

# PHARMACEUTICAL BENEFITS

## PRICING AUTHORITY

### ANNUAL REPORT

For the year ended 30 June 2010







**PHARMACEUTICAL**

**BENEFITS**

**PRICING**

**AUTHORITY**

**ANNUAL REPORT**

**For the year ended 30 June 2010**

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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-third 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 2010.

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



Michael Roche  
Chair  
2010

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## PREFACE

This is the twenty-third annual report of the Pharmaceutical Benefits Pricing Authority covering the operations of the PBPA for the year ended 30 June 2010.

### 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 2009-2010 financial year was:

Chair	Mr Michael Roche
Industry nominees	Dr Brendan Shaw – as the nominee of Medicines Australia Ms Kate Lynch – 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 Representatives	Ms Felicity McNeill – appointed with effect from February 2010 Ms Linda Jackson – immediate previous member
Department of Innovation, Industry, Science and Research Representative	Mr Peter Chesworth

## Meetings

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The PBPA met four times during the 2009-2010 financial year. The type and date of these meetings were as follows:

<i>Type of Meeting</i>	<i>Date</i>
Regular	19 August 2009
Special joint meeting with PBAC	22 September 2009
Regular	16 December 2009
Regular	21 April 2010

## 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 and consumer nominee, 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.

## PBPA Operating Costs

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For the year ended 30 June 2010 the PBPA operating costs were:

<i>PBPA operating costs</i>	<i>Total costs \$</i>
Direct costs including Chairman's and consumer nominees' expenses	17,427
Departmental Salaries	500,768
Members & secretariat travel and allowances	1,914
Administrative costs	4,662
Total costs	524,771

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## Secretariat Support

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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;~~\*

\* Factor (f) is no longer taken into consideration by PBPA when determining prices.

- 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.

### Establishing prices for new listings

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 2010 there were 90 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 2009-2010:

- Bevacizumab (Avastin®) for the treatment of metastatic colorectal cancer (also known as bowel cancer) was listed on 1 July 2009. Avastin has been shown to extend survival by up to four months; and
- Lenalidomide (Revlimid®) for the treatment of multiple myeloma (cancer of the bone marrow) was listed on 1 November 2009. Revlimid has been shown to extend survival by 11 months.

## 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. The therapeutic relativity sheets can be found at <http://www.pbs.gov.au>.

## 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	19 August 2009
M	Musculoskeletal system	19 August 2009
N	Nervous system	19 August 2009
P	Antiparasitic products	19 August 2009
	Section 100 items	19 August 2009
A	Alimentary tract & metabolism	16 December 2009
S	Sensory organs	16 December 2009
V	Various	16 December 2009
H	Systemic hormonal preparations, excluding sex hormones	16 December 2009
J	General antiinfectives for systemic use	16 December 2009
B	Blood & blood forming organs	21 April 2010
C	Cardiovascular system	21 April 2010
L	Antineoplastics & immunomodulating agents	21 April 2010
R	Respiratory system	21 April 2010
G	Genito urinary system & sex hormones	21 April 2010

## Statistical summary of items considered by the PBPA

### Results of ATC group reviews

<i>Product review results</i>	<i>2007-2008</i>	<i>2008-2009</i>	<i>2009-2010</i>
Number of brands reviewed	3,467	3,844	4,172
Number of brands for which price applications were received	372 10.73%	466 12.12%	432 10.35%
Number of brands for which price increases were granted	138 3.98%	160 4.16%	71 1.70%
Number of vaccines for which price applications were received*	3	3	1
Number of vaccines for which price increases were granted	1	0	0

### PBAC recommendations

<i>Recommendations and listings</i>	<i>2007-2008</i>	<i>2008-2009</i>	<i>2009-2010</i>
Number of items recommended for listing by the PBAC	54	146	124
Section 100 (based on PBAC meetings held in each financial year, including strengths)	14	11	22
Number of items listed	179	112	98
Section 100 (based on new items listed in the PBS Schedule)	14	10	21
Number of vaccines recommended for listing by the PBAC on the National Immunisation Program*	4	1	4
Estimate of additional cost of drugs for new or extensions to listings**	\$193.3 million	\$154.3 million	\$101.1 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 2009 and 30 June 2010. 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 2009–2010 financial year.
- \*\*\* \$23.3 million of this value is for drugs that were not considered by the Cabinet.

### Estimated cost of price increases of existing items

The general price increases granted to Responsible Persons in 2009–2010 are collectively estimated to add \$1.74 million to the cost of the PBS in a full year based on the latest available 12 months prescription volume for each item at the time of review. Further detail can be found at Table 1: Pharmaceutical Benefits Scheme – Summary of ATC Group Reviews for 2009–2010, beginning at page 25 of this report.

### Cost of the Pharmaceutical Benefits Scheme

The total cost of the PBS for 2009–2010 was \$8,342.03 million. This comprised \$5,602.70 million for persons covered by concession cards, and \$1,506.95 million for general patients not covered by concession cards. Other PBS expenditure was \$1,232.38 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 \$14.31 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	25.99	1,506.95
Concessional	157.59	5,602.70
PB Other	*	1,232.38
Total	183.58**	8,342.03
Revenue	***	-14.31
Total (incl. revenue)	***	8,327.72

\* 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 (0.33 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 \$33.30), 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 \$32.90 changing to \$33.30 effective 1 January 2010, while the concessional co-payment was \$5.30 changing to \$5.40 on 1 January 2010.

## 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 clinically 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 clinically 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 2010, 303 of the approximately 3,800 brands listed on the PBS during that year attracted a brand premium. Brand premiums ranged from \$0.08 to \$75.30.

## 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 2010, three of the seven current therapeutic 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, and the H2 Receptor Antagonists for the treatment of peptic ulcers. The prices of items in therapeutic groups are reviewed annually, as for all drugs listed on the PBS. As at 30 June 2010, there were 117 brands of items across the three groups affected by TGP policy. Six of these items attracted TGPs, which ranged from \$2.00 to \$4.35.

## Other Special Patient Contributions

There are currently four drugs with special patient contributions other than brand or therapeutic group premiums listed on the PBS. Three 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 fourth, 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
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 (brand premiums) or reduce approved prices to pharmacist without reference to the PBPA.

The following table shows the effect of brand substitution\*

	2006-07	2007-08	2008-09	2009-10
Number of products** with a premium	360	353	337	303
Average brand premium	\$2.88	\$3.03	\$3.29	\$3.18
Weighted average brand premium***	\$1.83	\$2.17	\$2.10	\$2.33
Brand premium range	\$0.09 to \$76.86	\$0.08 to \$76.86	\$0.08 to \$76.86	\$0.08 to \$75.30
Prescriptions dispensed with a brand premium during the year (million)	27.9	25.2	19.9	16.7
Prescriptions dispensed at the benchmark level during the year (million)	52.7	53.0	56.7	51.2
Percentage at the benchmark level	65%	68%	74%	75%
Products** at the benchmark price	1089	1183	1292	1271

\* 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:

scripts x premium = total premium value,

total premium value/total scripts = 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 seven 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);
- HMG Coenzyme A reductase inhibitors higher potency group (Statins-HP) – (atorvastatin and rosuvastatin only);
- Proton Pump Inhibitors (PPIs) (esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole); and
- Angiotensin II Receptor Antagonists (ATRA) (candesartan, eprosartan, irbesartan, olmesartan, telmisartan, valsartan).

There is currently no non-Therapeutic Group WAMTC group.

<i>WAMTC Group</i>	<i>Drugs in WAMTC Group</i>	<i>Schedule for WAMTC Groups (PBPA meeting)</i>
H <sub>2</sub> Receptor Antagonists (H2RA)	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
HMG Coenzyme A reductase inhibitors higher potency group (Statins-HP)	atorvastatin, rosuvastatin	December
Angiotensin II Receptor Antagonists (ATRA)	candesartan, eprosartan, irbesartan, olmesartan, telmisartan, valsartan	December
Proton Pump Inhibitors (PPIs)	esomeprazole, omeprazole, lansoprazole, pantoprazole, rabeprazole	December

The ACEIs and Statins groups were reviewed in August 2009, with resultant price adjustments applied from 1 December 2009.

The ATRA, PPIs and Statins-HP groups were reviewed in December 2009, with resultant price adjustments applied from 1 April 2010.

The CCBs and H2RA groups were reviewed in April 2010, with the resultant price reductions to be applied on 1 August 2010.

## 12.5% Price Reduction Policy

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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 2009-2010 financial year there has been three rounds of reductions, occurring in August 2009, December 2009 and April 2010 and a total of 13 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

Since 1 August 2007, drugs on the PBS have been 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.

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.

Since 1 August 2007, price links 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 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 unlisted drug/item may be in any formulary 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 at <http://www.pbs.gov.au> 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.

At the time of publication of this report, there is a Bill before Parliament that, if passed, will change some of the provisions from the 2007 PBS Reforms.

## 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, in conjunction with Medicare Australia, 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 each State and Territory health department, 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 2009–2010 there were 88 drugs subsidised under the HSD Program, compared to 2008–2009 when there were 83. There were five new drugs listed under the HSD Program during 2009–2010. These new drug listings are:

1. Ambrisentan
2. Lenalidomide
3. Maraviroc
4. Methoxy Polyethylene Glycol-Epoetin Beta
5. Tenofovir Disoproxil Fumarate with Emtricitabine and Efavirenz

The Government expenditure for 2009-2010 amounted to \$880 million.

Drugs were categorised as follows<sup>1</sup>:

<i>Indications Grouping</i>	<i>Number of Drugs</i>	<i>Public Hospital<sup>2</sup></i>	<i>Private Hospital</i>	<i>Combined</i>
Acromegaly Agents	2	\$16,856,653	\$9,653,939	\$26,510,592
Antiarthritic Agents	4	\$27,908,541	\$46,573,150	\$74,481,691
Bisphosphonate Agents	3	\$12,933,948	\$10,874,841	\$23,808,790
Haemopoietic Agents	7	\$108,633,930	\$35,048,440	\$143,682,370
Hepatitis B or C Agents	10	\$67,134,898	\$20,819,665	\$87,954,562
HIV/AIDS Antiretroviral Agents	26	\$166,534,593	\$1,471,394	\$168,005,986
Immunocompromised Conditions	10	\$11,340,521	\$427,737	\$11,768,258
Immunosuppressive Agents	8	\$78,432,507	\$14,787,385	\$93,219,892
Iron Overload Agents	3	\$11,241,506	\$3,673,450	\$14,914,956
Malignancy Agents	5	\$62,087,802	\$40,075,595	\$102,163,397
Other Conditions	4	\$74,970,509	\$11,780,795	\$86,751,303
Pulmonary Arterial Hypertension Agents	6	\$7,644,885	\$39,840,552	\$47,485,437
<b>Grand Total</b>	<b>88</b>	<b>\$645,720,293</b>	<b>\$235,026,943</b>	<b>\$880,747,234</b>

Note: Public and private expenditure include repatriation patients.

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.
2. 4th Quarter of public hospital expenditure is not yet available and has been forecast. In previous years some Complex Authority Required drugs categorised in the following indications groupings; antiarthritic agents, immunosuppressive agents and pulmonary arterial hypertension agents, prescribed in participating public hospitals have been included in private hospital expenditure as these claims are submitted directly to Medicare Australia through a diskette claiming system. Private hospital expenditure still contains some public hospital prescriptions claimed through community pharmacies.

Government expenditure based on utilisation through the HSD program in 2008-2009 was \$775.8 million. In 2009-2010, expenditure totalled \$880.7 million, an increase of 13.5 per cent from 2008-2009.

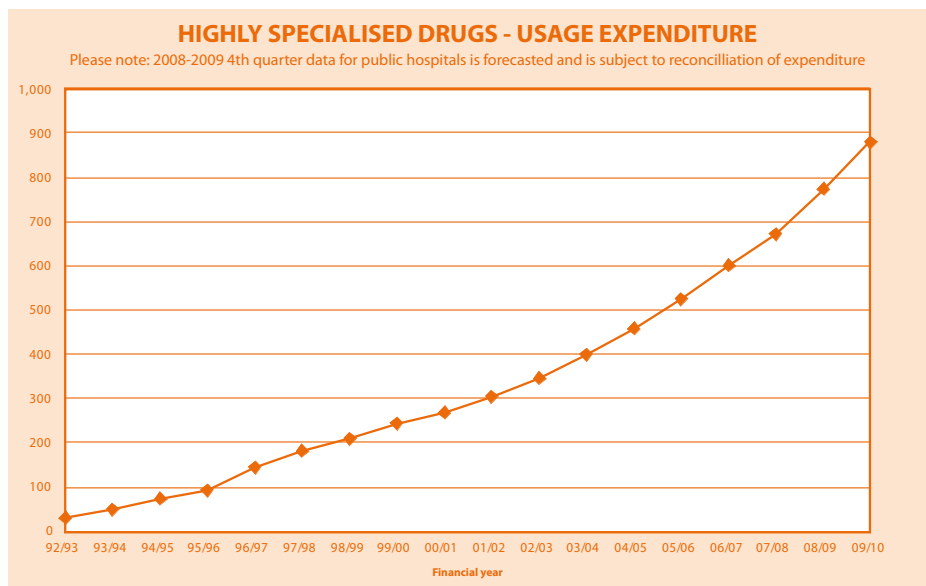
HSD expenditure based on utilisation in public hospitals in 2009-2010 was \$645.7 million, an increase of 11.7 per cent from the 2008-2009 expenditure of \$578.1 million<sup>3</sup>. Private hospital expenditure showed an increase of 18.9 per cent from the \$197.7 million in 2008-2009 to \$235.0 million in 2009-2010.

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 increased access and utilisation through the approval of eligible private hospitals.

- Figures quoted in the 2008-09 PBPA Report incorrectly reported some Complex Authority Required drugs prescribed in participating public hospitals in private hospital expenditure. In 2008-09, Private Hospital expenditure was \$197,705,713. Public expenditure was \$578,094,340. Combined expenditure was \$775,800,053.

### The Highly Specialised Drugs – Usage Government<sup>4</sup> Expenditure Chart

The Highly Specialised Drugs Usage Government Expenditure chart outlines the program’s Government expenditure from 1992-1993 to 2009-2010 financial years.



- 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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Prior to 1 July 2009, the Commonwealth Government expenditure for HSDs was processed through two avenues; a grants process for public hospitals, administered by the Department and a claims payment arrangement for private hospitals, administered through Medicare Australia.

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 moved from monthly advance payments by the Department of Health and Ageing, to payments in arrears by Medicare Australia following dispensing. This is consistent with the arrangements for private hospitals and community pharmacies.

Under the transition to COPE arrangements, an offline system was initially used to process payments to state and territory health departments. As of 1 July 2010, Medicare Australia introduced an electronic claiming and payment process for HSDs. Public hospitals will have till the end of 2012 to implement online claiming.

The move to an online claiming system will enable real time claiming by hospital pharmacies directly to Medicare Australia and align the HSD program with the remainder of the PBS.

## CHAPTER 6

### Tables

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Table 1: Pharmaceutical Benefits Scheme – Summary of ATC Group Reviews for 2009-2010

ATC group	Minor Group	No. of Products Reviewed	Script Volume	Govt cost \$	Total cost \$	Estimated cost to Government of Price Increases \$
A01	Stomatological preparations	10	211,718	1,650,838	2,467,180	–
A02	Drugs for acid related disorders	99	15,906,006	462,046,729	624,991,368	55,420
A03	Drugs for functional gastrointestinal disorders	7	750,483	5,144,845	7,898,942	14,010
A04	Antiemetics and antinauseants	73	856,260	19,106,195	26,045,495	–
A05	Bile and liver Therapy	1	25,745	7,991,436	8,370,379	–
A06	Laxatives	19	977,710	17,927,628	21,706,009	3,604
A07	Antidiarrheals, intestinal antiinflammatory/ antiinfective agents	37	854,700	56,773,718	67,396,131	32,468
A09	Digestives, incl. enzymes	10	68,923	9,924,028	10,675,842	–
A10	Drugs used in diabetes	134	6,888,893	339,371,823	380,226,305	–
A11	Vitamins	7	141,548	4,834,370	6,137,860	–
A12	Mineral supplements	7	275,860	2,722,513	3,747,249	44,605
A14	Anabolic agents for systemic use	1	6,661	123,219	148,301	–
B01	Antithrombotic agents	50	6,988,410	271,136,090	318,022,309	–
B02	Antihemorrhagics	1	38,504	1,125,012	1,972,509	–
B03	Antianemic preparations	8	666,206	8,798,224	12,025,051	–
B05	Blood substitutes and perfusion solutions	29	34,143	784,864	977,882	–
C01	Cardiac therapy	65	3,037,646	58,893,136	73,332,708	–
C02	Antihypertensives	24	978,150	14,073,406	18,159,168	–
C03	Diuretics	40	2,164,439	19,380,960	27,662,302	–
C04	Peripheral vasodilators	3	1,811	2,289,389	2,310,305	–
C07	Beta blocking agents	94	5,628,101	98,211,875	126,781,382	–
C08	Calcium channel blockers	87	7,066,825	115,643,174	146,308,327	–
C09	Agents acting on the renin-angiotensin system	301	20,853,311	433,089,601	539,109,212	–
C10	Lipid modifying agents	297	23,567,452	1,251,854,090	1,541,885,028	–

Table 1: Pharmaceutical Benefits Scheme – Summary of ATC Group Reviews for 2009–2010 (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	31	111,462	7,443,496	9,179,931	–
D05	Antipsoriatics	6	108,171	9,787,317	11,236,176	–
D06	Antibiotics and chemotherapeutics for dermatological use	2	40,612	618,996	792,770	–
D07	Corticosteroids, dermatological preparations	38	2,211,688	33,338,665	46,215,741	–
D10	Anti-acne preparations	6	162,843	18,125,469	22,565,826	–
D11	Other dermatological preparations	2	40,994	2,979,250	3,794,472	–
G02	Other gynecologicals	8	106,697	18,284,288	20,903,760	–
G03	Sex hormones and modulators of the genital system	108	2,213,759	65,710,316	82,050,890	–
G04	Urologicals	6	242,611	3,349,120	4,471,002	–
H01	Prutitary and hypothalamic hormones and analogues	9	68,462	8,201,203	9,514,755	–
H02	Corticosteroids for systemic use	33	1,795,313	13,453,770	20,986,837	–
H03	Thyroid therapy	11	809,806	17,229,645	21,107,168	–
H04	Pancreatic hormones	1	44,658	1,727,292	2,057,790	–
H05	Calcium homeostasis	6	11,541	6,062,665	6,159,687	–
J01	Antibacterials for systemic use	362	11,954,614	119,525,497	179,496,558	–
J02	Antimycotics for systemic use	32	56,066	20,028,890	20,784,758	–
J04	Antimycobacterials	8	10,866	487,860	590,449	1,124
J05	Antivirals for systemic use	33	552,269	92,308,319	105,446,758	–
J07	Vaccines	7	118,439	7,474,976	8,284,628	–
L01	Antineoplastic agents	243	634,171	508,244,613	517,863,956	–
L02	Endocrine therapy	41	586,214	158,512,172	166,795,163	–
L03	Immunostimulants	18	99,468	105,416,109	107,459,304	–
L04	Immunosuppressants	84	514,791	306,465,817	315,493,142	–
M01	Antiinflammatory and antirheumatic products	92	4,522,530	86,342,195	107,926,181	–
M03	Muscle relaxants	16	135,775	5,436,686	6,336,331	–
M04	Antigout preparations	17	878,011	7,193,656	10,810,862	–

Table 1: Pharmaceutical Benefits Scheme – Summary of ATC Group Reviews for 2009-2010 (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	34	3,307,424	156,808,373	182,087,581	–
N02	Analgesics	179	12,162,572	269,199,558	324,549,753	81,281
N03	Antiepileptics	136	1,877,994	98,840,243	117,768,427	814
N04	Anti-Parkinson drugs	44	718,981	41,046,723	46,383,390	–
N05	Psycholeptics	183	7,704,256	405,393,111	448,184,172	–
N06	Psychoanaesthetics	210	13,176,364	371,576,614	500,348,884	–
N07	Other nervous system drugs	18	578,295	75,615,135	87,640,771	–
P01	Antiprotozoals	6	2,980	192,597	207,393	–
P02	Anthelmintics	7	5,333	137,469	179,751	164
P03	Ectoparasiticides, incl. scabicides, insecticides and repellents	1	50,389	599,069	845,667	–
R01	Nasal preparations	1	1,130	17,877	23,464	–
R03	Drugs for obstructive airway diseases	77	9,638,700	395,645,373	491,407,142	–
R05	Cough and cold preparations	1	170,476	3,016,230	3,823,160	–
R06	Antihistamines for systemic use	1	20,309	432,998	457,694	–
S01	Ophthalmologicals	121	7,077,451	317,875,330	357,951,683	7,915
S02	Otologicals	9	643,576	3,155,999	5,898,925	–
S03	Ophthalmological and otological preparations	1	30,205	165,040	303,873	–
V01	Allergens	3	3,127	575,909	655,476	108,694
V03	All other therapeutic products	17	60,868	12,469,161	13,160,130	120,870
V04	Diagnostic agents	63	403,133	19,297,996	21,703,189	–
V06	General nutrients	96	83,234	30,345,374	32,035,931	–
V07	All other non-therapeutic products	1	2,230	60,224	69,153	–
	*Ad hoc	77	171,174	3,352,086	4,260,923	1,269,622
	<b># Total (excludes section 100 drugs)</b>	<b>3,910</b>	<b>183,911,537</b>	<b>7,032,463,931</b>	<b>8,416,628,674</b>	<b>1,740,591</b>

\*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 2010**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
1	8215	Atorvastatin	Tablet 40mg (as calcium)	3,762,081	247,389,387	297,147,727	78.98
2	8358	Clopidogrel	Tablet 75mg (as hydrogen sulfate)	2,676,941	188,703,278	212,682,108	79.45
3	1382	Ranibizumab	Solution for intravitreal injection 2.3mg in 0.23mL	89,753	187,650,894	188,494,722	2100.15
4	8214	Atorvastatin	Tablet 20mg (as calcium)	3,532,881	158,287,977	204,577,230	57.91
5	8521	Atorvastatin	Tablet 80mg (as calcium)	1,338,224	129,896,074	147,322,664	110.09
6	9043	Rosuvastatin	Tablet 10mg (as calcium)	2,234,825	117,809,273	153,061,251	68.49
7	8626	Tiotropium Bromide Monohydrate	Capsule containing powder for oral inhalation 18micrograms (base) (for use in Handihaler)	1,473,689	103,088,773	113,274,722	76.86
8	8601	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 40mg esomeprazole	2,268,797	102,526,874	129,998,539	57.30
9	8008	Pantoprazole Sodium Sesquihydrate	Tablet (enteric coated), equivalent to 40mg pantoprazole	2,920,584	89,353,117	119,168,596	40.80
10	8187	Olanzapine	Tablet 10mg	328,016	88,921,677	91,662,029	279.44
11	8600	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 20mg esomeprazole	3,474,505	85,334,028	130,554,649	37.58
12	9039	Insulin Glargine	Injections (human analogue) 100units per mL, 3mL, 5	195,462	80,595,329	83,163,617	425.47
13	9044	Rosuvastatin	Tablet 20mg (as calcium)	1,017,798	80,075,734	96,153,752	94.47
14	8519	Fluticasone Propionate with Salmeterol Xinafoate	Oral pressurised inhalation 250micrograms-25micrograms (base) per dose (120 doses), CFC-free formulation	1,101,784	72,376,829	86,720,649	78.71
15	8173	Simvastatin	Tablet 40mg	2,004,349	68,993,248	88,922,619	44.36
16	8302	Venlafaxine Hydrochloride	Capsule 150mg (base) (modified release)	1,345,081	60,804,609	82,346,990	61.22
17	8508	Rabeprazole Sodium	Tablet 20mg (enteric coated)	1,937,867	54,549,585	79,441,617	40.99
18	8757	Ezetimibe	Tablet 10mg	899,700	53,237,578	63,986,054	71.12
19	9045	Rosuvastatin	Tablet 40mg (as calcium)	456,449	53,142,596	60,186,098	131.86
20	9110	Omeprazole	Tablet 20mg (as magnesium)	1,684,736	49,717,830	58,790,693	34.90
21	8213	Atorvastatin	Tablet 10mg (as calcium)	1,615,616	49,471,972	68,804,678	42.59
22	9114	Imatinib	Tablet 400mg (as mesylate)	11,141	46,927,380	47,124,805	4229.85
23	8134	Valaciclovir Hydrochloride	Tablet 500mg (base)	322,626	46,120,298	54,185,817	167.95
24	8405	Ibesartan With Hydrochlorothiazide	Tablet 300mg-12.5mg	1,613,694	45,202,359	52,355,061	32.44
25	8243	Latanoprost	Eye drops 50micrograms per mL (0.005%), 2.5mL	1,337,274	44,830,460	56,286,980	42.09

Table 2: Pharmaceutical Benefits Scheme – Highest Cost Items – 12 Months to 30 June 2010 (continued)

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
26	8093	Goserelin Acetate	Subcutaneous implant (long acting) 10.8mg (base) in pre-filled injection syringe	40,111	44,124,194	44,464,846	1108.54
27	9100	Adalimumab	Injection 40mg in 0.8mL pre-filled pen	23,892	41,985,024	42,378,869	1773.77
28	8432	Fluticasone Propionate with Salmeterol Xinafoate	Powder for oral inhalation in breath actuated device 500micrograms-50micrograms (base) per dose (60 doses)	607,493	40,650,016	48,327,368	79.55
29	9090	Etanercept	Injections 50mg in 1mL single use pre-filled syringes, 4	23,038	40,551,845	40,910,029	1775.76
30	8101	Interferon Beta-1B	Injection set including 1 vial powder for injection 8,000,000i.u. (250micrograms) and solvent	32,200	37,344,676	37,996,032	1180.00
31	8625	Budesonide with Eformoterol Fumarate Dihydrate	Powder for oral inhalation in breath actuated device 200micrograms-6micrograms per dose (120 doses)	855,471	36,585,082	50,246,915	58.74
32	2012	Simvastatin	Tablet 20mg	1,348,718	35,630,549	44,673,473	33.12
33	8301	Venlafaxine Hydrochloride	Capsule 75mg (base) (modified release)	1,186,106	35,572,536	55,935,466	47.16
34	8248	Iribesartan	Tablet 300mg	1,344,168	35,008,351	40,903,793	30.43
35	8435	Insulin Aspart	Injections (human analogue) 100units per mL, 3mL, 5	140,521	34,142,244	36,374,184	258.85
36	8179	Anastrozole	Tablet 1mg	203,299	33,577,734	36,596,369	180.01
37	9129	Varencicline	Tablet 1mg (as tartrate)	158,157	33,299,396	36,808,912	232.74
38	8882	Ezetimibe With Simvastatin	Tablet 10mg-80mg	279,264	31,019,553	34,594,061	123.88
39	8609	Insulin Aspart-Insulin Aspart Protamine Suspension	Injections (human analogue) 100units (30units-70units) per mL, 3mL, 5	123,395	30,975,095	32,221,358	261.12
40	8881	Ezetimibe With Simvastatin	Tablet 10mg-40mg	314,744	30,007,209	33,914,388	107.75
41	8294	Rituximab	Solution for I.V. infusion 500mg in 50mL	11,674	29,473,667	29,677,505	2542.19
42	8431	Fluticasone Propionate with Salmeterol Xinafoate	Powder for oral inhalation in breath actuated device 250micrograms-50micrograms (base) per dose (60 doses)	653,971	28,762,927	38,822,437	59.36
43	8511	Alendronate Sodium	Tablet equivalent to 70mg alendronic acid	723,012	28,327,477	33,685,240	46.59
44	8440	Celecoxib	Capsule 200mg	941,280	26,983,061	31,139,990	33.08
45	8313	Simvastatin	Tablet 80mg	542,785	26,457,565	32,205,733	59.33

Table 2: Pharmaceutical Benefits Scheme – Highest Cost Items – 12 Months to 30 June 2010 (continued)

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
46	8074	Docetaxel	Injection set containing 1 single use vial concentrate for i.v. infusion 80mg (anhydrous) in 2mL with solvent	11,738	26,394,291	26,631,502	2268.83
47	9128	Varenicline	Box containing 11 tablets 0.5mg (as tartrate) and 14 tablets 1mg (as tartrate) in the first pack and 28 tablets 1mg (as tartrate) in the second pack	315,269	25,726,216	32,712,168	103.76
48	8814	Paracetamol	Tablet 665mg (modified release)	2,022,129	25,589,342	33,389,407	16.51
49	8580	Quetiapine	Tablet 300mg (as fumarate)	83,884	25,484,996	26,257,708	313.02
50	8185	Olanzapine	Tablet 5mg	249,203	25,466,102	27,839,860	111.72

**Table 3: Pharmaceutical Benefits Scheme – Most Prescribed Items – 12 Months to 30 June 2010**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
1	8215	Atorvastatin	Tablet 40mg (as calcium)	3,762,081	247,389,387	297,147,727	78.98
2	8214	Atonvastatin	Tablet 20mg (as calcium)	3,532,881	158,287,977	204,577,230	57.91
3	8600	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 20mg esomeprazole	3,474,505	85,334,028	130,554,649	37.58
4	1081	Atenolol	Tablet 50mg	2,920,963	18,666,176	31,145,770	10.66
5	8008	Pantoprazole Sodium Sesquihydrate	Tablet (enteric coated), equivalent to 40mg pantoprazole	2,920,584	89,353,117	119,168,596	40.80
6	8358	Clopidogrel	Tablet 75mg (as hydrogen sulfate)	2,676,941	188,703,278	212,682,108	79.45
7	8601	Esomeprazole Magnesium Trihydrate	Tablet (enteric coated), equivalent to 40mg esomeprazole	2,268,797	102,526,874	129,998,539	57.30
8	9043	Rosuvastatin	Tablet 10mg (as calcium)	2,234,825	117,809,273	153,061,251	68.49
9	8288	Salbutamol Sulfate	Oral pressurised inhalation 100micrograms (base) per dose (200 doses), CFC-free formulation	2,074,258	22,771,892	31,331,621	15.10
10	8814	Paracetamol	Tablet 665mg (modified release)	2,022,129	25,589,342	33,389,407	16.51
11	8173	Simvastatin	Tablet 40mg	2,004,349	68,993,248	88,922,619	44.36
12	8508	Rabeprazole Sodium	Tablet 20mg (enteric coated)	1,937,867	54,549,585	79,441,617	40.99
13	3119	Cephalexin	Capsule 500mg	1,904,818	12,198,419	20,766,200	10.90
14	2089	Temazepam	Tablet 10mg	1,704,552	6,362,699	13,123,598	7.70
15	9110	Omeprazole	Tablet 20mg (as magnesium)	1,684,736	49,717,830	58,790,693	34.90
16	8213	Atonvastatin	Tablet 10mg (as calcium)	1,615,616	49,471,972	68,804,678	42.59
17	8405	Irbesartan with Hydrochlorothiazide	Tablet 300mg-12.5mg	1,613,694	45,202,359	52,355,061	32.44
18	1215	Codaine Phosphate with Paracetamol	Tablet 30mg-500mg	1,488,242	6,693,666	13,010,632	8.74
19	8626	Tiotropium Bromide Monohydrate	Capsule containing powder for oral inhalation 18micrograms (base) (for use in HandiHaler)	1,473,689	103,088,773	113,274,722	76.86
20	3162	Diazepam	Tablet 5mg	1,430,114	5,108,017	11,280,104	7.89
21	2012	Simvastatin	Tablet 20mg	1,348,718	35,630,549	44,673,473	33.12
22	8302	Venlafaxine Hydrochloride	Capsule 150mg (base) (modified release)	1,345,081	60,804,609	82,346,990	61.22
23	8248	Irbesartan	Tablet 300mg	1,344,168	35,008,351	40,903,793	30.43
24	8521	Atonvastatin	Tablet 80mg (as calcium)	1,338,224	129,896,074	147,322,664	110.09
25	8243	Latanoprost	Eye drops 50micrograms per mL (0.005%), 2.5mL	1,337,274	44,830,460	56,286,980	42.09

**Table 3: Pharmaceutical Benefits Scheme – Most Prescribed Items – 12 Months to 30 June 2010 (continued)**

Rank	Item	Drug	Form	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
26	1889	Amoxicillin	Capsule 500mg	1,289,412	7,778,744	13,829,697	10.73
27	8254	Amoxicillin with Clavulanic Acid	Tablet 875mg-125mg	1,248,615	12,847,173	18,533,408	14.84
28	8301	Venlafaxine Hydrochloride	Capsule 75mg (base) (modified release)	1,186,106	35,572,536	55,935,466	47.16
29	8247	Irbesartan	Tablet 150mg	1,140,643	23,628,005	28,775,537	25.23
30	2430	Metformin Hydrochloride	Tablet 500mg	1,138,924	10,358,831	14,869,879	13.06
31	9007	Perindopril	Tablet containing 5mg perindopril arginine	1,118,399	15,839,366	20,853,664	18.65
32	8784	Paracetamol	Tablet 500mg	1,103,483	9,713,960	13,522,811	12.25
33	8519	Fluticasone Propionate with Salmeterol Xinafoate	Oral pressurised inhalation 250micrograms-25micrograms (base) per dose (120 doses), CFC-free formulation	1,101,784	72,376,829	86,720,649	78.71
34	8470	Ramipril	Capsule 10mg	1,092,939	20,738,051	25,470,344	23.30
35	9008	Perindopril	Tablet containing 10mg perindopril arginine	1,090,716	22,469,549	27,315,194	25.04
36	8535	Glucalazide	Tablet 30mg (modified release)	1,063,393	10,406,862	14,505,492	13.64
37	9044	Rosuvastatin	Tablet 20mg (as calcium)	1,017,798	80,075,734	96,153,752	94.47
38	8202	Aspirin	Tablet 100mg	1,014,205	4,453,454	8,159,231	8.04
39	2751	Amlodipine	Tablet 5mg (as besylate)	996,956	12,446,500	16,746,136	16.80
40	2412	Fruzemide	Tablet 40mg	991,927	5,173,955	8,693,198	8.76
41	2845	Perindopril with Indapamide-Hemihydrate	Tablet containing 5mg perindopril arginine-1.25mg indapamide hemihydrate	964,053	24,052,065	28,758,028	29.83
42	1324	Metoprolol Tartrate	Tablet 50mg	946,808	6,316,383	10,174,135	10.75
43	8440	Celecoxib	Capsule 200mg	941,280	26,983,061	31,139,990	33.08
44	8220	Citalopram Hydrobromide	Tablet 20mg (base)	940,997	19,412,761	26,754,392	28.43
45	8757	Ezetimibe	Tablet 10mg	899,700	53,237,578	63,986,054	71.12
46	8607	Metformin Hydrochloride	Tablet 1g	896,042	12,574,164	16,040,626	17.90
47	2843	Warfarin Sodium	Tablet 1mg	861,611	7,349,795	10,633,789	12.34
48	8625	Budesonide with Eformoterol Fumarate Dihydrate	Powder for oral inhalation in breath actuated device 200micrograms-6micrograms per dose (120 doses)	855,471	36,585,082	50,246,915	58.74
49	2237	Sertraline Hydrochloride	Tablet 100mg (base)	827,542	18,331,061	24,843,255	30.02
50	8884	Metformin Hydrochloride	Tablet 500mg (extended release)	823,799	8,571,495	11,914,994	14.46

**Table 4: Pharmaceutical Benefits Scheme – Top 20 Responsible Persons by Total Cost for 2009-2010 (from processed PBS prescriptions)**

Rank	Manufacturer	Script Volume	Govt Cost (\$)	Total Cost (\$)	Sales (Ex-Manufacturer) (\$)
1	Pfizer	18,207,909	957,526,458	1,161,404,562	882,232,920
2	AstraZeneca	17,747,381	838,491,704	1,040,960,485	780,588,759
3	Sanofi-Aventis	14,535,138	577,825,722	669,365,548	489,845,126
4	Alphapharm	26,337,138	368,109,038	499,056,921	269,806,654
5	Novartis	2,630,349	405,959,371	426,665,616	372,491,126
6	Merck Sharp & Dohme	7,981,702	352,187,572	420,914,372	311,095,885
7	GlaxoSmithKline	8,924,647	338,250,492	420,440,919	305,117,977
8	Sigma	16,717,837	236,819,449	318,907,126	171,551,436
9	Wyeth	3,884,878	241,775,348	302,349,509	239,976,082
10	Eli Lilly	2,275,963	271,733,922	297,932,034	240,757,546
11	Janssen-Cilag	3,804,975	243,516,414	285,986,118	221,189,481
12	Boehringer Ingelheim	5,553,130	203,637,914	234,693,026	165,465,449
13	Bristol Myers Squibb	4,964,745	198,020,151	226,312,248	163,830,708
14	Roche Products	1,747,352	195,904,357	209,635,569	177,618,345
15	Abbott	1,379,765	194,206,389	202,846,585	176,686,634
16	Apotex	8,777,682	154,858,973	202,765,766	118,130,648
17	Mycomed	3,558,158	103,767,215	139,085,744	94,404,784
18	Mundipharma	2,507,044	117,532,991	131,826,151	89,623,859
19	Novo Nordisk	802,362	118,920,259	126,396,054	104,585,263
20	Servier	5,245,128	92,318,772	116,280,879	67,787,725
	Others	26,328,254	821,101,421	982,803,441	681,004,358
	<b>Total</b>	<b>183,911,537</b>	<b>7,032,463,931</b>	<b>8,416,628,674</b>	<b>6,123,790,765</b>

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 2009–2010 (from processed PBS prescriptions)**

Rank	Manufacturer	Script Volume	Govt Cost (\$)	Total Cost (\$)	% of Total	Sales (Ex-Manufacturer) (\$)
1	Alphapharm	26,337,138	368,109,038	499,056,921	14.32	269,806,654
2	Pfizer	18,207,909	957,526,458	1,161,404,562	9.90	882,232,920
3	AstraZeneca	17,747,381	838,491,704	1,040,960,485	9.65	780,588,759
4	Sigma	16,717,837	236,819,449	318,907,126	9.09	171,551,436
5	Sanofi-Aventis	14,535,138	577,825,722	669,365,548	7.90	489,845,126
6	GlaxoSmithKline	8,924,647	338,250,492	420,440,919	4.85	305,117,977
7	Apotex	8,777,682	154,858,973	202,765,766	4.77	118,130,648
8	Merck Sharp & Dohme	7,981,702	352,187,572	420,914,372	4.34	311,095,885
9	Boehringer Ingelheim	5,553,130	203,637,914	234,693,026	3.02	165,465,449
10	Senvier	5,245,128	92,318,772	116,280,879	2.85	67,787,725
11	Bristol Myers Squibb	4,964,745	198,020,151	226,312,248	2.70	163,830,708
12	Sandoz	4,569,285	87,387,414	112,822,274	2.48	68,036,013
13	Wyeth	3,884,878	241,775,348	302,349,509	2.11	239,976,082
14	Janssen-Cilag	3,804,975	243,516,414	285,986,118	2.07	221,189,481
15	Nycomed	3,558,158	103,767,215	139,085,744	1.93	94,404,784
16	Aspen	3,105,370	30,299,327	45,842,009	1.69	21,225,253
17	Novartis	2,630,349	405,959,371	426,665,616	1.43	372,491,126
18	Solvay	2,617,385	65,972,985	84,182,612	1.42	54,904,338
19	Mundipharma	2,507,044	117,532,991	131,826,151	1.36	89,623,859
20	Eli Lilly	2,275,963	271,733,922	297,932,034	1.24	240,757,546
	Total Top 20	163,945,844	5,885,991,232	7,137,793,920	89%	5,128,061,768
	Others	19,965,693	1,146,472,699	1,278,834,754	11%	995,728,997

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 2009 to Year end June 2010**

	Year Ending June 2009					Year Ending June 2010				
	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	(%diff)	(%diff)
<b>ATC Group Level 2</b>										
Lipid modifying agents	22,425,722	1,157,766,315	1,420,351,269	63.34	23,567,452	1,251,854,090	1,541,885,028	65.42	8.1	8.6
Antineoplastic agents	584,120	441,788,063	450,380,993	771.04	634,171	508,244,613	517,863,956	816.60	15.0	15.0
Drugs for acid related disorders	15,664,402	465,366,346	624,069,644	39.84	15,906,006	462,046,729	624,991,368	39.29	-0.7	0.1
Agents acting on the renin-angiotensin system	20,799,632	423,466,235	531,517,082	25.55	20,853,311	433,089,601	539,109,212	25.85	2.3	1.4
Psycholeptics	7,754,497	393,862,776	434,576,649	56.04	7,704,256	405,393,111	448,184,172	58.17	-0.6	3.1
Drugs for obstructive airway diseases	9,503,507	385,717,371	475,774,894	50.06	9,638,700	395,645,373	491,407,142	50.98	1.4	3.3
Psychoanaesthetics	12,436,470	354,554,496	469,480,533	37.75	13,176,364	371,576,614	500,348,884	37.97	5.9	6.6
Drugs used in diabetes	6,618,703	309,835,649	346,811,563	52.40	6,888,893	339,371,823	380,226,305	55.19	4.1	9.6
Ophthalmologicals	7,025,550	242,024,604	279,312,357	39.76	7,077,451	317,875,330	357,951,683	50.58	0.7	28.2
Immunosuppressants	460,786	243,151,556	250,765,693	544.21	514,791	306,465,817	315,493,142	612.86	11.7	25.8
Antithrombotic agents	6,815,375	259,875,853	302,788,420	44.43	6,988,410	271,136,090	318,022,309	45.51	2.5	5.0
Analgesics	11,575,006	237,834,865	287,750,342	24.86	12,162,572	269,199,558	324,549,753	26.68	5.1	12.8
Endocrine therapy	564,689	153,530,228	161,144,188	285.37	586,214	158,512,172	166,795,163	284.53	3.8	3.5
Drugs for treatment of bone diseases	3,405,784	155,468,769	180,208,843	52.91	3,307,424	156,808,373	182,087,581	55.05	-2.9	1.0
Antibacterials for systemic use	12,137,391	120,280,150	178,464,644	14.70	11,954,614	119,525,497	179,496,558	15.01	-1.5	0.6
Calcium channel blockers	7,126,274	118,658,046	148,391,215	20.82	7,066,825	115,643,174	146,308,327	20.70	-0.8	-1.4
Immunostimulants	96,068	101,868,083	103,750,941	1079.97	99,468	105,416,109	107,459,304	1080.34	3.5	3.6

Table 6(b): Pharmaceutical Benefits Scheme – Significant Drug Groups (incl Doctor's Bag) by Highest Script Volume – Year end June 2009 to Year end June 2010

	Year Ending June 2009						Year Ending June 2010						
	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Script Volume	Average Price (\$)	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Script Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)
ATC Group Level 2													
Lipid modifying agents	22,425,722	1,157,766,315	1,420,351,269	63.34	23,567,452	5.1	1,251,854,090	8.1	1,541,885,028	8.6	65.42	3.3	
Agents acting on the renin-angiotensin system	20,799,632	423,466,235	531,517,082	25.55	20,853,311	0.3	433,089,601	2.3	539,109,212	1.4	25.85	1.2	
Drugs for acid related disorders	15,664,402	465,366,346	624,069,644	39.84	15,906,006	1.5	462,046,729	-0.7	624,991,368	0.1	39.29	-1.4	
Psychoanaesthetics	12,436,470	354,554,496	469,480,533	37.75	13,176,364	5.9	371,576,614	4.8	500,348,884	6.6	37.97	0.6	
Analgesics	11,575,006	237,834,865	287,750,342	24.86	12,162,572	5.1	269,199,558	13.2	324,549,753	12.8	26.68	7.3	
Antibacterials for systemic use	12,137,391	120,280,150	178,464,644	14.70	11,954,614	-1.5	119,525,497	-0.6	179,496,558	0.6	15.01	2.1	
Drugs for obstructive airway diseases	9,503,507	385,717,371	475,774,894	50.06	9,638,700	1.4	395,645,373	2.6	491,407,142	3.3	50.98	1.8	
Psycholeptics	7,754,497	393,862,776	434,576,649	56.04	7,704,256	-0.6	405,393,111	2.9	448,184,172	3.1	58.17	3.8	
Ophthalmologicals	7,025,550	242,024,604	279,312,357	39.76	7,077,451	0.7	317,875,330	31.3	357,951,683	28.2	50.58	27.2	
Calcium channel blockers	7,126,274	118,658,046	148,391,215	20.82	7,066,825	-0.8	115,643,174	-2.5	146,308,327	-1.4	20.70	-0.6	
Antithrombotic agents	6,815,375	259,875,853	302,788,420	44.43	6,988,410	2.5	271,136,090	4.3	318,022,309	5.0	45.51	2.4	
Drugs used in diabetes	6,618,703	309,835,649	346,811,563	52.40	6,888,893	4.1	339,371,823	9.5	380,226,305	9.6	55.19	5.3	
Beta blocking agents	5,625,356	97,915,215	124,792,783	22.18	5,628,101	0.0	98,211,875	0.3	126,781,382	1.6	22.53	1.5	
Antiinflammatory and antirheumatic products	4,863,879	89,065,965	114,698,770	23.58	4,522,530	-7.0	86,342,195	-3.1	107,926,181	-5.9	23.86	1.2	
Drugs for treatment of bone diseases	3,405,784	155,468,769	180,208,843	52.91	3,307,424	-2.9	156,808,373	0.9	182,087,581	1.0	55.05	4.0	
Cardiac therapy	3,147,540	59,368,769	73,302,204	23.29	3,037,646	-3.5	58,893,136	-0.8	73,332,708	0.0	24.14	3.7	
Sex hormones and modulators of the genital system	2,728,890	70,826,452	89,300,507	32.72	2,213,759	-18.9	65,710,316	-7.2	82,050,890	-8.1	37.06	13.3	

Table 7(a): Pharmaceutical Benefits Scheme – Significant Drugs (incl Doctor’s Bag) Sorted by Highest Change to Government Cost – Year end June 2009 to Year end June 2010

Rank	Drug	Year Ending June 2009				Year Ending June 2010				Change	
		Volume	Govt Cost (\$)	Total Cost(\$)	Average Price (\$)	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Govt Cost (\$)	%
1	Rosuvastatin	2,959,028	187,561,016	232,271,108	78.50	4,409,502	275,994,777	344,480,173	78.12	88,433,761	47.15
2	Ranibizumab	59,541	123,557,706	124,086,801	2084.06	89,753	187,650,894	188,494,722	2,100.15	64,093,188	51.87
3	Adalimumab	57,608	103,129,217	104,165,718	1808.18	82,204	146,543,311	148,167,640	1,802.44	43,414,094	42.10
4	Bevacizumab	0	0	0	0.00	12,096	26,485,000	26,680,285	2,205.71	26,485,000	New
5	Erancept	51,963	91,490,163	92,380,764	1777.82	62,959	110,970,490	112,125,500	1,780.93	19,480,327	21.29
6	Sunitinib	378	1,557,210	1,562,385	4,133.29	4,994	20,541,764	20,611,248	4,127.20	18,984,554	1219.14
7	Amlodipine Besylate with Atorvastatin Calcium	617,790	44,470,852	52,363,022	84.76	853,295	60,622,971	72,452,786	84.91	16,152,119	36.32
8	Quetiapine	431,096	71,633,399	75,755,830	175.73	545,410	86,144,922	91,616,904	167.98	14,511,523	20.26
9	Desvenlafaxine Succinate	48,073	1,274,174	2,216,705	46.11	505,039	14,563,352	24,278,049	48.07	13,289,178	1042.96
10	Insulin Glargine	164,346	67,475,910	69,606,267	423.53	195,462	80,595,329	83,163,617	425.47	13,119,419	19.44
11	Duloxetine Hydrochloride	227,490	7,617,534	11,565,650	50.84	525,109	18,250,995	27,380,362	52.14	10,633,461	139.59
12	Sitagliptin	109,271	8,543,018	9,942,638	90.99	239,123	18,903,481	21,854,027	91.39	10,360,462	121.27
13	Fentanyl	347,793	33,589,991	36,044,174	103.64	441,440	43,205,818	46,364,092	105.03	9,615,827	28.63
14	Paracetamol	3,484,635	29,637,067	41,814,363	12.00	3,786,747	38,852,389	52,826,038	13.95	9,215,322	31.09
15	Pantoprazole Sodium Sesquihydrate	3,249,745	94,845,168	128,567,658	39.56	3,571,642	104,043,871	138,953,760	38.90	9,198,704	9.70
16	Oxycodone Hydrochloride	1,791,805	61,129,320	70,057,943	39.10	2,004,190	69,474,821	79,926,524	39.88	8,345,502	13.65
17	Imatinib	18,527	76,850,649	77,169,121	4,165.22	20,587	84,498,148	84,863,853	4,122.21	7,647,498	9.95
18	Progiltazone Hydrochloride	373,747	30,347,842	34,202,725	91.51	462,125	37,936,355	42,892,254	92.82	7,588,514	25.01
19	Ezetimibe with Simvastatin	515,328	54,095,598	60,358,007	117.13	600,250	61,506,640	69,089,853	115.10	7,411,042	13.70
20	Nab Paclitaxel	116	241,690	243,790	2101.64	3,989	7,547,873	7,626,631	1,911.92	7,306,182	3022.95
21	Buprenorphine	639,964	27,435,677	30,994,688	48.43	777,244	34,456,453	38,891,962	50.04	7,020,775	25.59

Table 7(a): Pharmaceutical Benefits Scheme – Significant Drugs (incl Doctor's Bag) Sorted by Highest Change to Government Cost – Year end June 2009 to Year end June 2010 (continued)

Rank	Drug	Year Ending June 2009				Year Ending June 2010				Change	
		Volume	Govt Cost (\$)	Total Cost(\$)	Average Price (\$)	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Govt Cost (\$)	%
22	Atonastatin	10,510,102	591,700,692	724,642,901	68.95	10,468,431	597,784,244	733,670,794	70.08	6,083,552	1.03
23	Tiotropium Bromide Monohydrate	1,390,860	97,137,287	106,294,683	76.42	1,473,689	103,088,773	113,274,722	76.86	5,951,486	6.13
24	Zoledronic Acid	4,246	2,329,407	2,373,232	558.93	14,311	7,963,052	8,107,626	566.53	5,633,646	241.85
25	Budesonide with Eformoterol Fumarate Dihydrate	1,116,100	57,683,950	74,117,308	66.41	1,240,497	63,249,917	82,410,424	66.43	5,565,967	9.65
26	Voriconazole	406	1,001,404	1,007,035	2480.38	2,473	6,121,794	6,149,854	2,486.80	5,120,390	511.32
27	Erlotinib	3,318	10,548,954	10,586,345	3190.58	5,012	15,663,510	15,724,786	3,137.43	5,114,557	48.48
28	Sorafenib	272	1,765,685	1,768,728	6,502.68	1,008	6,517,855	6,529,835	6,478.01	4,752,170	269.14
29	Enoxaparin Sodium	289,612	23,982,914	28,531,628	98.52	294,823	28,689,903	33,464,613	113.51	4,706,989	19.63
30	Bortezomib	1,035	7,348,531	7,362,261	7113.30	1,620	11,602,218	11,621,829	7,173.97	4,253,687	57.88
31	Candesartan Cilexetil	1,816,580	44,950,569	55,955,317	30.80	1,950,889	49,107,851	62,052,805	31.81	4,157,282	9.25
32	Latanoprost	1,326,138	40,784,157	51,487,218	38.82	1,338,891	44,880,644	56,355,091	42.09	4,096,487	10.04
33	Pemetrexed Disodium	5,446	12,046,581	12,128,572	2,227.06	8,575	16,109,092	16,243,474	1,894.28	4,062,511	33.72
34	Escitalopram Oxalate	862,978	22,389,132	27,679,506	32.07	1,023,632	26,364,595	32,827,242	32.07	3,975,463	17.76
35	Macrogol 3350	351,503	7,227,479	8,554,777	24.34	523,655	11,035,389	13,063,230	24.95	3,807,910	52.69

**Table 7(b): Pharmaceutical Benefits Scheme – Significant Drugs (incl Doctor’s Bag) – Sorted by Highest Volume Change – Year end June 2009 to Year end June 2010**

Rank	Drug	Year Ending June 2009					Year Ending June 2010					Change	
		Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	%	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Volume	%	
1	Rosuvastatin	2,959,028	187,561,016	232,271,108	78.50	4,409,502	275,994,777	344,480,173	78.12	1,450,474	49.02		
2	Desvenlafaxine Succinate	48,073	1,274,174	2,216,705	46.11	505,039	14,563,352	24,278,049	48.07	456,966	950.57		
3	Pantoprazole Sodium Sesquihydrate	3,249,745	94,845,168	128,567,658	39.56	3,571,642	104,043,871	138,953,760	38.90	321,897	9.91		
4	Esomeprazole Magnesium Trihydrate	5,544,594	190,655,025	258,553,147	46.63	5,851,954	190,541,016	264,633,025	45.22	307,360	5.54		
5	Paracetamol	3,484,635	29,637,067	41,814,363	12.00	3,786,747	38,852,389	52,826,038	13.95	302,112	8.67		
6	Duloxetine Hydrochloride	227,490	7,617,534	11,565,650	50.84	525,109	18,250,995	27,380,362	52.14	297,619	130.83		
7	Amlodipine Besylate with Atorvastatin Calcium	617,790	44,470,852	52,363,022	84.76	853,295	60,622,971	72,452,786	84.91	235,505	38.12		
8	Oxycodone Hydrochloride	1,791,805	61,129,320	70,057,943	39.10	2,004,190	69,474,821	79,926,524	39.88	212,385	11.85		
9	Macrogol 3350	351,503	7,227,479	8,554,777	24.34	523,655	11,035,389	13,063,230	24.95	172,152	48.98		
10	Escitalopram Oxalate	862,978	22,389,132	27,679,506	32.07	1,023,632	26,364,595	32,827,242	32.07	160,654	18.62		
11	Metformin Hydrochloride	3,064,053	32,668,021	44,326,176	14.47	3,220,970	35,213,120	48,025,533	14.91	156,917	5.12		
12	Rabeprazole Sodium	2,065,671	58,469,528	83,882,499	40.61	2,214,373	61,415,521	89,884,205	40.59	148,702	7.20		
13	Buprenorphine	639,964	27,435,677	30,994,688	48.43	777,244	34,456,453	38,891,962	50.04	137,280	21.45		
14	Candesartan Cilexetil	1,816,580	44,950,569	55,955,317	30.80	1,950,889	49,107,851	62,052,805	31.81	134,309	7.39		
15	Sitagliptin	109,271	8,543,018	9,942,638	90.99	239,123	18,903,481	21,854,027	91.39	129,852	118.83		
16	Budesonide with Eformoterol Fumarate Dihydrate	1,116,100	57,683,950	74,117,308	66.41	1,240,497	63,249,917	82,410,424	66.43	124,397	11.15		
17	Clopidogrel	2,584,471	189,629,792	211,620,605	81.88	2,708,187	190,582,198	214,905,232	79.35	123,716	4.79		
18	Telmisartan with Hydrochlorothiazide	739,733	18,221,131	21,434,592	28.98	863,262	21,429,331	25,691,087	29.76	123,529	16.70		
19	Quetiapine	431,096	71,633,399	75,755,830	175.73	545,410	86,144,922	91,616,904	167.98	114,314	26.52		
20	Telmisartan	1,343,112	27,550,749	33,409,937	24.88	1,457,016	30,428,551	37,064,884	25.44	113,904	8.48		

Table 7(b): Pharmaceutical Benefits Scheme – Significant Drugs (incl Doctor's Bag) – Sorted by Highest Volume Change – Year end June 2009 to Year end June 2010 (continued)

Rank	Drug	Year Ending June 2009				Year Ending June 2010				Change	
		Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Volume	Govt Cost (\$)	Total Cost (\$)	Average Price (\$)	Volume	%
21	Amlodipine with Valsartan	2,892	58,927	103,669	35.85	114,687	2,357,246	4,145,616	36.15	111,795	3865.66
22	Moxonidine	68,272	1,338,415	1,604,290	23.50	178,241	3,544,847	4,284,474	24.04	109,969	161.07
23	Bisoprolol Fumarate	334,961	20,397,002	23,269,099	69.47	433,566	23,406,988	27,326,171	63.03	98,605	29.44
24	Fentanyl	347,793	33,589,991	36,044,174	103.64	441,440	43,205,818	46,364,092	105.03	93,647	26.93
25	Pliglitazone Hydrochloride	373,747	30,347,842	34,202,725	91.51	462,125	37,936,355	42,892,254	92.82	88,378	23.65
26	Lercanidipine Hydrochloride	1,434,491	29,058,520	35,273,536	24.59	1,521,127	30,910,191	37,695,705	24.78	86,636	6.04
27	Olmesartan Medoxomil	122,374	2,846,307	3,428,458	28.02	208,356	4,859,062	5,866,138	28.15	85,982	70.26
28	Ezetimibe with Simvastatin	515,328	54,095,598	60,358,007	117.13	600,250	61,506,640	69,089,853	115.10	84,922	16.48
29	Tiotropium Bromide Monohydrate	1,390,860	97,137,287	106,294,683	76.42	1,473,689	103,088,773	113,274,722	76.86	82,829	5.96
30	Fenofibrate	452,619	12,312,536	18,286,229	40.40	531,623	14,582,066	21,816,262	41.04	79,004	17.45
31	Olmesartan Medoxomil with Hydrochlorothiazide	121,661	2,537,977	3,911,243	32.15	199,476	4,569,038	6,525,889	32.72	77,815	63.96
32	Perindopril	3,618,747	58,296,033	73,564,393	20.33	3,693,561	56,966,232	73,395,537	19.87	74,814	2.07
33	Risedronate Sodium	378,089	17,972,342	20,745,946	54.87	448,905	21,464,123	25,074,085	55.86	70,816	18.73
34	Cephalexin	2,271,585	14,386,376	24,322,481	10.71	2,333,453	14,933,804	25,581,292	10.96	61,868	2.72
35	Strontium Ranelate	172,443	7,715,893	9,096,040	52.75	234,298	10,520,748	12,469,594	53.22	61,855	35.87

## List of Acronyms and Definitions

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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
Responsible Person	The person determined by the Minister to be the Responsible person for a brand of pharmaceutical item. This is the person who has notified the Minister they are, or will be, the supplier of a particular brand of pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The same person must be the Responsible person for all pharmaceutical items that have that brand. The Responsible person can be a company.
RPBS	Repatriation Pharmaceutical Benefits Scheme
SPC	Special Patient Contribution
TGP	Therapeutic Group Premium
WAMTC	Weighted Average Monthly Treatment Cost



