

# PHARMACEUTICAL BENEFITS

## PRICING AUTHORITY

### ANNUAL REPORT

For the year ended 30 June 2009





**PHARMACEUTICAL**

**BENEFITS**

**PRICING**

**AUTHORITY**

**ANNUAL REPORT**

**For the year ended 30 June 2009**

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PBPA

Pharmaceutical Benefits  
Pricing Authority

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Minister The Hon Nicola Roxon MP  
Minister for Health and Ageing  
Parliament House  
CANBERRA ACT 2600

Dear Ms Roxon

I present herewith the twenty-second 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 2009.

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 should be furnished to you as soon as practicable after the end of the report period.

Yours sincerely



Chair  
2009

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## PREFACE

This is the twenty-second annual report of the Pharmaceutical Benefits Pricing Authority covering the operations of the PBPA for the year ended 30 June 2009.

### Tabling requirements

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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

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The report is divided into six 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 contains information on the different pricing policies;
- chapter 4 addresses information on PBS Reforms;
- chapter 5 contains information on the Highly Specialised Drugs program; and
- chapter 6 contains related tables, figures and acronyms.

## CHAPTER 1

### Pharmaceutical Benefits Pricing Authority

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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) and, since 2006, the vaccines on the National Immunisation Program (NIP); and
- recommend prices for new items that are recommended for listing on the PBS and, since 2006, the NIP.

### Membership

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The PBPA's membership for the 2008–2009 financial year was:

Chair	Mr Michael Roche – appointed with effect from December 2008.
Industry nominees	Dr Brendan Shaw – as the nominee of Medicines Australia. Ms Kate Lynch – appointed with effect from March 2009 as the nominee of the Generic Medicines Industry Association.
Consumer nominee	Ms Jo Watson – as the nominee of the Consumers' Health Forum, Australian Consumer's Association and Australian Federation of AIDS Organisations.
Department of Health and Ageing Representative	Ms Linda Jackson – appointed with effect from April 2009. Ms Diana Macdonell – immediate previous member.
Department of Innovation, Industry, Science and Research	Mr Peter Chesworth

## Meetings

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The PBPA met four times during the 2008-2009 financial year. The type and date of these meetings were as follows:

<i>Type of Meeting</i>	<i>Date</i>
Regular	20 August 2008
Regular	17 December 2008
Working Group	20 April 2009
Regular	21 April 2009

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## Co-ordination to achieve timely outcomes

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The three regular scheduled meetings were coordinated with meetings of the Pharmaceutical Benefits Advisory Committee (PBAC) so that the PBAC outcomes can be dealt with as soon as possible, consistent with the need to collect pricing information.

## Financial arrangements

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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 2009 the PBPA operating costs were:

<b>PBPA operating costs 2008–2009</b>	<b>Total costs \$</b>
Direct costs including Chairman's, industry and consumer nominees' expenses	18,395
Salaries	428,791
Members & secretariat travel and allowances	4,510
Administrative costs	4,755
Total costs	456,452

### **Secretariat Support**

The PBPA is serviced by a Secretariat staffed within the Pharmaceutical Evaluation Branch of the Department of Health and Ageing.

The PBPA supports best management practice in communicating with Responsible Persons 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.

## CHAPTER 2

### Pharmaceutical Benefits Scheme

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The PBPA, along with the PBAC and its sub-committees, evaluate all submissions from sponsors for the listing and pricing of drugs on the Pharmaceutical Benefits Scheme. While the PBAC is a statutory committee that assesses the clinical benefit and cost-effectiveness of drugs, the PBPA is a non-statutory committee that recommends prices of drugs for PBS listing purposes.

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, 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 Responsible Persons, where necessary, on proposed prices.

### Factors considered by the PBPA

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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 items containing drugs in the same Anatomical Therapeutic Classification (ATC) Group;
- (d) costs information, when provided by the Responsible Person or estimated by the PBPA;
- (e) prescription volumes, economies of scale and other factors such as expiry dates, storage requirements, product stability and special manufacturing requirements;
- (f) level of activity being undertaken by the company in Australia, including new investment, production, research and development;\*

- (g) prices of items containing 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.

\* Factor (f) is presently not taken into consideration in determining prices.

The Pricing Authority is presently seeking advice on this matter.

### **Establishing prices for new listings**

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For new or extended listings recommended by the PBAC, the PBPA may advise the price to be negotiated by the Department of Health and Ageing. The PBAC recommendation, based on economic evaluations considered by the Economics Sub-Committee, is a major consideration in determining initial prices.

Increasingly, the PBPA considers deeds of agreement containing risk sharing arrangements to contain overall costs of drugs on the PBS and to manage the financial risks to the Government resulting from uncertainty about drugs utilisation.

At 30 June 2009 there were 74 deeds of agreement in place or in development.

A comprehensive overview of the different pricing methods used by the PBPA, including cost-plus method, reference pricing and different types of risk sharing arrangements, are provided in the PBPA's Policies, Procedures and Methods manual. This manual is available on the Department of Health and Ageing's website.

## High Cost Medicines

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All proposed listings with a predicted net cost to the PBS in excess of \$10 million per annum in at least one of the first four years of listing must be considered by Cabinet. This means that, where the Department of Health and Ageing, in consultation with the Department of Finance and Deregulation, has estimated the cost of a proposed new listing or extension to 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 had their listing extended or were newly listed in 2008–2009:

- Cinacalcet (Sensipar®) for the treatment of secondary hyperparathyroidism (increased calcium in the blood - drug will help manage this kidney disease complication) for a 1 July 2008 listing date;
- Natalizumab (Tysabri®) for the treatment of relapsing-remitting multiple sclerosis (an inflammatory disease of the central nervous system - drug reduces relapse rate and slows disease progression) for a 1 July 2008 listing date;
- Adalimumab (Humira®) for the treatment of Crohn disease (inflammatory disorder of the gastrointestinal tract - drug is a subcutaneous injection to treat the symptoms) for a 1 August 2008 listing date;
- Posaconazole (Noxafil®) for the prophylaxis and treatment of invasive fungal infections (drug provides protection against species of fungi not controlled by other PBS-subsidised therapies) for a 1 January 2009 listing date;
- Clopidogrel (Plavix® and Iscover®) for the treatment of Acute Coronary Syndrome (a set of signs and symptoms suggesting a heart attack - drug provides dual therapy to help prevent early and long term cardiovascular events) for a 1 February 2009 listing date; and
- Sunitinib (Sutent®) for the treatment of renal cell carcinoma (a form of kidney cancer - drug has been shown to reduce the symptoms and in many cases extends progression free survival by about 11 months) for a 1 May 2009 listing date.

## Reviewing prices for existing items

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

- reference pricing, i.e. 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 Responsible Person to the PBAC; and/or
- a margin on the cost of manufacture, or landed cost.

These mechanisms are outlined in the PBPA Policies, Procedures and Methods manual on the Department of Health and Ageing's website.

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

The Weighted Average Monthly Treatment Cost (WAMTC) methodology is a form of reference pricing that is outlined in the WAMTC manual. This can also be found on the Department of Health and Ageing's website.

### 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.

### Annual Scheduled Review of Anatomical Therapeutic Chemical (ATC) groups

The PBPA reviews annually the price of each drug listed in the Schedule of Pharmaceutical Benefits by ATC groupings. Responsible Persons are asked to submit cost and other data that they wish the PBPA to consider in reviewing product prices.

The ATC groups and the PBPA meetings at which they were reviewed are as follows:

<i>ATC Code</i>	<i>Major Group</i>	<i>PBPA Meeting</i>
D	Dermatologicals	20 August 2008
M	Musculoskeletal system	20 August 2008
N	Nervous system	20 August 2008
P	Antiparasitic products	20 August 2008
	Section 100 items	20 August 2008

A	Alimentary tract & metabolism	17 December 2008
S	Sensory organs	17 December 2008
V	Various	17 December 2008
H	Systemic hormonal preparations, excluding sex hormones	17 December 2008
J	General antiinfectives for systemic use	17 December 2008
<hr/>		
B	Blood & blood forming organs	21 April 2009
C	Cardiovascular system	21 April 2009
L	Antineoplastics & immunomodulating agents	21 April 2009
R	Respiratory system	21 April 2009
G	Genito urinary system & sex hormones	21 April 2009

### Statistical summary of items considered by the PBPA

Results of ATC group reviews for 2008-2009

<i>Product review results</i>	<i>2006-2007</i>	<i>2007-2008</i>	<i>2008-2009</i>
Number of brands reviewed	3,045	3,467	3,844
Number of brands for which price applications were received	385 12.64%	372 10.73%	466 12.12%
Number of brands for which price increases were granted	163 5.35%	138 3.98%	160 4.16%
Number of vaccines for which price applications were received*	7	3	3
Number of vaccines for which price increases were granted	5	1	0

## PBAC recommendations for 2008-2009

<i>Recommendations and listings</i>	<i>2006-2007</i>	<i>2007-2008</i>	<i>2008-2009</i>
Number of items recommended for listing by the PBAC	67	54	146
Section 100 (based on PBAC meetings held in 2008-2009 financial year, including strengths)	15	14	11
Number of items listed	125	179	112
Section 100 (based on new items listed in the PBS Schedule for 2008-2009)	33	14	10
Number of vaccines recommended for listing by the PBAC on the National Immunisation Program*	3	4	1
Estimate of additional cost of drugs for new or extensions to listings during 2008-2009**	\$212 million	\$193.3 million	\$154.3 million***

\* The PBPA assumed responsibility for pricing vaccines in December 2006.

\*\* Values are estimated net costs to the PBS and Repatriation Pharmaceutical Benefits Scheme (RPBS) for the financial year for each drug listed on the PBS between 1 July 2008 and 30 June 2009. Note that drugs are listed at stages throughout the year so the value is not the estimated cost to the PBS and RPBS for the full 2008-2009 financial year.

\*\*\* \$36.5 million of this value is for drugs that were not considered by the Cabinet.

### Estimated cost of price increases of existing items for 2008–2009

The general price increases granted to Responsible Persons in 2008–2009 are collectively estimated to add \$16.4 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>2007-2008 (\$ million)</i>	<i>2008-2009 (\$ million)</i>
Recommended by the PBPA and subsequently approved by the Minister for Health and Ageing	19.2	16.4

### Cost of the Pharmaceutical Benefits Scheme

The total cost of the PBS for 2008–2009 was \$7,654.72 million. This comprised \$5,178.39 million for persons covered by concession cards, and \$1,390.70 million for general patients not covered by concession cards. Other PBS expenditure was \$1,085.63 million, which includes expenditure on other categories including Highly Specialised Drugs, Doctor's Bag and Safety Net Card Supply. In addition, there was PBS revenue of \$22.82 million which has not been included in the above PBS total cost.

<i>Category</i>	<i>Processed script numbers (# million)</i>	<i>Cost to Government (excludes patient contributions) (\$ million)</i>
General	26.33	1,390.70
Concessional	155.14	5,178.39
PB Other	*	1,085.63
Total	181.47**	7,654.72
Revenue	***	-22.82
Total (incl. revenue)	***	7,631.90

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

\*\* Does not include Doctor's Bag (0.37 million).

\*\*\* Script numbers do not apply to PBS revenue.

Note: For the general public, where a pharmaceutical benefit has a dispensed price below the general patient contribution (that is, below \$32.90), the consumer pays the full amount. The above figures do not include these amounts.

## Effects of price adjustments

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

- Responsible Persons through adjusted selling prices;
- wholesalers through the margin on the prices 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 items 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 \$31.30 changing to \$32.90 effective 1 January 2009, while the concessional co-payment was \$5.00, changing to \$5.30 effective 1 January 2009.

## CHAPTER 3

### Special Patient Contributions (SPC)

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Special patient contributions may apply when a manufacturer and the Government cannot agree about the price of a product listed on the PBS. In these cases, the product continues to be listed on the PBS, but patients pay an amount in addition to the standard patient co-payment. These additional amounts are paid to the Responsible Person, not to the Government.

The advantage of special patient contributions is that patients are not denied subsidised access to the drugs altogether, increasing the treatment options available for doctors and patients. There are provisions to exempt special patient contributions in certain clinical circumstances.

There are three types of special patient contributions, which are discussed below.

#### Brand Premium Policy

The Brand Premium Policy was introduced in December 1990, at the request of the pharmaceutical industry. The policy allows Responsible Persons to set their own prices on PBS listed brands in particular circumstances. It applies mainly to drugs which are no longer under patent.

The policy operates where there are a number of therapeutically equivalent brands available. The Government subsidises each of the available brands to the level of the lowest priced brand. Responsible Persons of other brands are able to set a price higher than the price of the lowest priced brand. Patients then pay the difference between the price of the lowest priced brand and the price of the brand which is dispensed to them – this is known as the brand premium.

The brand premium is not paid to the Government. The Responsible Person receives the benefit of the brand premium paid.

The principle is that there should always be available at least one therapeutically equivalent brand without a brand premium. Unless the prescribing doctor or dentist has specifically indicated otherwise on the prescription, a pharmacist can dispense another brand of the same medicine at the patient's request. In this way, patients can avoid paying a brand premium.

In the year ending 30 June 2009, 337 of the approximately 3,800 brands listed on the PBS during that year attracted a brand premium. Brand premiums ranged from \$0.08 to \$76.86 with 75 per cent of all brand premiums costing patients less than \$3.00, with 62 per cent of these \$2.00 or less.

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## Therapeutic Group Premium Policy

The Therapeutic Group Premium Policy was introduced in 1998.

The policy applies within specifically defined groups of drugs which have similar safety and health outcomes. Within these groups, the drugs can be interchanged at the patient level. The Government subsidises all drugs within a group to the level of the lowest priced drug. The difference in price between the lowest priced drug and higher priced drugs within the group is called a therapeutic group premium (TGP). The TGP is paid by the patient and goes to the Responsible Person, not to the Government.

The principle is that there is always at least one drug within each group of drugs available without a TGP. In addition, when a patient, for a medical reason, is only able to take a drug with a premium, the prescribing doctor can request an exemption from the premium from Medicare Australia.

As at 30 June 2009, four of the six TGP groups were affected by the Therapeutic Group Premium Policy. These are Angiotensin II receptor antagonists and Calcium Channel Blockers that are used to treat cardiovascular disease, Proton Pump inhibitors and the H<sub>2</sub> receptor antagonists for the treatment of peptic ulcers. The prices of items in these groups are reviewed by the PBPA each year, as for all drugs listed on the PBS. As at 30 June 2009, there were 142 items within the four groups. Seven of the items attracted TGPs, which ranged from \$1.52 to \$4.02.

## Other Special Patient Contributions

There are currently five drugs with special patient contributions other than brand or therapeutic group premiums listed on the PBS. Four of these have been introduced because the companies and the Minister could not agree on a new price when a price reduction was required by the 12.5% price reduction policy. The fifth, bleomycin, has had a special patient contribution for a number of years.

<i>Drug</i>	<i>Use</i>	<i>SPC*</i>
Bleomycin	Some cancers	\$428.30
Levetiracetam	Epilepsy	\$7.13 - \$19.84
Amoxicillin (paediatric drops)	Antibiotic for use in children	\$0.61
Naratriptan	Migraine	\$2.78
Zolmitriptan	Migraine	\$2.76

- \* The Government has ensured that patients will not be financially disadvantaged. The treating doctor can seek an authority from Medicare Australia to waive this type of special patient contribution where there is no clinically suitable alternative listed on the PBS at the benchmark price. Doctors are encouraged to seek a waiver whenever appropriate so that patients are not financially disadvantaged. Bleomycin is the only drug for which the SPC cannot be waived.

## Brand Substitution

Since 1 December 1994 there has been a policy of brand substitution. 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 bioequivalent or therapeutically equivalent or that justification for not needing bioequivalence 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 Responsible Persons have been able to vary claimed prices or reduce approved prices to pharmacist without reference to the PBPA.

The following table shows the effect of brand substitution\*

	2005-06	2006-07	2007-08	2008-09
Number of products** with a premium	345	360	353	337
Average brand premium	\$2.76	\$2.88	\$3.03	\$3.29
Weighted average brand premium***	\$1.76	\$1.83	\$2.17	\$2.10
Brand premium range	\$0.06 to \$79.48	\$0.09 to \$76.86	\$0.08 to \$76.86	\$0.08 to \$76.86
Prescriptions dispensed with a brand premium during the year (million)	30.1	27.9	25.2	19.9
Prescriptions dispensed at the benchmark level during the year (million)	51.9	52.7	53.0	56.7
Percentage at the benchmark level	63%	65%	68%	74%
Products** at the benchmark price	1014	1089	1183	1292

\* Figures only include those scripts processed by Medicare Australia, so general scripts that fall under the co-payment are not included.

\*\* Product is defined as a unique combination of 'brand name' and 'form and strength'.

\*\*\* Weighted average brand premium is calculated by:  
 $\text{scripts} \times \text{premium} = \text{total premium value}$ ,  
 $\text{total premium value} / \text{total scripts} = \text{weighted average brand premium}$

### Weighted Average Monthly Treatment Cost (WAMTC)

The WAMTC methodology applies to groups of drugs that are considered to be therapeutically similar by the PBAC. Under the evidence-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 offered by a Responsible Person of a drug in a WAMTC group.

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

- Therapeutic Group drugs; and
- Non-Therapeutic Group 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. It may be that the group could form a Therapeutic Group but has not been designated so by a decision of the Government.

There are currently six Therapeutic Group WAMTC groups:

- H<sub>2</sub> receptor antagonists (H<sub>2</sub>RA)(cimetidine, ranitidine, nizatidine, famotidine);
- Calcium Channel Blockers (CCB) (dihydropyridines) (amlodipine, felodipine, lercanidipine, nifedipine);
- ACE inhibitors (captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril);
- HMG Coenzyme A reductase inhibitors (statins) (pravastatin and simvastatin only);
- Proton Pump Inhibitors (PPIs) (esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole); and
- Angiotensin II receptor antagonists (ATRA) (candesartan, eprosartan, irbesartan, olmesartan, telmisartan).

As part of the 2009–2010 Budget, the Government announced the establishment of a new therapeutic group for higher potency HMG Coenzyme A reductase inhibitors (Statins-HP) (atorvastatin and rosuvastatin). This group will form a Therapeutic Group WAMTC Group.

There is currently no non-Therapeutic Group WAMTC group.

The review of WAMTC groups has been aligned with the respective ATC groups that are reviewed at each of the PBPA meetings. Due to a number of factors, including changes in the groups being reviewed, i.e. SSRI plus group is no longer in WAMTC review, and the impact of PBS reforms with the statutory price reductions delaying the implementation of WAMTC reviews for F2 drugs on 1 August, the PBPA endorsed the new schedule of reviews for the WAMTC groups.

<i>WAMTC Group</i>	<i>Drugs in WAMTC Group</i>	<i>Schedule for WAMTC Groups (PBPA meeting)</i>
H <sub>2</sub> Receptor Antagonists (H <sub>2</sub> RA)	cimetidine, ranitidine, nizatidine, famotidine	April
Calcium Channel Blockers (CCBs)	amlodipine, felodipine, lercanidipine, nifedipine	April
Angiotensin Converting Enzyme (ACE) inhibitors	captopril, enalapril, fosinopril, lisinopril, perindopril, quinapril, ramipril, trandolapril	August
HMG Coenzyme A reductase inhibitors (Statins)	pravastatin, simvastatin	August
Angiotensin II Receptor Antagonists (ATRAAs)	candesartan, eprosartan, irbesartan, olmesartan, telmisartan	December
Proton Pump Inhibitors (PPIs)	esomeprazole, omeprazole, lansoprazole, pantoprazole, rabeprazole	December

The PPIs group was reviewed in December 2008, with resultant price adjustments applied from 1 April 2009.

The other WAMTC group scheduled for review in December 2008 was H<sub>2</sub>RA group.

The PBPA Secretariat has been approached by sponsors over the last year requesting that the H<sub>2</sub>RA WAMTC review be discontinued. To date the arguments put forward by sponsors have not been supported by the WAMTC guidelines and the H<sub>2</sub>RA WAMTC reviews have proceeded in accordance with those guidelines.

At the December 2008 PBPA meeting, members endorsed the Secretariat to proceed with the annual WAMTC review for H<sub>2</sub>RA and present the outcomes of this review at the April 2009 meeting.

The CCBs and H<sub>2</sub>RA groups were reviewed in April 2009, with the resultant price reductions to be applied on 1 August 2009.

## 12.5% Price Reduction Policy

Since October 2004, for the first new generic brand of a medicine already listed on the PBS, the Responsible Person must offer a price reduction of at least 12.5% compared to the current lowest priced brand.

From 1 August 2005 until 1 August 2007, 12.5% price reductions were applied administratively with agreement from industry. During this period 67 brands received 12.5% price reductions.

Since 1 August 2007 the 12.5% price reductions, triggered by the first listing of a new generic brand, are applied with statutory authority through the *National Health Act 1953*. In the 2008-2009 financial year there has been three rounds of reductions, occurring in August 2008 and December 2008 and April 2009 and a total of six new brands of drug have triggered 12.5% price reductions.

## CHAPTER 4

### Pharmaceutical Benefits Scheme (PBS) Reforms

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#### Overview of PBS reforms as it relates to PBPA considerations

From 1 August 2007, drugs on the PBS are included in separate formularies:

- a. Formulary 1 (F1) which comprises drugs with only a single brand;
- b. Formulary 2 (F2) comprising drugs with multiple brands and single brand drugs that are in a Therapeutic Group with a drug that has multiple brands.

For a transitional period, from 1 August 2007 until 31 December 2010, F2 will be divided into two parts: F2T and F2A. On 1 January 2011, F2T and F2A will be merged into a single formulary – F2.

The separation of drugs into F1 and F2 allows the Commonwealth to pay competitive prices for multiple brand drugs without affecting the viability of single-brand drugs that do not operate in a competitive market. This is achieved through de-linking the prices of drugs in F1 from the prices of drugs in F2 and then applying statutory price reductions to drugs in F2. In addition, it is anticipated that eventually, all drugs in F2 will be subject to price disclosure, thus reflecting real market prices.

From 1 August 2007, price links will exist between:

- a. drugs in F1 where the drugs are in the same Reference Pricing Group or Therapeutic Group;
- b. drugs in F2 that are members of a Therapeutic Group; and
- c. drugs listed on the Combination Drugs List and the individually listed component drugs (which may be in F1 or F2).

Formularies will affect the ongoing pricing arrangements for drugs once they are listed. However, the formularies are not intended to alter the current price setting practices for the listing of new drugs/items or extensions to listings. Consequently, comparators for an F1 drug may be in F2 and vice versa and form the basis of PBAC assessment of clinical benefit and cost-effectiveness of the drug, and subsequently PBPA consideration of price.

In order to meet the requirements of the above policies, the Reference Pricing Group document which groups drugs whose prices are linked has been amended to contain only drugs in F1 or drugs on the Combination Drugs List.

The Department of Health and Ageing publishes the names of drugs on the formularies on its website and updates the list monthly to reflect the latest version of the Schedule of Pharmaceutical Benefits.

The Department of Health and Ageing also publishes the Reference Pricing group and Therapeutic Relativity Sheets on a regular basis to reflect changes in these documents.

## CHAPTER 5

### The Highly Specialised Drugs Program

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#### Program overview

In addition to the drugs available under usual PBS arrangements, a number of drugs are also made available under alternative arrangements where the normal supply arrangements are inadequate or where the drugs cannot be conveniently or efficiently supplied.

These alternative arrangements are provided for under Section 100 (s100) of the *National Health Act 1953*. One of the programs under s100 is the Highly Specialised Drugs (HSD) Program. The Australian Government provides funding for medicines under the HSD Program.

Highly Specialised Drugs are for the treatment of chronic conditions, which, because of their clinical use or other specialist requirements, are restricted to supply through public and private hospitals that have appropriate specialist facilities. To prescribe these drugs as pharmaceutical benefit items, medical practitioners are required to be affiliated with these specialist hospital units.

The Access and Systems Branch, of the Pharmaceutical Benefits Division, administer the HSD Program while the process of selecting and reviewing drugs 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.

To gain access to a Government funded drug under this program, a patient must attend a participating hospital and be a day admitted patient, a non-admitted patient or a patient on discharge. Government subsidy is not available for hospital in-patients and funding for any in-patient use is provided by the state in public hospitals. Patients must also be under appropriate specialist medical care, meet the specific medical criteria and be an Australian resident in Australia (or other eligible person).

A patient will be required to pay a contribution for each supply of a Highly Specialised Drug at a similar rate to the PBS.

### Highly Specialised Drugs Working Party

The Australian Health Ministers' Advisory Council established the Highly Specialised Drugs Working Party in 1991. The Working Party 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 public hospitals under the section 100 arrangements to patients in community settings.

### Program expenditure

During 2008–2009 there were 83 drugs subsidised under the HSD Program, compared to 2007–2008 when there were 78. There were five new drugs listed under the HSD Program during 2008–2009. These new drug listings are:

1. Raltegravir Potassium
2. Natalizumab
3. Cinacalcet Hydrochloride
4. Telbivudine
5. Lanthanum Carbonate Hydrate

The Government expenditure for 2008-2009 amounted to \$775.8 million. Drugs were categorised as follows<sup>1</sup>:

<i>Indications Grouping</i>	<i>Number of Drugs</i>	<i>Public Hospital</i>	<i>Private Hospital</i>	<i>Combined</i>
Acromegaly Agents	2	\$15,307,661	\$8,189,914	\$23,497,575
Antiarthritic Agents	4	\$11,869,821	\$53,294,592	\$65,164,413
Bisphosphonate Agents	3	\$12,562,835	\$11,056,001	\$23,618,836
Haemopoietic Agents	6	\$103,865,666	\$33,809,524	\$137,675,190
Hepatitis B or C Agents	10	\$61,065,921	\$18,048,373	\$79,114,294
HIV/AIDS Antiretroviral Agents	24	\$145,598,142	\$600,608	\$146,198,750
Immunocompromised Conditions	10	\$10,356,629	\$390,413	\$10,747,042
Immunosuppressive Agents	7	\$64,069,569	\$5,878,942	\$69,948,511
Iron Overload Agents	3	\$11,291,622	\$3,640,917	\$14,932,539
Malignancy Agents	5	\$57,899,504	\$38,976,857	\$96,876,361
Other Conditions	4	\$64,590,179	\$9,850,400	\$74,440,579
Pulmonary Arterial Hypertension Agents	5	\$3,663,310	\$29,922,653	\$33,585,963
<b>Grand Total</b>	<b>83</b>	<b>\$562,140,859</b>	<b>\$213,659,194</b>	<b>\$775,800,053</b>

1. All expenditure figures quoted in the table refer to Government expenditure, which is total cost minus the patient co-payment. Some figures in this table are subject to final reconciliation with each state and territory and may change slightly.

Government expenditure based on utilisation through the HSD program in 2007-2008 was \$672.8 million. Before reconciliation, 2008-2009 costs totalled \$775.8 million, an increase of 15.3 per cent from 2007-2008. At the end of the 2008-2009 financial year, payments made to public hospitals via grants to the States and Territories will be reconciled against the actual drug usage.

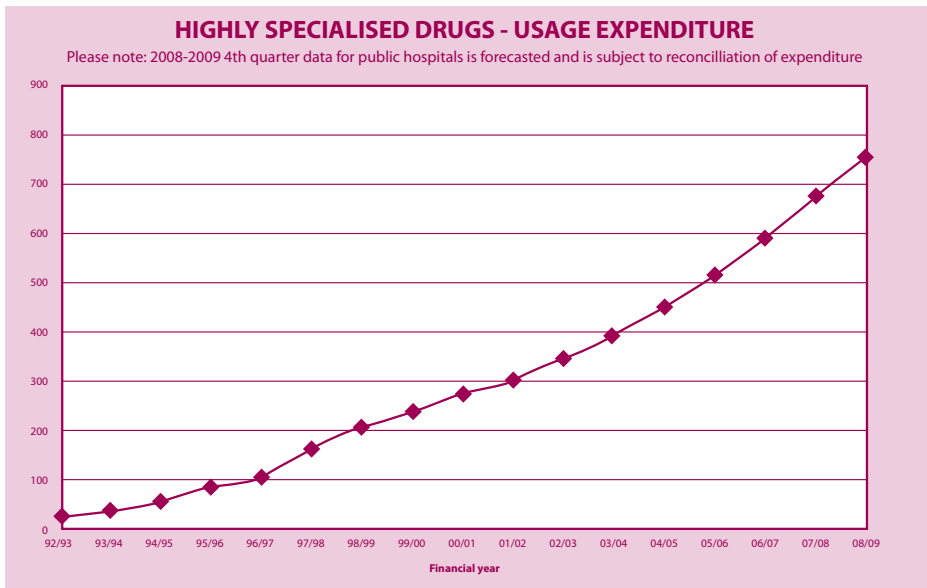
In 2008-2009, the Australian Government expenditure for HSDs was processed through two avenues; a grant process for public hospitals administered by the Department of Health and Ageing and a claims payment arrangement administered through Medicare Australia for private hospitals.

HSD expenditure based on utilisation in public hospitals in 2008-2009 was \$562.1 million, an increase of 12.9 per cent from the 2007-2008 expenditure of \$497.9 million. The expenditure processed through Medicare Australia showed an increase of 22.2 per cent from the \$174.9million in 2007-2008 to \$213.7 million in 2008-2009.

The HSD Program continues to increase at a steady rate across both public and private hospitals. The increase in expenditure over the last few years is due to the increase in number of drugs listed on the program and the increase of new private hospitals participating in the program.

### The Highly Specialised Drugs – Usage Government<sup>2</sup> Expenditure Chart

The Highly Specialised Drugs Usage Government Expenditure chart outlines the program’s Government expenditure from 1992-1993 to 2008-2009 financial years.



2. All expenditure figures quoted in chart refer to Government expenditure, which is total cost minus the patient co-payment.

## Move from Special Purpose Payments to Commonwealth Own Purpose Expenditure Arrangements

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In 2008, the Council of Australian Government (COAG), in conjunction with the Department of Health and Ageing, agreed to cease funding public patient access to HSDs through Special Purpose Payments (SPPs) to states and territories, and fund these payments through an alternative Commonwealth Own Purpose Expenditure (COPE) mechanism.

From 1 July 2009, payments for HSDs supplied through public hospitals will move from monthly advance payments by the Department of Health and Ageing, to payments in arrears by Medicare Australia following dispensing. This will be consistent with the arrangements for private hospitals and community pharmacies.

Under the transition to COPE arrangements, payments for these claims are initially being made through an offline solution to state and territory health departments. Beginning in 2010, Medicare Australia will transition hospitals to PBS Online in a phased approach over a three year period. The utilisation of PBS Online in public hospitals will enable real-time claiming by hospital pharmacies direct to Medicare Australia.

## CHAPTER 6

### Tables

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**Table 1: Pharmaceutical Benefits Scheme – Summary of ATC Group Reviews for 2008-2009**

ATC group	Minor Group	No. of Products Reviewed	Script Volume	Govt cost \$	Total cost \$	Estimated cost to Government of Price Increases \$
A01	Stomatological preparations	8	215,545	1,524,772	2,320,668	79,309
A02	Drugs for acid related disorders	93	15,664,402	465,366,346	624,069,644	-
A03	Drugs for functional gastrointestinal disorders	7	736,177	4,722,853	7,289,633	70,606
A04	Antiemetics and antinauseants	60	851,383	18,270,677	24,953,438	-
A05	Bile and liver Therapy	1	28,348	7,017,780	7,416,596	286,675
A06	Laxatives	20	816,062	14,200,107	17,239,226	17,558
A07	Antidiarrheals, inestinal antiinflammatory/ antiinfective agents	34	870,678	53,338,300	63,632,479	313,819
A09	Digestives, incl. enzymes	5	64,423	9,368,098	10,055,648	-
A10	Drugs used in diabetes	105	6,618,703	309,835,649	346,811,563	-
A11	Vitamins	6	144,765	5,266,221	6,518,891	-
A12	Mineral supplements	7	289,681	2,742,989	3,770,673	5,998
A14	Anabolic agents for systemic use	1	7,942	140,385	168,149	-
B01	Antithrombotic agents	43	6,815,375	259,875,853	302,788,420	-
B02	Antithemorrhagics	1	36,104	1,053,097	1,831,621	-
B03	Antianemic preparations	8	648,277	8,336,029	11,354,156	-
B05	Blood substitutes and perfusion solutions	11	35,305	903,516	1,111,588	-
C01	Cardiac therapy	66	3,147,540	59,368,769	73,302,204	-
C02	Antihypertensives	24	864,176	11,684,503	15,160,799	118,383
C03	Diuretics	39	2,219,706	19,270,334	27,563,897	-
C04	Peripheral vasodilators	3	2,226	1,482,095	1,504,973	-
C07	Beta blocking agents	80	5,625,356	97,915,215	124,792,783	-
C08	Calcium channel blockers	90	7,126,274	118,658,046	148,391,215	-
C09	Agents acting on the renin-angiotensin system	280	20,799,632	423,466,235	531,517,082	-
C10	Lipid modifying agents	287	22,425,722	1,157,766,315	1,420,351,269	-

**Table 1: Pharmaceutical Benefits Scheme – Summary of ATC Group Reviews for 2008–2009 (continued)**

ATC group	Minor Group	No. of Products Reviewed	Script Volume	Govt cost \$	Total cost \$	Estimated cost to Government of Price Increases \$
D01	Antifungals for dermatological use	29	104,474	7,773,619	9,434,074	-
D05	Antipsoriatics	6	94,149	8,790,618	9,839,628	-
D06	Antibiotics and chemotherapeutics for dermatological use	2	44,362	772,211	955,170	-
D07	Corticosteroids, dermatological preparations	38	2,219,782	30,596,463	42,501,133	1,602,518
D10	Anti-acne preparations	9	152,622	17,455,030	21,513,326	-
D11	Other dermatological preparations	2	41,112	3,067,496	3,859,352	-
G02	Other gynecologicals	7	99,811	17,071,939	19,455,108	-
G03	Sex hormones and modulators of the genital system	118	2,728,890	70,826,452	89,300,507	75,334
G04	Urologicals	4	205,748	2,551,497	3,325,163	-
H01	Pituitary and hypothalamic hormones and analogues	8	68,272	8,042,384	9,302,602	-
H02	Corticosteroids for systemic use	33	1,765,048	12,978,736	20,009,487	67,057
H03	Thyroid therapy	9	794,921	16,828,719	20,490,347	30,700
H04	Pancreatic hormones	1	46,262	1,693,049	2,004,712	94,191
H05	Calcium homeostasis	5	4,163	2,067,384	2,099,980	-
J01	Antibacterials for systemic use	349	12,137,391	120,280,150	178,464,644	1,095,489
J02	Antimycotics for systemic use	27	54,507	12,770,812	13,488,337	32,427
J04	Antimycobacterials	8	10,267	457,385	550,891	-
J05	Antivirals for systemic use	33	529,913	88,240,850	100,565,026	-
J07	Vaccines	7	550,734	14,206,003	17,436,338	-
L01	Antineoplastic agents	206	584,120	441,788,063	450,380,993	-
L02	Endocrine therapy	42	564,689	153,530,228	161,144,188	-
L03	Immunostimulants	21	96,068	101,868,083	103,750,941	-
L04	Immunosuppressants	78	460,786	243,151,556	250,765,693	-
M01	Antiinflammatory and antirheumatic products	94	4,863,879	89,065,965	114,698,770	574,258
M03	Muscle relaxants	18	140,636	5,570,198	6,679,989	-
M04	Antigout preparations	17	892,368	7,136,272	10,644,046	122,643

Table 1: Pharmaceutical Benefits Scheme Summary of ATC Group Reviews for 2008 - 2009 (continued)

ATC group	Minor Group	No. of Products Reviewed	Script Volume	Govt cost \$	Total cost \$	Estimated cost to Government of Price Increases \$
M05	Drugs for treatment of bone diseases	28	3,405,784	155,468,769	180,208,843	-
N02	Analgesics	159	11,575,006	237,834,865	287,750,342	1,318,384
N03	Antiepileptics	133	1,870,241	96,155,958	115,129,277	135,676
N04	Anti-Parkinson drugs	40	684,574	39,185,183	44,056,188	-
N05	Psycholeptics	132	7,754,497	393,862,776	434,576,649	23,567
N06	Psychoanaleptics	179	12,436,470	354,554,496	469,480,533	304,653
N07	Other nervous system drugs	19	558,803	72,812,386	84,053,747	1,547
P01	Antiprotozoals	5	2,888	96,912	108,334	-
P02	Anthelmintics	6	4,843	115,871	150,678	-
P03	Ectoparasitides, incl. scabicides, insecticides and repellents	1	45,151	523,151	733,673	-
R03	Drugs for obstructive airway diseases	80	9,503,507	385,717,371	475,774,894	-
R05	Cough and cold preparations	2	187,674	3,188,479	4,027,999	-
R06	Antihistamines for systemic use	1	24,962	513,713	538,645	-
S01	Ophthalmologicals	95	7,025,550	242,024,604	279,312,357	2,614,027
S02	Otologicals	9	660,740	2,895,630	5,587,632	186,274
S03	Ophthalmological and otological preparations	1	30,968	145,557	286,120	-
V01	Allergens	3	3,215	578,950	656,447	-
V03	All other therapeutic products	13	60,392	11,363,977	11,972,144	19,273
V04	Diagnostic agents	32	433,226	20,154,070	22,702,318	-
V06	General nutrients	86	79,345	27,972,144	29,539,305	149,274
V07	All other non-therapeutic products	1	1,094	46,648	49,710	-
	*Ad hoc	119	178,421	2,567,986	3,418,674	3,122,238
	#Total (excludes section 100 drugs)	3,594	181,836,127	6,577,934,842	7,886,691,565	12,461,878

\*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 2009**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
1	8215	Atorvastatin Calcium	Tablet 40mg (atorvastatin)	3,727,483	244,466,817	292,760,170	78.54
2	8358	Clopidogrel Hydrogen Sulfate	Tablet 75mg (base)	2,584,471	189,629,792	211,620,605	81.88
3	8214	Atorvastatin Calcium	Tablet 20mg (atorvastatin)	3,669,275	163,843,044	210,835,722	57.46
4	8521	Atorvastatin Calcium	Tablet 80mg (atorvastatin)	1,313,197	127,329,163	143,987,092	109.65
5	1382	Ranibizumab	Solution for intravitreal injection 2.3mg in 0.23mL	59,534	123,544,176	124,073,183	2084.07
6	8601	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 40mg esomeprazole	2,346,606	109,740,628	137,151,486	58.45
7	8626	Tiotropium Bromide Monohydrate	Capsule containing powder for oral inhalation 18micrograms (base) (for use in HandiHaler)	1,390,860	97,137,287	106,294,683	76.42
8	8187	Olanzapine	Tablet 10mg	324,060	90,223,875	92,903,916	286.69
9	9043	Rosuvastatin Calcium	Tablet 10mg (rosuvastatin)	1,582,959	85,503,108	109,817,055	69.37
10	8008	Pantoprazole Sodium Sesquihydrate	Tablet (enteric coated), equivalent to 40mg pantoprazole	2,695,305	82,095,656	111,105,793	41.22
11	8173	Simvastatin	Tablet 40mg	2,224,612	79,787,973	102,119,307	45.90
12	8600	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 20mg esomeprazole	3,089,591	78,159,045	117,294,323	37.96
13	8519	Fluticasone Propionate with Salmeterol Xinafoate	Oral pressurised inhalation 250micrograms-25micrograms (base) per dose (120 doses), CFC-free formulation	1,043,574	68,402,334	81,681,664	78.27
14	9039	Insulin Glargine	Injections (human analogue) 100units per mL, 3mL, 5	164,346	67,475,910	69,606,267	423.53
15	8302	Venlafaxine Hydrochloride	Capsule 150mg (base) (modified release)	1,397,912	66,048,066	88,223,320	63.11
16	9110	Omeprazole	Tablet 20mg (as magnesium)	2,055,626	59,581,726	72,333,782	35.19
17	8213	Atorvastatin Calcium	Tablet 10mg (atorvastatin)	1,738,602	52,681,503	72,858,736	41.91
18	9044	Rosuvastatin Calcium	Tablet 20mg (rosuvastatin)	650,538	52,383,969	62,389,456	95.90
19	8508	Rabeprazole Sodium	Tablet 20mg (enteric coated)	1,796,198	51,640,181	73,696,133	41.03
20	8757	Ezetimibe	Tablet 10mg	839,523	49,607,539	59,350,978	70.70
21	8405	Irbesartan with Hydrochlorothiazide	Tablet 300mg-12.5mg	1,994,247	47,592,245	63,492,516	31.84
22	8134	Valaciclovir Hydrochloride	Tablet 500mg (base)	309,932	44,397,920	51,992,127	167.75
23	8093	Goserelin Acetate	Subcutaneous implant (long acting) 10.8mg (base) in pre-filled injection syringe	40,029	44,016,446	44,341,553	1107.74
24	9090	Etonercept	Injections 50mg in 1mL single use pre-filled syringes, 4	24,163	42,425,088	42,782,410	1770.58

**Table 2: Pharmaceutical Benefits Scheme - Highest Cost Items - 12 Months to 30 June 2009 (continued)**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
25	2012	Simvastatin	Tablet 20mg	1,565,796	42,314,801	53,437,520	34.13
26	8432	Fluticasone Propionate with Salmeterol Xinafoate	Powder for oral inhalation in breath actuated device 500micrograms-50micrograms (base) per dose (60 doses)	630,448	42,128,641	49,911,923	79.17
27	9114	Imatinib	Tablet 400mg (as mesylate)	9,790	41,200,652	41,372,666	4226.01
28	8243	Latanoprost	Eye drops 50micrograms per mL (0.005%), 2.5mL	1,326,025	40,780,649	51,482,569	38.82
29	8301	Venlafaxine Hydrochloride	Capsule 75mg (base) (modified release)	1,272,024	39,520,259	61,027,699	47.98
30	8511	Alendronate Sodium	Tablet equivalent to 70mg alendronic acid	972,144	38,464,439	45,425,124	46.73
31	8101	Interferon Beta-1B	Injection set including 1 vial powder for injection 8,000,000i.u. (250micrograms) and solvent	32,424	37,592,565	38,217,740	1178.69
32	8248	Ibuprofen	Tablet 300mg	1,351,287	34,649,254	40,320,116	29.84
33	9045	Rosuvastatin Calcium	Tablet 40mg (rosuvastatin)	279,802	33,354,241	37,521,174	134.10
34	8625	Budesonide with Formoterol Fumarate Dihydrate	Powder for oral inhalation in breath actuated device 200micrograms-6micrograms; per dose (120 doses)	752,057	32,384,688	43,827,624	58.28
35	8179	Anastrozole	Tablet 1mg	193,197	32,285,362	35,093,745	181.65
36	9129	Varenicline	Tablet 1mg (as tartrate)	148,067	31,250,047	34,382,074	232.21
37	8435	Insulin Aspart	Injections (human analogue) 100units per mL, 3mL, 5	127,247	30,854,956	32,843,700	258.11
38	8313	Simvastatin	Tablet 80mg	593,020	30,623,799	36,774,001	62.01
39	8294	Rituximab	Solution for I.V. infusion 500mg in 50mL	11,364	29,896,996	30,083,052	2647.22
40	8431	Fluticasone Propionate with Salmeterol Xinafoate	Powder for oral inhalation in breath actuated device 250micrograms-50micrograms (base) per dose (60 doses)	670,020	29,467,769	39,474,018	58.91
41	9100	Adalimumab	Injection 40mg in 0.8mL pre-filled pen	16,750	29,375,343	29,633,727	1769.18
42	8074	Docetaxel	Injection set containing 1 single use vial concentrate for I.V. infusion 80mg (anhydrous) in 2mL and 1 single use vial solvent 6mL	12,183	29,087,435	29,334,603	2407.83
43	9012	Alendronate Sodium with Colecalciferol	Tablet equivalent to 70mg alendronic acid with 70micrograms colecalciferol	720,408	28,665,002	33,669,730	46.74

**Table 2: Pharmaceutical Benefits Scheme - Highest Cost Items - 12 Months to 30 June 2009 (continued)**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
44	8440	Celecoxib	Capsule 200mg	1,123,477	28,506,423	36,402,830	32.40
45	8609	Insulin Aspart-Insulin Aspart Protamine Suspension	Injections (human analogue) 100units (30units-70units) per mL, 3mL, 5	111,786	28,022,317	29,112,815	260.43
46	8197	Pravastatin Sodium	Tablet 40mg	775,628	27,681,049	35,050,298	45.19
47	8881	Ezetimibe with Simvastatin	Tablet 10mg-40mg	278,458	27,101,147	30,446,331	109.34
48	8882	Ezetimibe with Simvastatin	Tablet 10mg-80mg	236,870	26,994,452	29,911,676	126.28
49	8185	Olanzapine	Tablet 5mg	249,245	26,352,870	28,684,550	115.09
50	2845	Perindopril with Indapamide Hemihydrate	Tablet containing 5mg perindopril arginine-1.25mg indapamide hemihydrate	1,024,584	25,613,697	30,279,212	29.55

**Table 3: Pharmaceutical Benefits Scheme - Most Prescribed Items - 12 Months to 30 June 2009**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
1	8215	Atorvastatin Calcium	Tablet 40mg (atorvastatin)	3,727,483	244,466,817	292,760,170	78.54
2	8214	Atorvastatin Calcium	Tablet 20mg (atorvastatin)	3,669,275	163,843,044	210,835,722	57.46
3	8600	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 20mg esomeprazole	3,089,591	78,159,045	117,294,323	37.96
4	1081	Atenolol	Tablet 50mg	3,026,809	19,083,706	31,475,208	10.40
5	8008	Pantoprazole Sodium Sesquihydrate	Tablet (enteric coated), equivalent to 40mg pantoprazole	2,695,305	82,095,656	111,105,793	41.22
6	8358	Clopidogrel Hydrogen Sulfate	Tablet 75mg (base)	2,584,471	189,629,792	211,620,605	81.88
7	8601	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 40mg esomeprazole	2,346,606	109,740,628	137,151,486	58.45
8	8173	Simvastatin	Tablet 40mg	2,224,612	79,787,973	102,119,307	45.90
9	9110	Omeprazole	Tablet 20mg (as magnesium)	2,055,626	59,581,726	72,333,782	35.19
10	8288	Salbutamol Sulfate	Oral pressurised inhalation 100micrograms (base) per dose (200 doses), CF-free formulation	2,053,989	22,877,482	30,972,784	15.08
11	8405	Irbesartan with Hydrochlorothiazide	Tablet 300mg-12.5mg	1,994,247	47,592,245	63,492,516	31.84
12	3119	Cephalexin	Capsule 500mg	1,845,155	11,718,979	19,671,011	10.66
13	8508	Rabeprazole Sodium	Tablet 20mg (enteric coated)	1,796,198	51,640,181	73,696,133	41.03
14	2089	Temazepam	Tablet 10mg	1,788,016	6,567,679	13,341,877	7.46
15	8213	Atorvastatin Calcium	Tablet 10mg (atorvastatin)	1,738,602	52,681,503	72,858,736	41.91
16	1215	Codeine Phosphate with Paracetamol	Tablet 30mg-500mg	1,595,727	7,033,747	13,481,657	8.45
17	9043	Rosuvastatin Calcium	Tablet 10mg (rosuvastatin)	1,582,959	85,503,108	109,817,055	69.37
18	2012	Simvastatin	Tablet 20mg	1,565,796	42,314,801	53,437,520	34.13
19	3162	Diazepam	Tablet 5mg	1,449,288	5,001,038	10,941,446	7.55
20	8302	Venlafaxine Hydrochloride	Capsule 150mg (base) (modified release)	1,397,912	66,048,066	88,223,320	63.11
21	8626	Tiotropium Bromide Monohydrate	Capsule containing powder for oral inhalation 18micrograms (base) (for use in HandiHaler)	1,390,860	97,137,287	106,294,683	76.42
22	8248	Irbesartan	Tablet 300mg	1,351,287	34,649,254	40,320,116	29.84
23	8243	Latanoprost	Eye drops 50micrograms per mL (0.005%), 2.5mL	1,326,025	40,780,649	51,482,569	38.82
24	1889	Amoxicillin	Capsule 500mg	1,316,630	7,944,241	13,810,121	10.49
25	8521	Atorvastatin Calcium	Tablet 80mg (atorvastatin)	1,313,197	127,329,163	143,987,092	109.65

**Table 3: Pharmaceutical Benefits Scheme – Most Prescribed Items – 12 Months to 30 June 2009 (continued)**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
26	8254	Amoxicillin with Clavulanic Acid	Tablet 875mg-125mg	1,279,805	13,426,612	18,970,378	14.82
27	8814	Paracetamol	Tablet 665mg (modified release)	1,277,266	13,778,514	18,551,224	14.52
28	8301	Venlafaxine Hydrochloride	Capsule 75mg (base) (modified release)	1,272,024	39,520,259	61,027,699	47.98
29	8784	Paracetamol	Tablet 500mg	1,263,173	11,119,321	15,308,918	12.12
30	2430	Metformin Hydrochloride	Tablet 500mg	1,230,693	11,265,901	15,920,209	12.94
31	9007	Perindopril	Tablet containing 5mg perindopril arginine	1,186,594	17,833,180	22,865,705	19.27
32	8247	Irbesartan	Tablet 150mg	1,180,205	23,982,544	29,068,646	24.63
33	8470	Ramipril	Capsule 10mg	1,158,750	23,180,034	28,014,035	24.18
34	8440	Celecoxib	Capsule 200mg	1,123,477	28,506,423	36,402,830	32.40
35	8202	Aspirin	Tablet 100mg	1,067,340	4,325,417	8,124,182	7.61
36	9008	Perindopril	Tablet containing 10mg perindopril arginine	1,062,007	23,219,904	27,684,457	26.07
37	8519	Fluticasone Propionate with Salmeterol Xinafoate	Oral pressurised inhalation 250micrograms-25micrograms (base) per dose (120 doses), (CFC-free formulation)	1,043,574	68,402,334	81,681,664	78.27
38	2845	Perindopril with Indapamide Hemihydrate	Tablet containing 5mg perindopril arginine-1.25mg indapamide hemihydrate	1,024,584	25,613,697	30,279,212	29.55
39	2412	Fruosemide	Tablet 40mg	1,010,420	5,069,134	8,506,453	8.42
40	8220	Citalopram Hydrobromide	Tablet 20mg (base)	980,039	21,021,702	28,521,611	29.10
41	8511	Alendronate Sodium	Tablet equivalent to 70mg alendronic acid	972,144	38,464,439	45,425,124	46.73
42	2751	Amlodipine	Tablet 5mg (as besylate)	955,814	12,316,669	16,293,249	17.05
43	8535	Gliclazide	Tablet 30mg (modified release)	949,327	9,300,170	12,818,713	13.50
44	1324	Metoprolol Tartrate	Tablet 50mg	912,153	5,990,027	9,552,064	10.47
45	8607	Metformin Hydrochloride	Tablet 1g	862,889	12,283,962	15,492,975	17.95
46	2843	Warfarin Sodium	Tablet 1mg	848,762	6,797,380	9,891,322	11.65
47	8757	Ezetimibe	Tablet 10mg	839,523	49,607,539	59,350,978	70.70
48	8504	Candesartan Cilexetil with Hydrochlorothiazide	Tablet 16mg-12.5mg	831,854	20,129,756	26,972,934	32.43
49	3133	Oxazepam	Tablet 30mg	821,712	2,995,100	6,073,065	7.39
50	1746	Paracetamol	Tablet 500mg	818,551	3,866,710	6,539,191	7.99

**Table 4: Pharmaceutical Benefits Scheme - Top 20 Responsible Persons by Total Cost for 2008-2009 (from processed PBS prescriptions)**

Rank	Manufacturer	Script Volume	Govt Cost (\$)	Total Cost (\$)	Sales (Ex-Manufacturer) (\$)
1	Pfizer	18,494,607	912,351,252	1,112,369,381	844,482,192
2	AstraZeneca	16,185,045	734,676,155	907,411,060	683,439,477
3	Sanofi-Aventis	15,257,367	553,435,022	644,615,222	472,219,828
4	Alphapharm	26,291,316	358,435,227	484,916,794	269,969,257
5	GlaxoSmithKline	8,717,625	345,566,211	427,039,481	315,573,566
6	Novartis	2,540,321	316,809,545	334,778,852	290,059,848
7	Sigma	17,294,052	248,281,181	331,172,320	186,618,024
8	Merck Sharp & Dohme	5,613,681	243,872,982	292,957,640	217,490,086
9	Wyeth	4,140,422	228,116,172	285,440,705	225,360,971
10	Eli Lilly	1,909,320	259,545,995	279,365,536	228,630,634
11	Janssen-Cilag	3,636,757	235,344,485	273,953,367	213,596,224
12	Bristol Myers Squibb	5,981,384	229,405,478	266,708,561	195,404,930
13	Boehringer Ingelheim	5,312,583	192,055,814	219,965,243	156,955,787
14	Roche Products	1,865,916	171,248,080	185,012,406	154,805,607
15	Abbott	1,517,294	152,194,628	160,684,712	137,704,746
16	Apotex	6,811,204	121,727,050	158,562,916	95,546,814
17	Nycomed	3,312,597	96,592,681	131,062,046	90,995,616
18	Novo Nordisk	929,905	117,774,472	125,513,251	103,336,244
19	Servier	5,511,469	96,704,320	120,266,934	72,137,052
20	Mundipharma	2,297,782	105,716,870	118,202,695	81,273,471
	Others	28,215,480	858,081,221	1,026,692,442	724,113,171
	Total	181,836,127	6,577,934,842	7,886,691,565	5,759,713,548

Note: Includes branded and unbranded scripts and Doctor's bag scripts. 'Others' contains scripts written for Extemporaneously-prepared items and where the manufacturer is unknown.

**Table 5: Pharmaceutical Benefits Scheme – Top 20 Responsible Persons by Market Share (Scripts) for 2008–2009 (from processed PBS prescriptions)**

Rank	Manufacturer	Script Volume	Govt Cost (\$)	Total Cost (\$)	% of Total	Sales (Ex-Manufacturer) (\$)
1	Alphapharm	26,291,316	358,435,227	484,916,794	14.46	269,969,257
2	Pfizer	18,494,607	912,351,252	1,112,369,381	10.17	844,482,192
3	Sigma	17,294,052	248,281,181	331,172,320	9.51	186,618,024
4	AstraZeneca	16,185,045	734,676,155	907,411,060	8.90	683,439,477
5	Sanofi-Aventis	15,257,367	553,435,022	644,615,222	8.39	472,219,828
6	GlaxoSmithKline	8,717,625	345,566,211	427,039,481	4.79	315,573,566
7	Apotex	6,811,204	121,727,050	158,562,916	3.75	95,546,814
8	Bristol Myers Squibb	5,981,384	229,405,478	266,708,561	3.29	195,404,930
9	Merck Sharp & Dohme	5,613,681	243,872,982	292,957,640	3.09	217,490,086
10	Senvier	5,511,469	96,704,320	120,266,934	3.03	72,137,052
11	Boehringer Ingelheim	5,312,583	192,055,814	219,965,243	2.92	156,955,787
12	Wyeth	4,140,422	228,116,172	285,440,705	2.28	225,360,971
13	Sandoz	4,091,354	76,111,732	98,136,085	2.25	60,326,457
14	Janssen-Cilag	3,636,757	235,344,485	273,953,367	2.00	213,596,224
15	Nycomed	3,312,597	96,592,681	131,062,046	1.82	90,995,616
16	Aspen	2,921,644	24,652,851	37,617,462	1.61	16,483,880
17	Novartis	2,540,321	316,809,545	334,778,852	1.40	290,059,848
18	Mundipharma	2,297,782	105,716,870	118,202,695	1.26	81,273,471
19	Solvay	2,276,537	56,653,291	71,278,575	1.25	47,411,540
20	Hospira	2,196,857	79,989,318	91,907,483	1.21	66,898,329
	Total Top 20	158,884,604	5,256,497,638	6,408,362,824	87%	4,602,243,351
	Others	22,951,523	1,321,437,204	1,478,328,741	13%	1,157,470,197
	Total	181,836,127	6,577,934,842	7,886,691,565	100%	5,759,713,548

Note: Includes branded and unbranded scripts and Doctor's bag scripts. 'Others' contains scripts written for Extemporaneously-prepared items and where the manufacturer is unknown.

**Table 6(a): Pharmaceutical Benefits Scheme - Significant Drug Groups (incl Doctor's Bag) by Highest Government Cost - Year end June 2008 to Year end June 2009**

ATC Group Level 2	Year Ending June 2008				Year Ending June 2009							
	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	(%diff)	(%diff)	(%diff)	(%diff)
Lipid modifying agents	20,412,460	1,057,703,802	1,290,215,470	63.21	22,425,722	1,157,766,315	1,420,351,269	63.34	9.9	9.5	10.1	0.2
Drugs for acid related disorders	15,009,069	446,323,494	602,215,990	40.12	15,664,402	465,366,346	624,069,644	39.84	4.4	4.3	3.6	-0.7
Antineoplastic agents	517,034	322,532,788	329,831,405	637.93	584,120	441,788,063	450,380,993	771.04	13.0	37.0	36.5	20.9
Agents acting on the renin-angiotensin system	19,187,089	400,500,965	493,236,045	25.71	20,799,632	423,466,235	531,517,082	25.55	8.4	5.7	7.8	-0.6
Psycholeptics	7,406,379	359,298,151	395,604,612	53.41	7,754,497	393,862,776	434,576,649	56.04	4.7	9.6	9.9	4.9
Drugs for obstructive airway diseases	9,125,482	368,273,792	451,322,773	49.46	9,503,507	385,717,371	475,774,894	50.06	4.1	4.7	5.4	1.2
Psychoanalitics	11,685,830	346,187,809	453,430,271	38.80	12,436,470	354,554,496	469,480,533	37.75	6.4	2.4	3.5	-2.7
Drugs used in diabetes	6,129,136	278,141,612	310,595,448	50.68	6,618,703	309,835,649	346,811,563	52.40	8.0	11.4	11.7	3.4
Antithrombotic agents	6,278,877	230,069,150	267,264,756	42.57	6,815,375	259,875,853	302,788,420	44.43	8.5	13.0	13.3	4.4
Immunosuppressants	395,365	181,470,780	187,628,691	474.57	460,786	243,151,556	250,765,693	544.21	16.5	34.0	33.6	14.7
Ophthalmologicals	6,739,664	170,579,957	204,625,902	30.36	7,025,550	242,024,604	279,312,357	39.76	4.2	41.9	36.5	30.9
Analgesics	10,756,891	201,031,062	245,376,193	22.81	11,575,006	237,834,865	287,750,342	24.86	7.6	18.3	17.3	9.0
Drugs for treatment of bone diseases	3,412,505	157,442,951	181,866,498	53.29	3,405,784	155,468,769	180,208,843	52.91	-0.2	-1.3	-0.9	-0.7
Endocrine therapy	514,780	141,305,991	147,957,988	287.42	564,689	153,530,228	161,144,188	285.37	9.7	8.7	8.9	-0.7
Antibacterials for systemic use	11,475,696	122,360,055	175,859,209	15.32	12,137,391	120,280,150	178,464,644	14.70	5.8	-1.7	1.5	-4.1
Calcium channel blockers	7,017,573	133,409,801	165,457,623	23.58	7,126,274	118,658,046	148,391,215	20.82	1.5	-11.1	-10.3	-11.7
Immunostimulants	92,251	97,888,847	99,623,226	1079.91	96,068	101,868,083	103,750,941	1079.97	4.1	4.1	4.1	0.0

**Table 6(b): Pharmaceutical Benefits Scheme - Significant Drug Groups (incl Doctor's Bag) by Highest Script Volume - Year end June 2008 to Year end June 2009**

ATC Group Level 2	Year Ending June 2008					Year Ending June 2009				
	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	(% diff)	(% diff)
Lipid modifying agents	20,412,460	1,057,703,802	1,290,215,470	63.21	22,425,722	1,157,766,315	1,420,351,269	63.34	9.9	10.1
Agents acting on the renin-angiotensin system	19,187,089	400,500,965	493,236,045	25.71	20,799,632	423,466,235	531,517,082	25.55	8.4	7.8
Drugs for acid related disorders	15,009,069	446,323,494	602,215,990	40.12	15,664,402	465,366,346	624,069,644	39.84	4.4	3.6
Psychoanalitics	11,685,830	346,187,809	453,430,271	38.80	12,436,470	354,554,496	469,480,533	37.75	6.4	3.5
Antibacterials for systemic use	11,475,696	122,360,055	175,859,209	15.32	12,137,391	120,280,150	178,464,644	14.70	5.8	1.5
Analgesics	10,756,891	201,031,062	245,376,193	22.81	11,575,006	237,834,865	287,750,342	24.86	7.6	17.3
Drugs for obstructive airway diseases	9,125,482	368,273,792	451,322,773	49.46	9,503,507	385,717,371	475,774,894	50.06	4.1	5.4
Psycholeptics	7,406,379	359,298,151	395,604,612	53.41	7,754,497	393,862,776	434,576,649	56.04	4.7	9.9
Calcium channel blockers	7,017,573	133,409,801	165,457,623	23.58	7,126,274	118,658,046	148,391,215	20.82	1.5	-10.3
Ophthalmologicals	6,739,664	170,579,957	204,625,902	30.36	7,025,550	242,024,604	279,312,357	39.76	4.2	36.5
Antithrombotic agents	6,278,877	230,069,150	267,264,756	42.57	6,815,375	259,875,853	302,788,420	44.43	8.5	13.3
Drugs used in diabetes	6,129,136	278,141,612	310,595,448	50.68	6,618,703	309,835,649	346,811,563	52.40	8.0	11.7
Beta blocking agents	5,347,163	95,520,429	119,689,120	22.38	5,625,356	97,915,215	124,792,783	22.18	5.2	4.3
Antiinflammatory and antirheumatic products	4,749,078	87,046,488	108,283,843	22.80	4,863,879	89,065,965	114,698,770	23.58	2.4	5.9
Drugs for treatment of bone diseases	3,412,505	157,442,951	181,866,498	53.29	3,405,784	155,468,769	180,208,843	52.91	-0.2	-0.9
Cardiac therapy	3,111,975	59,350,861	72,670,089	23.35	3,147,540	59,368,769	73,302,204	23.29	1.1	0.9
Sex hormones and modulators of the genital system	2,792,230	68,688,592	86,621,982	31.02	2,728,890	70,826,452	89,300,507	32.72	-2.3	3.1

**Table 7(a): Pharmaceutical Benefits Scheme - Significant Drugs (incl Doctor's Bag) Sorted by Highest Change to Government Cost - Year end June 2008 to Year end June 2009**

Rank	Drug	Year Ending June 2008				Year Ending June 2009				Change	
		Volume	Govt Cost (\$)	Total Cost(\$)	Average Price (\$)	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Govt Cost (\$)	%
1	Rosuvastatin Calcium	1,504,336	93,651,497	115,787,443	76.97	2,959,028	187,561,016	232,271,108	78.50	93,909,519	100.28
2	Ramibizumab	31,240	63,974,200	64,266,594	2057.19	59,541	123,557,706	124,086,801	2,084.06	59,583,506	93.14
3	Imatinib	5,934	24,024,284	24,126,032	4065.73	18,527	76,850,649	77,169,121	4,165.22	52,826,365	219.89
4	Atonvastatin Calcium	9,866,405	544,148,644	665,454,521	67.45	10,510,102	591,700,692	724,642,901	68.95	47,552,048	8.74
5	Varenicline	107,550	12,680,048	14,754,514	137.19	450,302	55,993,284	65,617,671	145.72	43,313,236	341.59
6	Adalimumab	35,926	62,106,436	62,679,097	1,744.67	57,608	103,129,217	104,165,718	1,808.18	41,022,780	66.05
7	Esomeprazole Magnesium Trihydrate	4,780,929	166,227,430	223,161,239	46.68	5,544,594	190,655,025	258,553,147	46.63	24,427,595	14.70
8	Insulin Glargine	117,591	48,026,507	49,540,331	421.29	164,346	67,475,910	69,606,267	423.53	19,449,403	40.50
9	Clopidogrel Hydrogen Sulfate	2,309,279	171,178,105	189,701,902	82.15	2,584,471	189,629,792	211,620,605	81.88	18,451,687	10.78
10	Etanercept	42,087	73,323,632	73,997,543	1758.20	51,963	91,490,163	92,380,764	1,777.82	18,166,532	24.78
11	Amlodipine Besylate with Atonvastatin Calcium	367,823	27,901,808	32,189,249	87.51	617,790	44,470,852	52,363,022	84.76	16,569,044	59.38
12	Quetiapine Fumarate	316,415	57,070,262	59,925,723	189.39	431,096	71,633,399	75,755,830	175.73	14,563,138	25.52
13	Progiltazone Hydrochloride	224,825	18,357,701	20,521,568	91.28	373,747	30,347,842	34,202,725	91.51	11,990,141	65.31
14	Pantoprazole Sodium Sesquihydrate	2,868,405	83,098,361	111,599,941	38.91	3,249,745	94,845,168	128,567,658	39.56	11,746,807	14.14
15	Oxycodone Hydrochloride	1,509,547	49,700,137	56,804,787	37.63	1,791,805	61,129,320	70,057,943	39.10	11,429,183	23.00
16	Fentanyl	238,426	22,256,370	23,899,337	100.24	347,793	33,589,991	36,044,174	103.64	11,333,622	50.92
17	Risedronate Sodium and Calcium Carbonate with Colecalciferol	3,091	134,521	159,957	51.75	242,151	10,937,934	12,791,401	52.82	10,803,412	8031.02
18	Erlotinib	0	0	0	0.00	3,318	10,548,954	10,586,345	3,190.58	10,548,954	New
19	Rituximab	36,965	70,084,377	70,683,956	1912.19	41,454	80,430,571	81,105,977	1,956.53	10,346,194	14.76

**Table 7(a): Pharmaceutical Benefits Scheme - Significant Drugs (incl Doctor's Bag) Sorted by Highest Change to Government Cost - Year end June 2008 to Year end June 2009 (continued)**

Rank	Drug	Year Ending June 2008				Year Ending June 2009				Change	
		Volume	Govt Cost (\$)	Total Cost(\$)	Average Price (\$)	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Govt Cost (\$)	%
20	Venlafaxine Hydrochloride	2,493,259	97,230,944	135,780,979	54.46	2,751,308	107,474,364	151,558,803	55.09	10,243,420	10.54
21	Tiotropium Bromide Monohydrate	1,254,746	87,317,369	95,262,205	75.92	1,390,860	97,137,287	106,294,683	76.42	9,819,919	11.25
22	Buprenorphine	453,785	17,818,011	20,286,917	44.71	639,964	27,435,677	30,994,688	48.43	9,617,667	53.98
23	Budesonide with Eformoterol Fumarate Dihydrate	924,600	48,387,026	61,511,687	66.53	1,116,100	57,683,950	74,117,308	66.41	9,296,924	19.21
24	Ezetimibe with Simvastatin	378,441	44,848,913	49,352,912	130.41	515,328	54,095,598	60,358,007	117.13	9,246,685	20.62
25	Gandesartan Cilexetil	1,557,108	36,113,385	44,517,855	28.59	1,816,580	44,950,569	55,955,317	30.80	8,837,184	24.47
26	Sitagliptin	0	0	0	0.00	109,271	8,543,018	9,942,638	90.99	8,543,018	New
27	Risperidone	503,042	84,021,319	87,812,666	174.56	576,841	92,202,710	96,608,257	167.48	8,181,391	9.74
28	Docetaxel	16,900	34,592,578	34,914,792	2,065.96	20,314	42,367,703	42,773,052	2,105.59	7,775,125	22.48
29	Duloxetine Hydrochloride	97	3,330	4,921	50.73	227,490	7,617,534	11,565,650	50.84	7,614,204	228671.26
30	Irbesartan with Hydrochlorothiazide	2,245,601	56,195,649	65,781,458	29.29	2,719,448	63,393,192	84,502,463	31.07	7,197,543	12.81
31	Rabeprazole Sodium	1,841,907	51,644,566	73,507,885	39.91	2,065,671	58,469,528	83,882,499	40.61	6,824,962	13.22
32	Fluticasone Propionate with Salmeterol Xinafoate	2,702,298	149,808,946	186,764,601	69.11	2,797,781	156,630,533	195,538,304	69.89	6,821,586	4.55
33	Ezetimibe	735,737	43,324,791	51,667,303	70.23	839,523	49,607,539	59,350,978	70.70	6,282,748	14.50
34	Paracetamol	3,195,156	23,736,603	34,461,528	10.79	3,484,635	29,637,067	41,814,363	12.00	5,900,465	24.86
35	Bisoprolol Fumarate	235,852	14,567,739	16,490,974	69.92	334,961	20,397,002	23,269,099	69.47	5,829,262	40.01

**Table 7(b): Pharmaceutical Benefits Scheme - Significant Drugs (incl Doctor's Bag) - Sorted by Highest Volume Change - Year end June 2008 to Year end June 2009**

Rank	Drug	Year Ending June 2008					Year Ending June 2009					Change	
		Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Volume	Average Price (\$)	Volume	%
1	Rosuvastatin Calcium	1,504,336	93,651,497	115,787,443	76.97	2,959,028	187,561,016	232,271,108	78.50	1,454,692	96.70		
2	Esomeprazole Magnesium Trihydrate	4,780,929	166,227,430	223,161,239	46.68	5,544,594	190,655,025	258,553,147	46.63	763,665	15.97		
3	Atorvastatin Calcium	9,866,405	544,148,644	665,454,521	67.45	10,510,102	591,700,692	724,642,901	68.95	643,697	6.52		
4	Irbesartan with Hydrochlorothiazide	2,245,601	56,195,649	65,781,458	29.29	2,719,448	63,393,192	84,502,463	31.07	473,847	21.10		
5	Pantoprazole Sodium Sesquihydrate	2,868,405	83,098,361	111,599,941	38.91	3,249,745	94,845,168	128,567,658	39.56	381,340	13.29		
6	Varenicline	107,550	12,680,048	14,754,514	137.19	450,302	55,993,284	65,617,671	145.72	342,752	318.69		
7	Metformin Hydrochloride	2,766,870	33,181,747	43,239,190	15.63	3,064,053	32,668,021	44,326,176	14.47	297,183	10.74		
8	Paracetamol	3,195,156	23,736,603	34,461,528	10.79	3,484,635	29,637,067	41,814,363	12.00	289,479	9.06		
9	Oxycodone Hydrochloride	1,509,547	49,700,137	56,804,787	37.63	1,791,805	61,129,320	70,057,943	39.10	282,258	18.70		
10	Clopidogrel Hydrogen Sulfate	2,309,279	171,178,105	189,701,902	82.15	2,584,471	189,629,792	211,620,605	81.88	275,192	11.92		
11	Candesartan Cilexetil	1,557,108	36,113,385	44,517,855	28.59	1,816,580	44,950,569	55,955,317	30.80	259,472	16.66		
12	Venlafaxine Hydrochloride	2,493,259	97,230,944	135,780,979	54.46	2,751,308	107,474,364	151,558,803	55.09	258,049	10.35		
13	Amlodipine Besylate with Atorvastatin Calcium	367,823	27,901,808	32,189,249	87.51	617,790	44,470,852	52,363,022	84.76	249,967	67.96		
14	Risedronate Sodium and Calcium Carbonate with Colecalciferol	3,091	134,521	159,957	51.75	242,151	10,937,934	12,791,401	52.82	239,060	7734.07		
15	Duloxetine Hydrochloride	97	3,330	4,921	50.73	227,490	7,617,534	11,565,650	50.84	227,393	234425.77		
16	Rabeprazole Sodium	1,841,907	51,644,566	73,507,885	39.91	2,065,671	58,469,528	83,882,499	40.61	223,764	12.15		
17	Telmisartan	1,120,560	21,792,540	26,490,298	23.64	1,343,112	27,550,749	33,409,937	24.88	222,552	19.86		
18	Budesonide with Eformoterol Fumarate Dihydrate	924,600	48,387,026	61,511,687	66.53	1,116,100	57,683,950	74,117,308	66.41	191,500	20.71		

Table 7(b): Pharmaceutical Benefits Scheme - Significant Drugs (incl Doctor's Bag) - Sorted by Highest Volume Change - Year end June 2008 to Year end June 2009 (continued)

Rank	Drug	Year Ending June 2008				Year Ending June 2009				Change	
		Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Volume	%
19	Buprenorphine	453,785	17,818,011	20,286,917	44.71	639,964	27,435,677	30,994,688	48.43	186,179	41.03
20	Macrogol 3350	182,330	3,588,940	4,235,556	23.23	351,503	7,227,479	8,554,777	24.34	169,173	92.78
21	Telmisartan with Hydrochlorothiazide	581,638	13,597,620	16,024,207	27.55	739,733	18,221,131	21,434,592	28.98	158,095	27.18
22	Cephalexin	2,113,671	14,629,259	23,576,649	11.15	2,271,585	14,386,376	24,322,481	10.71	157,914	7.47
23	Warfarin Sodium	2,162,561	14,913,854	22,561,733	10.43	2,315,573	19,533,181	28,098,535	12.13	153,012	7.08
24	Amoxicillin with Clavulanic Acid	1,545,800	17,515,364	24,136,686	15.61	1,697,691	16,904,536	24,399,173	14.37	151,891	9.83
25	Pioglitazone Hydrochloride	224,825	18,357,701	20,521,568	91.28	373,747	30,347,842	34,202,725	91.51	148,922	66.24
26	Ezetimibe with Simvastatin	378,441	44,848,913	49,352,912	130.41	515,328	54,095,598	60,358,007	117.13	136,887	36.17
27	Celecoxib	1,177,512	31,645,029	36,380,844	30.90	1,314,229	33,201,492	42,420,069	32.28	136,717	11.61
28	Tiotropium Bromide Monohydrate	1,254,746	87,317,369	95,262,205	75.92	1,390,860	97,137,287	106,294,683	76.42	136,114	10.85
29	Alendronate Sodium with Colecalciferol	672,949	28,302,266	32,943,896	48.95	808,352	32,088,958	37,782,088	46.74	135,403	20.12
30	Escitalopram Oxalate	731,778	18,582,633	23,805,841	32.53	862,978	22,389,132	27,679,506	32.07	131,200	17.93
31	Amlodipine	1,977,329	38,063,256	47,431,533	23.99	2,099,063	34,731,978	43,465,698	20.71	121,734	6.16
32	Fenofibrate	332,577	8,589,237	12,874,040	38.71	452,619	12,312,536	18,286,229	40.40	120,042	36.09
33	Ibuprofen	2,800,022	59,258,309	70,637,519	25.23	2,919,203	64,979,269	77,367,687	26.50	119,181	4.26
34	Lercanidipine Hydrochloride	1,318,607	27,297,903	34,764,952	26.36	1,434,491	29,058,520	35,273,536	24.59	115,884	8.79
35	Quetiapine Fumarate	316,415	57,070,262	59,925,723	189.39	431,096	71,633,399	75,755,830	175.73	114,681	36.24

## List of Acronyms

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Acronym	Full Meaning
ATC	Anatomical Therapeutic Chemical
HSD	Highly Specialised Drugs
NIP	National Immunisation Program
OECD	Organisation for Economic Co-operation and Development
PBAC	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
SPC	Special Patient Contribution
TGP	Therapeutic Group Premium
WAMTC	Weighted Average Monthly Treatment Cost