses	4,456	0	4,456
Salaries	402,387	64,595*	466,982
Members & secretariat travel and allowances	1,259	5,364	6,623
Administrative and property costs	11,733	17,615**	29,348
Total costs	419,835	87,574	507,409

* Includes operation of the Secretariat for the PIIP.

** Includes legal fees and the PIIP database maintenance costs.

CHAPTER 2

Pharmaceutical Benefits Scheme

The PBPA's objective in reviewing prices of items listed under the PBS is to secure a reliable supply of pharmaceutical products at the most reasonable cost to Australian taxpayers and consumers and consistent with maintaining a sustainable pharmaceutical industry in Australia.

Under its terms of reference the PBPA is required to determine or recommend to the Minister for Health and Ageing prices of items listed as pharmaceutical benefits or recommended by the PBAC for listing. The Pricing Secretariat also conducts negotiations with suppliers, where necessary, on proposed prices.

Factors considered by the PBPA

In reviewing the price of listed items and in considering the price of items recommended for listing, the PBPA takes account of the following factors:

- (a) PBAC comments on clinical and cost effectiveness aspects of items;
- (b) the prices of alternative brands of a drug;
- (c) comparative prices of drugs in the same therapeutic group;
- (d) costs information, when provided by the supplier or estimated by the PBPA;
- (e) prescription volumes, economies of scale and other factors such as expiry dating, storage requirements, product stability and special manufacturing requirements;
- (f) the level of activity being undertaken by the company in Australia, including new investment, production, research and development (this factor is met by the PIIP);
- (g) prices of the drug in reasonably comparable overseas countries;
- (h) other relevant factors which the applicant company may wish the PBPA to consider; and
- (i) any directions of the Minister.

Price adjustments for items require the approval of the Minister for Health and Ageing.

Establishing prices for new listings

For new listings recommended by the PBAC, the PBPA recommends the prices to be negotiated by the Department of Health and Ageing.

The advice of the PBAC is the big factor in determining initial prices.

Increasingly, the PBPA recommends the use of risk share pricing arrangements to help contain costs for drugs that are a significant annual cost to the PBS. The most common type of arrangement is a price-volume agreement, where the sponsor of a particular drug agrees to a price reduction for any sales that exceed a pre-agreed sales volume.

Example: A sponsor agrees to reduce the price of the drug by 15% once the sales volume exceeds \$20 million in any year.

There are a number of other types of risk share pricing arrangements negotiated with pharmaceutical companies. These include:

1. Estimating the potential use outside the PBS restriction and rebating a proportion of this use.
Example: the sponsor accepts that 25% of a particular drug's sales may be for uses that are not subsidised by the PBS. The sponsor agrees to rebate 20% of that drug's total sales to the government.
2. Agreeing to an annual cap (based on cost or script volumes) for a drug and rebating any excess over the cap.
3. Agreeing to a common annual sales cap for all the drugs used to treat a particular condition and rebating any excess according to each sponsor's market share.

Example: Four drugs are used to treat a particular condition and the agreed cap for their combined sales is \$80 million per year. In a particular year, sales are \$100 million, with the four sponsors having sold: \$10 million, \$20 million, \$30 million and \$40 million respectively. Sponsors agree to rebate a total of \$20 million to the government, paying: \$2 million, \$4 million, \$6 million and \$8 million, respectively.

Currently there are 11 risk share pricing arrangements in place or in development.

All proposed listings with a predicted net cost to the PBS in excess of \$10 million per annum must be considered by Cabinet. This means that, where the Department of Health and Ageing, in consultation with the Department of Finance and Administration, has estimated the cost of a proposed new listing as being above this threshold, Cabinet consideration will be required before the listing can be finalised.

The following products expected to cost more than \$10 million per annum were listed in 2003–2004:

Etanercept (Enbrel®) — This drug was listed on 1 August 2003 to treat severe forms of rheumatoid arthritis.

Rituximab (Mabthera®) — This was an extension of an existing listing to cover patients aged over 60 years with previously untreated diffuse large B-cell non-Hodgkin's lymphoma where the drug is used in combination with chemotherapy. This occurred on 1 August 2003.

Imatinib Mesylate (Glivec®) — This was an extension of an existing listing to cover the treatment of chronic phase Chronic Myeloid Leukaemia. This occurred on 1 November 2003.

Adrenaline (EpiPen®) — EpiPen was listed on 1 November 2003 to treat anaphylaxis, a life-threatening condition resulting from severe allergic reactions to insect stings and foods such as peanuts.

Infliximab (Remicade®) — Remicade is a drug used for the treatment of rheumatoid arthritis and is available to patients with severe rheumatoid arthritis unresponsive to existing therapies. It was listed on 1 November 2003.

Pioglitazone Hydrochloride (Actos®) and Rosiglitazone Maleate (Avandia®) — These drugs were listed on 1 November 2003 for the treatment of Type II Diabetes.

Reviewing prices for existing items

The main mechanisms used by the PBPA for reviewing prices of pharmaceutical products supplied through the PBS are:

- reference pricing, ie comparative prices of products that are considered by the PBAC to have a similar therapeutic effect or benefit; or, where this is not available;
- on the basis of further cost effectiveness justification by the sponsor to the PBAC; or
- gross margin on the cost of manufacture, or landed cost.

The PBPA may also request additional data from applicants, including drug utilisation data, so that relevant treatment costs can be independently calculated.

The Weighted Average Monthly Treatment Cost (WAMTC) is a form of reference pricing applied to specified groups of drugs considered by the PBAC as having similar therapeutic outcomes. This methodology was reinstated in January 2004 (see Implementation of the Weighted Average Monthly Treatment Cost (WAMTC) methodology on page 10 of this report).

Therapeutic Relativities

The PBPA issues relativity sheets that identify the basis of pricing comparisons between therapeutically similar products. These are mainly based on the advice from the PBAC. If necessary, clarification can be obtained from the secretariat, and the relativities may be changed by the presentation of further data to the PBAC.

Effects of price adjustments

Prices or price adjustments determined or recommended by the PBPA have an impact on:

- suppliers through adjusted selling prices;
- wholesalers through the margin on the agreed price of products to pharmacist;
- pharmacists through the mark-up on wholesale prices;
- hospitals dispensing highly specialised drugs to community based patients through the special distribution arrangements provided for under Section 100 of the *National Health Act 1953*; and
- consumers and taxpayers that, either directly or indirectly, bear part or all of the cost of the drugs dispensed under the PBS.

The prices set by the PBPA cover not only subsidised products, but also products listed in the Schedule priced below the maximum co-payment for general patients. The co-payment for general patients for the period of the report was \$23.10 changing to \$23.70 effective 1 January 2004.

Brand Premium Policy

The Brand Premium Policy was introduced in December 1990 to reduce price control where possible by allowing pharmaceutical suppliers to set their own prices on multi-branded and therapeutically interchangeable brands listed on the PBS, provided one brand was available at the subsidised price. This also encourages the development of the generic pharmaceutical industry in Australia.

The policy for alternative brands has the effect of making it possible for prescribers and patients to be more aware of the price of drugs. The policy also allows companies to establish prices taking into account competition and the heightened consumer awareness of price differentials.

The policy operates where there is more than one brand of a particular drug available through the PBS and where the brands are therapeutically interchangeable. The policy mainly applies, therefore, to out of patent drugs.

Under the policy, suppliers of multi-branded items are able to set their own prices at a level they think the market will bear. At the same time, prescribers, pharmacists and patients can decide whether it is necessary to pay more for a particular brand when a lower priced equivalent and therapeutically interchangeable brand is available.

Basically, the policy operates by:

- the Government subsidising a drug to the level of the lowest priced brand;
- suppliers of other brands of that drug being able to set a price above the price charged by the supplier of the lowest priced brand, where the brands are therapeutically equivalent (usually bio-equivalent); and
- the patient paying the brand premium which is the price difference between the lowest priced brand and the brand prescribed.

As the brand premium is not a Government charge, it does not count toward a patient's safety net. The premium arises from the supplier's price setting and the majority of it goes to the supplier, with wholesalers and pharmacists receiving a percentage.

As at 30 June 2004 there were 305 benefit items with a brand premium that could be therapeutically interchanged. The average brand premium was \$2.94 and premiums ranged from \$0.06 to \$79.48. The majority of brand premiums were in the range of \$1.30 to \$3.00.

Brand Substitution

The Government introduced a policy of brand substitution from 1 December 1994. Under the policy, a pharmacist can substitute a brand other than that prescribed by the patient's doctor without reference back to the prescriber. This practice is only allowed in cases where the brand to be substituted is equivalent to that prescribed by the doctor.

Equivalent brands are shown in the Schedule of Pharmaceutical Benefits as having been demonstrated to be bio-equivalent or therapeutically equivalent, or that justification for not needing bio-equivalence or therapeutic equivalence data have been provided to and accepted by the Therapeutic Goods Administration. If other brands are not shown in this way it does not imply that they are not equivalent, but simply that it is unknown whether or not they are equivalent.

Since 1 May 1999, sponsors have been able to vary premium prices or reduce benchmark prices without reference to the PBPA. Applications for increases to the benchmark prices continue to be considered by the PBPA.

The following table shows the effect of brand substitution*.

	<i>May 2001</i>	<i>May 2002</i>	<i>May 2003</i>	<i>May 2004</i>
Number of products with a premium	297	293	303	305
Average brand premium	\$2.20	\$2.83	\$3.06	\$2.94
Weighted average brand premium**	\$1.68	\$1.57	\$1.57	\$1.91
Brand premium Range	\$0.01 to \$45.33	\$0.01 to \$79.48	\$0.06 to \$79.48	\$0.06 to \$79.48
Prescriptions dispensed with a brand premium in the previous 12 months	33.4m	33.3m	32.6m	30.4m
Prescriptions dispensed at the benchmark level in the previous 12 month period	29.4m	22.6m	37.8m	40.3m
Percentage at the benchmark level	47%	49%	54%	57%
Brands at the Benchmark price	766	854	943	1004

* Figures only include those scripts processed by HIC, so general scripts that fall under the copayment are not included.

** Weighted average brand premium is calculated by:

Scripts x premium = total premium value,

Total premium value/total scripts = weighted average brand premium

Therapeutic Group Premium (TGP) Policy

The TGP policy was introduced by the Government in 1998 to extend the practice of stimulating competition between pharmaceutical suppliers that was started with introducing price premiums for generic brands of a drug (the Brand Premium Policy), to groups of drugs which have very similar clinical activity. Under this approach, the Government subsidy is based on the benchmark price (ie. the lowest priced drug/s in each group) and the price difference for a more expensive drug within the relevant group is paid by the patient over and above the relevant patient co-payment.

There are currently four drug groups under the TGP policy. These are ACE Inhibitors and Calcium Channel Blockers that are used to treat cardiovascular disease, HMG CoA reductase inhibitors (statins) used for lowering blood cholesterol and the H2 receptor antagonists for the treatment of peptic ulcers. As these drug groups present high costs to the PBS, there are significant savings achieved by Government through the TGP policy.

Under the TGP policy, where a patient cannot for clinical or compliance reasons tolerate the benchmark priced drug, the prescriber can apply to the Health Insurance Commission for an exemption to supply the dearer alternative drug at no extra cost to the patient.

The prices of items in the four therapeutic groups under the TGP policy are reviewed by the PBPA on a weighted average monthly treatment cost basis. This methodology was reinstated in January 2004.

As at 30 June 2004 there were 70 items within the four groups under the TGP policy. 11 of the items were listed with therapeutic premiums with a range from \$0.64 to \$7.01. The 70 items consisted of 172 brands at the benchmark price and 37 brands with a brand premium.

Implementation of the Weighted Average Monthly Treatment Cost (WAMTC) Methodology

The comparison of monthly treatment costs is a pricing tool which has been used by the PBPA to review prices of closely related drugs for several years.

The WAMTC methodology is applied to groups of drugs that are considered to be therapeutically similar by the PBAC. Under the evidenced-based approach used for the listing and pricing of drugs, it is the practice to price these at the same level.

In 1999, the Minister for Health and Ageing announced a review of the WAMTC methodology following concern being expressed about aspects of its operation.

Pharmaceutical suppliers, Medicines Australia, the Department of Health and Ageing and the Department of Industry Tourism and Resources were all consulted during the course of the review by Ernst and Young ABC Pty Ltd.

The PBPA recommended a number of changes to the Minister who approved the use of a revised WAMTC methodology with effect from January 2004.

Each WAMTC group is reviewed annually in line with PBPA meetings, and may be subject to ad hoc reviews if a price reduction is requested for any of the drugs in a group.

There are two categories of drug groups to which the WAMTC methodology applies:

- Therapeutic group premium (TGP) drugs; and
- Non-TGP drugs, where the mode of action is not necessarily the same but the drugs have been listed on a cost minimisation basis as providing similar health outcomes. In some cases, it may be that the group could form a TGP class but has not been designated as such.

There are currently four TGP WAMTC groups:

- H2 receptor antagonists (cimetidine, ranitidine, nizatidine, famotidine)
- CCBs (dihydropyridines) (amlodipine, felodipine, lercanidipine, nifedipine)
- ACE inhibitors (captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril,trandolapril)
- HMGs (statins) (atorvastatin, pravastatin, simvastatin)

There are also two non-TGP WAMTC groups:

- Antidepressants (SSRIs plus) (citalopram, fluoxetine, fluvoxamine, mirtazapine, moclobemide, reboxetine, paroxetine, sertraline)
- Proton Pump Inhibitors (PPIs) (esomeprazole, lansoprazole, omeprazole, omeprazole magnesium, pantoprazole, rabeprazole)

Note: The four dihydropyridines CCBs plus diltiazem form a WAMTC group through diltiazem's relativity to the other drugs.

In January 2004, a review of five groups took place, with the resultant price or therapeutic group premium adjustments commencing from 1 May 2004. The review of the final group, the SSRIs plus, will be undertaken in August 2004.

The methodology will operate on a regular cycle from August 2004.

Highly Specialised Drugs

Section 100 of the National Health Act provides for an alternative means of providing a pharmaceutical benefit in circumstances where the usual PBS supply arrangements are unsuitable. There are certain drugs that because of their clinical use or other special features are restricted to prescription through hospitals having access to appropriate specialist facilities. These drugs, called Highly Specialised Drugs (HSDs), are among those supplied via Section 100. The Highly Specialised Drugs Program is a Government subsidy mechanism for the supply of HSDs. The Government provides funding for the drug cost for community based patients. The State and Territory Governments fund the in-patient usage of HSDs within public hospitals.

For a drug to be approved under these arrangements and be included in the scheme, it must comply with specific criteria agreed between the Government and the State and Territory governments and be recommended by the PBAC. If a drug is suitable for supply through the normal PBS arrangements it is not eligible for funding through the Highly Specialised Drugs Program. The funding to the States and Territories, additional to the Australian Health Care Agreement funding, is only available when the public hospitals are used as the necessary mode of supply to PBS patients.

The PBPA's role in respect of these drugs is to review and negotiate national prices for their supply. Prices are negotiated at ex-manufacturer level. The prices and prescribing restrictions for these HSDs are separately listed in the Schedule of Pharmaceutical Benefits.

At 30 June 2004 there were 58 Highly Specialised Drugs listed under Section 100. Subject to reconciliation of expenditure, payments made for both Public and Private Hospitals was \$397.6 million, which is a 14.1% increase on the previous year.

<i>Indications Grouping</i>	<i>Number of drugs</i>	<i>Public Hospital \$</i>	<i>Private Hospital \$</i>	<i>Combined \$</i>
Acromegaly	3	10,589,256	3,865,670	14,454,926
Bisphosphonates	2	9,520,566	7,722,843	17,243,409
Haemopoietics	2	83,129,517	14,886,582	98,016,100
HIV/AIDS Antiretroviral Agent	18	82,598,860	125,996	82,724,856
Immunocompromised Conditions	9	4,915,584	368,268	5,283,851
Immunostimulating Agent	10	55,990,559	26,133,715	82,124,274
Immunosuppressing Agents	7	49,836,215	4,341,728	54,177,943
Other Conditions	7	40,514,490	3,056,998	43,571,488
Grand Total	58	337,095,047	60,501,800	397,596,847

Special Pharmaceutical Benefits

A product may require a special patient contribution when a pricing agreement between the Government and supplier cannot be reached for unique products. Such products are 'special pharmaceutical benefits'. There is currently one product listed that has a special patient contribution.

The special patient contribution is the difference between the dispensed price requested by the supplier and the Government's dispensed price. The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients.

Therapeutic Group Reviews

The PBPA reviews annually the price of each drug listed in the PBS by therapeutic groupings. Suppliers are asked to submit cost and other data that they wish the PBPA to consider in reviewing product prices.

Confidentiality of information

All information provided on a confidential basis to the PBPA is strictly treated as such. This confidential information is not disclosed to any person apart from members of the PBPA and relevant officers of the Department of Health and Ageing and the Department of Industry, Tourism and Resources, without the express permission of the Chairman and the company concerned.

Results of therapeutic group reviews 2003–2004

In the 2003–2004 financial year, the PBPA held four therapeutic group reviews, the summary results of which are compared below with those for the previous year:

<i>Product review results</i>	<i>2002–2003</i>	<i>2003–2004</i>
Number of items reviewed:	2,871	2,866
Number of products (includes individual brands) for which price applications were received	496 17.38%	505 17.62%
Number of products for which price increases were granted:	104 3.6%	120 4.2%

The number of new items recommended for listing and new items actually listed for the financial year 2003–2004 was:

Number of items recommended for listing by the PBAC	88	73
Section 100 (based on PBAC meetings held in 2003–2004 financial year, includes different strengths)	18	18
Number of items listed	85	*140
Section 100 (based on new items listed in the PBS Schedules for 2003–2004)	14	**79

* 2003/2004 figures include secretariat listings (ie. listings that did not go to PBAC/PBPA meetings).

Figure includes 10 drugs listed under 42 items in the new sub-section of Palliative Care.

** Figure includes 20 drugs with several drugs having a large number of different pack sizes/combinations.

Estimate of additional cost of drugs newly listed during 2003–04*	-	\$267.5 million**
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* The estimated costs to the PBS and RPBS is for first 12 months of listing each drug, based on estimated net costs from major PBAC submissions for drugs listed on PBS between 1 July 03 to 30 June 04. Note that drugs are listed at stages throughout the year so the total is not the estimated cost to the PBS and RPBS in the financial year 2003–04.

** Includes \$50.3 million for drugs that did not require Cabinet consideration.

Estimated cost of price increases of existing items 2003–2004

The general price increases granted to suppliers in 2003–2004 are collectively estimated to add \$4.8 million to the cost of the PBS in a full year based on the latest available twelve months prescription volume for each item at the time of review. A comparison with the estimated full year costs in the previous year is set out below:

<i>Approval of price increases</i>	<i>2002–2003 \$ million</i>	<i>2003–2004 \$ million</i>
Recommended by the PBPA and subsequently approved by the Minister	5.3	4.8

These cost estimates do not include any expenditure for increased Australian activities considered under the PIIIP.

Cost of Pharmaceutical Benefits Scheme, 2003–2004

The total cost of the PBS for 2003–2004 was \$5,607.5 million. This comprised \$4,023.4 million for persons covered by concession cards, and \$1,013.6 million for general patient, ie those patients not covered by concession cards. PB Other expenditure was \$570.5 million, which includes a range of categories of expenditure, including Highly Specialised Drugs.

<i>Category</i>	<i>Processed script numbers million</i>	<i>Cost to Govt (excludes patient contributions) \$ million</i>
General	28.0	1,013.6
Concessional	137.4	4,023.4
PB Other	*	570.5
Total	165.4	5,607.5

* PB Other contains diverse programs. The majority of data are collected by State Governments and script volume is unavailable

Note: For the general public, where a pharmaceutical benefit has a dispensed price below the general patient contribution (that is, below \$23.70), the consumer pays the full amount. The above figures do not include these amounts.

CHAPTER 3

Pharmaceutical Industry Investment Program

A supplementary Annual Report on the Pharmaceutical Industry Investment Program (PIIP) for the full 2002–03 financial year was released in May 2004.

The PIIP commenced on 1 July 1999 and concluded on 30 June 2004. Total funding of up to \$300 million was allocated for the five years. PIIP was designed to compensate the pharmaceutical industry, in part, for the impact on activity of the Government exercising its monopsony purchasing power under the Pharmaceutical Benefits Scheme. It also aimed to increase the total level of activity undertaken in Australia that has a direct link to or is of direct relevance to the pharmaceutical industry.

Participating companies received partial compensation for the effects of price and volume constraints under the PBS in exchange for performing additional Production Value Added and Research and Development activities. Partial compensation was paid in the form of either notional or actual price increases on PBS products nominated by participating companies.

Participating Companies

Nine companies signed contracts for entry into PIIP. These companies were:

- Amrad Corporation Limited
- Bristol-Myers Squibb Australia Pty Ltd
- CSL Limited
- Eli Lilly Australia Pty Ltd
- FH Faulding & Co Limited (now Mayne Pharma Pty Ltd)
- Glaxo Wellcome Australia Pty Ltd (now GlaxoSmithKline Australia Pty Ltd)
- Janssen-Cilag Pty Ltd
- Pfizer Pty Limited (now Pfizer Australia Pty Limited)
- Pharmacia & Upjohn Pty Ltd (now Pharmacia Australia Pty Ltd)

2003–2004 Activity

Payments totalling \$33,818,457 were made for activity undertaken in the first three quarters of 2003–04. This included \$20,654,223 for production value added and \$13,164,234 for research and development. Data for payments made for activity undertaken in the full financial year only become available in December.

A supplementary Annual Report for the PIIP for the year ended 30 June 2004 will be released by the Department of Industry, Tourism and Resources in 2005. The supplementary report will contain complete financial data for activity undertaken in 2003–04.

CHAPTER 4

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Table 1: PBS — summary of therapeutic group reviews for 2003–2004

<i>ATC Group</i>	<i>Minor Group</i>	<i>No. of Products Reviewed</i>	<i>Script Volume Total cost</i>	<i>Govt cost \$</i>	<i>Total Cost</i>	<i>Estimated cost to Government of Price increases \$</i>
A02	Drugs for Acid Related Disorders	92	12,266,029	480,817,576	567,359,408	-
A04	Antiemetics and Antinauseants	22	761,936	14,699,703	18,305,097	-
A06	Laxatives	18	617,489	9,866,713	11,503,237	35,841
A07	Antidiarrheals, Intestinal Antiinflammatory/Anti-infective Agents	24	894,998	35,488,933	42,086,107	209,237
A10	Drugs used in Diabetes	78	4,931,545	167,446,211	185,154,380	-
B01	Antithrombotic Agents	45	4,540,455	154,544,380	172,118,921	-
B05	Blood Substitutes and Perfusion Solutions	11	45,195	1,112,740	1,507,989	-
C01	Cardiac Therapy	74	3,450,371	60,872,657	72,290,385	98,532
C02	Antihypertensives	32	726,253	10,166,040	12,928,797	2,108
C03	Diuretics	43	2,362,800	22,073,817	28,925,148	-
C07	Beta Blocking Agents	57	4,628,098	67,136,235	81,738,886	-
C08	Calcium Channel Blockers	80	7,380,410	152,512,663	191,221,993	55,661
C09	Agents Acting on the Renin-Angiotensin System	149	19,376,940	402,709,093	551,727,000	27,116
C10	Serum Lipid Reducing Agents	35	14,709,118	835,541,042	952,617,922	8,158
D07	Corticosteroids, Dermatological Preparations	38	2,352,540	20,894,191	29,594,847	-
D10	Anti-Acne Preparations	14	133,400	17,383,661	19,733,789	-
G03	Sex Hormones and Modulators of the Genital System	140	3,791,359	77,297,819	94,217,005	286,329
H02	Corticosteroids for Systemic use	31	1,619,198	11,675,635	16,782,073	34,418
J01	Antibacterials for Systemic use	378	11,092,683	130,574,361	170,580,847	65,231
J05	Antivirals for Systemic use	32	370,122	76,967,632	82,919,798	-
L01	Antineoplastic Agents	110	406,132	167,801,228	171,875,909	217,719
L02	Endocrine Therapy	38	396,251	102,127,519	105,417,506	18,349
L03	Immunostimulants	17	78,088	87,444,765	88,485,435	8,274

Table 1: PBS — summary of therapeutic group reviews for 2003–2004 (continued)

ATC Group	Minor Group	No. of Products Reviewed	Script Volume Total cost	Govt cost \$	Total Cost	Estimated cost to Government of Price increases \$
L04	Immunosuppressive Agents	34	215,165	39,396,300	41,616,710	31
M01	Anti-inflammatory and Antirheumatic Products	90	9,143,205	212,956,211	271,757,010	-
M03	Muscle Relaxants	20	119,878	5,769,319	6,491,343	-
M04	Antigout Preparations	22	865,526	7,054,985	9,532,338	155,587
M05	Drugs for Treatment of Bone Diseases	20	2,439,353	135,028,145	147,684,827	-
N02	Analgesics	92	10,914,950	141,925,677	174,370,911	225,398
N03	Antiepileptics	74	1,595,871	90,791,297	102,931,713	33,044
N04	Anti-Parkinson Drugs	39	606,665	30,393,310	33,310,831	72,311
N05	Psycholeptics	112	7,224,566	247,431,938	271,038,710	1,715
N06	Psychoanaleptics	111	12,000,862	350,523,725	460,123,457	28,617
R03	Drugs for Obstructive Airway Diseases	90	9,523,344	348,071,969	412,367,828	35,641
S01	Ophthalmologicals	103	6,233,638	89,823,235	111,914,982	260,628
V04	Diagnostic Agents	19	492,709	23,449,923	25,672,508	-
V06	General Nutrients	63	55,198	16,725,354	17,396,530	1,620
	*Ad hoc	199	7,499,761	154,580,666	183,569,997	3,108,321
	Total (excludes section 100 drugs)	2,646	165,862,101	5,001,076,669	5,938,892,174	4,989,886

*Ad hoc — comprised of groups with less than 4 manufacturers and/or less than 10 products (for confidentiality) and items on an ad hoc basis.

Table 2: PBS — highest cost items 12 months to 30 June 2004

Rank	Item	Drug	Form	Volume	Govt Cost \$	Total Cost \$	Ave Price \$
1	8333	OMEPRAZOLE	Tablet 20 mg, 30	3,724,660	161,782,740	189,683,373	50.93
2	8173	SIMVASTATIN	Tablet 40 mg	1,844,164	135,352,123	149,966,482	81.32
3	8214	ATORVASTATIN	Tablet 20 mg	2,622,776	132,738,540	156,354,933	59.61
4	8215	ATORVASTATIN	Tablet 40 mg	1,611,674	120,322,429	134,922,962	83.72
5	2012	SIMVASTATIN	Tablet 20 mg	2,280,951	117,204,301	132,806,129	58.22
6	8358	CLOPIDOGREL	Tablet 75mg	1,369,634	108,117,378	115,058,695	84.01
7	8187	OLANZAPINE	Tablet 10 mg, 30	249,706	84,379,375	85,755,618	343.43
8	8511	ALENDRONIC ACID	Tablet 70 mg alendronic acid	1,641,417	83,099,232	91,719,569	55.88
9	8197	PRAVASTATIN	Tablet 40 mg, 30	1,094,909	78,559,814	87,042,652	79.50
10	8008	PANTOPRAZOLE	Tablet (enteric coated) equivalent to 40mg	1,747,408	75,484,648	88,150,724	50.45
11	8440	CELECOXIB	Capsule 200 mg, 60	2,703,703	71,838,767	91,107,358	33.70
12	8472	ROFECOXIB	Tablet 25 mg, 30	1,988,600	68,830,898	85,371,766	42.93
13	8213	ATORVASTATIN	Tablet 10 mg	1,957,229	68,032,699	84,327,816	43.09
14	8432	SALMETEROL and FLUTICASON	Pdr oral inhal breth actu dev 50ug/500ug	804,779	57,479,551	64,812,857	80.53
15	8601	ESOMEPRAZOLE	Tablet 40 mg (enteric coated), 30	818,839	54,220,731	61,638,271	75.28
16	8519	SALMETEROL and FLUTICASON	Oral Press inhal 25ug/250ug	681,589	47,978,009	54,245,479	79.59
17	8521	ATORVASTATIN	Tablet 80 mg	437,729	47,460,485	51,424,506	117.48
18	8405	IRBESARTAN with HYDROCHLOROTHIAZIDE	Tablet 300 mg—12.5 mg	1,891,022	46,827,127	64,410,134	34.06
19	8313	SIMVASTATIN	Tablet 80 mg	438,739	46,753,684	50,244,343	114.52
20	8600	ESOMEPRAZOLE	Tablet 20 mg (enteric coated), 30	1,232,758	46,028,892	56,893,854	46.15
21	8220	CITALOPRAM	Tablet 20 mg (base)	1,717,164	44,628,801	63,663,124	37.07
22	8626	TIOTROPIUM BROMIDE	Capsule 18ug (base)(oral inhalation), 30	578,834	42,315,436	44,836,583	77.46
23	8302	VENLAFAXINE	Capsule 150 mg (base)modified release	782,954	41,906,169	50,158,582	64.06
24	2242	PAROXETINE	Tablet 20 mg (base)	1,263,133	39,399,084	53,063,868	42.01
25	8101	INTERFERON BETA-1b	Injection set 1 vial powder dose 8,000,000 i.u.	31,929	37,173,869	37,600,453	1177.63

Table 2: PBS — highest cost items 12 months to 30 June 2004 (continued)

Rank	Item	Drug	Form	Volume	Govt Cost	Total Cost	Ave Price
					\$	\$	\$
26	2237	SERTRALINE	Tablet 100 mg (base)	1,160,606	35,366,274	48,246,868	41.57
27	8243	LATANOPROST	Eye drops 50 ug per mL (0.005%), 2.5 mL	1,226,993	35,350,549	41,851,333	34.11
28	2236	SERTRALINE	Tablet 50 mg (base)	1,326,563	35,343,542	49,660,912	37.44
29	2241	LANSOPRAZOLE	Capsule 30 mg	778,724	34,500,708	41,343,899	53.09
30	8093	GOSERELIN	Subcutaneous implant 10.8 mg (base) in prefilled i	29,860	34,042,493	34,200,552	1145.36
31	8134	VALACLOVIR	Tablet 500 mg	187,958	33,372,524	36,591,467	194.68
32	8449	PERINDOPRIL and INDAPAMIDE	Tablet 4 mg-1.25 mg	1,411,208	33,235,350	46,318,021	32.82
33	2011	SIMVASTATIN	Tablet 10 mg	915,736	33,207,964	38,660,853	42.22
34	8431	SALMETEROL and FLUTICASON	Pdr oral inhal breth actu dev 50ug/250ug	651,220	31,687,954	38,700,055	59.43
35	8248	IRBESARTAN	Tablet 300 mg	1,267,505	31,410,367	42,398,888	33.45
36	2834	PRAVASTATIN	Tablet 20 mg, 30	679,875	30,758,101	35,578,531	52.33
37	3051	PERINDOPRIL	Tablet 4 mg, 30	1,622,104	30,227,941	43,473,967	26.80
38	8247	IRBESARTAN	Tablet 150 mg	1,587,163	28,718,450	43,434,127	27.37
39	8508	RABEPRAZOLE	Tablet 20 mg, 30	727,189	28,627,596	35,084,430	48.25
40	8288	SALBUTAMOL	Oral pressurised inhal 100 ug (base) (CFC-free	2,099,851	27,786,214	33,996,397	16.19
41	8185	OLANZAPINE	Tablet 5 mg, 30	197,151	26,389,791	27,531,842	139.65
42	1763	INSULIN (HUMAN)	Injection 100 units (30 units—70 units)	114,174	25,269,922	25,914,006	226.97
43	8301	VENLAFAXINE	Capsule 75 mg (base) modified release	677,690	24,386,233	32,014,795	47.24
44	1978	RANITIDINE HYDROCHLORIDE	Tablet 150 mg (base)	1,209,342	23,111,940	26,453,268	21.86
45	1434	FLOXETINE HYDROCHLORIDE	Capsule 20 mg (base)	692,951	22,541,467	30,240,623	43.64
46	2430	MEFORMIN HYDROCHLORIDE	Tablet 500 mg	1,754,310	21,502,130	26,676,520	15.21
47	8470	RAMIPRIL	Capsule 10 mg, 30	839,082	21,375,042	29,224,245	34.83
48	1761	INSULIN (HUMAN)	Injection 100 units per ml, 3ml, 5	97,506	21,184,629	22,124,334	226.90
49	8217	FAMCICLOVIR	Tablet 250 mg	50,739	20,544,245	21,376,038	421.29
50	1081	ATENOLOL	Tablet 50 mg	2,856,440	20,458,579	28,917,567	10.12

Table 3: PBS — most prescribed items — 12 Months to 30 June 2004

Rank	Item	Drug	Form	Volume	Govt Cost \$	Total Cost \$	Ave Price \$
1	1746	PARACETAMOL	Tablet 500 mg	3,865,223	19,824,794	29,764,269	7.70
2	8333	OMEPRAZOLE	Tablet 20 mg, 30	3,724,660	161,782,740	189,683,373	50.93
3	1081	ATENOLOL	Tablet 50 mg	2,856,440	20,458,579	28,917,567	10.12
4	8440	CELECOXIB	Capsule 200 mg, 60	2,703,703	71,838,767	91,107,358	33.70
5	8214	ATORVASTATIN	Tablet 20 mg	2,622,776	132,738,540	156,354,933	59.61
6	1215	CODEINE with PARACETAMOL	Tablet 30 mg–500 mg	2,442,610	18,154,531	25,380,499	10.39
7	2012	SIMVASTATIN	Tablet 20 mg	2,280,951	117,204,301	132,806,129	58.22
8	8288	SALBUTAMOL	Oral pressurised inhal 100 ug (base) CFC-free	2,099,851	27,786,214	33,996,397	16.19
9	8472	ROFECOXIB	Tablet 25 mg, 30	1,988,600	68,830,898	85,371,766	42.93
10	2089	TEMAZEPAM	Tablet 10 mg, 25	1,980,187	7,759,523	13,096,123	6.61
11	8213	ATORVASTATIN	Tablet 10 mg	1,957,229	68,032,699	84,327,816	43.09
12	8405	IRBESARTAN with HYDROCHLOROTHIAZIDE	Tablet 300 mg–12.5 mg	1,891,022	46,827,127	64,410,134	34.06
13	8173	SIMVASTATIN	Tablet 40 mg	1,844,164	135,352,123	149,966,482	81.32
14	2430	METFORMIN HYDROCHLORIDE	Tablet 500 mg	1,754,310	21,502,130	26,676,520	15.21
15	8008	PANTOPRAZOLE	Tablet (enteric coated) equivalent to 40mg	1,747,408	75,484,648	88,150,724	50.45
16	8220	CITALOPRAM	Tablet 20 mg (base)	1,717,164	44,628,801	63,663,124	37.07
17	8511	ALENDRONIC ACID	Tablet 70 mg alendronic acid	1,641,417	83,099,232	91,719,569	55.88
18	3051	PERINDOPRIL	Tablet 4 mg, 30	1,622,104	30,227,941	43,473,967	26.80
19	8215	ATORVASTATIN	Tablet 40 mg	1,611,674	120,322,429	134,922,962	83.72
20	8247	IRBESARTAN	Tablet 150 mg	1,587,163	28,718,450	43,434,127	27.37
21	8449	PERINDOPRIL and INDAPAMIDE	Tablet 4 mg–1.25 mg	1,411,208	33,235,350	46,318,021	32.82
22	3162	DIAZEPAM	Tablet 5 mg	1,403,217	5,653,376	9,725,341	6.93
23	3119	CEPHALEXIN	Capsule 500 mg	1,400,527	11,612,942	16,102,253	11.50
24	8358	CLOPIDOGREL	Tablet 75mg	1,369,634	108,117,378	115,058,695	84.01
25	2236	SERTRALINE	Tablet 50 mg (base)	1,326,563	35,343,542	49,660,912	37.44

Table 3: PBS — most prescribed items — 12 Months to 30 June 2004 (continued)

Rank	Item	Drug	Form	Volume	Govt Cost \$	Total Cost \$	Ave Price \$
26	8248	IRBESARTAN	Tablet 300 mg	1,267,505	31,410,367	42,398,888	33.45
27	2242	PAROXETINE	Tablet 20 mg (base)	1,263,133	39,399,084	53,063,868	42.01
28	8600	ESOMEPRAZOLE	Tablet 20 mg (enteric coated), 30	1,232,758	46,028,892	56,893,854	46.15
29	8243	LATANOPROST	Eye drops 50 ug per mL (0.005%), 2.5 mL	1,226,993	35,350,549	41,851,333	34.11
30	1978	RANITIDINE HYDROCHLORIDE	Tablet 150 mg (base)	1,209,342	23,111,940	26,433,268	21.86
31	2237	SERTRALINE	Tablet 100 mg (base)	1,160,606	35,366,274	48,246,868	41.57
32	1889	AMOXYCILLIN	Capsule 500 mg	1,101,977	8,710,407	12,328,579	11.19
33	1946	RAMIPRIL	Capsule 5.0 mg, 28	1,096,095	19,390,627	27,906,236	25.46
34	8197	PRAVASTATIN	Tablet 40 mg, 30	1,094,909	78,559,814	87,042,652	79.50
35	3133	OXAZEPAM	Tablet 30 mg	1,027,822	3,592,020	6,335,109	6.16
36	2412	FRUSEMIDE	Tablet 40 mg	1,014,299	5,376,338	7,889,227	7.78
37	8254	AMOXYCILLIN with CLAVULANIC ACID	Tablet 875 mg—125 mg	948,076	13,517,068	16,565,278	17.47
38	2011	SIMVASTATIN	Tablet 10 mg	915,736	33,207,964	38,660,853	42.22
39	2751	AMLODIPINE BESYLATE	Tablet 5 mg (base), 30	891,234	16,795,083	19,444,593	21.82
40	8470	RAMIPRIL	Capsule 10 mg, 30	839,082	21,375,042	29,224,245	34.83
41	8202	ASPIRIN	Tablet 100mg	828,634	2,877,945	5,066,930	6.11
42	8471	ROFECOXIB	Tablet 12.5 mg, 30	826,713	18,879,245	24,446,625	29.57
43	8601	ESOMEPRAZOLE	Tablet 40 mg (enteric coated), 30	818,839	54,220,731	61,638,271	75.28
44	2752	AMLODIPINE BESYLATE	Tablet 10 mg (base), 30	817,602	20,241,510	27,779,920	33.98
45	8432	SALMETEROL and FLUTICASON	Pdr oral inhal breth actu dev 50ug/500ug	804,779	57,479,551	64,812,857	80.53
46	8302	VENLAFAXINE	Capsule 150 mg (base)modified release	782,954	41,906,169	50,158,582	64.06
47	2241	LANSOPRAZOLE	Capsule 30 mg	778,724	34,500,708	41,343,899	53.09
48	1558	ISOSORBIDE MONONITRATE	Tablets sustained release 60mg, 30	754,057	8,122,449	9,995,735	13.26
49	8404	IRBESARTAN with HYDROCHLOROTHIAZIDE	Tablet 150 mg—12.5 mg	749,496	13,948,545	21,048,308	28.08
50	8508	RABEPRAZOLE	Tablet 20 mg, 30	727,189	28,627,596	35,084,430	48.25

Table 4: PBS — top 20 suppliers by total cost for 2003–2004 (from processed PBS prescriptions)

Rank	Manufacturer	Script Vol	Govt Cost \$	Total Cost \$	Sales (Ex-Manufacturer) \$
1	Pfizer	21,570,489	809,214,196	970,749,712	712,007,373
2	Merck Sharp & Dohme	12,495,471	550,430,021	632,922,940	470,204,219
3	Alphapharm	24,951,226	402,221,277	505,486,066	318,447,289
4	GlaxoSmithKline	9,684,409	386,585,075	455,974,770	336,146,256
5	AstraZeneca	9,619,224	367,230,200	433,977,132	318,396,721
6	Bristol Myers Squibb	8,255,448	294,190,493	355,075,377	259,040,446
7	Aventis	9,133,093	225,968,069	271,696,044	187,474,770
8	Sanofi-Synthelabo	8,567,030	181,844,972	224,474,251	150,997,002
9	Eli Lilly	1,937,240	209,307,220	219,904,590	172,535,769
10	Wyeth	4,176,894	138,470,423	168,594,591	122,015,671
11	Boehringer	3,651,118	119,669,830	142,825,081	102,936,167
12	Roche Products	2,112,496	124,307,906	135,772,208	103,031,981
13	Servier	4,791,723	90,240,514	121,870,126	81,442,388
14	Novartis	3,000,708	102,499,594	116,306,374	83,718,879
15	Janssen-Cilag	1,601,172	95,303,161	106,736,517	81,225,046
16	Novo Nordisk	884,567	92,101,128	97,006,420	75,996,276
17	Sigma	8,181,494	68,613,769	94,661,046	46,256,142
18	Schering	1,008,339	68,635,421	75,011,531	57,528,550
19	Mayne	3,152,457	55,961,235	68,493,381	44,020,580
20	CSL	2,840,583	52,198,738	62,992,165	40,708,676
Others		24,246,920	566,083,429	678,361,852	462,576,440
Total		165,862,101	5,001,076,669	5,938,892,174	4,226,706,641

Note: Includes branded and unbranded scripts and Doctor's bag scripts written for Extemporaneously-prepared items contained in 'Others' total.

Table 5: PBS — top 20 suppliers by market share (scripts) for 2003–2004 (from processed PBS prescriptions)

<i>Rank</i>	<i>Manufacturer</i>	<i>Script Vol</i>	<i>Govt Cost</i> \$	<i>Total Cost</i> \$	<i>% of Total</i>	<i>Sales (Ex-Manufacturer)</i> \$
1	Alphapharm	24,951,226	402,221,277	505,486,066	15.04	318,447,289
2	Pfizer	21,570,489	809,214,196	970,749,712	13.01	712,007,373
3	Merck Sharp & Dohme	12,495,471	550,430,021	632,922,940	7.53	470,204,219
4	GlaxoSmithKline	9,684,409	386,585,075	455,974,770	5.84	336,146,256
5	AstraZeneca	9,619,224	367,230,200	433,977,132	5.80	318,396,721
6	Aventis	9,133,093	225,968,069	271,696,044	5.51	187,474,770
7	Sanofi Synthelabo	8,567,030	181,844,972	224,474,251	5.17	150,997,002
8	Bristol Myers Squibb	8,255,448	294,190,493	355,075,377	4.98	259,040,446
9	Sigma	8,181,494	68,613,769	94,661,046	4.93	46,256,142
10	Servier	4,791,723	90,240,514	121,870,126	2.89	81,442,388
11	Wyeth	4,176,894	138,470,423	168,594,591	2.52	122,015,671
12	Boehringer	3,651,118	119,669,830	142,825,081	2.20	102,936,167
13	Mayne	3,152,457	55,961,235	68,493,381	1.90	44,020,580
14	Novartis	3,000,708	102,499,594	116,306,374	1.81	83,718,879
15	CSL	2,840,583	52,198,738	62,992,165	1.71	40,708,676
16	Abbott	2,192,263	50,312,190	57,379,472	1.32	38,588,340
17	Roche Products	2,112,496	124,307,906	135,772,208	1.27	103,031,981
18	Eli Lilly	1,937,240	209,307,220	219,904,590	1.17	172,535,769
19	Boots	1,835,488	11,190,054	16,205,120	1.11	6,260,519
20	Janssen-Cilag	1,601,172	95,303,161	106,736,517	0.97	81,225,046
Total Top 20		143,750,026	4,335,758,935	5,162,096,963	87%	3,675,454,234
Others		22,112,075	665,317,734	776,795,211	13%	551,252,407
Total		165,862,101	5,001,076,669	5,938,892,174	100%	4,226,706,641

Note: Includes branded and unbranded scripts and Doctor's bag scripts written for Extemporaneously-prepared items contained in 'Others' total.

Table 6a: PBS — significant drug groups (incl Dr's Bag) by highest Government cost

ATC Group Level 2	Year ending June 2003					Year ending June 2004						
	Scripts Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Scripts Volume (% diff)	Govt Cost \$	Total Cost \$	Ave Price \$	Scripts Volume (% diff)	Govt Cost \$	Total Cost \$	Ave Price \$
SERUM LIPID REDUCING AGENTS	13,320,021	731,459,087	834,056,359	62.62	14,709,118	835,541,042	952,617,922	64.76	10.4	835,541,042	952,617,922	64.76
DRUGS FOR ACID RELATED DISORDERS	11,291,472	428,527,814	503,333,267	44.58	12,266,029	480,817,576	567,359,408	46.25	8.6	480,817,576	567,359,408	46.25
AGENTS ACTING ON RENIN-ANGIOTENSIN SYSTEM	17,775,765	366,439,144	500,877,361	28.18	19,376,940	402,709,093	551,727,000	28.47	9.0	402,709,093	551,727,000	28.47
PSYCHOANAESTHETICS	11,104,099	317,253,523	413,323,120	37.22	12,000,862	350,523,725	460,123,457	38.34	8.1	350,523,725	460,123,457	38.34
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	9,485,438	322,017,132	383,165,145	40.40	9,523,344	348,071,969	412,367,828	43.30	0.4	348,071,969	412,367,828	43.30
PSYCHOLEPTICS	7,245,658	227,409,173	250,359,041	34.55	7,224,566	247,431,938	271,038,710	37.52	-0.3	247,431,938	271,038,710	37.52
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	9,095,431	209,262,297	265,718,378	29.21	9,143,205	212,956,211	271,757,010	29.72	0.5	212,956,211	271,757,010	29.72
ANTINEOPLASTIC AGENTS	378,693	147,183,954	150,771,360	398.14	406,132	167,801,228	171,875,909	423.20	7.2	167,801,228	171,875,909	423.20
ANTIDIABETIC THERAPY	4,630,466	152,633,689	168,702,981	36.43	4,931,545	167,446,211	185,154,380	37.54	6.5	167,446,211	185,154,380	37.54
ANTITHROMBOTIC AGENTS	3,936,792	123,746,618	138,180,344	35.10	4,540,455	154,544,380	172,118,921	37.91	15.3	154,544,380	172,118,921	37.91
CALCIUM CHANNEL BLOCKERS	7,308,106	149,135,783	187,675,374	25.68	7,380,410	152,512,663	191,221,993	25.91	1.0	152,512,663	191,221,993	25.91
ANALGESICS	10,588,558	130,774,063	160,742,278	15.18	10,914,950	141,925,677	174,370,911	15.98	3.1	141,925,677	174,370,911	15.98
DRUGS FOR TREATMENT OF BONE DISEASES	1,966,630	110,739,959	120,724,968	61.39	2,439,353	135,028,145	147,684,827	60.54	24.0	135,028,145	147,684,827	60.54
ANTIBACTERIALS FOR SYSTEMIC USE	10,910,845	130,435,199	168,825,427	15.47	11,092,683	130,574,361	170,580,847	15.38	1.7	130,574,361	170,580,847	15.38
ENDOCRINE THERAPY	387,190	96,546,669	99,607,628	257.26	396,251	102,127,519	105,417,506	266.04	2.3	102,127,519	105,417,506	266.04
ANTIPILEPTICS	1,524,052	83,966,068	95,266,862	62.51	1,595,871	90,791,297	102,931,713	64.50	4.7	90,791,297	102,931,713	64.50
OPHTHALMOLOGICALS	5,964,619	83,438,278	103,749,357	17.39	6,233,638	89,823,235	111,914,982	17.95	4.5	89,823,235	111,914,982	17.95

Table 6b: PBS — significant drug groups (incl Dr's Bag) by highest script volume

ATC Group Level 2	Year ending June 2003					Year ending June 2004						
	Scripts Volume	Govt Cost m	Total Cost \$	Ave Price \$	Scripts Volume (% diff)	Govt Cost \$	Total Cost \$	Ave Price \$	Scripts Volume (% diff)	Govt Cost \$	Total Cost \$	Ave Price \$
AGENTS ACTING ON RENIN-ANGIOTENSIN SYSTEM	17,775,765	366,439,144	500,877,361	28.18	19,376,940	402,709,093	551,727,000	28.47	9.0	402,709,093	551,727,000	28.47
SERUM LIPID REDUCING AGENTS	13,320,021	731,459,087	834,056,359	62.62	14,709,118	835,541,042	952,617,922	64.76	10.4	835,541,042	952,617,922	64.76
DRUGS FOR ACID RELATED DISORDERS	11,291,472	428,527,814	503,333,267	44.58	12,266,029	480,817,576	567,359,408	46.25	8.6	480,817,576	567,359,408	46.25
PSYCHOANAESTHETICS	11,104,099	317,253,523	413,323,120	37.22	12,000,862	350,523,725	460,123,457	38.34	8.1	350,523,725	460,123,457	38.34
ANTIBACTERIALS FOR SYSTEMIC USE	10,910,845	130,435,199	168,825,427	15.47	11,092,683	130,574,361	170,580,847	15.38	1.7	130,574,361	170,580,847	15.38
ANALGESICS	10,588,558	130,774,063	160,742,278	15.18	10,914,950	141,925,677	174,370,911	15.98	3.1	141,925,677	174,370,911	15.98
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	9,485,438	322,017,132	383,165,145	40.40	9,523,344	348,071,969	412,367,828	43.30	0.4	348,071,969	412,367,828	43.30
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	9,095,431	209,262,297	265,718,378	29.21	9,143,205	212,956,211	271,757,010	29.72	0.5	212,956,211	271,757,010	29.72
CALCIUM CHANNEL BLOCKERS	7,308,106	149,135,783	187,675,374	25.68	7,380,410	152,512,663	191,221,993	25.91	1.0	152,512,663	191,221,993	25.91
PSYCHOLEPTICS	7,245,658	227,409,173	250,359,041	34.55	7,224,566	247,431,958	271,038,710	37.52	-0.3	247,431,958	271,038,710	37.52
OPHTHALMOLOGICALS	5,964,619	83,438,278	103,749,357	17.39	6,233,638	89,823,235	111,914,982	17.95	4.5	89,823,235	111,914,982	17.95
ANTIDIABETIC THERAPY	4,630,466	152,633,689	168,702,981	36.43	4,931,545	167,446,211	185,154,380	37.54	6.5	167,446,211	185,154,380	37.54
BETA BLOCKING AGENTS	4,342,791	57,038,283	70,316,472	16.19	4,628,098	67,136,235	81,758,886	17.67	6.6	67,136,235	81,758,886	17.67
ANTITHROMBOTIC AGENTS	3,936,792	123,746,618	138,180,344	35.10	4,540,455	154,544,380	172,118,921	37.91	15.3	154,544,380	172,118,921	37.91
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	4,370,599	91,284,414	110,205,268	25.22	3,791,359	77,297,819	94,217,005	24.85	-13.3	77,297,819	94,217,005	24.85
CARDIAC THERAPY	3,485,959	60,831,109	71,977,886	20.65	3,450,371	60,872,657	72,290,385	20.95	-1.0	60,872,657	72,290,385	20.95
DRUGS FOR TREATMENT OF BONE DISEASES	1,966,630	110,739,959	120,724,968	61.39	2,439,353	135,028,145	147,684,827	60.54	24.0	135,028,145	147,684,827	60.54

Table 7a: PBS — significant drugs (incl Dr's Bag) — sorted by highest change to Government cost

Rank	Drug	Year ending June 2003				Year ending June 2004				Change	
		Volume	Govt Cost	Total Cost	Ave Price	Volume	Govt Cost	Total Cost	Ave Price	Govt Cost	%
			\$	\$	\$		\$	\$	\$	\$	
1	ATORVASTATIN	5,848,277	314,430,315	364,689,743	62.36	6,629,408	368,554,153	427,030,219	64.41	54,123,838	17.21
2	ESOMEPRAZOLE	944,849	48,861,880	57,445,910	60.80	2,051,597	100,249,623	118,532,126	57.78	51,387,743	105.17
3	SIMVASTATIN	5,056,541	294,159,174	328,778,719	65.02	5,526,791	333,669,341	373,139,090	67.51	39,510,167	13.43
4	TIOPIRODUM BROMIDE	97,217	7,006,564	7,528,038	77.44	578,834	42,315,436	44,836,583	77.46	35,308,872	503.94
5	CLOPIDOGREL	1,023,755	81,173,216	86,023,463	84.03	1,369,634	108,117,378	115,058,695	84.01	26,944,162	33.19
6	RABEPRAZOLE	486,786	18,942,004	23,281,321	47.83	864,542	33,451,099	41,180,444	47.63	14,509,095	76.60
7	ALENDRONIC ACID	1,445,217	74,623,621	82,072,489	56.79	1,701,990	87,403,280	96,313,566	56.59	12,779,659	17.13
8	ETANERCEPT	0	0	0	0.00	6,525	12,240,040	12,299,100	1,884.92	12,240,040	New
9	PRAWASTATIN	1,796,074	103,032,372	116,150,045	64.67	1,949,376	114,253,847	128,718,054	66.03	11,221,474	10.89
10	VENLAFAXINE	1,358,842	61,188,159	75,171,786	55.32	1,615,790	72,403,802	89,846,713	55.61	11,215,643	18.33
11	FORMOTEROL and OTHER DRUGS FOR OBSTR	37,849	1,712,514	2,119,557	56.00	279,306	12,834,225	15,651,897	56.04	11,121,710	649.44
12	RISEDRONIC ACID	158,824	8,953,481	9,753,580	61.41	374,011	19,889,467	21,878,530	58.50	10,935,986	122.14
13	IRBESARTAN with HYDROCHLOROTHIAZIDE	2,243,913	51,711,014	72,327,296	32.23	2,640,518	60,775,672	85,458,442	32.36	9,064,658	17.53
14	RITUXIMAB	14,656	29,094,188	29,276,832	1997.60	19,829	37,225,784	37,471,225	1,889.72	8,131,596	27.95
15	RAMIPRIL	2,277,813	46,768,502	62,862,126	27.60	2,625,971	54,801,695	73,672,277	28.06	8,033,193	17.18
16	MELOXICAM	663,799	14,884,745	19,926,770	30.02	973,400	22,548,914	29,980,207	30.80	7,664,169	51.49
17	CARVEDILOL	292,713	26,676,865	28,230,616	96.44	376,375	34,188,567	36,188,940	96.15	7,511,702	28.16
18	AMISULPRIDE	26,814	4,826,835	4,997,960	186.39	66,685	12,265,209	12,690,039	190.30	7,438,374	154.10
19	PANTOPRAZOLE	1,845,851	77,953,816	91,369,013	49.50	2,037,525	85,330,042	100,197,565	49.18	7,376,226	9.46
20	SALMETEROL and FLUTICASONE	2,354,087	144,983,983	167,543,052	71.17	2,508,244	152,343,064	177,374,020	70.72	7,359,081	5.08
21	PERINDOPRIL and INDAPAMIDE	1,092,871	26,354,930	36,270,482	33.19	1,411,208	33,235,350	46,318,021	32.82	6,880,420	26.11
22	MIRTAZAPINE	374,829	11,951,329	15,169,530	40.47	580,982	18,798,447	23,709,045	40.81	6,847,118	57.29
23	QUETIAPINE	103,361	20,940,796	21,575,394	208.74	130,785	27,156,781	27,959,470	213.78	6,215,985	29.68
24	INSULIN ASPART/PROTAMINE ASPART	9,538	2,484,511	2,560,381	268.44	32,651	8,489,634	8,738,798	267.64	6,005,123	241.70
25	VALACICLOVIR	194,765	35,421,035	38,557,808	197.97	227,702	41,203,800	45,001,835	197.63	5,782,765	16.33

Table 7a: PBS — significant drugs (incl Dr's Bag) — sorted by highest change to Government cost (continued)

Rank	Drug	Year ending June 2003				Year ending June 2004				Change	
		Volume	Govt Cost	Total Cost	Ave Price	Volume	Govt Cost	Total Cost	Ave Price	Govt Cost	%
			\$	\$	\$		\$	\$	\$	\$	
26	LERCANIPIDINE	362,356	6,388,039	8,935,120	24.66	595,013	12,133,609	15,689,936	26.37	5,745,570	89.94
27	IRBESARTAN	2,859,697	59,565,886	83,763,075	29.29	3,116,535	65,284,235	91,766,427	29.45	5,718,349	9.60
28	OLANZAPINE	656,166	140,283,078	143,898,046	219.30	678,390	145,619,364	149,425,509	220.26	5,336,287	3.80
29	OXYCODONE	597,262	17,644,481	19,774,395	33.11	721,213	22,714,178	25,397,882	35.22	5,069,697	28.73
30	ROFECOXIB	2,709,713	82,972,554	103,676,594	38.26	2,819,111	87,811,844	109,954,158	39.00	4,839,291	5.83
31	TRAMADOL	1,378,006	19,434,192	23,604,304	17.13	1,622,303	24,052,043	29,053,744	17.91	4,617,851	23.76
32	CITALOPRAM	1,546,341	40,586,734	57,309,669	37.06	1,718,789	44,684,014	63,734,632	37.08	4,097,280	10.10
33	PLASTIC IUD with PROGESTERONE	7,291	1,479,395	1,604,417	220.05	27,305	5,535,249	6,002,749	219.84	4,055,854	274.16
34	BIMATOPROST	24,275	646,207	826,087	34.03	166,497	4,635,137	5,674,450	34.08	3,988,930	617.28
35	INSULIN ASPART	25,258	6,327,030	6,611,778	261.77	40,927	10,059,707	10,526,281	257.20	3,732,677	59.00

Table 7b: PBS — significant drugs (incl Dr's Bag) — sorted by highest volume change

Rank	Drug	Year ending June 2003					Year ending June 2004					Change	
		Volume	Govt Cost	Total Cost	Ave Price	Volume	Govt Cost	Total Cost	Ave Price	Volume	%		
			\$	\$	\$		\$	\$	\$	\$		\$	
1	ESOMEPRAZOLE	944,849	48,861,880	57,445,910	60.80	2,051,597	100,249,623	118,532,126	57.78	1,106,748	117.13		
2	ATORVASTATIN	5,848,277	314,430,315	364,689,743	62.36	6,629,408	368,554,153	427,030,219	64.41	781,131	13.36		
3	TIOPIROPIUM BROMIDE	97,217	7,006,564	7,528,038	77.44	578,834	42,315,436	44,836,583	77.46	481,617	495.40		
4	SIMVASTATIN	5,056,541	294,159,174	328,778,719	65.02	5,526,791	333,669,341	373,139,090	67.51	470,250	9.30		
5	IRBESARTAN with HYDROCHLOROTHIAZIDE	2,243,913	51,711,014	72,327,296	32.23	2,640,518	60,775,672	85,458,442	32.36	396,605	17.67		
6	RABEPRAZOLE	486,786	18,942,004	23,281,321	47.83	864,542	33,451,099	41,180,444	47.63	377,756	77.60		
7	RAMIPRIL	2,277,813	46,768,502	62,862,126	27.60	2,625,971	54,801,695	73,672,277	28.06	348,158	15.28		
8	CLOPIDOGREL	1,023,755	81,173,216	86,023,463	84.03	1,369,634	108,117,378	115,058,695	84.01	345,879	33.79		
9	PERINDOPRIL and INDAPAMIDE	1,092,871	26,354,930	36,270,482	33.19	1,411,208	33,235,350	46,318,021	32.82	318,337	29.13		
10	MELOXICAM	663,799	14,884,745	19,926,770	30.02	973,400	22,548,914	29,980,207	30.80	309,601	46.64		
11	VENLAFAXINE	1,358,842	61,188,159	75,171,786	55.32	1,615,790	72,403,802	89,846,713	55.61	256,948	18.91		
12	IRBESARTAN	2,859,697	59,565,886	83,763,075	29.29	3,116,535	65,284,235	91,766,427	29.45	256,838	8.98		
13	ALENDRONIC ACID	1,445,217	74,623,621	82,072,489	56.79	1,701,990	87,403,280	96,313,566	56.59	256,773	17.77		
14	TRAMADOL	1,378,006	19,434,192	23,604,304	17.13	1,622,303	24,052,043	29,053,744	17.91	244,297	17.73		
15	FORMOTEROL and OTHER DRUGS FOR OBSTR	37,849	1,712,514	2,119,557	56.00	279,306	12,834,225	15,651,897	56.04	241,457	637.95		
16	LERCANIPIDINE	362,356	6,388,039	8,935,120	24.66	595,013	12,133,609	15,689,936	26.37	232,657	64.21		
17	RISEDRONIC ACID	158,824	8,953,481	9,753,580	61.41	374,011	19,889,467	21,878,530	58.50	215,187	135.49		
18	MIRTAZAPINE	374,829	11,951,329	15,169,530	40.47	580,982	18,798,447	23,709,045	40.81	206,153	55.00		
19	PERINDOPRIL	2,161,837	39,632,199	53,454,433	24.73	2,358,909	42,901,225	58,618,039	24.85	197,072	9.12		
20	PANTOPRAZOLE	1,845,851	77,953,816	91,369,013	49.50	2,037,525	85,330,042	100,197,565	49.18	191,674	10.38		
21	TELMIARTAN and DIURETICS	16,188	286,882	455,729	28.15	195,570	3,582,345	5,506,318	28.16	179,382	1108.12		
22	AMOXICILLIN	2,169,403	15,818,016	23,027,331	10.61	2,343,193	16,862,334	24,853,491	10.61	173,790	8.01		
23	CITALOPRAM	1,546,341	40,586,734	57,309,669	37.06	1,718,789	44,684,014	63,734,632	37.08	172,448	11.15		
24	SERTRALINE	2,321,988	66,980,933	91,262,139	39.30	2,487,169	70,709,816	97,907,780	39.37	165,181	7.11		
25	METFORMIN HYDROCHLORIDE	2,281,837	28,817,185	35,574,815	15.59	2,445,487	31,323,081	38,623,640	15.79	163,650	7.17		

Table 7b: PBS — significant drugs (incl Dr's Bag) — sorted by highest volume change (continued)

Rank	Drug	Year ending June 2003				Year ending June 2004				Change	
		Volume	Govt Cost	Total Cost	Ave Price	Volume	Govt Cost	Total Cost	Ave Price	Volume	%
			\$	\$	\$		\$	\$	\$	\$	
26	CANDESARTAN with HYDROCHLOROTHIAZIDE	383,934	7,397,415	10,958,868	28.54	545,579	10,443,448	15,550,198	28.50	161,645	42.10
27	WARFARIN	1,563,699	7,958,322	12,076,077	7.72	1,718,226	8,717,821	13,335,091	7.76	154,527	9.88
28	SALMETEROL and FLUTICASONE	2,354,087	144,983,983	167,543,052	71.17	2,508,244	152,343,064	177,374,020	70.72	154,157	6.55
29	PRAVASTATIN	1,796,074	103,032,372	116,150,045	64.67	1,949,376	114,253,847	128,718,054	66.03	153,302	8.54
30	BIMATOPROST	24,275	646,207	826,087	34.03	166,497	4,635,137	5,674,450	34.08	142,222	585.88
31	ATENOLOL	2,718,486	19,775,545	27,681,546	10.18	2,856,440	20,458,579	28,917,567	10.12	137,954	5.07
32	OXYCODONE	597,262	17,644,481	19,774,395	33.11	721,213	22,714,178	25,397,882	35.22	123,951	20.75
33	MOMETASONE	502,068	6,096,585	8,392,450	16.72	625,962	7,480,486	10,364,042	16.56	123,894	24.68
34	ROFECOXIB	2,709,713	82,972,554	103,676,594	38.26	2,819,111	87,811,844	109,954,158	39.00	109,398	4.04
35	CEPHALEXIN	1,684,354	13,859,075	19,203,548	11.40	1,785,290	14,422,099	20,219,265	11.33	100,936	5.99