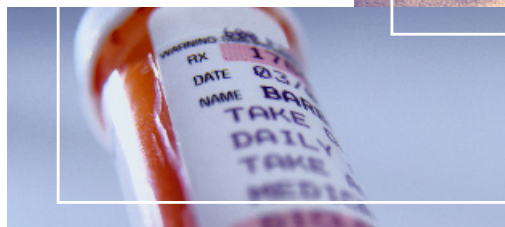
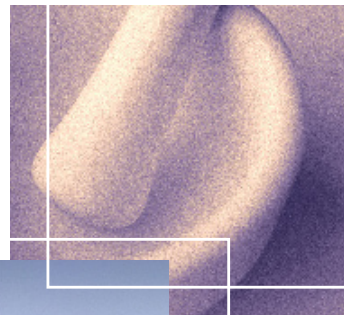


PHARMACEUTICAL BENEFITS

PRICING AUTHORITY

ANNUAL REPORT

For the year ended 30 June 2005





PHARMACEUTICAL

BENEFITS

PRICING

AUTHORITY

Annual Report

For the year ended 30 June 2005

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Minister The Hon Tony Abbott MP
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Parliament House
CANBERRA ACT 2600

Dear Mr Abbott

I present herewith the eighteenth 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 2005.

This report is made in accordance with the requirement of sub-section 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
2005

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PREFACE

This is the eighteenth annual report of the Pharmaceutical Benefits Pricing Authority covering the operations of the PBPA for the year ended 30 June 2005.

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 2004–2005 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 Penniford — appointed with effect from 15 December 1999.

Secretariat Support

The PBPA is serviced by two secretariats, viz:

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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.

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.

For the year ended 30 June 2005 the PBPA operating costs were:

<i>PBPA operating costs 2004–2005</i>	<i>Health portfolio \$</i>	<i>Industry portfolio \$</i>	<i>Total costs \$</i>
Direct costs including Chairman's, industry and consumer nominees' expenses	2,651	0	2,651
Salaries	498,382	29,618*	528,000
Members and secretariat travel and allowances	1,619	686	2,305
Administrative and property costs	8,453	3,737**	12,190
Total costs	511,105	34,041	545,146

* 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 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 a major consideration 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. One 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 33 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 2004–2005:

Ezetimibe (Ezetrol®) — This drug is the first in a new class of agents for the reduction of high blood cholesterol levels. It was listed on 1 August 2004.

Risperidone (Risperdal Consta®) — This drug was listed on 1 February 2005 to treat patients who are not adequately controlled by current treatments for schizophrenia.

Olanzapine (Zyprexa®) — This was an extension of an existing listing to treat patients for bipolar 1 disorder. This occurred on 1 February 2005.

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 comparing the prices of products that are considered by the PBAC to produce similar health benefits; 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 \$23.70 changing to \$28.60 effective 1 January 2005.

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 has 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 2002</i>	<i>May 2003</i>	<i>May 2004</i>	<i>May 2005</i>
Number of products with a premium	293	303	305	321
Average brand premium	\$2.83	\$3.06	\$2.94	\$2.65
Weighted average brand premium**	\$1.57	\$1.57	\$1.91	\$1.74
Brand premium Range	\$0.01 to \$79.48	\$0.06 to \$79.48	\$0.06 to \$79.48	\$0.06 to \$79.48
Prescriptions dispensed with a brand premium in the previous 12 months	33.3m	32.6m	30.4m	33.6m
Prescriptions dispensed at the benchmark level in the previous 12 month period	22.6m	37.8m	40.3m	42.9m
Percentage at the benchmark level	49%	54%	57%	56%
Products at the Benchmark price	854	943	1004	826

* 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.

Special Patient Contributions

Special patient contributions may apply to some drugs when there is a disagreement between the manufacturer and the Government about the price for subsidy purposes. Despite the disagreement about price, the drug continues to be listed and subsidised, but the patient must pay an additional amount on top of the normal patient copayment.

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 benchmark 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 2005 there were 321 benefit items with a brand premium that could be therapeutically interchanged. The average brand premium was \$2.65 and premiums ranged from \$0.06 to \$79.48. The majority of brand premiums were in the range of \$1.00 to \$3.00.

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 Medicare Australia for an exemption to supply the more expensive 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.

As at 30 June 2005 there were 72 items within the four groups under the TGP policy. Nine of the items were listed with therapeutic group premiums with a range from \$1.35 to \$7.01. The 72 items consisted of 139 brands at the benchmark price and 37 brands with a brand premium.

Other forms of Special Patient Contributions

Other special patient contribution arrangements can also apply where brand or therapeutic group premiums are not applicable.

There is currently one product listed that has this type of special patient contribution.

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 many years.

The WAMTC methodology applies 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.

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 so by a decision of the Government.

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 three 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)
- Angiotensin II receptor antagonists (ATRA) (candesartan, eprosartan, irbesartan, telmisartan)

The SSRIs plus were reviewed in August 2004, with resultant price adjustments commencing from 1 December 2004.

The PPIs and H2 receptor antagonists were reviewed in December 2004, with resultant price adjustments commencing from 1 April 2005.

The cardiovascular groups (CCBs, statins, ATRA, and ACEs) were all reviewed in April 2004, with resultant price adjustments to commence from 1 August 2005.

Ad hoc WAMTC reviews were conducted for the statins in August 2004, and for the PPIs in April 2005.

12.5% Price Reduction Policy

This policy, which was part of the 2005-06 Federal Budget, will require a price reduction of at least 12.5% for the first generic brand of an existing PBS medicine listed on or after 1 August 2005. The price reductions will flow to all brands of the medicine, all forms and strengths of the medicine which are administered in the same way, and to all other medicines in the same reference pricing group which are administered in the same way.

The first group of medicines whose pricing will be impacted by this policy will be listed on the PBS on 1 August 2005.

The Highly Specialised Drugs Program

Highly Specialised Drugs (HSD) are medicines for chronic conditions that, because of their clinical use or other special features, are restricted to supply through hospitals having access to appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items medical practitioners are required to be affiliated with these specialist hospital units.

The HSD Program is administered by the Pharmaceutical Access and Quality Branch of the Australian Government Department of Health and Ageing, while the process of selecting and reviewing drugs and procedures is the responsibility of the Highly Specialised Drugs Working Party.

Subsidy for drugs under this program commences following recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC), approval by the Australian Government and the States and Territories accepting the offer of subsidy.

The Australian Government provides funding to the States and Territory Governments and through private hospitals for the drug to be supplied to community based patients, i.e. not in-patient. Subsidy is available for the Pharmaceutical Benefits Scheme approved clinical indication only.

Highly Specialised Drugs Working Party

The Australian Health Ministers' Advisory Council established the Highly Specialised Drugs Working Party in 1991. It consists of representatives from the Health Department of each of the States and Territories, the Australian Private Hospitals Association and the Commonwealth as chair. The Working Party's terms of reference are:

- selecting drugs proposed for inclusion in the funding arrangements for highly specialised drugs;
- referring proposed drugs with supporting information to the PBAC for consideration for listing as pharmaceutical benefits under section 100 supply arrangements;
- monitoring information on potential new highly specialised drugs which might come under the funding arrangements;
- monitoring the quality use of drugs supplied under these arrangements; and
- investigating and making recommendations on procedures to monitor drugs supplied by hospitals under the section 100 arrangements to patients in community settings.

Criteria for selection of Highly Specialised Drugs

Drugs recommended for inclusion in the program must satisfy the following criteria:

- Ongoing specialised medical supervision required.
- Treatment of longer term medical conditions not episodes of in-patient treatment or treatment of acute conditions.
- Drugs highly specialised and an identifiable patient target group.
- Subject to marketing approval by the Therapeutic Goods Administration (TGA) and specific therapeutic indications covered by the terms of the marketing letter from TGA.
- High unit cost.

Program expenditure

During 2004–2005 there were 65 drugs subsidised under the HSD Program, compared to 2003–2004 when 58 were subsidised. Of the seven new inclusions, four are HIV/AIDS antiretroviral agents, two are immunostimulating agents, and two are for the treatment of pulmonary arterial hypertension. The drugs are:

1. Adefovir dipivoxil
2. Atazanavir sulfate
3. Emtricitabine
4. Enfuvirtide
5. Fosamprenavir calcium
6. Iloprost trometamol
7. Peginterferon alfa-2a

Before reconciliation, the expenditure for 2004–2005 (including Repatriation Pharmaceutical Benefits Scheme), with the drugs categorised, is as follows:

<i>Indications Grouping</i>	<i>No. of Drugs</i>	<i>Public Hospital</i>	<i>Private Hospital</i>	<i>Combined</i>
Acromegaly	3	\$12,196,870	\$4,636,805	\$16,833,675
Bisphosphonates	2	\$13,497,279	\$10,234,143	\$23,731,423
Haemopoietics	2	\$87,645,908	\$20,130,066	\$107,775,974
HIV/AIDS Antiretroviral Agent	22	\$92,564,800	\$267,134	\$92,831,934
Immunocompromised Conditions	9	\$6,542,973	\$369,511	\$6,912,484
Immunostimulating Agent	12	\$71,903,074	\$30,868,845	\$102,771,919
Immunosuppressing Agents	7	\$53,374,956	\$9,053,541	\$62,428,497
Other Conditions	6	\$44,918,584	\$5,331,425	\$50,250,008
Pulmonary Arterial Hypertension	2	\$2,724,720	\$2,568,853	\$5,293,573
Grand Total	65	\$385,369,164	\$83,460,323	\$468,829,487

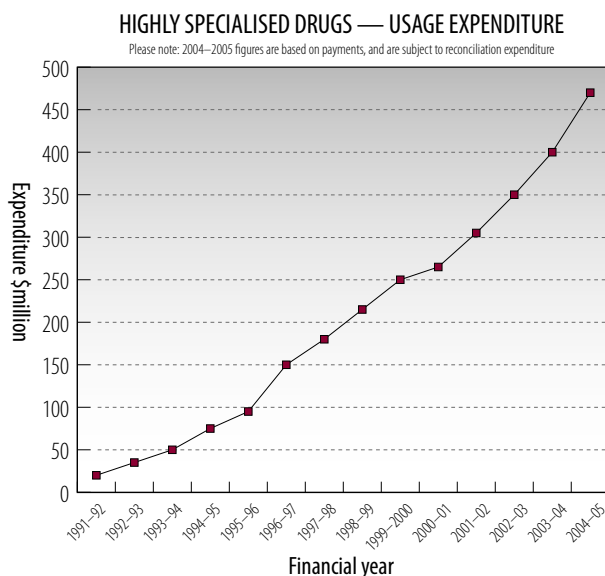
The acquitted expenditure through the program in 2003–2004 was \$402.2 million. Before reconciliation, the costs totalled \$468.8 million in 2004–2005, a 16.5 per cent increase. The previous year's increase was 13.5 per cent. The payments made to public hospitals via grants to the States and Territories are reconciled, following the end of the financial year, against the actual drug usage (payments made to private hospitals are reconciled at time of claim and the above figures are therefore final expenditure figures).

For 2004–2005 the expenditure in public hospitals was \$385.4 million, an increase of 12.8 per cent from 2003–2004 expenditure of \$341.7 million. Private hospital expenditure increased by 37.9 per cent from \$60.5 million in 2003–2004 to \$83.5 million in 2004–2005.

The percentage increase in private hospital expenditure for the past 3 financial years are as follows:

- 38.9 per cent in 2002–2003
- 37.7 per cent in 2003–2004
- 37.9 per cent in 2004–2005

The Highly Specialised Drugs — Usage Expenditure chart outlines the program expenditure from 1991–1992 to 2004–2005 financial years.



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 2004–2005

In the 2004–2005 financial year, the PBPA held three therapeutic group reviews, the summary results of which are compared below with those for the previous year:

<i>Product review results</i>	<i>2003–2004</i>	<i>2004–2005</i>
Number of products reviewed	2,866	2,586
Number of products (includes individual brands) for which price applications were received:	505 17.62%	364 14.07%
Number of products for which price increases were granted	120 4.2%	114 4.4%

The number of new items recommended for listing and new items actually listed for the financial year 2004–2005 was:

Number of items recommended for listing by the PBAC:	73	69
Section 100 (based on PBAC meetings held in 2004–2005 financial year, includes different strengths)	18	10
# Number of items listed	*140	74
Section 100 (based on new items listed in the PBS Schedules for 2004–2005)	**79	12

#2004–2005 figures include secretariat listings (ie. listings that did not go to PBAC/PBPA meetings)

* Figure includes 42 listings for new sub-section of Palliative Care.

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

Estimate of additional cost of drugs newly listed during 2004–2005* \$75.6 million**

* Values are estimated costs to PBS and RPBS 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 04 to 30 June 05. Note that drugs are listed at stages throughout the year so the value is not the estimated cost to PBS and RPBS in financial year 2004–05.

** \$55.7 million of this value is for drugs that were not considered by Cabinet.

Estimated cost of price increases of existing items 2004–2005

The general price increases granted to suppliers in 2004–2005 are collectively estimated to add \$9.8 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>2003–2004 \$ million</i>	<i>2004–2005 \$ million</i>
Recommended by the PBPA and subsequently approved by the Minister	4.8	9.8

Cost of Pharmaceutical Benefits Scheme, 2004–2005

The total cost of the PBS for 2004–2005 was \$6,001.2 million. This comprised \$4,252.7 million for persons covered by concession cards, and \$1,075.5 million for general patient, ie those patients not covered by concession cards. PB Other expenditure was \$673.0 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	28.4	1,075.5
Concessional	141.5	4,252.7
PB Other	*	673.0
Total	169.9	6,001.2

* PB Other contains diverse programs. The majority of data is 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 \$28.60), the consumer pays the full amount. The above figures do not include these amounts.

CHAPTER 3

Pharmaceutical Industry Investment Program

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 had a direct link to or was 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 (PVA) and Research and Development (R&D) activities. Partial compensation was paid in the form of either notional or actual price increases on PBS products nominated by participating companies.

In the second quarter of 2004–2005, the PBPA assessed participating companies' final annual monitoring reports and authorised companies' final payments in November 2004. This completed the PBPA's role in administering the program.

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)

Activity Undertaken During the Life of the Program

During the life of the program, PIIP participants undertook over \$7 billion of activity, including almost \$6.2 billion for PVA and almost \$950 million for R&D. The Australian Government invested \$246 million of the \$300 million that was allocated to the program — \$182.5 million in PVA and \$63.3 million in R&D. In return, PIIP companies invested an additional \$1.74 billion in pharmaceuticals PVA and R&D in Australia. The underspend of around \$52 million was due to participants underperforming against the activity targets specified in their contracts and the effect of contractual renegotiations in which companies agreed to reduce their entitlements. These monies were returned to consolidated revenue.

The Supplementary Annual Report for the PIIP for the year ended 30 June 2004 was tabled in Parliament on 14 June 2005. The Supplementary Annual Report contains complete financial data for activity undertaken by each company over the duration of the program.

CHAPTER 4

Tables and figures

- Table 1 Pharmaceutical Benefits Scheme: Summary of therapeutic group reviews for 2004–2005.
- Table 2 Pharmaceutical Benefits Scheme: Highest cost items 12 months to 30 June 2005.
- Table 3 Pharmaceutical Benefits Scheme: Most prescribed items 12 months to 30 June 2005.
- Table 4 Pharmaceutical Benefits Scheme: Top 20 suppliers by total cost for 2004–2005 (from processed PBS prescriptions).
- Table 5 Pharmaceutical Benefits Scheme : Top 20 suppliers by market share (scripts) for 2004–2005 (from processed PBS prescriptions).
- Table 6a Pharmaceutical Benefits Scheme: Significant drug groups (incl Dr's Bag) by highest Government cost.
- Table 6b Pharmaceutical Benefits Scheme: Significant drug groups (incl Dr's Bag) by highest volume.
- Table 7a Pharmaceutical Benefits Scheme: Significant drugs (incl Dr's Bag) sorted by highest change to Government cost.
- Table 7b Pharmaceutical Benefits Scheme: Significant drugs (incl Dr's Bag) sorted by highest volume change.

Table 1: Pharmaceutical Benefits Scheme: Summary of Therapeutic Group Reviews for 2004–2005

<i>ATC group</i>	<i>Minor Group</i>	<i>No. of Products Reviewed</i>	<i>Script Volume</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	13,147,448	504,362,281	608,511,692	-
A04	Antiemetics and Antinauseants	25	797,134	15,350,410	19,749,550	-
A06	Laxatives	18	646,345	10,394,319	12,264,164	153,034
A07	Antidiarrheals, Intestinal Antiinflammatory/ Antiinfective Agents	28	881,797	37,390,582	44,679,802	388,838
A10	Drugs used in Diabetes	85	5,245,377	191,338,930	212,065,298	-
B01	Antithrombotic Agents	45	5,158,431	177,220,579	199,772,409	270,187
B05	Blood Substitutes and Perfusion Solutions	10	41,935	1,099,293	1,393,096	-
C01	Cardiac Therapy	72	3,387,350	61,073,672	72,889,642	142,153
C02	Antihypertensives	25	726,247	10,131,964	12,853,371	307,664
C03	Diuretics	39	2,333,945	21,696,927	29,111,751	35,713
C07	Beta Blocking Agents	58	4,946,575	76,258,362	93,610,274	91,203
C08	Calcium Channel Blockers	74	7,484,348	152,198,989	193,071,216	-
C09	Agents Acting on the Renin-Angiotensin System	139	19,901,853	419,765,729	566,875,473	-
C10	Serum Lipid Reducing Agents	46	16,215,278	918,740,374	1,062,593,113	8,257
D07	Corticosteroids, Dermatological Preparations	38	2,346,816	20,716,502	29,942,865	-
D10	Anti-Acne Preparations	12	132,092	16,910,063	19,501,165	-
G03	Sex Hormones and Modulators of the Genital System	145	3,563,199	77,046,408	94,868,295	6,852
H02	Corticosteroids for Systemic use	33	1,650,792	11,805,264	17,265,763	124,471
J01	Antibacterials for Systemic use	367	11,316,053	133,286,487	177,619,177	9,498
J05	Antivirals for Systemic use	32	398,021	81,738,358	88,851,324	-

Table 1: Pharmaceutical Benefits Scheme: Summary of Therapeutic Group Reviews for 2004–2005 (continued)

<i>ATC group</i>	<i>Minor Group</i>	<i>No. of Products Reviewed</i>	<i>Script Volume</i>	<i>Govt cost \$</i>	<i>Total cost \$</i>	<i>Estimated cost to Government of Price Increases \$</i>
L01	Antineoplastic Agents	114	439,848	199,821,921	204,788,268	47,298
L02	Endocrine Therapy	36	405,932	109,507,753	113,331,321	-
L03	Immunostimulants	18	83,135	90,720,188	91,946,367	43,112
L04	Immunosuppressive Agents	42	259,251	67,148,120	70,100,959	-
M01	Antiinflammatory and Antirheumatic Products	85	7,695,891	159,623,334	208,747,990	123,323
M03	Muscle Relaxants	18	127,752	6,064,745	6,917,427	65,526
M04	Antigout Preparations	21	897,836	7,438,767	10,240,004	27,389
M05	Drugs for Treatment of Bone Diseases	16	2,835,103	153,758,487	170,150,958	-
N02	Analgesics	87	11,183,969	153,387,586	190,472,773	2,147,874
N03	Antiepileptics	79	1,659,870	98,305,336	111,836,650	3,693
N04	Anti-Parkinson Drugs	36	636,294	32,496,669	35,872,723	126,455
N05	Psycholeptics	112	7,299,988	272,719,845	299,491,398	292,933
N06	Psychoanalaptics	108	12,595,291	360,111,529	488,986,698	417,701
R03	Drugs for Obstructive Airway Diseases	85	9,409,505	365,128,310	434,522,671	-
S01	Ophthalmologicals	98	6,576,334	94,755,247	120,472,817	216,790
V04	Diagnostic Agents	24	481,605	22,830,475	25,221,967	17,773
V06	General Nutrients	71	55,550	17,981,496	18,763,841	239,995
	*Ad hoc	153	7,315,312	154,930,661	186,538,165	4,466,300
	# Total (excludes section 100 drugs)	2,586	170,279,502	5,305,255,960	6,345,892,437	9,774,032

* 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: Pharmaceutical Benefits Scheme: highest cost items 12 months to 30 June 2005

<i>Rank</i>	<i>Item</i>	<i>Drug</i>	<i>Form</i>	<i>Volume</i>	<i>Govt Cost \$</i>	<i>Total Cost \$</i>	<i>Ave Price \$</i>
1	8173	SIMVASTATIN	Tablet 40 mg	2,193,607	152,161,702	171,136,455	78.02
2	8215	ATORVASTATIN	Tablet 40 mg	2,069,940	150,544,522	171,499,684	82.85
3	8214	ATORVASTATIN	Tablet 20 mg	2,931,690	145,682,679	174,860,269	59.64
4	8333	OMEPRAZOLE	Tablet 20 mg 30	3,610,764	145,542,497	174,586,490	48.35
5	8358	CLOPIDOGREL	Tablet 75mg	1,665,471	130,283,908	139,951,859	84.03
6	2012	SIMVASTATIN	Tablet 20 mg	2,246,170	108,354,719	125,213,853	55.75
7	8511	ALENDRONIC ACID	Tablet 70 mg alendronic acid	1,872,082	93,762,305	104,668,142	55.91
8	8187	OLANZAPINE	Tablet 10 mg 30	252,041	84,844,508	86,396,199	342.79
9	8008	PANTOPRAZOLE	Tablet (enteric coated) equivalent to 40mg	1,977,518	82,298,747	97,995,225	49.55
10	8197	PRAVASTATIN	Tablet 40 mg, 30	1,153,073	78,982,043	88,551,112	76.80
11	8521	ATORVASTATIN	Tablet 80 mg	680,690	72,282,353	79,162,231	116.30
12	8601	ESOMEPRAZOLE	Tablet 40 mg (enteric coated), 30	1,048,259	68,737,721	78,897,194	75.27
13	8213	ATORVASTATIN	Tablet 10 mg	1,946,901	65,016,891	82,757,378	42.51
14	8626	TIOTROPIUM BROMIDE	Capsule 18ug (base)(oral inhalation) 30	885,784	64,398,798	68,659,649	77.51
15	8440	CELECOXIB	Capsule 200 mg 60	2,437,419	62,683,212	80,792,476	33.15
16	8600	ESOMEPRAZOLE	Tablet 20 mg (enteric coated), 30	1,697,135	62,044,580	78,419,329	46.21
17	8432	SALMETEROL and FLUTICASON	Pdr oral inhal breth actu dev 50ug/500ug	778,431	54,944,300	62,664,763	80.50
18	8313	SIMVASTATIN	Tablet 80 mg	540,196	54,669,483	59,416,353	109.99
19	8519	SALMETEROL and FLUTICASON	Oral Press inhal 25ug/250ug	767,454	53,327,225	61,086,879	79.60
20	8405	IRBESARTAN with HYDROCHLORTHIAZIDE	Tablet 300 mg-12.5 mg	2,144,086	51,051,650	73,017,753	34.06
21	8302	VENLAFAXINE	Capsule 150 mg (base)modified release	884,903	46,308,815	56,714,767	64.09
22	8220	CITALOPRAM	Tablet 20 mg (base)	1,541,972	39,083,282	57,437,297	37.25
23	8101	INTERFERON BETA-1b	Injection set 1 vial powder dose 8,000,000 i.u.	33,009	38,415,671	38,904,485	1,178.60
24	8134	VALACICLOVIR	Tablet 500 mg	216,392	38,245,342	42,349,653	195.71
25	8243	LATANOPROST	Eye drops 50 ug per mL (0.005%), 2.5 mL	1,331,499	37,585,735	45,463,297	34.14

Table 2: Pharmaceutical Benefits Scheme: highest cost items 12 months to 30 June 2005 (continued)

<i>Rank</i>	<i>Item</i>	<i>Drug</i>	<i>Form</i>	<i>Volume</i>	<i>Govt Cost \$</i>	<i>Total Cost \$</i>	<i>Ave Price \$</i>
26	8508	RABEPRAZOLE	Tablet 20 mg 30	962,653	37,542,059	46,891,588	48.71
27	8093	GOSERELIN	Subcutaneous implant 10.8 mg (base) in prefilled injection syringe	32,019	36,566,182	36,755,679	1,147.93
28	8449	PERINDOPRIL and INDAPAMIDE	Tablet 4 mg-1.25 mg	1,586,178	35,457,092	51,678,904	32.58
29	2242	PAROXETINE	Tablet 20 mg (base)	1,186,644	34,871,065	49,116,569	41.39
30	8248	IRBESARTAN	Tablet 300 mg	1,429,751	34,239,271	47,904,925	33.51
31	2237	SERTRALINE	Tablet 100 mg (base)	1,170,275	32,876,791	47,416,948	40.52
32	8431	SALMETEROL and FLUTICASONE	Pdr oral inhal breth actu dev 50ug/250ug	677,363	32,171,659	40,259,782	59.44
33	2236	SERTRALINE	Tablet 50 mg (base)	1,303,609	31,672,793	47,420,007	36.38
34	2241	LANSOPRAZOLE	Capsule 30 mg	777,303	31,450,795	38,889,255	50.03
35	8562	MELOXICAM	Tablet 15 mg	1,208,116	29,427,856	40,070,735	33.17
36	8247	IRBESARTAN	Tablet 150 mg	1,437,950	29,010,595	39,422,486	27.42
37	2011	SIMVASTATIN	Tablet 10 mg	825,219	27,844,005	33,259,519	40.30
38	8621	RISEDRONIC ACID	Tablet 35 mg	552,960	27,591,310	30,910,862	55.90
39	3051	PERINDOPRIL	Tablet 4 mg 30	1,445,690	27,427,085	36,955,713	25.56
40	2834	PRAVASTATIN	Tablet 20 mg, 30	638,873	27,233,843	32,113,721	50.27
41	8288	SALBUTAMOL	Oral pressurised inhal 100 ug (base) (CF-free	2,092,837	27,216,907	33,963,955	16.23
42	8301	VENLAFAXINE	Capsule 75 mg (base) modified release	752,822	26,070,324	35,562,506	47.24
43	8185	OLANZAPINE	Tablet 5 mg 30	192,084	25,472,738	26,733,366	139.18
44	1763	INSULIN (HUMAN)	Injection 100 units (30 units-70 units)	115,136	25,350,555	26,052,339	226.27
45	8470	RAMIPRIL	Capsule 10 mg 30	1,072,648	24,225,369	35,327,555	32.94
46	8513	MIRTAZAPINE	Tablet 30 mg	713,789	22,797,609	29,273,929	41.01
47	1761	INSULIN (HUMAN)	Injection 100 units per ml, 3ml,5	105,291	22,715,604	23,822,662	226.26
48	8294	RITUXIMAB	Soln for IV infusion 500mg/50ml	8,911	22,550,405	22,673,938	2,544.49
49	8472	ROFECOXIB	Tablet 25 mg 30	623,805	21,674,867	26,805,473	42.97
50	1434	FLUOXETINE HYDROCHLORIDE	Capsule 20 mg (base)	725,963	21,213,825	30,305,064	41.74

Table 3: Pharmaceutical Benefits Scheme: most prescribed items 12 months to 30 June 2005

<i>Rank</i>	<i>Item</i>	<i>Drug</i>	<i>Form</i>	<i>Volume</i>	<i>Govt Cost \$</i>	<i>Total Cost \$</i>	<i>Ave Price \$</i>
1	1746	PARACETAMOL	Tablet 500 mg	3,942,595	19,607,192	30,584,219	7.76
2	8333	OMEPRAZOLE	Tablet 20 mg 30	3,610,764	145,542,497	174,586,490	48.35
3	1081	ATENOLOL	Tablet 50 mg	2,992,318	20,773,549	30,455,611	10.18
4	8214	ATORVASTATIN	Tablet 20 mg	2,931,690	145,682,679	174,860,269	59.64
5	8440	CELECOXIB	Capsule 200 mg 60	2,437,419	62,683,212	80,792,476	33.15
6	1215	CODEINE with PARACETAMOL	Tablet 30 mg—500 mg	2,418,998	17,823,435	25,617,202	10.59
7	2012	SIMVASTATIN	Tablet 20 mg	2,246,170	108,354,719	125,213,853	55.75
8	8173	SIMVASTATIN	Tablet 40 mg	2,193,607	152,161,702	171,136,455	78.02
9	8405	IRBESARTAN with HYDROCHLOROTHIAZIDE	Tablet 300 mg—12.5 mg	2,144,086	51,051,650	73,017,753	34.06
10	8288	SALBUTAMOL	Oral pressurised inhal 100 ug (base) (CFC-free)	2,092,837	27,216,907	33,963,955	16.23
11	8215	ATORVASTATIN	Tablet 40 mg	2,069,940	150,544,522	171,499,684	82.85
12	2089	TEMAZEPAM	Tablet 10 mg 25	1,986,865	7,300,944	13,222,072	6.65
13	8008	PANTOPRAZOLE	Tablet (enteric coated) equivalent to 40mg	1,977,518	82,298,747	97,995,225	49.55
14	8213	ATORVASTATIN	Tablet 10 mg	1,946,901	65,016,891	82,757,378	42.51
15	8511	ALENDRONIC ACID	Tablet 70 mg alendronic acid	1,872,082	93,762,305	104,668,142	55.91
16	8600	ESOMEPRAZOLE	Tablet 20 mg (enteric coated), 30	1,697,135	62,044,580	78,419,329	46.21
17	2430	METFORMIN HYDROCHLORIDE	Tablet 500 mg	1,674,722	20,039,954	25,195,205	15.04
18	8358	CLOPIDOGREL	Tablet 75mg	1,665,471	130,283,908	139,951,859	84.03
19	8449	PERINDOPRIL and INDAPAMIDE	Tablet 4 mg -1.25 mg	1,586,178	35,457,092	51,678,904	32.58
20	3119	CEFALEXIN	Capsule 500 mg	1,547,833	12,388,276	17,841,710	11.53
21	8220	CITALOPRAM	Tablet 20 mg (base)	1,541,972	39,083,282	57,437,297	37.25
22	3051	PERINDOPRIL	Tablet 4 mg 30	1,445,690	27,427,085	36,955,713	25.56
23	8247	IRBESARTAN	Tablet 150 mg	1,437,950	29,010,595	39,422,486	27.42
24	8248	IRBESARTAN	Tablet 300 mg	1,429,751	34,239,271	47,904,925	33.51
25	3162	DIAZEPAM	Tablet 5 mg	1,428,627	5,351,963	9,955,514	6.97

Table 3: Pharmaceutical Benefits Scheme: most prescribed items 12 months to 30 June 2005 (continued)

<i>Rank</i>	<i>Item</i>	<i>Drug</i>	<i>Form</i>	<i>Volume</i>	<i>Govt Cost \$</i>	<i>Total Cost \$</i>	<i>Ave Price \$</i>
26	8243	LATANOPROST	Eye drops 50 ug per mL (0.005%), 2.5 mL	1,331,499	37,585,735	45,463,297	34.14
27	2236	SERTRALINE	Tablet 50 mg (base)	1,303,609	31,672,793	47,420,007	36.38
28	8562	MELOXICAM	Tablet 15 mg	1,208,116	29,427,856	40,070,735	33.17
29	2242	PAROXETINE	Tablet 20 mg (base)	1,186,644	34,871,065	49,116,569	41.39
30	2237	SERTRALINE	Tablet 100 mg (base)	1,170,275	32,876,791	47,416,948	40.52
31	8197	PRAVASTATIN	Tablet 40 mg, 30	1,153,073	78,982,043	88,551,112	76.80
32	1889	AMOXYCILLIN	Capsule 500 mg	1,103,718	8,432,041	12,394,810	11.23
33	8470	RAMIPRIL	Capsule 10 mg 30	1,072,648	24,225,369	35,327,555	32.94
34	8601	ESOMEPRAZOLE	Tablet 40 mg (enteric coated), 30	1,048,259	68,737,721	78,897,194	75.27
35	8254	AMOXYCILLIN with CLAVULANIC ACID	Tablet 875 mg- 125 mg	1,018,863	14,265,038	17,833,295	17.50
36	1978	RANITIDINE HYDROCHLORIDE	Tablet 150 mg (base)	1,013,995	19,137,427	22,193,569	21.89
37	2412	FRUSEMIDE	Tablet 40 mg	1,010,323	5,169,276	7,902,015	7.82
38	3133	OXAZEPAM	Tablet 30 mg	993,548	3,217,436	6,162,820	6.20
39	8202	ASPIRIN	Tablet 100mg	972,466	3,161,643	6,007,256	6.18
40	8508	RABEPRAZOLE	Tablet 20 mg 30	962,653	37,542,059	46,891,588	48.71
41	2751	AMLODIPINE BESYLATE	Tablet 5 mg (base), 30	905,753	16,440,464	19,398,123	21.42
42	8626	TIOTROPIUM BROMIDE	Capsule 18ug (base)(oral inhalation) 30	885,784	64,398,798	68,659,649	77.51
43	8302	VENLAFAXINE	Capsule 150 mg (base)modified release	884,903	46,308,815	56,714,767	64.09
44	1946	RAMIPRIL	Capsule 5.0 mg 28	868,660	15,874,342	18,950,300	21.82
45	2752	AMLODIPINE BESYLATE	Tablet 10 mg (base), 30	856,872	19,861,540	28,575,833	33.35
46	2011	SIMVASTATIN	Tablet 10 mg	825,219	27,844,005	33,259,519	40.30
47	8432	SALMETEROL and FLUTICASONE	Pdr oral inhal breth actu dev 50ug/500ug	778,431	54,944,300	62,664,763	80.50
48	1300	DICLOFENAC	Tablet 50 mg (enteric coated), 50	778,199	5,737,834	8,386,500	10.78
49	2241	LANSOPRAZOLE	Capsule 30 mg	777,303	31,450,795	38,889,255	50.03
50	3117	CALCIUM CARBONATE	Tablet 600 mg (as carbonate)	767,749	7,323,883	9,605,331	12.51

Table 4: Pharmaceutical Benefits Scheme: Top 20 suppliers by total cost 2004–2005 (from processed PBS prescriptions)

<i>Rank</i>	<i>Manufacturer</i>	<i>Script Vol</i>	<i>Govt Cost \$</i>	<i>Total Cost \$</i>	<i>Sales (Ex-Manufacturer) \$</i>
1	Pfizer	22,310,713	867,899,695	1,052,346,712	775,216,113
2	Alphapharm	26,304,275	415,051,769	534,492,206	336,159,911
3	Merck Sharp & Dohme	9,871,686	452,148,838	518,932,460	386,619,984
4	AstraZeneca	9,898,744	395,681,257	470,380,925	346,791,950
5	GlaxoSmithKline	9,222,075	384,201,649	457,972,149	339,241,415
6	Bristol Myers Squibb	8,416,028	315,211,023	378,273,165	277,132,773
7	Aventis	9,065,453	230,947,558	275,983,100	190,943,567
8	Sanofi Synthelabo	9,031,056	208,354,489	255,565,838	174,370,806
9	Eli Lilly	1,418,391	210,236,113	220,036,057	174,575,143
10	Wyeth	4,352,402	151,723,976	187,241,917	136,460,968
11	Boehringer	4,461,894	152,735,159	180,797,655	130,767,344
12	Roche Products	2,129,167	135,897,214	148,406,474	113,235,863
13	Servier	5,330,705	104,179,620	139,968,817	94,020,958
14	Janssen-Cilag	1,906,639	115,011,310	130,277,431	99,258,732
15	Arrow	3,566,944	96,023,136	119,412,342	83,984,486
16	Novartis	2,811,890	103,484,998	117,941,779	85,684,824
17	Novo Nordisk	927,072	102,021,327	107,801,968	84,636,597
18	Sigma	7,894,754	64,272,695	91,781,382	44,734,941
19	Schering	1,097,339	72,058,838	79,636,479	60,937,352
20	Abbott	2,105,034	60,675,574	68,225,536	47,726,080
	Others	24,556,416	558,592,183	682,650,696	464,101,806
	Total	166,678,677	\$5,196,408,419	\$6,218,125,086	\$4,446,601,612

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

Table 5: Pharmaceutical Benefits Scheme: Top 20 suppliers by market share (scripts) for 2004–2005 (from processed PBS prescriptions)

Rank	Manufacturer	Script Vol	Govt Cost \$	Total Cost \$	% of Total	Sales (Ex-Manufacturer) \$
1	Alphapharm	26,304,275	415,051,769	534,492,206	15.78	336,159,911
2	Pfizer	22,310,713	867,899,695	1,052,346,712	13.39	775,216,113
3	AstraZeneca	9,898,744	395,681,257	470,380,925	5.94	346,791,950
4	Merck Sharp & Dohme	9,871,686	452,148,838	518,932,460	5.92	386,619,984
5	GlaxoSmithKline	9,222,075	384,201,649	457,972,149	5.53	339,241,415
6	Aventis	9,065,453	230,947,558	275,983,100	5.44	190,943,567
7	Sanofi Synthelabo	9,031,056	208,354,489	255,565,838	5.42	174,370,806
8	Bristol Myers Squibb	8,416,028	315,211,023	378,273,165	5.05	277,132,773
9	Sigma	7,894,754	64,272,695	91,781,382	4.74	44,734,941
10	Servier	5,330,705	104,179,620	139,968,817	3.20	94,020,958
11	Boehringer	4,461,894	152,735,159	180,797,655	2.68	130,767,344
12	Wyeth	4,352,402	151,723,976	187,241,917	2.61	136,460,968
13	Arrow	3,566,944	96,023,136	119,412,342	2.14	83,984,486
14	Novartis	2,811,890	103,484,998	117,941,779	1.69	85,684,824
15	Aspen	2,437,068	20,386,969	28,420,053	1.46	13,881,137
16	Roche Products	2,129,167	135,897,214	148,406,474	1.28	113,235,863
17	Abbott	2,105,034	60,675,574	68,225,536	1.26	47,726,080
18	Mayne	2,005,884	50,036,893	58,767,936	1.20	40,369,321
19	CSL	1,912,902	38,443,462	47,012,603	1.15	31,108,879
20	Janssen-Cilag	1,906,639	115,011,310	130,277,431	1.14	99,258,732
	Total Top 20	145,035,313	4,362,367,282	5,262,200,478	87%	3,747,710,051
	Others	21,643,364	834,041,137	955,924,608	13%	698,891,561
	Total	166,678,677	\$5,196,408,419	\$6,218,125,086	100%	\$4,446,601,612

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

Table 6(a): Pharmaceutical Benefits Scheme: Significant drug groups (incl Dr's Bag) by highest Government cost, year end June 2004 to year end June 2005

ATC Group Level2	Year ending June 2004					Year ending June 2005							
	Script Volume	Govt Cost \$	Total Cost \$	Ave Price \$		Script Volume	(% diff)	Govt Cost \$	(% diff)	Total Cost \$	(% diff)	Ave Price \$	(% diff)
SERUM LIPID REDUCING AGENTS	14,709,118	835,541,042	952,617,922	64.76		16,215,278	10.2	918,740,374	10.0	1,062,593,113	11.5	65.53	1.2
DRUGS FOR ACID RELATED DISORDERS	12,266,029	480,817,576	567,359,408	46.25		13,147,448	7.2	504,362,281	4.9	608,511,692	7.3	46.28	0.1
AGENTS ACTING ON RENIN--ANGIOTENSIN SYSTEM	19,376,940	402,709,093	551,727,000	28.47		19,901,853	2.7	419,765,729	4.2	566,875,473	2.7	28.48	0.0
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	9,523,344	348,071,969	412,367,828	43.30		9,409,505	-1.2	365,128,310	4.9	434,522,671	5.4	46.18	6.6
PSYCHOANALPTICS	12,000,862	350,523,725	460,123,457	38.34		12,595,291	5.0	360,111,529	2.7	488,986,698	6.3	38.82	1.3
PSYCHOLEPTICS	7,224,566	247,431,938	271,038,710	37.52		7,299,988	1.0	272,719,845	10.2	299,491,398	10.5	41.03	9.4
ANTINEOPLASTIC AGENTS	406,132	167,801,228	171,875,909	423.20		439,848	8.3	199,821,921	19.1	204,788,268	19.1	465.59	10.0
ANTIDIABETIC THERAPY	4,931,545	167,446,211	185,154,380	37.55		5,245,377	6.4	191,338,931	14.3	212,065,298	14.5	40.43	7.7
ANTITHROMBOTIC AGENTS	4,540,455	154,544,380	172,118,921	37.91		5,158,431	13.6	177,220,579	14.7	199,772,409	16.1	38.73	2.2
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	9,143,205	212,956,211	271,757,010	29.72		7,695,891	-15.8	159,623,334	-25.1	208,747,990	-23.2	27.12	-8.7
DRUGS FOR TREATMENT OF BONE DISEASES	2,439,353	135,028,145	147,684,827	60.54		2,835,103	16.2	153,738,487	13.9	170,150,958	15.2	60.02	-0.9
ANALGESICS	10,914,950	141,925,677	174,370,911	15.98		11,183,969	2.5	153,387,586	8.1	190,472,773	9.2	17.03	6.6
CALCIUM CHANNEL BLOCKERS	7,380,410	152,512,663	191,221,993	25.91		7,484,348	1.4	152,198,989	-0.2	193,071,216	1.0	25.80	-0.4
ANTIBACTERIALS FOR SYSTEMIC USE	11,092,683	130,574,361	170,580,847	15.38		11,316,053	2.0	133,286,487	2.1	177,619,177	4.1	15.70	2.1
ENDOCRINE THERAPY	396,251	102,127,519	105,417,506	266.04		405,932	2.4	109,507,753	7.2	113,331,321	7.5	279.19	4.9
ANTIEPILEPTICS	1,595,871	90,791,297	102,931,713	64.50		1,659,870	4.0	98,305,336	8.3	111,836,650	8.7	67.38	4.5
OPHTHALMOLOGICALS	6,233,638	89,823,235	111,914,982	17.95		6,576,334	5.5	94,755,247	5.5	120,472,817	7.6	18.32	2.0

Table 6(b): Pharmaceutical Benefits Scheme: Significant drug groups (incl Dr's Bag) by highest script volume, year end June 2004 to year end June 2005

ATC Group Level 2	Year ending June 2004				Year ending June 2005				Ave Price \$	Price diff %		
	Script Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Script Volume	Govt Cost \$	Total Cost \$	Price diff %				
AGENTS ACTING ON RENIN—ANGIOTENSIN SYSTEM	19,376,940	402,709,093	551,727,000	28.47	19,901,853	419,765,729	566,875,473	2.7	4.2	2.7	28.48	0.0
SERUM LIPID REDUCING AGENTS	14,709,118	835,541,042	952,617,922	64.76	16,215,278	918,740,374	1,062,593,113	10.2	10.0	11.5	65.53	1.2
DRUGS FOR ACID RELATED DISORDERS	12,266,029	480,817,576	567,359,408	46.25	13,147,448	504,362,281	608,511,692	7.2	4.9	7.3	46.28	0.1
PSYCHOANALEPTICS	12,000,862	350,523,725	460,123,457	38.34	12,595,291	360,111,529	488,986,698	5.0	2.7	6.3	38.82	1.3
ANTIBACTERIALS FOR SYSTEMIC USE	11,092,683	130,574,361	170,580,847	15.38	11,316,053	133,286,487	177,619,177	2.0	2.1	4.1	15.70	2.1
ANALGESICS	10,914,950	141,925,677	174,370,911	15.98	11,183,969	153,387,586	190,472,773	2.5	8.1	9.2	17.03	6.6
DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES	9,523,344	348,071,969	412,367,828	43.30	9,409,505	365,128,310	434,522,671	-1.2	4.9	5.4	46.18	6.6
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	9,143,205	212,956,211	271,757,010	29.72	7,695,891	159,623,334	208,747,990	-15.8	-25.1	-23.2	27.12	-8.7
CALCIUM CHANNEL BLOCKERS	7,380,410	152,512,663	191,221,993	25.91	7,484,348	152,198,989	193,071,216	1.4	-0.2	1.0	25.80	-0.4
PSYCHOLEPTICS	7,224,566	247,431,938	271,038,710	37.52	7,299,988	272,719,845	299,491,398	1.0	10.2	10.5	41.03	9.4
OPHTHALMOLOGICALS	6,233,638	89,823,235	111,914,982	17.95	6,576,334	94,755,247	120,472,817	5.5	5.5	7.6	18.32	2.0
ANTIIDIABETIC THERAPY	4,931,545	167,446,211	185,154,380	37.55	5,245,377	191,338,931	212,065,298	6.4	14.3	14.5	40.43	7.7
ANTITHROMBOTIC AGENTS	4,540,455	154,544,380	172,118,921	37.91	5,158,431	177,220,579	199,772,409	13.6	14.7	16.1	38.73	2.2
BETA BLOCKING AGENTS	4,628,098	67,136,235	81,758,886	17.67	4,946,575	76,258,362	93,610,274	6.9	13.6	14.5	18.92	7.1
SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM	3,791,359	77,297,819	94,217,005	24.85	3,563,199	77,046,408	94,868,295	-6.0	-0.3	0.7	26.62	7.1
CARDIAC THERAPY	3,450,371	60,872,657	72,290,385	20.95	3,387,350	61,073,672	72,889,642	-1.8	0.3	0.8	21.52	2.7
DRUGS FOR TREATMENT OF BONE DISEASES	2,439,353	135,028,145	147,684,827	60.54	2,835,103	153,758,487	170,150,958	16.2	13.9	15.2	60.02	-0.9

Table 7(a): Pharmaceutical Benefits Scheme: Significant drugs (incl Dr's Bag) — sorted by highest change to Government cost, year end June 2004 to year end June 2005

Rank	Drug	Year ending June 2004				Year ending June 2005				Change	
		Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Govt Cost \$	%
1	ATORVASTATIN	6,629,408	368,554,153	427,030,219	64.41	7,629,221	433,526,445	508,279,562	66.62	64,972,292	17.63
2	ESOMEPRAZOLE	2,051,597	100,249,623	118,532,126	57.78	2,745,394	130,782,301	157,316,523	57.30	30,532,678	30.46
3	CLOPIDOGREL	1,369,634	108,117,378	115,058,695	84.01	1,665,471	130,283,908	139,951,859	84.03	22,166,530	20.50
4	TIOTROPIUM BROMIDE	578,834	42,315,436	44,836,583	77.46	885,784	64,398,798	68,659,649	77.51	22,083,361	52.19
5	MELOXICAM	973,400	22,548,914	29,980,207	30.80	1,732,160	39,483,197	52,792,274	30.48	16,934,283	75.10
6	EZETIMIBE	0	0	0	0.00	219,944	13,410,384	15,720,458	71.47	13,410,384	0.00
7	ESCITALOPRAM	93,486	2,223,485	3,474,639	37.17	627,708	15,593,122	24,434,359	38.93	13,369,638	601.29
8	ARIPIPRAZOLE	2,610	623,508	642,829	246.29	54,168	13,487,922	13,913,837	256.86	12,864,414	New
9	ETANERCEPT	6,525	12,240,040	12,299,100	1,884.92	12,875	24,233,858	24,353,047	1,891.50	11,993,819	97.99
10	EFORMOTEROL with BUDESONIDE	279,306	12,834,225	15,651,897	56.04	464,286	24,440,881	29,552,307	63.65	11,606,656	90.44
11	RISEDROMIC ACID	374,011	19,889,467	21,878,530	58.50	590,651	30,581,947	34,092,769	57.72	10,692,480	53.76
12	SIMVASTATIN	5,526,791	333,669,341	373,139,090	67.51	5,849,104	344,032,752	390,347,804	66.74	10,363,411	3.11
13	RABEPRAZOLE	864,542	33,451,099	41,180,444	47.63	1,141,132	43,743,625	54,806,673	48.03	10,292,525	30.77
14	PERINDOPRIL	2,358,909	42,901,225	58,618,039	24.85	2,609,633	53,172,307	69,291,212	26.55	10,271,081	23.94
15	ADALIMUMAB	51	95,789	96,299	1,888.21	5,295	9,935,361	9,995,538	1,887.73	9,839,572	10,272.09
16	PANTOPRAZOLE	2,037,525	85,330,042	100,197,565	49.18	2,375,124	95,142,299	114,027,965	48.01	9,812,257	11.50
17	ALENDRONIC ACID	1,701,990	87,403,280	96,313,566	56.59	1,894,038	96,720,775	107,739,213	56.88	9,317,495	10.66
18	PIOGLITAZONE HYDROCHLORIDE	33,906	2,812,262	3,076,534	90.74	117,823	10,504,577	11,339,976	96.25	7,692,315	273.53
19	RITUXIMAB	19,829	37,225,784	37,471,225	1889.72	24,344	44,623,298	44,954,102	1,846.62	7,397,514	19.87
20	LERCANIPIDINE	595,013	12,133,609	15,689,936	26.37	851,565	19,511,324	24,950,585	29.30	7,377,715	60.80

Table 7(a): Pharmaceutical Benefits Scheme: Significant drugs (incl Dr's Bag) — sorted by highest change to Government cost, year end June 2004 to year end June 2005 (continued)

Rank	Drug	Year ending June 2004				Year ending June 2005				Change	
		Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Govt Cost \$	%
21	OXALIPLATIN	11,053	15,183,049	15,320,354	1,386.08	15,423	22,479,571	22,691,233	1,471.26	7,296,523	48.06
22	OXYCODONE	721,213	22,714,178	25,397,882	35.22	897,009	29,289,518	32,766,367	36.53	6,575,340	28.95
23	QUETIAPINE	130,785	27,156,781	27,959,470	213.78	163,013	33,670,218	34,769,335	213.29	6,513,437	23.98
24	ROSGLITAZONE	41,807	2,742,118	3,077,362	73.61	129,274	8,939,007	9,940,378	76.89	6,196,889	225.99
25	VENLAFAXINE	1,615,790	72,403,802	89,846,713	55.61	1,797,874	78,372,000	100,106,031	55.68	5,968,198	8.24
26	INSULIN ASPART/PROTAMINE ASPART	32,651	8,489,634	8,738,798	267.64	55,299	14,348,180	14,799,158	267.62	5,858,545	69.01
27	PACLITAXEL	10,389	20,972,807	21,111,853	2,032.14	12,950	26,772,082	26,975,801	2,083.07	5,799,275	27.65
28	VALACICLOVIR	227,702	41,203,800	45,001,835	197.63	258,976	46,543,600	51,339,761	198.24	5,339,800	12.96
29	CARVEDILOL	376,375	34,188,567	36,188,940	96.15	440,184	39,201,437	41,775,088	94.90	5,012,870	14.66
30	RISPERIDONE	226,256	31,017,317	32,370,349	143.07	245,659	35,961,783	37,575,787	152.96	4,944,466	15.94
31	LEVETIRACETAM	22,306	3,268,299	3,449,197	154.63	56,855	8,073,254	8,577,773	150.87	4,804,956	147.02
32	SALMETEROL and FLUTICASONE	2,508,244	152,343,064	177,374,020	70.72	2,626,899	156,522,842	185,480,569	70.61	4,179,778	2.74
33	IRBESARTAN with HYDROCHLOROTHIAZIDE	2,640,518	60,775,672	85,458,442	32.36	2,811,442	64,840,819	91,774,105	32.64	4,065,147	6.69
34	MIRTAZAPINE	580,982	18,798,447	23,709,045	40.81	713,789	22,797,609	29,273,929	41.01	3,999,162	21.27
35	INSULIN ASPART	40,927	10,059,707	10,526,281	257.20	57,749	14,050,894	14,773,195	255.82	3,991,187	39.68

Table 7(b): Pharmaceutical Benefits Scheme: Significant Drugs (incl Dr's Bag) — sorted by highest volume change, year end June 2004 to year end June 2005

Rank	Drug	Year ending June 2004				Year ending June 2005				Change	
		Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Volume	%
1	ATORVASTATIN	6,629,408	368,554,153	427,030,219	64.41	7,629,221	433,526,445	508,279,562	66.62	999,813	15.08
2	MELOXICAM	973,400	22,548,914	29,980,207	30.80	1,732,160	39,483,197	52,792,274	30.48	758,760	77.95
3	ESOMEPRAZOLE	2,051,597	100,249,623	118,532,126	57.78	2,745,394	130,782,301	157,316,523	57.30	693,797	33.82
4	ESCITALOPRAM	93,486	2,223,485	3,474,639	37.17	627,708	15,593,122	24,434,359	38.93	534,222	571.45
5	PANTOPRAZOLE	2,037,525	85,330,042	100,197,565	49.18	2,375,124	95,142,299	114,027,965	48.01	337,599	16.57
6	SIMVASTATIN	5,526,791	333,669,341	373,139,090	67.51	5,849,104	344,032,752	390,347,804	66.74	322,313	5.83
7	TIOTROPIUM BROMIDE	578,834	42,315,436	44,836,583	77.46	885,784	64,398,798	68,659,649	77.51	306,950	53.03
8	CLOPIDOGREL	1,369,634	108,117,378	115,058,695	84.01	1,665,471	130,283,908	139,951,859	84.03	295,837	21.60
9	RABEPRAZOLE	864,542	33,451,099	41,180,444	47.63	1,141,132	43,743,625	54,806,673	48.03	276,590	31.99
10	LERCANIPIDINE	595,013	12,133,609	15,689,936	26.37	851,565	19,511,324	24,950,585	29.30	256,552	43.12
11	PERINDOPRIL	2,358,909	42,901,225	58,618,039	24.85	2,609,633	53,172,307	69,291,212	26.55	250,724	10.63
12	EZETIMIBE	0	0	0	0.00	219,944	13,410,384	15,720,458	71.47	219,944	0.00
13	RISEDRONIC ACID	374,011	19,889,467	21,878,530	58.50	590,651	30,581,947	34,092,769	57.72	216,640	57.92
14	ALENDRONIC ACID	1,701,990	87,403,280	96,313,566	56.59	1,894,038	96,720,775	107,739,213	56.88	192,048	11.28
15	EFORMOTEROL with BUDESONIDE	279,306	12,834,225	15,651,897	56.04	464,286	24,440,881	29,552,307	63.65	184,980	66.23
16	VENLAFAXINE	1,615,790	72,403,802	89,846,713	55.61	1,797,874	78,372,000	100,106,031	55.68	182,084	11.27
17	TELMISARTAN and DIURETICS	195,570	3,582,345	5,506,318	28.16	377,017	6,746,539	10,667,131	28.29	181,447	92.78
18	OXYCODONE	721,213	22,714,178	25,397,882	35.22	897,009	29,289,518	32,766,367	36.53	175,796	24.38
19	PERINDOPRIL and INDAPAMIDE	1,411,208	33,235,350	46,318,021	32.82	1,586,178	35,457,092	51,678,904	32.58	174,970	12.40

Table 7(b): Pharmaceutical Benefits Scheme: Significant Drugs (incl Dr's Bag) — sorted by highest volume change, year end June 2004 to year end June 2005 (continued)

Rank	Drug	Year ending June 2004				Year ending June 2005				Change	
		Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Volume	Govt Cost \$	Total Cost \$	Ave Price \$	Volume	%
20	IRBESARTAN with HYDROCHLOROTHIAZIDE	2,640,518	60,775,672	85,458,442	32.36	2,811,442	64,840,819	91,774,105	32.64	170,924	6.47
21	CEFALEXIN	1,785,290	14,422,099	20,219,265	11.33	1,950,588	15,247,547	22,211,425	11.39	165,298	9.26
22	WARFARIN	1,718,226	8,717,821	13,335,091	7.76	1,870,426	9,107,420	14,600,628	7.81	152,200	8.86
23	ATENOLOL	2,856,440	20,458,579	28,917,567	10.12	2,992,318	20,773,549	30,455,611	10.18	135,878	4.76
24	MIRTAZAPINE	580,982	18,798,447	23,709,045	40.81	713,789	22,797,609	29,273,929	41.01	132,807	22.86
25	CANDESARTAN with HYDROCHLOROTHIAZIDE	545,579	10,443,448	15,550,198	28.50	671,977	12,747,922	19,643,749	29.23	126,398	23.17
26	ASPIRIN	1,124,396	4,137,906	7,096,372	6.31	1,243,201	4,278,398	7,876,608	6.34	118,805	10.57
27	SALMETEROL and FLUTICASONE	2,508,244	152,343,064	177,374,020	70.72	2,626,899	156,522,842	185,480,569	70.61	118,655	4.73
28	ARTIFICIAL TEARS and OTHER INDIFFERS	28,992	159,400	252,979	8.73	140,687	829,232	1,240,780	8.82	111,695	385.26
29	ARTIFICIAL TEARS	150,866	1,295,410	1,691,436	11.21	259,532	2,175,270	2,919,633	11.25	108,666	72.03
30	LATANOPROST	1,226,993	35,350,549	41,851,333	34.11	1,331,499	37,585,735	45,463,297	34.14	104,506	8.52
31	CANDESARTAN	854,855	16,235,713	21,593,991	25.26	944,178	18,890,698	23,740,920	25.14	89,323	10.45
32	GLICLAZIDE	984,921	12,544,294	15,237,184	15.47	1,073,228	13,468,287	16,657,923	15.52	88,307	8.97
33	METOPROLOL TARTRATE	957,432	7,879,129	10,608,502	11.08	1,045,675	9,213,643	12,523,840	11.98	88,243	9.22
34	ROSIGLITAZONE	41,807	2,742,118	3,077,362	73.61	129,274	8,939,007	9,940,378	76.89	87,467	209.22
35	TRAMADOL	1,622,303	24,052,043	29,053,744	17.91	1,707,655	26,673,722	32,527,667	19.05	85,352	5.26

