Trends and Outcomes in the Australian Pharmaceutical Benefits Scheme

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1. Introduction

The cost of the Pharmaceutical Benefits Scheme (PBS) to the Government has been the subject of regular controversy and policy responses for a number of years. Recent changes to Government policy described in Sweeny (2007b) are principally aimed at cutting the price of medicines once competitors appear but are also driven in part by a concern about the difficulty of giving patients access in the future to those innovative medicines currently in the pipeline that will be more effective in treating disease but could also be more costly. This recognises that the share of biotechnology-based medicines in new listings has become more significant in recent years and these types of medicines are inherently more expensive than traditional small-molecule based medicines. Industry acceptance of these most recent policy changes has been gained by the argument that they are needed to give more "headroom" to allow for more new medicines to be listed and to insulate newer medicines from price cuts.

From time to time the impact of individual new medicines coming onto the PBS has been highlighted, particularly when the demand for some of these medicines exceeds the estimates of their net cost made by both companies and Government. This was the case in 2000-01 when medicines for treating pain (*Celebrex* – celecoxib and *Vioxx* - rofecoxib) and for smoking cessation (*Zyban* – bupropion) were responsible for expenditure of over $270 million.

Over the past few years, long-term projections about the cost of health services caused by an ageing population have been made by the Department of the Treasury (2002, 2007) and more recently and comprehensively by the Productivity Commission firstly in a report about the economic implications of an ageing Australia and secondly in an analysis of the impact of medical technology on healthcare expenditure (Productivity Commission 2005a, 2005b). In the first of these reports the Productivity Commission estimates that the share of the PBS in GDP will rise from 0.68% in 2003-04 to 2.59% over a forty year period to 2044-45 – a faster increase than either Medicare or hospital expenditure. In a recent report for Medicines Australia however, Access Economics (2006) argues that if growth rates in the PBS return to more historical rates, the share of GDP is likely to be at least 0.9 % lower in forty years than the Productivity Commission's estimates.

Against this background, this paper is concerned with describing aspects of the growth in PBS expenditure and how this growth has been affected by the operations of PBS pricing and listing policies

2. Expenditure growth in the PBS and its composition

Over the period from 1991-92 to 2005-06, the average rate of growth in the PBS expenditure was 11.8% although this growth has moderated in recent years (Table 1 and Figure 1). Historically however, this expenditure has been relatively constant as a proportion of GDP for extended periods of time (Figure 2), particularly through the 1960s, 1970s, and 1980s. It is only since the beginning of the 1990s that PBS growth

has been consistently higher than the growth in overall economic activity. In 1991-92 PBS expenditure was 0.37% of GDP while it reached 0.78% in 2004-05 before falling slightly to 0.75% in 2005-06. Historical data on PBS expenditure is available at DoHA (2006).

Table 1 PBS expenditure, 1991-92 to 2005-06

	Expenditure $m	Growth %
1991-92	1,528.6	10.5
1992-93	1,864.9	22.0
1993-94	2,197.0	17.8
1994-95	2,435.9	10.9
1995-96	2,804.8	15.1
1996-97	3,068.3	9.4
1997-98	3,356.3	9.4
1998-99	3,671.1	9.4
1999-00	4,140.0	12.8
2000-01	4,902.3	18.4
2001-02	5,390.1	10.0
2002-03	5,912.3	9.7
2003-04	6,500.0	9.9
2004-05	6,996.5	7.6
2005-06	7,272.3	3.9

Figure 1 Annual growth rate of PBS expenditure, 1991-92 to 2005-06, %

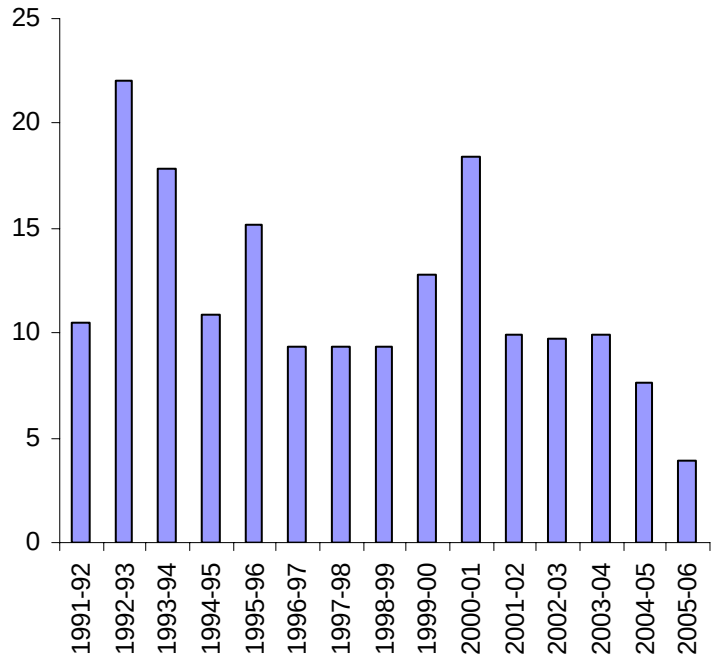
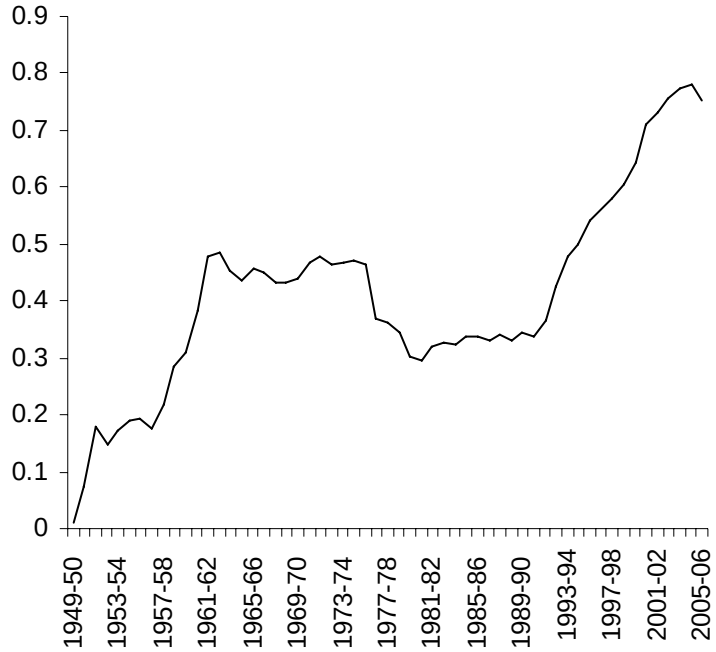


Figure 2 PBS expenditure as percentage of GDP, %



Sources: DoHA 2006 Table 16a, 16b; ABS 2007 5402.0 Table 5; RBA 2007, Table 5.1a.

In part the growth in cost has been driven by the increasing availability of new medicines for treating conditions that were previously either not treated or inadequately treated. This has resulted in a shift in the importance of classes of medicines over time as reflected in Table 2 and Figure 3, which compare the shares of medicines in PBS expenditure at the Anatomical main group level (ie the ATC1 level) in 1991-92 with that in 2005-06.

In the most recent year, three ATC1 groups have dominated PBS cost.

Medicines classified to *Cardiovascular system (C)* accounted for 29.4% of cost in 2005-06 and within this group the main contributors are medicines to treat high blood pressure (ACE inhibitors, A2RAs, betas blockers, calcium channel blockers – 12.2%) and to lower cholesterol (statins – 15.6%). The share of PBS expenditure due to cardiovascular medicines has fallen a little since 1991-92 and part of this fall is because of the impact of reduced prices arising from the operation of the PBS pricing system. The second most important ATC group is *Nervous system (N)* which took 17.0% of the PBS market in 2005-06. This group is dominated by medicines for treating psychosis (5.4%) and depression (6.4%). The third most important group in terms of cost is *Alimentary tract and metabolism (A)* - 13.7% in which the two most important classes are treatments for peptic ulcers (8.8%) and diabetes (3.3%).

Aside from the antidepressants, the groups that have increased most in importance have been *Antineoplastic and immunomodulating agents (L)* to 11.2% of PBS cost due mainly to growth in medicines to treat cancer but also because of medicines working on the immune system, and *Blood and blood forming organs (B)* although this latter group remains small in its share of cost (4.8%).

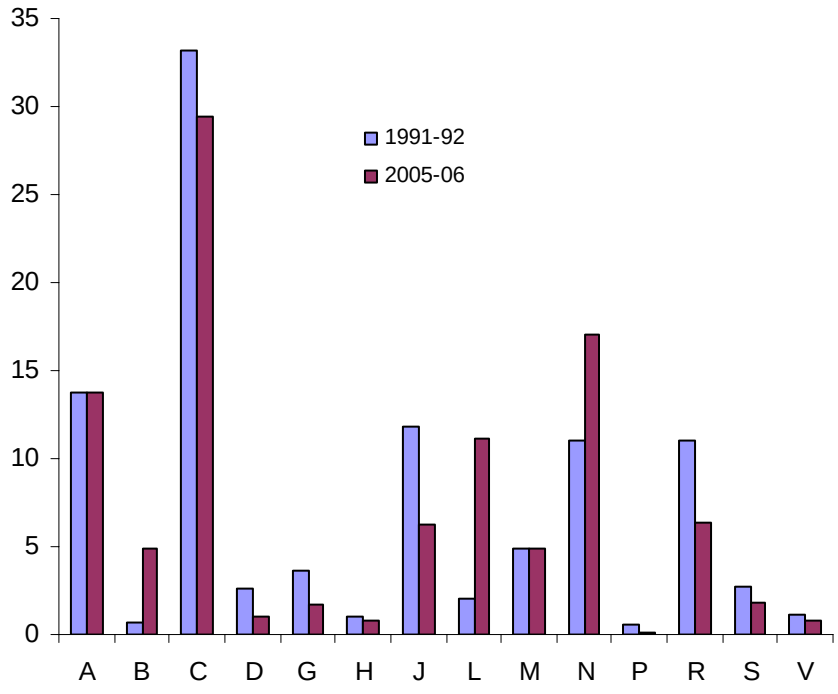
By way of contrast the two significant groups that have seen their shares fall are the *Antiinfectives for systemic use (J)* and *Respiratory system (R)* although for the first of these a dramatic fall in the shares of antibiotics has been offset to some extent by an increase in antiviral medicines for treating hepatitis, AIDS and other viruses. Within

the respiratory group, medicines for treating asthma and other obstructive airways disease are still a significant component of PBS cost (6.2%).

Table 2 Shares of PBS expenditure by ATC main group, 1991-92 and 2005-06, %

Code	Main group name	1991-92	2005-06	Value in 2005-06 $m.
A	Alimentary tract and metabolism	13.8	13.7	979.2
B	Blood and blood forming organs	0.7	4.8	345.8
C	Cardiovascular system	33.2	29.4	2,099.4
D	Dermatologicals	2.6	1.0	71.7
G	Genito urinary system and sex hormones	3.6	1.7	123.4
H	Systemic hormonal preparations, excl. sex hormones/insulins	1.0	0.8	57.9
J	Antiinfectives for systemic use	11.8	6.3	448.6
L	Antineoplastic and immunomodulating agents	2.0	11.2	798.1
M	Musculo-skeletal system	4.9	4.8	344.5
N	Nervous system	11.0	17.0	1,214.9
P	Antiparasitic products, insecticides and repellents	0.6	0.1	9.1
R	Respiratory system	11.0	6.3	450.0
S	Sensory organs	2.8	1.8	130.5
V	Various	1.1	0.8	57.2

Figure 3 Shares of PBS expenditure by ATC main group, 1991-92 and 2005-06, %

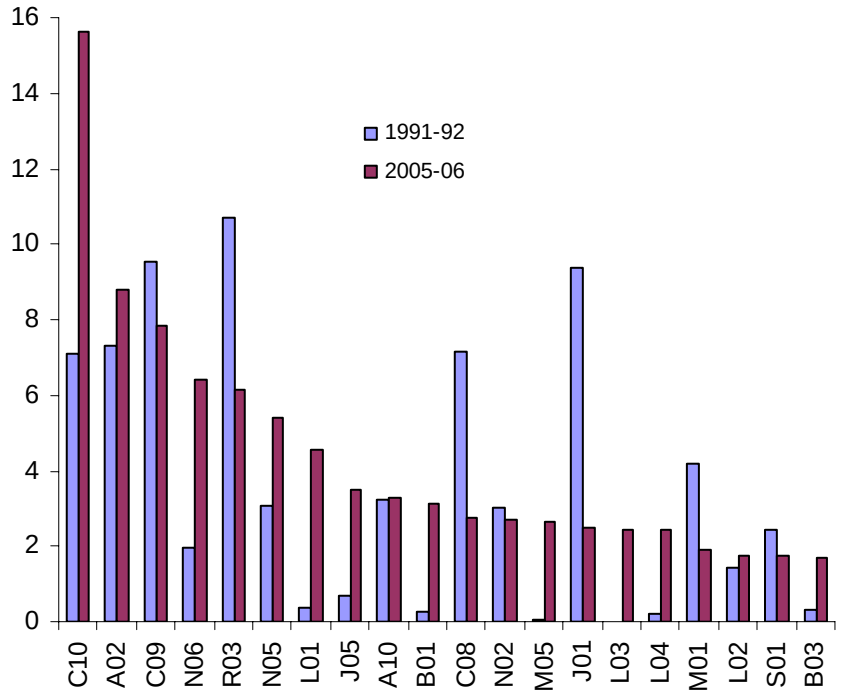


The top 20 (of 71) ATC therapeutic groups (ie at the ATC3 level) were responsible for 87.3% of PBS cost in 2005-06 with the top 6 accounting just over half (50.3%). Table 3 and Figure 4 show there have been marked changes in shares between 1991-92 and 2005-06 for most of these groups.

Table 3 Shares of PBS expenditure by top 20 ATC therapeutic groups, 1991-92 and 2005-06, %

Code	Main group name	1991-92	2005-06
C10	Lipid modifying agents	7.1	15.6
A02	Drugs for acid related disorders	7.3	8.8
C09	Agents acting on the renin-angiotensin system	9.5	7.9
N06	Psychoanaleptics	2.0	6.4
R03	Drugs for obstructive airway diseases	10.7	6.2
N05	Psycholeptics	3.1	5.4
L01	Antineoplastic agents	0.4	4.6
J05	Antivirals for systemic use	0.7	3.5
A10	Drugs used in diabetes	3.2	3.3
B01	Antithrombotic agents	0.2	3.1
C08	Calcium channel blockers	7.1	2.7
N02	Analgesics	3.0	2.7
M05	Drugs for treatment of bone diseases	0.0	2.7
J01	Antibacterials for systemic use	9.4	2.5
L03	Immunostimulants	0.0	2.4
L04	Immunosuppressive agents	0.2	2.4
M01	Antiinflammatory and antirheumatic products	4.2	1.9
L02	Endocrine therapy	1.4	1.8
S01	Ophthalmologicals	2.4	1.8
B03	Antianemic preparations	0.3	1.7
	Top 20 ATC therapeutic groups	72.4	87.3

Figure 4 Shares of PBS expenditure by top 20 ATC therapeutic groups, 1991-92 and 2005-06, %

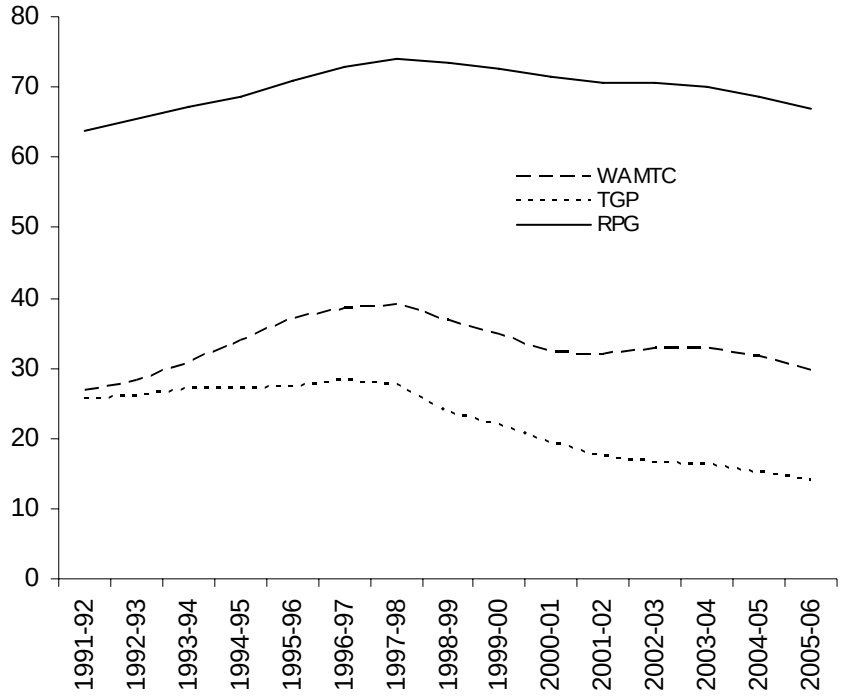


Medicines listed on the PBS on a cost-minimisation basis become members of Reference Pricing Groups (RPGs) in which the prices of the group members are set together (Sweeny 2007b). About half of all PBS medicines can be classified into these 111 RPGs. In addition 7 of these RPGs are also Weighted Average Monthly Treatment Cost (WAMTC) groups whose prices are reviewed and set on the basis of equalising the cost of a month's treatment among the medicines in the group. Further there are 4 WAMTC groups there are also Therapeutic Premium Groups (TPG). The importance of each of these groups within the PBS is illustrated in Table 5 and Figure 4.

Table 4 PBS expenditure in WAMTC, TGP and RPG groups

Year	WAMTC	TGP	RPG	Total	% WAMTC	% TGP	% RPG
1991-92	384.1	369.6	522.0	1,442.2	26.6	25.6	63.8
1992-93	511.7	473.7	627.3	1,822.9	28.1	26.0	65.6
1993-94	659.8	581.8	707.8	2,151.8	30.7	27.0	67.1
1994-95	815.7	656.9	761.7	2,417.9	33.7	27.2	68.5
1995-96	1,025.8	759.5	807.5	2,780.5	36.9	27.3	71.0
1996-97	1,162.8	855.1	821.1	3,031.1	38.4	28.2	72.9
1997-98	1,287.2	915.1	854.8	3,298.7	39.0	27.7	74.1
1998-99	1,324.5	849.4	957.9	3,610.6	36.7	23.5	73.5
1999-00	1,416.8	902.0	1,125.4	4,091.1	34.6	22.0	72.5
2000-01	1,558.2	939.1	1,373.7	4,834.5	32.2	19.4	71.6
2001-02	1,689.8	924.4	1,555.3	5,313.5	31.8	17.4	70.7
2002-03	1,893.1	963.6	1,713.2	5,802.5	32.6	16.6	70.5
2003-04	2,096.3	1,028.0	1,908.8	6,388.9	32.8	16.1	70.1
2004-05	2,183.3	1,031.9	2,168.7	6,887.9	31.7	15.0	68.5
2005-06	2,107.1	988.7	2,366.1	7,135.4	29.5	13.9	66.8

Figure 5 WAMTC, TGP and RPG group shares of PBS expenditure



While RPGs accounted for over two thirds of PBS expenditure in 2005-06, the peak of their importance was in the late 1990s and their share of the PBS has declined steadily since then, in part due to market saturation for some of the main RPGs and through the influence of falling prices. Similar declines in importance are evident for both WAMTC and TPG groups for the same reasons.

3. Contribution of new medicines

Associated with this changing mix of medicines in different therapeutic areas has been a steady increase in the number of medicines listed. Table 5 gives for each year from 1991-92 to 2006-07, the number of new medicines listed, the number of medicines that were in their last year of listing and the overall numbers of medicines on the PBS. This latter number increased from 544 in 1991-92 to 699 in 2006-07 and increase of 155 or 28%. This increase however understates the 402 new medicines listed over the period which were offset by 231 medicines which exited the PBS formulary for a variety of reasons. Table 5 and Figure 6 demonstrate that the number of new medicines listed on the PBS has usually been in the range of 20 to 25 per year despite some larger numbers in years such as 1996-97 and 1997-98. The average number listed per year over the period was 25.1. The number of exiting medicines has shown more variation from year to year but averaged 14.4 per year.

The contribution to the increase in PBS expenditure from new medicines can be examined in a number of ways but two are undertaken here. Firstly the average annual expenditure per new medicine is calculated based on PBS expenditure data from 1991-92 to 2005-06. Following that the relationship is explored econometrically.

The average cost to the PBS for each medicine can be calculated by adding the costs from the year of entry to 2005-06 (or the year the medicine exited the PBS) and dividing by the number of years. This average gives an indication of the typical contribution to the annual cost of the PBS from that medicine. For medicines listed in recent years this measure must be treated with some caution because, as demonstrated below, it takes a number of years for a medicine to reach its typical annual PBS cost. In addition, this only measures the gross addition to the cost of the PBS from listing the new medicine, and does not take account of reductions in the cost of medicines from which the new medicine may take market share.

In Table 6, the cost of new medicines is shown in 2 ways – in terms of the average annual cost per medicine listed and the average annual cost for all medicines listed. In 2003-04 for instance there were 22 new medicines listed and the average annual cost of all 22 medicines was $149.7 million, or $6.8 million per new medicine on average. The number of new medicines each year given in Table 6 is different from that in Table 5 mainly because there are a number of medicines listed on the Schedule for which no cost information is available.

A profile of cost over time was developed for each of the medicines included in Table 6 and on the basis of this a profile for the average new medicine was calculated. Table 7 shows the cost for this average new medicine in the first to seventh year of life on the PBS. The first column shows the profile for all medicines since 1991-92 while the second column gives the calculations for a more recent cohort – all medicines listed since 1996-97. As might be expected the cost to the PBS rises steadily over time to reach a steady state level in about the sixth year. The most recent cohort has a somewhat higher cost profile than that for all medicines.

While the average annual cost provides some idea of the impact of new medicines, most new medicines cost considerably less than this amount. Table 8 and Figure 7 show the number of new medicines that fall into different cost ranges. About three quarters of new medicines listed (75.8%) cost less than $10 million per year, about two thirds (64.3%) end up costing less than $5 million per year, with about a third (36.1%) costing less than $1 million. PBS medicines expected to cost more than $5 million per year require approval by the Department of Finance and Administration, while those with an expected cost greater than $10 million require Cabinet approval. There are a handful of medicines (4.5%) that cost more than $50 million per year, with the rest (19.7%) falling between $10 and $50 million.

When suppliers apply to have a new medicine listed on the PBS, the usual (and most successful) type of economic analysis presented is a cost-minimisation one. This accepts that the new medicine is similar in efficacy and side effects to one or more medicines already available on the PBS and the degree of innovation or novelty in the new medicine is small compared to these other medicines. Researchers have sought to characterise medicines by their degree of novelty and used this to explain their varying degrees of success in the market, either in terms of prices or sales. A common method is to follow the practice of the FDA in the United States which classifies medicines being presented for approval into either “Priority” or “Standard” according to an assessment by the FDA. For “Priority” medicines the FDA believes that the candidate medicine offers a “significant improvement compared to marketed products, in the treatment, diagnosis, or prevention of a disease” while a “Standard” medicine “appears to have therapeutic qualities similar to those of one or more already marketed drugs” (FDA 2004). Lu and Comanor (1998) have explained differential prices in US pharmaceutical markets using this classification.

The age of medicines has also been used a proxy for degree of novelty (for example Lichtenberg 2003, 2007).

An alternative to these approaches is to assess the novelty of a new medicine by whether it is assigned a new ATC code within the ATC system. Any new medicine is assigned a unique seven digit ATC code but this is usually as an addition within an existing ATC5 level code. Occasionally a new medicine initiates a new code at ATC5 level or higher because it has a sufficiently new mode of action to warrant separate classification. Simvastatin (C10AA01) for instance initiated a new class of cholesterol lowering agents at the ATC5 level, namely *C10AA - HMG CoA reductase inhibitors*, while losartan (C09CA01) began both new ATC4 and ATC5 codes for blood pressure lowering medicines, namely *C09C* and *C09CA* both of which are called *Angiotensin II antagonists, plain*.

From June 1991 to July 2007 there were 93 medicines that were novel in that they introduced a new ATC5 code. These additions amount to about 6 per year on average and account for about 25% of all current ATC5 codes. Medicines introducing a new ATC3 or ATC4 code were much rarer at 21 and 5 over the 16 year period. Their distribution over the period is shown in Table 9 and Figure 8. While there is considerable year to year variation, the number of novel medicines listed per year has fallen, particularly when compared to the levels of the first half of the 1990s. Over the eight years to 2006-07, the average number of medicines introducing a new ATC5 code per year was 4.5, while over the previous eight years the average was 7.1.

The determinants of PBS expenditure are likely to be complex and vary considerably among the different treatment markets. Expenditure has both a price and a volume or quantity component and the decomposition of expenditure into these components is

described in a forthcoming working paper in this series. Demand equations typically are based on a volume or quantity measure as the dependent variable and relate the amount and type of medicines demanded by patients to the influence of a number of factors, such as the incidence and prevalence of the disease being treated, the degree of restriction placed on prescribing for particular medicines, and the cost to the patient as measured by the levels of copayments, safety net levels and price premiums. Demand equations of this type are explored in the forthcoming paper. These equations have as the dependent variable a measure of the quantity consumed measured in physical units such as doses or defined daily doses.

When estimated at an aggregate level, these demand equations can include the number of molecules as an explanatory variable to ascertain how the expansion in demand is related to the increasing availability of medicines to treat disease. The impact of the number of molecules on the level of expenditure, rather than the quantity demanded can also be explored econometrically by a simple equation relating expenditure to a trend variable and the number of molecules.

The CSES has assembled a number of pharmaceutical-related datasets. The analysis in this section draws upon annual financial year data for the period 1991-92 to 2005-06 covering PBS expenditure and scripts for each combination of PBS item and manufacturer code. This data is cross-classified using the scheme developed by the WHO Collaborating Centre for Drug Statistics Methodology (2006, 2007). Each medicine has a unique 7-digit code but medicines are also classified at higher levels. These higher level codes can be used to define pharmaceutical treatment markets consisting of medicines used to treat a particular disease and this process is described more fully in Sweeny (2007a).

Tables 10 to 12 set out the results of estimating equations using PBS expenditure as the dependent variable and the number of medicines and a population trend as explanatory variables. Equations are estimated using data defined at ATC1, ATC3, ATC4 and ATC5 levels and for both linear and logarithmic specifications. ATC dummy variables are used to control for market specific conditions. The variables are

constant	*Constant*
$ccop_t$	*Average level of concessional copayment in year t*
d_a	*Dummy variable with value 1 for ATC code a, 0 otherwise*
mol_{at}	*Number of molecules in ATC code a in year t*
$pbsexp_{at}$	*PBS expenditure in ATC code a in year t*
pop_t	*Australian population at June in year t*

Equations were estimated using a time trend and the size of the population in age categories such as “55 and over” and “65 and over” as alternatives to using the total population as an explanatory variable. However all these alternatives are highly correlated and produce virtually identical results, so only results using total population are reported. In addition equations were estimated including the average level for the concessional copayment to capture the impact of this on expenditure. Because the general and concessional copayment levels over the period 1991-92 to 2005-06 are highly correlated (r = 0.999), the concessional copayment is used as a proxy for both. In most equations however the copayment is insignificant so results are only reported including it for the logarithmic specification including ATC dummy variables (Table 12).

In general the logarithmic specification performs better than the linear. However as the adjusted coefficient of determination indicates, the amount of variance explained by the independent variables declines steadily as the ATC level increases, indicating

the increasing predominance of ATC-specific factors. This can be seen clearly when comparing the fit statistics for results including and excluding the ATC dummy variables.

In all cases the population trend and the number of molecules have significant coefficients with the expected signs but the contribution from population becomes less as the ATC level rises, while the contribution from the number of molecules remains relatively constant. The linear specification with ATC dummy variables suggest that every additional molecule will add between $13 million and $15 million to PBS expenditure. At the ATC4 level an increase of 1 million to population adds a further $9 million to PBS expenditure. The logarithmic version implies that expenditure will increase by about twice the increase in the number of molecules and 2.5 times the increase in population (at the ATC4 level).

The results including the concessional copayment show that the coefficient on this variable has the expected sign although its significance is not as great as for the other variables. The results in Table 11 imply that a 1% increase in the copayment will lead to a fall in expenditure of about 1.5%. It should be noted that the inclusion of this variable does not significantly change the coefficient on the number of molecules but increase the size of the coefficient on the population variable while reducing its significance somewhat. This latter result is probably because the two variables are highly correlated (r = 0.963). Omitting the population variable results in a positive (and significant) coefficient for the copayment variable.

All equations were tested for cointegration using the Pedroni residual cointegration test using panel data within Eviews. This provides 11 test statistics for cointegration and the number of tests which indicate cointegration at the 5% level of significance are reported for each regression result in Tables 10 and 11. This test indicates no cointegration at the ATC1 level but the high scores at higher ATC levels indicate cointegrating relationships among the variables for these specifications.

In summary, the regression results show that as the number of PBS medicines available increases, this leads to a more than proportionate increase in expenditure on PBS medicines as the choice of medicines expands and as new medicines become available to improve the treatment of disease.

4. The extent of competition in the PBS

Once patents protecting medicines have expired, new brands competing with the originator brand are able to enter the market if they have demonstrated bioequivalence to the satisfaction of the regulatory authority. It is a relatively straightforward process for the supplier of a competing brand to have that brand listed on the PBS once approved by the TGA (Sweeny 2007b).

These competing brands are often referred to as “generic” brands and the suppliers “generic” suppliers. It is important to note however that it is not possible to draw a hard and fast line between originator and generic brands or suppliers.

“Generic” brands are often taken to be those medicines where the supplier provides them under the molecular or chemical name. For instance “Zocor” is the name of the brand of the medicine simvastatin provided by the originator company Merck, Sharp & Dohme (Australia) while the competing brand from Winthrop Pharmaceuticals is called “Simvastatin Winthrop” and the version from Genepharm Australasia Limited is simply called “Simvastatin”. However the brand from Alphapharm Pty Limited has the

distinctive name of “Zimstat”. There is a difference therefore between branded and unbranded generics.

While Alphapharm Pty Limited is usually described as a “generic” supplier because it does not develop its own medicines, it also acts as the single supplier of some patent-protected medicines licensed from other companies, as is the case with other “generic” suppliers. Often these are brands licensed from the originator company once that company has decided it no longer wants to supply that particular medicine any more. Aspen Pharmacare Australia Pty Ltd is another example of such a company.

Some “originator” companies also produce “generic” brands that compete with other “originator” companies once their medicines are no longer patent-protected. For instance Winthrop Pharmaceuticals only supplies off-patent medicines but is a subsidiary of Sanofi-Aventis, the second largest research-based pharmaceutical company in the world. Similarly Real-RL supplies a generic version of simvastatin (“Simvastatin-RL”) but is a subsidiary of GlaxoSmithKline Australia Pty Ltd, the third largest research-based pharmaceutical company.

The picture is further complicated by the practice of originator companies licensing a “generic” company to list a “friendly” generic brand before patent expiry to protect market share and price once patent expiry has occurred.

The operation of the minimum pricing policy within the PBS means that competing suppliers have relatively little incentive to offer a lower price for their brand to the PBS because all other brands of the same medicine will have their price reduced to this level, although there is an opportunity for suppliers to add a brand premium to the price. This lack of incentive to lower prices has been the main reason why the Government introduced changes to PBS policy in 2004 and 2006 focussed on mandatory price reductions.

Assessing the shares of “generics” in the PBS is therefore not straightforward and is best approached by establishing whether a medicine is provided on a single or multiple supplier basis. Where a medicine has multiple brands indicating competing suppliers, these brands are classified as either the “Originator” brand or as a “Competing” brand. Classifying PBS medicines in this way is a significant task and has only been undertaken completely for the year 2005-06.

Table 13 provides a break-down of the PBS expenditure in 2005-06 according to the supplier status and patent status of each medicine listed. Medicines are either provided by a single supplier (which can include multiple brands from the same one supplier) or by multiple suppliers, which are classified as either the “originator brand” or as a “competing brand”. Medicines are “patented” if their patent expiry date is given as after 30 June 2006 or “off-patent” if expiry date is up to 30 June 2006 or is unpatented. There is a small unclassified component of expenditure – mainly extemporaneously prepared medicines, where the supplier is unknown and are assumed to be off-patent.

Table 13 PBS expenditure by supplier and patent status, 2005-06

	Off-patent	Patented	Total	Off-patent	Patented	Total
	$m	$m	$m	%	%	%
Single supplier	828.0	3,895.0	4,723.0	26.8	96.2	66.2
Multiple supplier	2,254.6	152.7	2,407.3	73.0	3.8	33.7
Originator brand	1,247.2	134.5	1,381.7	40.4	3.3	19.4
Competing brand	1,007.4	18.2	1,025.6	32.6	0.4	14.4
Other	5.1	0.0	5.1	0.2	0.0	0.1
All medicines	3,087.7	4,047.7	7,135.4	100.0	100.0	100.0

In 2005-06, just under two thirds of PBS expenditure was on single supplier medicines, with the remaining third made up of medicines from multiple suppliers. Of these multiple brands, 57.4% of the expenditure was on originator brands with 42.6% on brands competing with the originator. As Table 13 shows however, even within the off-patent section of the PBS where competition among brands predominantly occurs, there is still a sizable share taken by single supplier medicines (26.8%). For the whole of the off-patent market, the share of competing brands is 32.6%, while for the whole of the PBS their share is 14.4%. This latter value then can be taken as the "generics" share within the PBS.

Not surprisingly the patented section of the PBS is dominated by single supplier medicines, although the small presence of originator and competing brands indicates that originators may have licensed competing brands for some medicines with patent expiries after 30 June 2006.

Despite the caveats discussed earlier it is possible to classify PBS suppliers as either predominantly "Research-based" in that they usually supply medicines based on their own research and development (or in alliance with other researchers) or as "Generic" companies principally supplying generic brands. Table 14 shows expenditure classified in this way with a small residual category of "Other" companies which supply other products such as diagnostics or act as suppliers of off-patent medicines but not in competition with other suppliers.

Table 14 PBS expenditure by supplier status and type of company, 2005-06

	Research-based $m	Generic $m	Other $m
Single supplier	4,583.0	125.5	14.4
Originator	1,176.9	201.6	3.3
Competing brand	71.2	953.7	0.7
Other	0.0	0.0	5.1
Total	5,831.1	1,280.8	23.5

The "generic" companies account for about 17.9% of PBS expenditure and although their medicines are predominantly "competing" brands, medicines provided by them as single suppliers and as suppliers of "originator" brands under license account for about 25% of their contribution to PBS cost. The "research-based" companies on the other hand are overwhelmingly suppliers of either single supplier medicines or of "originator" brands.

The opportunities open to competing brands are mainly in the off-patent market which represents about 43.3% of the PBS. Within this segment competing brands

have 44.7% of the markets in which they compete and 32.6% of all off-patent markets. While these shares are significant, they are much less than those in markets such as the USA were generics take up to 80% of the market once patent expiry has occurred.

There are a number of factors responsible for this such as the size of off-patent markets and barriers to entry, but an important reason is likely to be the absence of significant price competition among originator and competing brands. Patients consuming PBS medicines pay a fixed copayment plus any premium added by the supplier to the base price determined by the PBS. The incentive to switch between originator and competing brands therefore will be influenced by the size of this premium.

There are three kinds of premium that can apply to brands listed on the PBS. The most common is the *brand premium* which is the addition made by a supplier to the base price of a particular PBS item where there are other suppliers of that item. Where they occur, brand premiums are almost always added by originator companies rather than generic companies. In recent years about 12% of all brands have had a brand premium.

Therapeutic premiums can be added by a manufacturer to the base price even if there are no direct competitor brands. This only applies to medicines within the four Therapeutic Premium Groups (described in Sweeny 2007b) and has only ever been applied to 42 brands. The third premium is a *Special Patient Contribution* (SPC) which arises when the Government and manufacturer are unable to agree on a price and the SPC is the difference between the Government base price and the manufacturer's price. Historically SPCs have applied only to one or two medicines but have become more widely used since the introduction of the 12.5% price reduction policy.

All brands with a brand premium for all items listed on the PBS from July 1991 to April 2007 were extracted from the PBS Schedule database maintained by the Centre for Strategic Economic Studies (CSES). The size of the premium was calculated by subtracting the Commonwealth dispensed price for maximum quantity (CDPMQ) from the manufacturer's dispensed price for maximum quantity (MDPMQ). Annual premiums were taken as averages of the relevant 12 monthly premiums. The premium margin was obtained by dividing the premium by CDPMQ.

The importance of premiums can be looked at in a number of ways. Firstly the number of brands with premiums can be compared to the number of brands overall. The number of brands with premiums increased from 7.3% of all brands on average in 1991-92 to 12.1% in 2005-06 (Table 15). The (unweighted) average margin for those brands with premiums has also risen steadily over the period from 9.2% of the base price in 1991-92 to 15.2% in 2005-06. However if the average is calculated by weighting the margin on a brand by its importance (its share of PBS expenditure on brands with premiums) the weighted average margin is significantly less than the unweighted average margin and shows no real increase over the period although there is substantial variation from year to year. This suggests that while the practice of adding a premium has become more common as more originator medicines face competition from generic suppliers, the size of the margin sought by originators is proportionally smaller the larger is the market for that brand. This may be due to the greater intensity of competition from generic suppliers in the market for more popular medicines.

The size of the differential between the prices sought by originator and generic suppliers is quite small compared to the usual experience in markets such as the USA where the originator brand maintains its price and generic prices are of the order of 20% or less of the originator price (Berndt 2002, Lu and Comanor 1998). It should be recognised however that the patients generally will not pay the dispensed price but a combination of the relevant copayment and the premium if any. The comparison that matters to patients is therefore the size of the margin with respect to the copayment not the dispensed price.

Inspection of the premiums in comparison to the base dispensed price suggests that originators initially seek a premium that will simply maintain the dispensed price at its previous level, even though this means an increase in the amount paid by the patient. Originators are therefore relying on brand loyalty to maintain market share. Similarly, if the base dispensed price falls in periods thereafter the premium will be kept constant so that there is no change in the price paid by the patient (assuming there has been no change in the copayment).

Table 15 PBS brand premium margins

	Brands with premium	All brands	%	Unweighted average margin, %	Weighted average margin, %
1991-92	132	1800	7.3	9.2	6.3
1992-93	169	1842	9.2	9.8	6.8
1993-94	186	1866	10.0	13.3	8.5
1994-95	223	2129	10.5	13.6	8.3
1995-96	230	2174	10.6	12.7	8.6
1996-97	252	2352	10.7	13.0	7.2
1997-98	288	2661	10.8	12.5	7.6
1998-99	336	2794	12.0	12.7	8.0
1999-00	359	2927	12.3	13.8	7.3
2000-01	429	3182	13.5	13.2	7.4
2001-02	417	3592	11.6	14.5	7.6
2002-03	413	3759	11.0	15.9	9.2
2003-04	413	3871	10.7	16.4	9.4
2004-05	414	3594	11.5	15.2	6.4
2005-06	455	3750	12.1	15.2	6.0

The relatively small margins added by suppliers to the base price account in part for the fact that competing brands have only a minority share on average in markets in which they compete. As part of the work undertaken by the author modeling the impact of the recent changes to PBS policy (CSES 2006), the rate at which originators lose market share was calculated using PBS expenditure data from 1991-2 to 2004-05. Table 16 reports this share both as an unweighted average of all PBS medicines for which this occurred during the period and as an average where the medicine is weighted by its importance as measured by its PBS expenditure.

Both profiles show that loss of market share is gradual so that by the fourth year after entry of competing brands, the originator still retains about 70-75% of the market and over half the market after 9 years. The reduction in share is slightly faster for the weighted average suggesting that competitors strive more aggressively for market share within larger markets.

Table 16 Average market share of originator brand after entry of competitors

Year after competitive entry	Unweighted %	Weighted %
0	100.0	100.0
1	94.2	94.4
2	85.6	87.0
3	79.3	78.1
4	75.3	71.5
5	73.0	67.7
6	68.5	62.2
7	66.6	61.3
8	63.0	61.6
9	56.9	56.8

5. Price changes after patent expiry and new entry

In the study conducted prior to the introduction of the mandatory 12.5% price reduction policy (CSES 2005), the author examined the extent to which patent expiry and any subsequent entry by competing brands led to changes in the prices paid by the PBS for these medicines. The analysis for that study covered the period from August 1994 to August 2004 but the results reported below extend this to cover a longer range from August 1991 to July 2005, ie until just before the introduction of the new policy.

During this period some 103 medicines experienced patent expiry but some had more than one expiry because of different patents for different forms. Because of this there were 112 patent expiries in total. Of these only 46 attracted competing brands for at least one of the formulations of the medicine. For each of these medicines the most popular item was identified and the price per unit was charted and examined. The price chosen was the Commonwealth price to pharmacist divided by the manufacturer's pack size because it provides the clearest picture of trends in prices. It is preferable to the dispensed price because changes in the latter will include changes made to the dispensing fee. In addition the Commonwealth price to pharmacist does not include any changes due to premiums added by the manufacturer.

Visual examination of the price data indicated that 17 of the medicines experienced either price increases, or no change in prices, or only very minor decreases (less than 5%) across the period even though there were competing brands present. The remaining 29 medicines which are listed in Table 17 were considered in two broad groups. The first consists of 14 medicines that are either not members of a Reference Pricing Group (RPG) or are the only member of the group which experienced patent expiry. The second group consists of 15 medicines within 6 RPGs of which 5 are WAMTC groups. By and large these groups are more important in terms of overall PBS sales than the medicines in the first group.

The experience of the medicines in the first group is as follows.

Aciclovir experienced patent expiry in September 1995 although Arrow Pharmaceuticals and Alphapharm had brands listed prior to this in December 1994 and February 1995 respectively. Two price decreases of about 3% each occurred in August 1999 and February 2003 possibly due to new brands from Douglas

Pharmaceuticals, Genepharm and Hexal Australia in May 1999 and Biochemie Australia in August 2002. However there were other entrants between these two dates that were not associated with price falls. There were no changes in the "Authority required" restriction level during the period. Aciclovir belongs to an RPG but the other two members – *famciclovir* and *valaciclovir* were patent protected during the period.

The patent on *carboplatin* expired in June 1993 but the only significant change in prices occurred in August 1998 when the price fell by about 25%. David Bull Laboratories already had a brand on the PBS in July 1991 and Pfizer introduced a brand in December 1992. At that time the restriction level change from "R" to "U". True generic entry from InterPharma only occurred in December 2006.

For *cyclosporin* the patent expired in March 1999 but significant price falls totalling around 9% occurred earlier in May 1997 and May 1998. New entry commenced in May 2002. The restriction level changed from "R" to "A" in November 2000.

Clarithromycin also had a major price fall of 55% in May 1999 well before patent expiry in March 2005 and entry of competing brands in December 2004. In May 1999 a new item for *clarithromycin* with a "U" restriction level was introduced and the other item went from "R" to "A".

Flecainide acetate experienced patent expiry in March 1995 and new entry in November 1999. Its price rose steadily until a fall of about 7% in February 2000. While this may be associated with the new entrant, subsequent small falls of 1-2% were not. It changed from "A" to "R" in December 1994.

The first new entrant for *flutamide* occurred in August 1999 about a year before patent expiry in September 2000. This new entry coincided with a price fall of about 15% followed by smaller falls over the next few years. Its restriction level remained unchanged at "A".

The patent on *gabapentin* expired in December 1991 but the first new entry by Arrow only occurred in August 2001 followed by other brands in August 2002. The price fell by 10% in February 2003. There was no change in the "A" restriction level. The other member of the RPG – *lamotrigine* only had new entry in May 2005.

For *ipratropium bromide* patent expiry happened in July 1999 although new brands from Alphapharm were listed in May 1997 and May 1998. Other brands entered in February 1999 and November 2000. A price drop of 10% occurred in November 1998 followed by another 10% drop in May 1999. Surprisingly the restriction level changed from "U" to "R" in May 1998.

Patent expiry for *irinotecan* occurred in July 2004 with new entry in April 2005. A price fall of about 9% has preceded this in December 2004. Restriction levels remained unchanged at "A" while new entry for the other member of the RPB – *oxaliplatin* only happened in December 2006.

The patent on *isotretinoin* expired in June 1991 but the first new brand was from Alphapharm in August 1995 followed by Douglas in August 1999. A price fall of 18% occurred three months later in November 1999. Restriction levels remained unchanged at "A".

The only significant price fall for *naproxen* was 6% and this happened in April 1992. The patent expired in January 1992 but Alphapharm already had a brand listed prior to July 1991 and no new brands were listed thereafter.

For *norfloxacin* the patent expired in January 1998 with first new entry in February 2001 from Hexal followed by an 8% price fall in May 2001. Restriction levels were "A" throughout.

For *paclitaxel* patent expiry occurred in January 1999 but the first true generic from InterPharma was listed in April 2005. Paclitaxel had a number of price reductions from June 1995 to February 2001 none of which can be linked to new entry. The other member of the RPG – *vinorelbine* only had new entry in August 2006. Restriction levels were "A" throughout.

The patent on *timolol maleate* expired in September 1996 and this was followed by new entry from Alphapharm in February 1998 coinciding with a 10% price fall.

Of these 14 medicines with patent expiry, price reductions due to new entry can only be reasonably associated with 7 of them – *flecainide* (7%), *flutamide* (15%), *gabapentin* (10%), *ipratropium* (10%), *isotretinoin* (18%) , *norfloxacin* (8%), and *timolol* (10%). For only two of these did the price fall coincide with new entry – *flutamide* and *timolol*. The large falls for *clarithromycin* were associated with a change in restriction level.

The experience of members of the second group of medicines is discussed in terms of the dynamics of the RPGs of which they are members.

One of the largest price falls in the period was felt by the two antibiotics which make up the RPG of third generation cephalosporins. This occurred in February 2003 when the prices of *cefotaxime* and *ceftriaxone* both fell by about 53%. Patent expiry for the two medicines was in August 1998 and May 1999 respectively and the first new entrant was listed in November 2001 followed by further entrants in February 2002. Restriction status changed from "A" to "R" in December 1994. The price fall appears unrelated to either new entry or restriction status.

The patent expiry on *felodipine* in June 1999 was preceded by the listing of a brand from a subsidiary of the originator company in February 1998 which was accompanied by a fall of 8% in the price. No other new entrants have been listed. Another member of the same RPG (calcium channel blockers) *nifedipine* experienced patent expiry on a particular form of the medicine in September 2001 with new entry in May 2003. Although this medicine had experienced a number of price falls since 1995 none had any relationship with these events. Patent expiry and new entry had occurred for other members of the RPG (*dilitazem* and the other forms of *nifedipine*) well before 1991 while two were patent protected during the period (*amlodipine* and *lercanidipine*).

From 1991 to 2005 patents expired on three ACE inhibitors – *captopril* in January 1997, *enalapril* in December 1999 and *lisinopril* in April 2001. These were the first expiries within the RPG. In June 1992 the price of *enalapril* fell by 9% which coincided with a shift from "A" to "R" for the ACE inhibitors. There was no change when it changed from "R" to "U" in April 1995. In February 1998 the price of both *captopril* and *enalapril* fell by about 15%. Prior to this, there had been new entries for *captopril* in May 1996 (ie before patent expiry), and in May, August and November 1997. There were a further 6 new entries for *captopril* before the next major price drop of 12% in August 2001 which was the same for all the ACE inhibitors. While this

coincided with a new entrant for *lisinopril* there had been an earlier one in May 2001 and new entrants for *enalapril* in February and May 2001.

There are two broad classes of medicines for treating peptic ulcers and patent expiry occurred in both during the period. In the older H2-receptor antagonists group these were *ranitidine* in August 1993, *cimetidine* in September 1993, and *famotidine* in July 2003. The switch from "A" to "U" for these medicines in October 1992 caused a price fall of about 18%, although there was no price change when it moved to "R" in December 1994. The first new entrant for the group was for *cimetidine* in June 1994 preceding a price fall of 8-12% in August 1994 for all three medicines. *Ranitidine* and *famotidine* suffered falls of about 25% in February 1998 although this did not coincide with a new entry and 4 other brands of *cimetidine* or *ranitidine* had been listed in the previous 2 years. There was no fall for *cimetidine* at this time. New entrants for *famotidine* beginning in August 2003 had no effect on prices.

The more recent class of peptic ulcer treatments is the proton pump inhibitors and the patent on one of these *omeprazole* expired in April 1999. The first new entries for *omeprazole* were in February and May 1999 and these were followed by a 35% price fall in August 1999 for *omeprazole*, *lansoprazole* and *pantoprazole*. This also coincided with the release of a tablet form of *omeprazole* following entry of *pantoprazole* in tablet form in November 1995. A further fall of about 20% in August 2001 for all medicines in the group is unrelated to patent expiry or new entry although *rabeprazole* was first listed in May 2001.

The final group to be considered is the newer types of antidepressants including the selective serotonin reuptake inhibitors. The patents expired on *citalopram* in January 1993, on *fluoxetine* in December 1994, and on *moclobemide* in January 1997. The patent expiry date for *paroxetine* is the subject of some dispute but new entry occurred for this medicine in August 2001. Curiously *citalopram* was only first listed on the PBS in February 1998 or 5 years after patent expiry. With the exception of *sertraline*, the other medicines within this group had no significant price changes. The major price fall for this group of medicines occurred between August and December 1996 when prices fell by 30-35% for *fluoxetine, paroxetine* and *sertraline*. The first new entrant in the group was a new brand from Alphapharm for *fluoxetine* in February 1996 followed by a brand from Douglas in November 1996. The first new brand for *moclobemide* also entered in August 1996. However these reductions in price cannot be ascribed to these new entries because of a change in restriction status from "A" to "R". For *fluoxetine* this happened in August 1996 and for *paroxetine* and *sertraline* in November 1996 at the same times as the price changes. The price of *moclobemide* did not change at this time because it moved from "A" to "R" in April 1995 at which time its price fell by 12%. It is difficult to find a link between a series of further price reductions for *moclobemide* in February 1998, November 1998 and February 2002 and either patent expiry or new entry.

Summarising this somewhat complicated picture of patent expiry, new entry and restriction change for these groups, it is difficult to find unambiguous instances where the listing of new brands for a medicine resulted in a price reduction in the absence of any change in restriction status. For the ACE inhibitors captopril and enalapril the price reductions may have been come about after the cumulative listings of new brands and this may also have been the case for the peptic ulcer treatments ranitidine and cimetidine. The large falls for omeprazole after new entry present a stronger case for an association but the price reductions for the antidepressants are clearly linked to a change in restriction status.

The evidence from a close examination of those 46 cases of patent expiry followed by new entry over the period 1991 to 2005 therefore shows only a handful of medicines where the new entrant may have offered a lower price than the prevailing price at the time and for most of these the price reduction was less than 15%. Furthermore, in the majority of cases the price reduction did not coincide with the time of listing and it is difficult to think of reasons why a new entrant should subsequently offer a lower price than the one offered and accepted at listing.

Price reductions are most likely to have arisen from the operation of annual price reviews within the PBS, especially for those medicines that fall within the WAMTC and RPG groups. In addition it should be recognised that price reductions may have been negotiated when other changes were made to listing conditions aside from changes in restriction status. For instance a medicine may be made available for a larger range of conditions even though its restriction status remains unchanged.

In summary the operation of reference pricing within the PBS means that there is little incentive for a new entrant to offer a lower price knowing that this will set the base price for all other brands and that the premium added by originator brands when this occurs is traditionally quite small. The scope for price competition for a new entrant is thus very restricted which in turn is responsible for the rather slow gain in market share by brands competing against the originator. The recognition of this by the Government is largely responsible for the introduction in August 2005 of a new policy requiring a mandatory 12.5% price reduction on entry of a new brand for all medicines that are members of the same Reference Pricing Group.

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Table 2 Shares of PBS expenditure by ATC main group, 1991-92 and 2005-06, %

Code	Main group name	1991-92	2005-06	Value in 2005-06 $m
A	Alimentary tract and metabolism	13.8	13.7	979.2
B	Blood and blood forming organs	0.7	4.8	345.8
C	Cardiovascular system	33.2	29.4	2,099.4
D	Dermatologicals	2.6	1.0	71.7
G	Genito urinary system and sex hormones	3.6	1.7	123.4
H	Systemic hormonal preparations, excl. sex hormones/insulins	1.0	0.8	57.9
J	Antiinfectives for systemic use	11.8	6.3	448.6
L	Antineoplastic and immunomodulating agents	2.0	11.2	798.1
M	Musculo-skeletal system	4.9	4.8	344.5
N	Nervous system	11.0	17.0	1,214.9
P	Antiparasitic products, insecticides and repellents	0.6	0.1	9.1
R	Respiratory system	11.0	6.3	450.0
S	Sensory organs	2.8	1.8	130.5
V	Various	1.1	0.8	57.2

Figure 3 Shares of PBS expenditure by ATC main group, 1991-92 and 2005-06, %

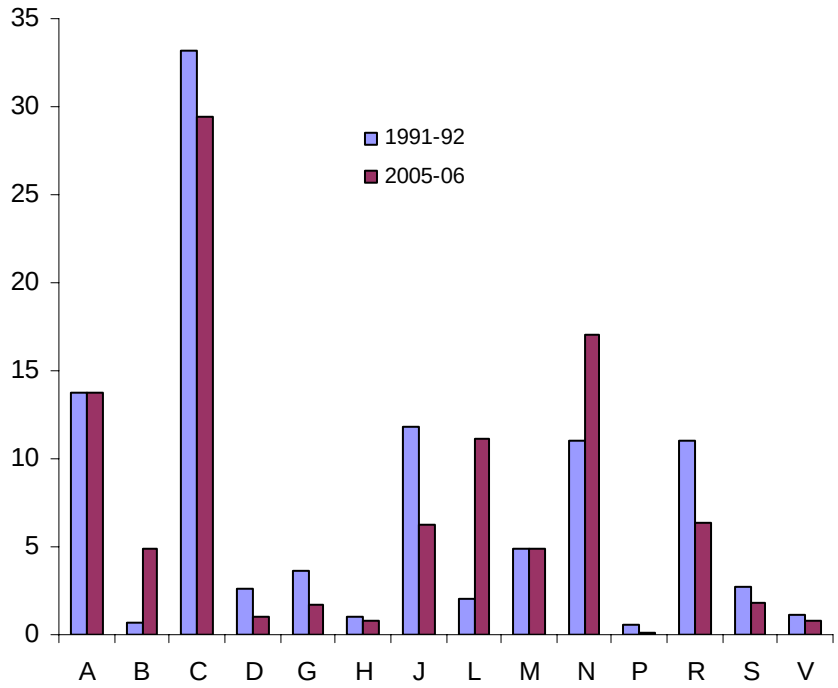

Table 3 Shares of PBS expenditure by top 20 ATC therapeutic groups, 1991-92 and 2005-06, %

Code	Main group name	1991-92	2005-06
C10	Lipid modifying agents	7.1	15.6
A02	Drugs for acid related disorders	7.3	8.8
C09	Agents acting on the renin-angiotensin system	9.5	7.9
N06	Psychoanaleptics	2.0	6.4
R03	Drugs for obstructive airway diseases	10.7	6.2
N05	Psycholeptics	3.1	5.4
L01	Antineoplastic agents	0.4	4.6
J05	Antivirals for systemic use	0.7	3.5
A10	Drugs used in diabetes	3.2	3.3
B01	Antithrombotic agents	0.2	3.1
C08	Calcium channel blockers	7.1	2.7
N02	Analgesics	3.0	2.7
M05	Drugs for treatment of bone diseases	0.0	2.7
J01	Antibacterials for systemic use	9.4	2.5
L03	Immunostimulants	0.0	2.4
L04	Immunosuppressive agents	0.2	2.4
M01	Antiinflammatory and antirheumatic products	4.2	1.9
L02	Endocrine therapy	1.4	1.8
S01	Ophthalmologicals	2.4	1.8
B03	Antianemic preparations	0.3	1.7
	Top 20 ATC therapeutic groups	72.4	87.3

Figure 4 Shares of PBS expenditure by top 20 ATC therapeutic groups, 1991-92 and 2005-06, %

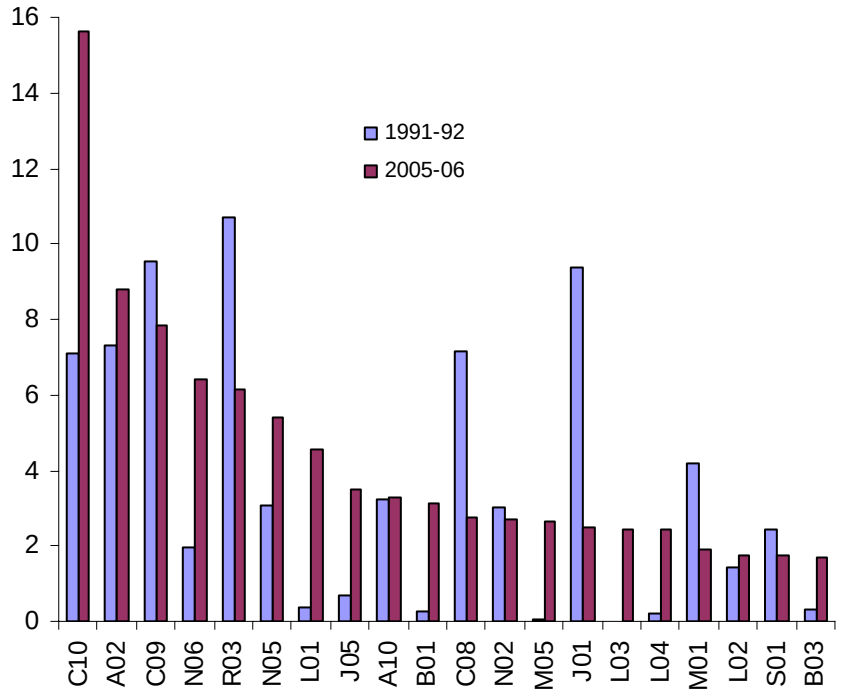

Table 4 PBS expenditure in WAMTC, TGP and RPG groups

Year	WAMTC	TGP	RPG	Total	% WAMTC	% TGP	% RPG
1991-92	384.1	369.6	522.0	1,442.2	26.6	25.6	63.8
1992-93	511.7	473.7	627.3	1,822.9	28.1	26.0	65.6
1993-94	659.8	581.8	707.8	2,151.8	30.7	27.0	67.1
1994-95	815.7	656.9	761.7	2,417.9	33.7	27.2	68.5
1995-96	1,025.8	759.5	807.5	2,780.5	36.9	27.3	71.0
1996-97	1,162.8	855.1	821.1	3,031.1	38.4	28.2	72.9
1997-98	1,287.2	915.1	854.8	3,298.7	39.0	27.7	74.1
1998-99	1,324.5	849.4	957.9	3,610.6	36.7	23.5	73.5
1999-00	1,416.8	902.0	1,125.4	4,091.1	34.6	22.0	72.5
2000-01	1,558.2	939.1	1,373.7	4,834.5	32.2	19.4	71.6
2001-02	1,689.8	924.4	1,555.3	5,313.5	31.8	17.4	70.7
2002-03	1,893.1	963.6	1,713.2	5,802.5	32.6	16.6	70.5
2003-04	2,096.3	1,028.0	1,908.8	6,388.9	32.8	16.1	70.1
2004-05	2,183.3	1,031.9	2,168.7	6,887.9	31.7	15.0	68.5
2005-06	2,107.1	988.7	2,366.1	7,135.4	29.5	13.9	66.8

Figure 5 WAMTC, TGP and RPG group shares of PBS expenditure

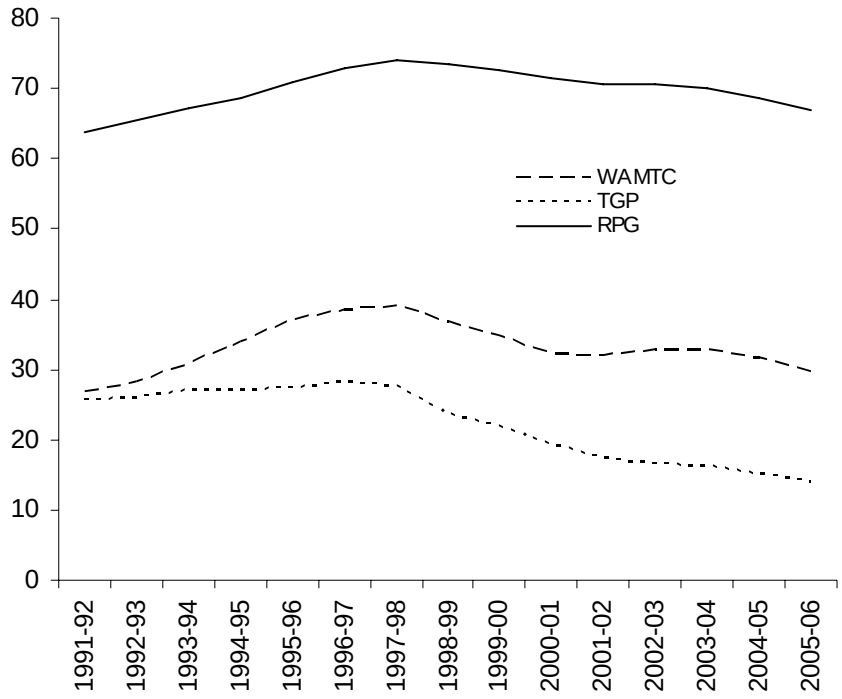

Table 5 Numbers of newly listed and exiting PBS medicines

Year	Number of new listings	Number in last year of listing	Total number of medicines
1991-92	29	9	544
1992-93	24	6	559
1993-94	24	29	577
1994-95	26	15	574
1995-96	20	23	579
1996-97	39	10	595
1997-98	34	23	619
1998-99	20	13	616
1999-00	28	7	631
2000-01	27	14	651
2001-02	19	14	656
2002-03	22	16	664
2003-04	22	7	670
2004-05	22	16	685
2005-06	19	16	688
2006-07	27	13	699
Total	402	231	
Average	25.1	14.4	

Figure 6 Numbers of newly listed and exiting PBS medicines

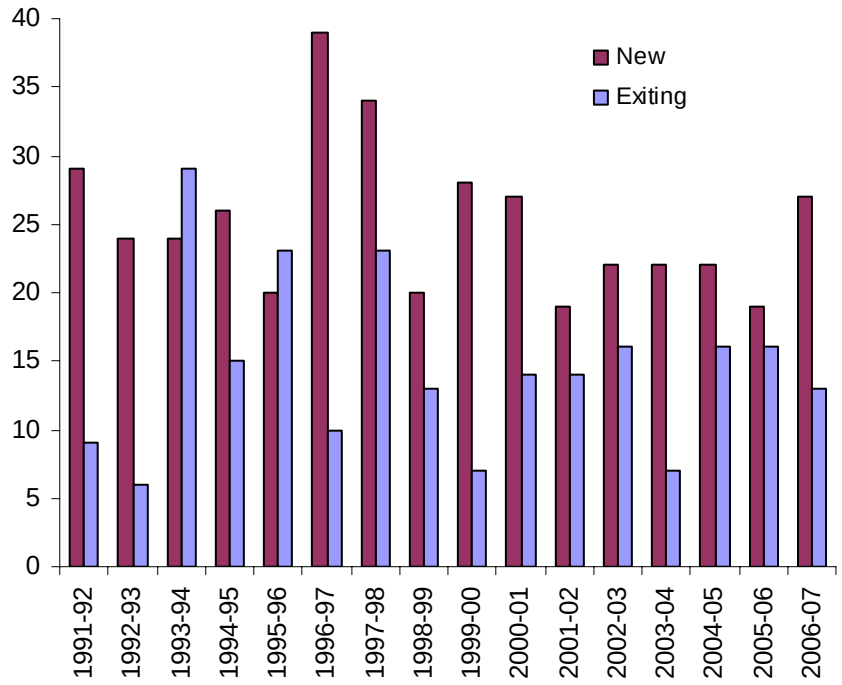

Table 6 Average cost of new medicines to the PBS

Year	Number of new listings	Average annual PBS cost per medicine listed $m	Average annual PBS cost for all listed in year $m
1991-92	20	15.4	308.4
1992-93	21	6.1	128.0
1993-94	22	6.5	143.2
1994-95	25	10.1	252.1
1995-96	20	7.8	156.9
1996-97	39	7.4	289.5
1997-98	34	21.4	726.4
1998-99	20	5.6	111.7
1999-00	27	11.4	308.0
2000-01	26	22.1	574.1
2001-02	18	10.3	184.8
2002-03	21	14.7	309.7
2003-04	22	6.8	149.7
2004-05	22	2.3	51.4
2005-06	18	1.2	21.2
Average 1991-92 to 2005-06			
	23.7	9.9	247.7

Table 7 Average cost of a new medicine by year, $m

	All medicines since 1991-92	All medicines since 1996-97
First	2.5	3.1
Second	6.7	8.0
Third	9.9	12.2
Fourth	12.2	15.0
Fifth	13.0	15.6
Sixth	13.9	16.9
Seventh	14.0	16.8

Table 8 Distribution of the cost to the PBS of new medicines

Average annual PBS cost $m	Number of medicines	Percentage of all medicines
0 to 1	128	36.1
1 to 5	100	28.2
5 to 10	41	11.5
10 to 20	36	10.1
20 to 50	34	9.6
50 to 100	11	3.1
Over 100	5	1.4
Total	355	100.0

Figure 7 Distribution of the cost to the PBS of new medicines

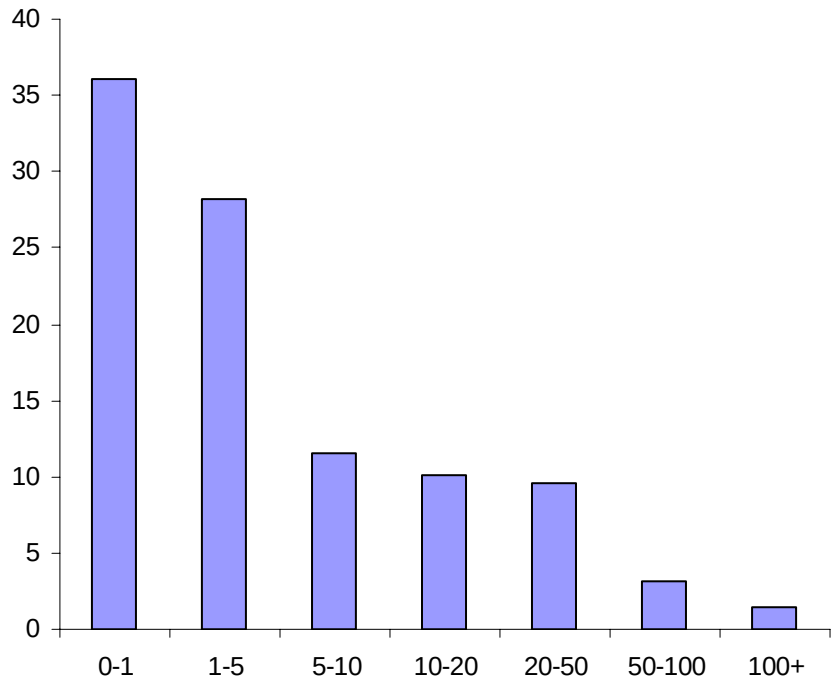

Table 9 Novel medicines listed on the PBS

	ATC5	ATC4	ATC3
Pre 1991-92	285	146	74
1991-92	12	4	2
1992-93	9	2	1
1993-94	4	0	0
1994-95	9	2	0
1995-96	3	0	0
1996-97	8	0	0
1997-98	8	1	0
1998-99	4	1	0
1999-00	7	2	0
2000-01	6	2	1
2001-02	1	0	0
2002-03	3	1	0
2003-04	3	2	0
2004-05	7	2	1
2005-06	4	1	0
2006-07	5	1	0
1991-92 to 2006-07	93	21	5
Total	378	167	79
% since 1991-92	24.6	12.6	6.3

Figure 8 Novel medicines listed on the PBS, ATC5 level

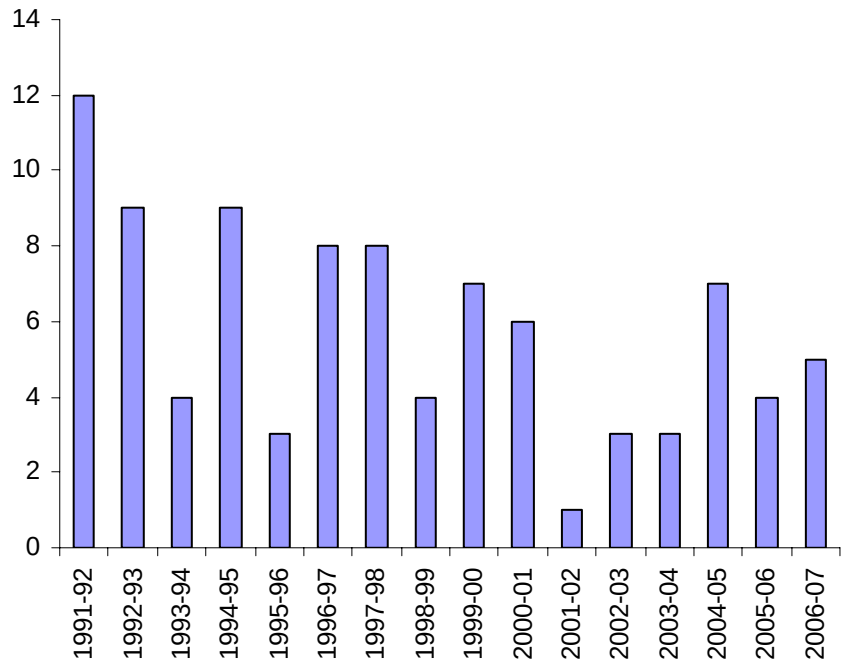

Table 10 **Regression results for PBS expenditure, linear**

a. with ATC dummy variables

	ATC1		ATC3		ATC4		ATC5	
	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat
constant	-1885.9	-9.4	-385.0	-11.5	-204.4	-11.4	-99.1	-10.0
pop	89.2	8.0	18.3	11.0	8.9	10.7	3.6	8.9
mol	15.4	8.5	12.7	16.4	12.5	20.6	16.4	25.6
atc dummies								
Adjusted R^2	0.871		0.803		0.765		0.718	
D-W	0.111		0.119		0.114		0.117	
n	210		1111		2245		4620	

b. without ATC dummy variables

	ATC1		ATC3		ATC4		ATC5	
	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat
constant	-2115.3	-6.2	-416.6	-7.2	-195.8	-7.6	-96.1	-7.7
pop	104.8	5.8	22.4	7.4	9.5	7.0	4.5	6.8
mol	10.1	14.7	5.9	17.4	11.0	29.7	12.8	26.8
Adjusted R^2	0.565		0.255		0.302		0.148	
D-W	0.026		0.026		0.034		0.032	
Pedroni tests	1/11		7/11		8/11		9/11	

Table 11 **Regression results for PBS expenditure, logarithmic**

a. with ATC dummy variables

	ATC1		ATC3		ATC4		ATC5	
	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat
constant	-22.890	-21.5	-11.826	-5.7	-8.949	-6.4	-19.565	-3.2
lpop	7.935	21.0	3.444	4.9	2.459	5.3	1.129	3.1
lmol	1.335	9.7	2.034	16.4	2.050	24.1	1.737	23.4
atc dummies								
Adjusted R^2	0.962		0.828		0.821		0.810	
D-W	0.320		0.463		0.514		0.495	

b. without ATC dummy variables

	ATC1		ATC3		ATC4		ATC5	
	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat
constant	-23.521	-8.3	-17.510	-5.2	-18.116	-7.3	-107.5	-9.5
lpop	7.696	8.0	5.590	4.9	5.957	7.0	6.378	9.4
lmol	1.635	22.0	1.973	34.1	1.892	35.4	2.217	36.0
Adjusted R^2	0.732		0.521		0.370		0.239	
D-W	0.048		0.154		0.135		0.119	
Pedroni tests	3/11		8/11		8/11		9/11	

Table 12 Regression results for PBS expenditure including copayment

	ATC1		ATC3		ATC4		ATC5	
	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat	Coeff	t-stat
constant	-36.272	-9.0	-25.928	-3.3	-22.152	-4.2	-93.734	-3.8
lpop	13.075	8.5	8.857	3.0	7.525	3.8	5.645	3.8
lmol	1.330	10.0	2.034	16.4	2.054	24.1	1.738	23.5
lccop	-1.482	-3.4	-1.567	-1.9	-1.464	-2.6	-1.300	-3.1
atc dummies								
Adjusted R^2	0.964		0.829		0.822		0.810	
D-W	0.308		0.459		0.511		0.494	
Pedroni tests	4/11		7/11		8/11		9/11	

Table 17 Patent expiries and new entry with price falls, 1991 to 2005

RPG/Name	ATC code	Item	PBS cost 2005-06	PBS cost 1991-92 to 2005-06	Patent expiry date
Aciclovir	J05AB01	1007B	8.5	291.4	2/09/1995
Carboplatin	L01XA02	1161D	7.0	39.8	6/06/1993
Clarithromycin	J01FA09	6152T	5.0	36.8	26/03/2005
Cyclosporin	L04AA01	6114T	24.3	394.6	5/03/1999
Flecainide acetate	C01BC04	1090J	5.6	53.2	27/03/1995
Flutamide	L02BB01	1417N	0.8	34.2	19/09/2000
Gabapentin	N03AX12	1835N	9.2	81.4	19/12/1991
Ipratropium bromide	R03BB01	1542E	21.0	685.6	4/07/1999
Irinotecan hydrochloride	L01XX19	8415X	14.1	61.1	13/07/2004
Isotretinoin	D10BA01	2592K	18.4	340.8	20/06/1991
Naproxen	M01AE02	1659H	4.8	126.1	12/01/1992
Norfloxacin	J01MA06	3010K	2.6	46.1	24/01/1998
Paclitaxel	L01CD01	3026G	33.0	183.6	29/01/1999
Timolol maleate	S01ED01	1279H	8.1	136.9	13/09/1996
Third-generation cephalosporins					
Cefotaxime	J01DD01	1085D	0.2	9.4	15/08/1998
Ceftriaxone	J01DD04	1784X	3.9	56.5	23/05/1999
Calcium channel blockers					
Felodipine	C08CA02	2367N	31.7	575.7	21/06/1999
Nifedipine	C08CA05	1695F	21.0	411.9	21/08/1988
ACE inhibitors					
Captopril	C09AA01	1149L	5.2	546.3	13/01/1997
Enalapril maleate	C09AA02	1369C	18.2	968.3	3/12/1999
Lisinopril	C09AA03	2458J	16.9	430.1	16/04/2001
H2-receptor antagonists					
Cimetidine	A02BA01	1158Y	0.9	167.8	14/09/1993
Famotidine	A02BA03	2487X	3.2	337.3	1/07/2003
Ranitidine hydrochloride	A02BA02	1978D	25.0	1,045.7	1/08/1993
Proton pump inhibitors					
Omeprazole	A02BC01	1327W	170.2	2,081.4	11/04/1999
Antidepressants					
Citalopram hydrobromide	N06AB04	8220P	41.0	344.2	5/01/1993
Fluoxetine hydrochloride	N06AB03	1434L	27.3	458.8	24/12/1994
Moclobemide	N06AG02	1900B	7.3	268.5	6/01/1997
Paroxetine hydrochloride	N06AB05	2242B	41.9	503.2	na

Acronyms

ABS	Australian Bureau of Statistics
ACE	Angiotensin converting enzyme
ATC	Anatomical Therapeutic Classification
CDPMQ	Commonwealth dispensed price for maximum quantity
CSES	Centre for Strategic Economic Studies
DoHA	Department of Health and Ageing
FDA	US Food and Drug Administration
GDP	Gross domestic product
MDPMQ	Manufacturer's dispensed price for maximum quantity
PBS	Pharmaceutical Benefits Scheme
RBA	Reserve Bank of Australia
RPG	Reference Pricing Group
SPC	Special Patient Contribution
TPG	Therapeutic Premium Group
WAMTC	Weighted average monthly treatment cost
WHO	World Health Organisation