Trends in the Use and Cost of Pharmaceuticals Under the Pharmaceutical Benefits Scheme

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Abbreviations

DHCA	Department of Health and Aged Care
HIC	Health Insurance Commission
PBCA	Pharmaceutical Benefits Advisory Committee
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
RPBS	Repatriation Pharmaceutical Benefits Scheme
TGA	Therapeutic Goods Administration

1. Introduction

Most pharmaceuticals in Australia are provided under the Pharmaceuticals Benefits Scheme (PBS) administered by the Commonwealth Department of Health and Aged Care through the Health Insurance Commission (HIC). The scheme is financed primarily from a budgetary allocation of the Commonwealth Government.

Over the past few years, the cost to the Government of the PBS has increased markedly – from $2.5 billion in 1997-98 to $3.8 billion in 2000-01. In explaining these cost increases, a lot of attention has been paid to the role of new "blockbuster" drugs, such as the anti-inflammatory celcoxib, the cholesterol reducing statins, the anti-psychotic olanzapine and treatments for peptic ulcers such as omeprazole.

Aside from the impact of these new drugs, other factors have also been cited as influencing costs, including:

- strong growth in demand for established drugs;
- changes in the prices of these drugs;
- a general ageing of the population;
- more of the population being able to qualify to receive drugs at lower cost; and
- the prescribing by doctors of these and other drugs for conditions outside the guidelines specified by the PBS.

In its annual budget brought down in May 2002, the Government introduced measures to curb the increase in the cost of the PBS, principally through increasing the amount paid by the final consumer (the maximum patient contribution). A report released at the same time as the budget highlighted the ageing of the population over the next 40 years, and claimed that this would lead to an increase in the use of pharmaceuticals.[1]

The aim of this current study is to provide an empirical analysis of major trends within the PBS and to examine the contribution to these trends from some of the factors listed above.

Section 2 provides an overview of the PBS, including a description of its administration, the process involved in listing a drug on the PBS, and the methods used to set prices for drugs.

A profile of the types of patients covered by PBS and their relative importance is provided in Section 3, while Section 4 shows how the usage of drugs in Australia varies with age.

Section 5 examines the relative importance of changes in the cost of PBS due to new drugs, and the price and usage changes among established drugs.

More than two thirds of the cost of the PBS is due to a handful of popular drugs, so this group of drugs is examined in more detail in Section 6.

[1] Department of the Treasury, "Intergenerational Report 2002-03", Budget Paper No 5, 14 May 2002.

This in one in a series of reports by the Centre for Strategic Economic Studies on the Australian pharmaceutical and health care system.[2] A companion report in this series analyses the demand and price dynamics within the PBS using case studies of 3 top selling classes of drugs, namely treatments for peptic ulcers, antidepressants, and cholesterol reducers.[3]

Most of the analysis undertaken in this paper is based on a database provided by the Pharmaceutical Access and Quality (PAQ) Branch of the Department of Health and Aged Care. The database covers the period 1991-92 to 2000-01 and consists of annual script and cost data for each brand of drug supplied under the PBS, as well as the conditions under which they are listed.[4] This has been supplemented where necessary with information from the regular bulletins published by the PAQ Branch.[5]

[2] Reports in this series can be found at www.cses.edu.au
[3] Sweeny, Kim, "Demand and Price Dynamics within the Pharmaceutical Benefits Scheme", CSES, June 2002.
[4] The author would like to thank Peter Marlton of the PAQ Branch and John Abrams of the PBS Branch of the Department of Health and Aged Care for their assistance in providing this data and guidance in its use and interpretation.
[5] Such as their Expenditure and Prescription series for the years 1998-99 to 2000-01 at www.health.gov.au/haf/docs/pbbexp/index.htm.

2. The Pharmaceutical Benefits Scheme – An Overview

The Pharmaceuticals Benefit Scheme was introduced in 1948 and "makes a large range of necessary prescription medicines affordable for Australian residents and eligible overseas visitors by subsidising the cost".[6] Its basic rationale is to ensure that Australians can access the drugs they need and that these drugs are provided at prices which are affordable to both the patient and the Government. It achieves this by negotiating prices for drugs with suppliers of pharmaceuticals using its effectively monopsonist powers and caps the cost to the patient at a fixed sum per prescription.

2.1 Administration of PBS

Before a drug can be sold in Australia, it must be listed on the Australian Register of Therapeutic Goods maintained by the Therapeutic Goods Administration, a division of the Department of Health and Aged Care. The TGA 's assessment of a drug for registration is based on data relating to quality, safety and efficacy but not cost.[7]

There are four main bodies involved in the PBS.[8]

The ***Pharmaceutical Benefits Advisory Committee*** (PBAC) is an independent statutory body established in 1954 to make recommendations and give advice to the Minister for Health and Aged Care about which drugs and medicinal preparations should be made available as pharmaceutical benefits. No new drug may be made available as a pharmaceutical benefit unless the Committee has so recommended. The Committee is required to consider the effectiveness and cost of a proposed benefit compared to alternative therapies. In making its recommendations the Committee, on the basis of community usage, recommends maximum quantities and repeats and may also recommend restrictions as to the indications where PBS subsidy is available. When recommending listings, the Committee provides advice to the Pharmaceutical Benefits Pricing Authority (PBPA) regarding comparison with alternatives or their cost effectiveness.

The PBAC has 2 sub-committees. The Economics Subcommittee was established in 1993 to:

- review and interpret economic analyses of drugs submitted to the PBAC;
- advise the PBAC on these analyses; and
- advise the PBAC on technical aspects of requiring and using economic evaluations.

The Drug Utilisation Sub-Committee collects and analyses data on drug utilisation in Australia.

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[6] HIC, "Pharmaceutical Benefits Scheme Explanation of Current Pricing – 2000", p1.
[7] Salkeld, G, Mitchell, A, and Hill, S, "Pharmaceuticals", in Mooney, G and Scotton, R eds., "Economics and Health Policy", Allen and Unwin, 1998, p 116.
[8] The operations of the PBS are described in PBPA, "Pharmaceutical Benefits Pricing Authority Procedures and Methods", August 2001, and HIC, op cit, HIC, "Pharmaceutical Benefits Scheme Reference Guide", 1999, PBPA, "Annual Report for the year ended 30 June 2000", 2000. See also Salkeld, G, Mitchell, A, and Hill, S, "Pharmaceuticals", in Mooney, G and Scotton, R eds., "Economics and Health Policy", Allen and Unwin, 1998, and www.health.gov.au/pbs.

The ***Pharmaceutical Benefits Pricing Authority*** is an independent non-statutory body established in 1988 with the objective of securing a reliable supply of pharmaceutical benefits at the most reasonable cost to Australian taxpayers and consumers. It does this by:

- reviewing the prices of products listed as pharmaceutical benefits;
- recommending prices for new items recommended for subsidisation by the PBAC.

The main mechanism to determine prices for new drugs to be listed on the PBS is the advice of the PBAC based on its evaluation of thee cost effectiveness information supplied by the pharmaceutical company proposing to have its drug listed. For new listings recommended by the PBAC and approved by the Minister, the Authority recommends prices to be negotiated by the Department of Health and Aged Care. The prices set by the Authority cover not only subsidised products, but also products listed in the Schedule priced below the maximum co-payment.

The PBPA can also recommend revised prices where uses of drugs are extended or changed and reviews the prices of all items listed on the PBS at least once each year.

The ***Department of Health and Aged Care*** provides secretariat support for the PBAC and the PBPA and undertakes the negotiations over price with pharmaceutical suppliers. The Minister for Health and Aged Care has final approval of drugs for listing on PBS and can also refer matters to the PBAC and PBPA for consideration.

2.2 Listing a Drug on PBS

If a pharmaceutical supplier wishes to have a new drug listed on the PBS it must make an application to the Department of Health and Aged Care based on guidelines developed by the PBAC. Since 1993, this application must include a cost-effectiveness analysis, which is considered by the Pharmaceutical Evaluation Section (Pharmaceutical Benefits Branch) of the Department and the Economics Sub-committee of the PBAC. Before their advice is passed to the PBAC, there is an opportunity for the supplier to respond to their assessments.

According to Salkeld et al a new drug may be recommended for listing by the PBS if:

- it is needed for the prevention or treatment of significant medical conditions not already covered by drugs already listed and is of acceptable cost-effectiveness
- it is more effective, less toxic (or both) than a drug already listed for the same indications and is of acceptable cost-effectiveness; or
- it is at least as effective and safe as a drug already listed for the same indications and is of similar or better cost-effectiveness.[9]

Drugs can be also delisted if they fail to meet these criteria.

Once a drug has been recommended by the PBAC, the PBPA recommends a price to be negotiated by the Department. To do this the PBPA takes account of the following factors:[10]

[9] Salkeld et al, op cit, p.118.
[10] PBPA, op cit, p4.

- PBAC advice on clinical and cost effectiveness;
- Prices of alternative brands;
- Comparative prices of drugs in the same therapeutic group;
- Cost data information;
- Prescription volumes, economies of scale, expiry dating, storage requirements, product stability, special arrangements;
- Level of activity being undertaken by the company in Australia, including new investment, production, research and development;
- Overseas prices;
- Other factors the applicant may wish the Authority to cover; and
- Other directions as advised by the Minister.

The Pharmaceutical Pricing Section of the Department undertakes price negotiations with the supplier based on PBPA recommendations, and if agreement is reached, this is sent to the Minister for Health and Aged Care for approval.

Drugs expected to cost more than $5 million per year require approval also from the Department of Finance and Administration, while those expected to cost over $10 million per year require approval from the Prime Minister as well.

Applications from suppliers wishing to list a new brand of a drug already on the PBS are not consider by PBAC or PBPA, but processed by the Pharmaceutical Pricing Section of DHAC.

The procedures described above are aimed at setting the wholesale price of the drug, i.e. the maximum price to be paid by the pharmacist in purchasing the drug. The retail price is determined by adding a profit margin determined by the Department (10% for most drugs) as well as a dispensing fee (currently $4.58 for most drugs).

Once a drug has been approved for listing under the PBS, it is included in the Schedule of Pharmaceutical Benefits. This schedule is published in February, May, August and November and contains details of all the items available under the PBS and RPBS.

Pharmaceutical benefits can only be prescribed by registered doctors and by dentists who are approved to work within the PBS.

2.3 Pricing Methods

The PBPA reviews the prices of all drugs listed on the PBS at least once per year.

Drugs are divided into therapeutic groups with drugs used for the same purpose being reviewed together.

Where the drug is unique in its class, or when a benchmark price is being calculated for a therapeutic group, a **cost plus method** is used, i.e. the price is equal to the cost of manufacture plus a margin. This method relies on cost information provided by the supplier.

For drugs in the same therapeutic category, the lowest priced brand sets the benchmark price for either the other brands of the same drug, or the other drugs within the same therapeutic group. This is known as **therapeutic group pricing** or reference pricing.

The prices of a selected group of drugs are determined by a method called **weighted average monthly treatment cost (WAMTC)**. The drugs in this category include H_2 receptor antagonists, ACE inhibitors, HMG CoA reductase inhibitors, proton pump inhibitors and selective serotonin reuptake inhibitors. The benchmark price among these classes is calculated as the lowest weighted treatment cost per month i.e. total cost of the drug provided over a period divided by the total number of months treatment provided.

Where a benchmark price has been set by reference to the lowest cost brand, other suppliers may charge a **brand premium** above this price. The level is determined by the supplier but must be approved by PBPA.

For four classes of drugs, namely the H_2 receptor antagonists, calcium channel blockers, ACE inhibitors, and HMG CoA reductase inhibitors, suppliers may charge a **therapeutic premium** above the benchmark price.

In addition to these pricing methods, the PBPA sometimes negotiates price/volume arrangements for new drugs when unit prices are relatively high and there is potential for high demand or demand is uncertain. This may also occur when restrictions on drugs already listed are relaxed or the indications for the drug are widened. Under this arrangement, unit prices fall as volume increases

At May 2002, there were 29 brands that had a therapeutic premium (of which 21 were less than $5.50) and 391 with a brand premium (of which 324 were $3.00 or less).

2.4 Types of Drugs

A drug is listed on the PBS for treatment of specific conditions (indications) and use for other indications requires a further submission to PBS for approval. In addition some drugs carry further restrictions – for instance they can only be used to treat an indication if other conditions apply ("restricted benefit"). For other drugs, a doctor needs approval from the HIC before being able to prescribe the drug ("authority required").

At May 2002, there were 2303 items listed on PBS (primary reference), of which 500 were in the "authority required" category, 669 were "restricted benefit", and 1443 had no restrictions. Despite having to receive specific authority from the PBS before being prescribed, "authority required" drugs were 24.5% of PBS cost in 2000-01 (Table 2.1).

Table 2.1 Restriction Levels for Items in PBS

	Number of items	Cost in 2000-01	
		$m	%
Authority required	500	1,092.4	24.5

Restricted benefit	669	1,913.0	42.9
No restriction	1,134	1,449.0	32.5
Total	2,303	4,454.5	100.0

In addition to drugs, there are other therapeutic goods provided under the PBS. These are classed as "Stoma Appliances" and include items such as creams and ointments, protective films, colostomy, ileostomy and urostomy bags, belts and irrigation sets.

Most drugs available under the PBS are supplied by community pharmacists under a doctor's or dentist's prescription. Although the great majority of these are in the form of ready-prepared medicines, pharmacists can also make up extemporaneous preparations.

There are other drugs called "Section 100 Items" that are provided under special arrangements - typically to a patient in a hospital. Section 100 items require specialised medical supervision and have a high unit cost. They include treatments for in-vitro fertilization, drug addiction, cancer, and HIV/AIDS.

Certain pharmaceutical benefits are provided without charge to doctors who in turn can supply them free to patients for emergency use. These are collectively known as "Doctor's Bag" items.

Table 2.2 shows the number of brands and items in these categories and their total cost in 2000-01, where known.

Table 2.2 Types of Items in PBS

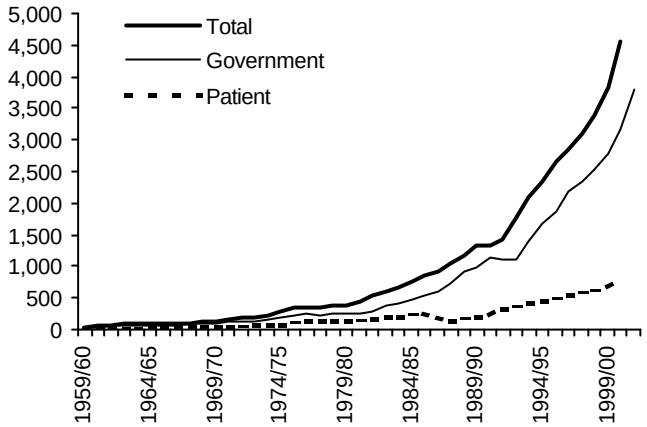
	Brands	Items	Cost in 2000-01 ($m)
General	2,499	1,460	4,545.2
Dentals	474	222	2.9
Extemporaneously prepared		22	3.1
Doctors' Bag	49	32	10.3
Section 100			
Highly Specialised	134	130	268.3
Other	167	142	na
Stoma Appliances	244	242	na
Miscellaneous	18	14	na
Repatriation	419	366	325.1

3. Types of Patients within the PBS

3.1 Contributions by Patients to PBS Cost

The long-term trend in PBS expenditure is presented in Figure 1, which plots the annual cost of the scheme in terms of the amounts paid by the government and the patient since its inception over 50 years ago.

Figure 3.1 Trend in PBS Expenditure ($m)



The graph highlights the rapid rise in costs during the 1990s and the relatively small proportion of the cost borne directly by the consumer of drugs.

While this patient proportion is still relatively low, it has varied considerably over time. From very low levels in the 1950s, it jumped to around 15-20% in the 1960s before increasing again to a maximum of 33.1% in 1978-79. After that it fell markedly during the latter part of the 1980s, rose again in the early 1990s but has fallen consistently since 1991-92 to 16.3% in 2000-01 (Figure 3.2).

Figure 3.2 Patient Share of PBS Cost (%)

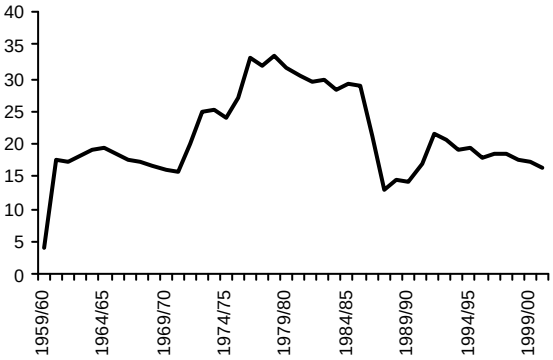
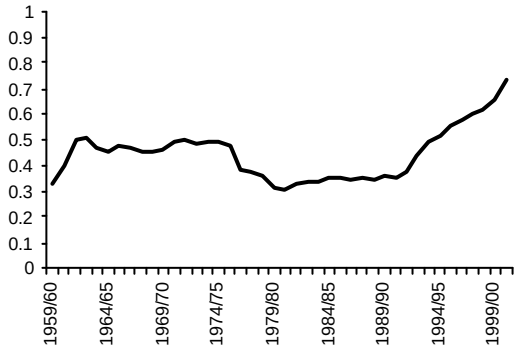


Figure 3.3 Cost of PBS as % of GDP



Although PBS expenditure has increased, it is important to put this in perspective by looking at this expenditure as a percentage of GDP. Figure 3.3 plots this ratio since 1959-60, and shows that it was relatively stable during the 1960s and 1970s and decreased somewhat in the late 1970s and 1980s. The major increase in the cost of the

PBS has been during the 1990s, with the PBS essentially doubling its share of GDP from around 0.35% in 1990-91 to 0.73% in 2000-01.

3.2 Patient Categories

The PBS distinguishes between 2 major categories of patients (i.e. consumers of drugs supplied under the PBS).

Concessional patients (excluding those covered by the Repatriation PBS) hold one of the following cards from Centrelink:[11]

- Commonwealth Seniors Health Card;
- Health Care Card; or
- Pensioner Concession Card

Commonwealth Seniors Health Cards are available for all Australian residents of pension age or older (65 for men, 62.5 for women) and have either a single income of less than $50,000 per year or a combined income of less than $80,000 per year.

Health Care Cards are issued to people under 60 receiving various kinds of government support payments such as Newstart Allowance, Partner Allowance, Widow Allowance, Special Benefit, Exceptional Circumstances Relief Payment, Youth Allowance (Unemployed), Parenting Payment and Sickness Allowance.

Pensioner Concession Cards are issued to all pensioners and recipients of Mature Age Allowance, Mature Age Partner Allowance, Carer Payment and Single Parenting Payment.

The number of people covered by concession cards (card holders plus dependants) at May 2002 was about 7.0 million or 36% of the total population (Table 3.1).[12]

Table 3.1 People Covered by Concession Cards, May 2002

	Number	% increase July 2000 to May 2002
Age Pension	1,774,468	4.3
Carer Payment	100,275	50.2
Child Disability Allowance	125,063	6.7
Disability Support Pension	799,205	0.0
Family Tax Benefits	374,075	-77.2
Low Income Concession Card	390,198	3.9
Newstart Allowance	838,936	-8.8
Parenting Payment (Partnered)	647,832	1.3
Parenting Payment (Single)	1,266,260	27.7
Partner Allowance	105,700	5.9
Senior Health Care Card	276,418	25.7
Youth Allowance	98,845	-4.8
Others	246,742	-17.0
Total	7,044,037	6.4

[11] Centrelink, "Commonwealth Seniors Health Card", 2002; "Health Care Card A guide to concessions in Victoria", 2001; "Pensioner Concession Card A guide to concessions in Victoria", 2001.
[12] Concessional card holder information provided by the Department of Family and Community Services.

The largest category consisted of 2.1 million people covered by age related cards (age pension, senior health care card) or about 79% of the population of pension age (men 65 and over, women 62 and over). The other major categories were those on disability support pensions, Newstart allowance (unemployed) and single parent payments.

The most rapidly growing categories are the carer payment, the disability support pension, the single parenting payment, and the senior health care card.

For people with a concession card the maximum payment per prescription was $3.60 at May 2002.

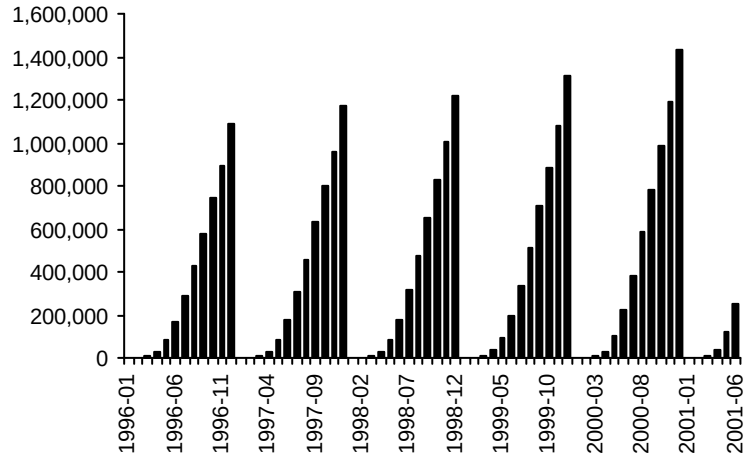
General patients (i.e. non-concessional card holders) pay a maximum of $22.40 for drugs available under PBS. These prices are revised regularly, usually once a year on 1 January.

In addition if concessional cardholders incur costs singly or as a family above a safety threshold amount (currently $187.20) during the course of a year, they can apply for a Safety Net Entitlement Card under which drugs are supplied at no cost to the patient for the rest of the year. General patients can also apply for similar status once their expenditure exceeds a threshold, currently $686.40.

The PBS pays the pharmacist the difference between the co-payment and the retail price of the drug as listed in the Schedule of Pharmaceutical Benefits. If the drug carries a brand premium or therapeutic premium, this premium is paid by the patient in addition to the co-payment.

Because of its nature, the number of people qualifying for the Safety Net entitlement increases during the year (Figure 3.4). Over the course of the year 2000, for instance, the number of people covered by the Safety Net rose from 220,703 in June to 1,428,010 in December. Of these 75% had been concessional cardholders rather than general patients.

Figure 3.4 Safety Net Cards
Number of People Covered



3.3 Differential Patient Costs

The relative importance of the different types of patients, in terms of total cost, can be seen in Table 3.2.

Table 3.2 PBS Cost by Patient Category
$m

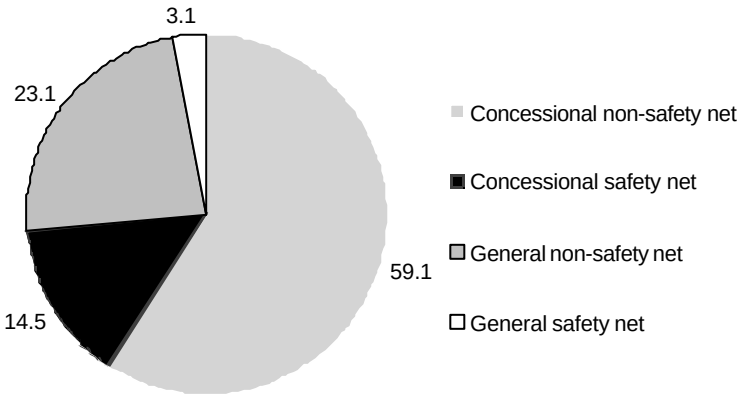
	CONCESSIONAL		GENERAL		TOTAL
	Non-Safety Net	Safety Net	Non-Safety Net	Safety Net*	
1991-92	881.6	195.0	289.8	61.4	1,442.2
1992-93	1,031.7	251.2	351.2	129.1	1,779.4
1993-94	1,221.2	297.6	407.7	153.8	2,097.0
1994-95	1,409.2	302.5	508.9	105.7	2,341.9
1995-96	1,596.0	360.1	580.3	132.9	2,685.5
1996-97	1,717.8	401.8	662.0	81.2	2,878.5
1997-98	1,852.5	440.0	693.6	111.2	3,112.3
1998-99	2,022.7	467.1	774.1	119.8	3,397.0
1999-00	2,306.8	547.8	854.0	119.6	3,839.0
2000-01	2,697.0	660.3	1,054.5	142.5	4,564.7

* From 1991-92 to 1995-96 includes General Free Safety Net.

About three quarters of the cost of the PBS is within the "Concessional" category, with the "Safety Net" categories accounting for about 18% of the cost. The proportions of cost for each category have remained relatively unchanged over the past 5 years, although the "General Non-Safety Net" category is growing somewhat faster than the others.

Figure 4 shows the relative shares in total PBS cost of each category for 2000-01.

Figure 3.5 PBS Cost by Patient Category, 2000-01



4. The Use of Medicines in Australia

The most comprehensive picture of the use of medicines in Australia is provided by the National Health Survey undertaken by the Australian Bureau of Statistics in 1995.

The survey found that 59% of the population used one or more medications over a two week period, the most popular of which were pain relievers, skin ointments and creams, medicines for coughs and colds, and medications for heart problems or high blood pressure (Table 4.1).

Overall, medicine use rises strongly with age – from 52% of those aged 15-24 to 86% of those aged 65 and over.

However there is significant variation in the age profile of medicine use depending on the type of medicine. Asthma medication use is higher among younger age groups, as is the use of medications for coughs and colds, pain relievers, and skin ointments and creams.

The incidence of medicines to treat the illnesses of ageing – type 2 diabetes, arthritis, stomach problems, fluid retention, heart problems, high blood pressure, and high cholesterol – all increase rapidly after the age of 45 and particularly after 65.

Table 4.1 Medication Use by Age, 1995

Type of medication used	Number using	0-14	15-24	25-44	45-64	65 and over	Total
	000's	%	%	%	%	%	%
Medication for diabetes	262.2	0.1	0.3	0.5	2.5	5.8	1.5
Asthma medications	1,197.5	8.2	8.1	5.5	5.7	6.5	6.6
Medication for arthritis	621.4	0.1	0.2	1.1	6.4	14.4	3.4
Medication for cough/colds	1,283.8	11.4	7.8	6.7	5.0	3.3	7.1
Skin ointments/creams	1,761.6	8.0	12.0	11.1	9.4	7.2	9.8
Stomach medications	730.3	0.7	1.5	3.0	6.3	11.9	4.0
Laxatives	98.8	0.4	0.1	0.3	0.6	1.9	0.5
Medications for allergies	571.5	1.8	3.4	4.0	3.7	2.3	3.2
Fluid tablets/diuretics	394.8	0.1	0.0	0.3	2.8	12.5	2.2
Medications for heart problems/blood pressure	1,910.3	0.1	0.2	2.2	19.3	49.2	10.6
Medications to lower cholesterol/triglycerides	307.8	0.0	0.0	0.4	4.0	6.3	1.7
Pain relievers	4,265.2	13.9	25.1	30.2	25.2	19.4	23.6
Sleeping medications	265.6	0.2	0.3	0.9	2.1	5.6	1.5
Medications for anxiety, nervous tension, depression	395.9	0.1	0.8	2.2	3.9	4.7	2.2
Tranquillisers or sedatives not included above	79.3	0.2	0.2	0.3	0.6	1.2	0.4
Other medications	3,221.8	9.4	13.1	14.6	24.8	35.5	17.8
Total *	10,671.7	41.6	51.8	57.4	69.6	85.9	59.1
Total persons		3,872.7	2,710.3	5,583.5	3,739.6	2,155.0	18,061.1

* Persons may have reported more than on type of medication so components do not add to totals.
Source: ABS, Table 1, 4377.0, 1995.

The use of tranquillisers, sedatives and sleeping medications is also more pronounced among older age groups.

People aged 45 and over account for about 32% of the total population. However they make up 41% of people taking medications and a much higher proportion of those taking the more expensive types of drugs (Table 4.2).

Table 4.2 Distribution of Medication Use by Age, 1995

	45-64	65 and over	45 and over
Medication for diabetes	34.5	46.1	80.6
Medication for arthritis	39.0	50.5	89.5
Stomach medications	32.6	35.5	68.1
Fluid tablets/diuretics	26.4	67.8	94.1
Medications for heart problems/blood pressure	37.7	55.4	93.1
Medications to lower cholesterol/triglycerides	48.7	44.2	92.9
Sleeping medications	29.0	44.5	73.5
Medications for anxiety, nervous tension, depression	36.7	25.5	62.2
Total	24.4	17.3	41.7

Source: ABS, Table 1, 4377.0, 1995.

5. Determinants of Cost Changes in PBS

5.1 Introduction

This section describes some of the main drivers of cost changes within the PBS. They include:

- the addition of new drugs;
- changes in prices of drugs; and
- changes in the demand for drugs.

The Commonwealth Government controls the first two of these factors, while the third is largely determined by the prescribing habits of doctors, although patients are increasingly influencing this as they become more knowledgeable and discriminating about the drugs they take.

The database of detailed information on individual drug brands provided by PAQ Branch of the Department was used to determine the impact of each of these sources of cost change.

This database covers the financial years 1991-92 to 2000-01 and contains information on the number of prescriptions (scripts) and cost for each unique drug brand. Each entry also identifies the drug's generic name and its supplier.

5.2 Contributions to Cost

The data for each year was compared pair-wise with data from the preceding year. This enabled each year of data to be divided into:

- drugs that were introduced during that year (and therefore did not appear in preceding years);
- drugs that were listed in preceding years but had been dropped before the current year; and
- drugs common to both years.

Within this last set of common drugs, the price of each drug were estimated for both years by dividing the cost by the number of scripts. For each drug, an estimate was made of its constant price value in the current year by multiplying the number of scripts in the current year by the price in the preceding year.

This constant price estimate was used to assess the relative impacts of price and volume in the change in cost.

An example of these calculations for the year 2000-01 is presented as Table A1 in Appendix A. Similar calculations were made for the other years for which comparable information was available (1992-93 to 1999-00).

In 2000-01, the listing of 153 new drugs and the removal of a further 86 was responsible for a net increase of $357.0 million or 49.2% of the total increase of $725.7 million. On the other hand, the increase due to drugs common to both 2000-01 and 1999-00 was $368.7 million (or 50.8% of the total).

The effect of price changes in the common drugs was to reduce the cost by $61.1 million while the effect of demand caused an increase of $429.8 million. There was a difference in the price effects between the category of cost borne by the government and by the patient. The government used its pricing strength with the pharmaceutical suppliers to reduce its costs (giving a net price reduction for these common drugs of $64.4 million). The patient cost was largely unchanged, however, with a small net price increase effect of $3.3 million (Table A2 in Appendix A).

These influences on cost acted in a similar way in previous years, except for the impact of new drugs, which was much higher in 2000-01 than the other years (Table 5.1). The negative effect on government cost of price changes began in 1996-97 following a period of moderate increases, but the impact on patient cost varies from year to year.

Table 5.1 PBS Cost Changes 1992-93 to 2000-01, $m

	Total increase	Increase due to net new drugs	Increase due to common drugs	Effect of prices	Effect of volume
1992-93	337.2	9.0	328.2	31.0	297.2
1993-94	317.6	19.7	297.9	47.3	250.5
1994-95	245.0	51.5	193.5	22.1	171.4
1995-96	343.6	26.4	317.2	33.2	284.0
1996-97	193.0	40.0	153.0	-42.7	195.7
1997-98	233.8	110.3	123.4	-48.9	172.3
1998-99	284.7	31.2	253.5	-89.2	342.7
1999-00	442.0	133.7	308.3	-65.0	373.3
2000-01	725.7	357	368.7	-61.1	429.8

The picture that emerges therefore is of the Government exerting continuing downward pressure on prices paid to suppliers (at least since 1996-97), while regularly increasing the patient co-payment. This however is not enough to offset the strong upwards pressure on cost as new drugs are introduced and as demand for new and established drugs continues to rise.

5.3 The Price of New Drugs

In 2000-01, new drugs introduced during that year were responsible for about half the increase in cost. While this impact is mainly due to strong growth in the number of prescriptions written by doctors, part of the contribution to cost is due to the fact that new drugs on average have a higher price than drugs that have been listed for a number of years.

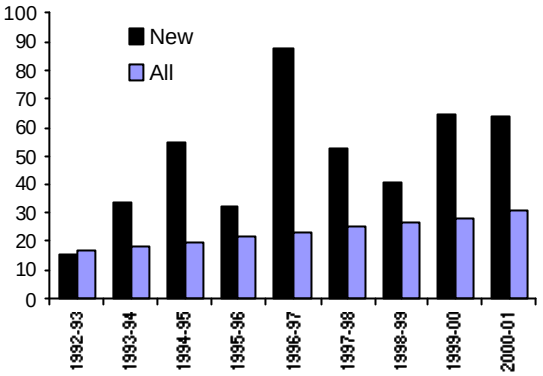
Table 5.2 and Figure 5.1 show the average price of new drugs in their year of introduction compared to the average price of all drugs in that year.

Although there is considerable variation from year to year, the price of new drugs is around twice the average price of drugs on the PBS. The price of new drugs has increased by around 19% per year against an 8% growth for all PBS drugs.

Table 5.2 Price of New Drugs on PBS ($)

	New Drugs	All Drugs
1992-93	15.92	16.76
1993-94	33.31	18.23
1994-95	54.43	19.73
1995-96	32.38	21.50
1996-97	87.47	23.20
1997-98	52.31	24.88
1998-99	40.63	26.35
1999-00	64.21	27.80
2000-01	63.64	30.83

Figure Average Price of PBS Drugs ($)



6. The Influence of the Top Selling Drugs

6.1 Major Drug Categories within the PBS

The PBS Schedule is organised according to the Anatomical Therapeutic Classification (ATC), the internationally recognised classification scheme for drugs maintained by the WHO Collaborating Centre for Drug Statistics Methodology in Oslo.

The ATC has five levels of classification, the highest level reflecting the various systems within the body.

Of the 14 classes, 3 contribute about two thirds of the cost of the PBS. They are:

A. Alimentary tract and metabolism
C. Cardiovascular system
N. Nervous system

A further three classes account for another 20% of PBS cost, namely:

L. Antineoplastic and immunomodulating agents
M. Musculo-skeletal system
R. Respiratory system

With the exception of drugs for the cardiovascular and respiratory systems, all these classes of drugs have been growing more strongly than the average (Table B1 in Appendix B). Figure 6.1 compares the cost of these categories in 1991-92 and 2000-01, while Figure 6.2 shows the average annual growth rates between these two years.

Figure PBS Major Classes Total Cost ($m)

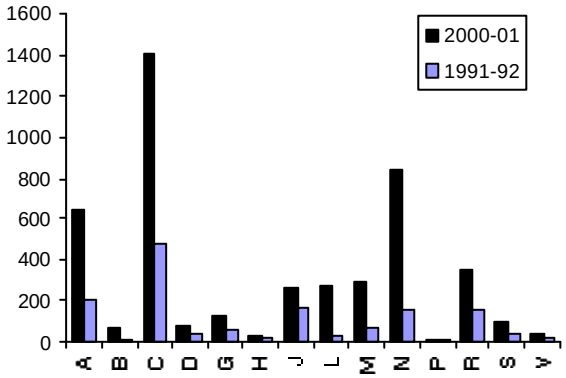
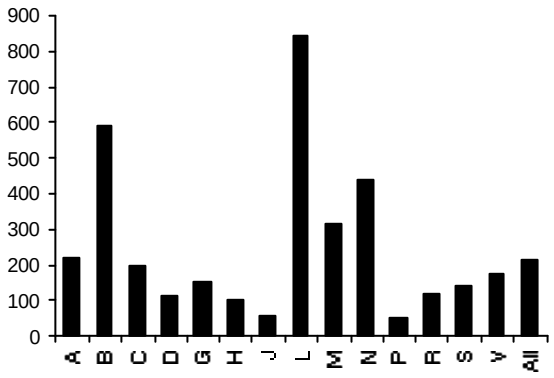


Figure PBS Major Classes Growth 1991-92 to 2000-01



Within the broad classes of drugs reported in Table B1, 11 sub-categories account for about two thirds of the PBS cost (Table B2 in Appendix B).

These comprise drugs to treat peptic ulcers, diabetes, high blood pressure, cancer and asthma, as well as antiinflammatories and antirheumatics, antidepressants and antipsychotics, and drugs to lower cholesterol.

6.2 The Top Selling Drugs

The PBS covers around 600 different chemical and medical entities (known as generic name drugs). These drugs vary widely however in their influence on the cost of the PBS.

The top selling 100 generic name drugs accounted for about 80% of the total cost of drugs in 2000-01. Of these drugs, ten were responsible for 30% of the cost, with the top 30 representing just over half the cost (Table 6.1).

Table 6.1 Generic Name Drugs, 2000-01

Drugs ranked	Share of Total Cost	Average Price
1-5	22.1	65.72
1-10	30.7	60.54
1-20	43.1	48.84
1-25	47.6	46.73
1-30	51.5	46.49
1-40	58.2	43.65
1-50	63.6	39.97
1-100	80.8	36.03
Total	100.0	30.83

This latter group of 30 drugs was responsible for 69% of the total increase in PBS costs from 1999-00 to 2000-01, and included three new drugs – Celecoxib, Buproprion, and Salmeterol (with Fluticasone) – which collectively increased cost by $305.3 million.

The top selling drugs represent such a major cost for the PBS because they are generally more expensive than the other drugs covered by PBS (Table 6.1).

The top 30 selling generic name drugs for 2000-01 are listed in Table 6.2.

Prominent in this group are the HMG CoA reductase inhibitors (or "Statin") class of drugs, which includes, Atorvastatin, Fluvastatin, Pravastatin, and Simvastatin. These drugs are different types of cholesterol and triglyceride reducers and are used for treating high levels of cholesterol.

The new drug Celecoxib is an anti-inflammatory treatment for arthritis.

Lansoprazole, Omeprazole, and Ranitidine Hydrochloride are used for peptic ulcers.

Included are the anti-depressants Citalopram, Paroxetine, Sertraline, and Venlafaxine and the anti-psychotic Olanzapine.

Asthma drugs are a major cost (Budesonide, Fluticasone, Ipratropium Bromide, Salbutamol, and Salmeterol), but the largest category of drugs is for treating heart conditions – either the angiotensin II antagonist (Irbesartan), the ACE inhibitors (Perindopril, Enalapril Maleate, Lisinopril, and Ramipril), or the calcium channel blockers (Amlodipine Besylate and Felodipine).

While some of these top 30 drugs have shown declining costs over the past 3 years, most have experienced high rates of growth in both cost and in the number of scripts dispensed. Of the top 30 drugs listed in Table 6.2 only 4 showed declining use in both costs and number of scripts, while a further 3 had declining cost although the number of scripts rose.

This may indicate that most of the drugs in the top 30 are meeting unmet need rather than displacing existing drugs. For treatments of asthma, however, there is some evidence that the newer drugs Salmeterol and Fluticasone are displacing Ipratropium Bromide and Budesonide. Similarly the ACE inhibitors Perindopril and Ramipril are growing at the expense of Enalapril Maleate and Lisinopril.

By contrast all the Statins and the anti-depressants are growing strongly.

For 17 drugs, the number of scripts rose faster than cost, indicating downward pressure on prices from the Commonwealth Government.

Table 6.2 Top 30 Generic Name Drugs in 2000-01

Name	Condition treated	Total Cost	Growth* in	
			Total Cost	Scripts
		$m	%	%
Simvastatin	Cholesterol reducer	267.1	13.6	7.3
Atorvastatin	Cholesterol reducer	265.5	44.7	48.8
Celecoxib	Antiinflammatory	184.0	na	na
Omeprazole	Peptic ulcer treatment	181.2	-2.5	15.6
Olanzapine	Antipsychotic	110.1	48.4	58.5
Sertraline	Antidepressant	84.0	19.5	19.8
Pravastatin	Cholesterol reducer	81.6	23.0	19.4
Ranitidine Hydrochloride	Peptic ulcer treatment	81.1	-3.1	0.6
Insulin (Human)	Diabetes	76.7	10.7	5.1
Bupropion	Nicotine dependence	69.2	na	na
Irbesartan	Heart disease[1]	68.2	30.3	33.7
Salbutamol	Asthma	64.3	9.0	-0.2
Amlodipine Besylate	Heart disease[2]	61.7	5.5	3.8
Perindopril	Heart disease[3]	57.0	17.1	18.6
Ipratropium Bromide	Asthma	55.9	-6.0	-1.7
Paroxetine	Antidepressant	55.0	13.6	13.0
Enalapril Maleate	Heart disease[3]	52.6	-12.2	-10.9
Venlafaxine	Antidepressant	52.1	60.5	66.0
Salmeterol + Fluticasone	Asthma	52.1	na	na
Fluticasone	Asthma	48.9	15.8	25.4
Lansoprazole	Peptic ulcer treatment	42.0	3.6	19.6
Budesonide	Asthma	41.9	-10.5	-13.1
Lisinopril	Heart disease[3]	40.5	-2.5	-1.7
Ramipril	Heart disease[3]	39.8	20.8	21.0
Felodipine	Heart disease[2]	38.8	0.1	0.4
Citalopram	Antidepressant	37.5	80.4	76.8
Goserelin	Cancer treatment	36.7	9.2	2.1
Diltiazem Hydrochloride	Heart disease[2]	35.8	-3.2	1.4
Latanoprost	Glaucoma treatment	34.5	53.4	55.2
Morphine	Pain treatment	33.5	9.1	6.4

1 Angiotensin II antagonist, 2 Calcium channel blocker, 3 ACE inhibitor.
* Average annual growth rate 1998-99 to 2000-01.

In general, the importance of these drugs reflects the leading causes of disease burden in Australia. The Australian Institute of Health and Welfare has estimated that about 43% of the total disease burden in Australia is attributable to the following 10 causes.[13]

Ischaemic heart disease	12.4
Stroke	5.4
Chronic obstructive pulmonary disease (COPD)	3.7
Depression	3.7
Lung cancer	3.6
Dementia	3.5
Diabetes mellitus	3.0
Colorectal cancer	2.7
Asthma	2.6
Osteoarthritis	2.2

Drugs for heart disease, stroke (anti-cholesterol), COPD and asthma, depression, diabetes and osteoarthritis are well represented among the top 30 drugs. On the other hand there are no drugs for the direct treatment of dementia (Alzheimer's disease) and lung and colorectal cancer (Goserelin is a treatment for prostrate and breast cancer).

The top 30 drugs are also broadly representative of the National Health Priority Areas of cardiovascular health, cancer control, injury prevention and control, mental health, diabetes mellitus and asthma.[14] Aside from injuries, cancer control is the priority area which is underrepresented.

The intense efforts that are being devoted by pharmaceutical and biotechnology companies as well as researchers to drugs for cancer and dementia reflects the need for improved treatments for these conditions.

[13] Mathers C, Vos T, Stevenson C, "The burden of disease and injury in Australia", Australian Institute of Health and Welfare, Canberra, November 1999.
[14] Mathers C et al, ibid, Chapter 6.

7. Conclusion

This paper has attempted to set out describe some of the main characteristics of the PBS over the past 10 years.

The cost of the PBS both to the Commonwealth Government and the patient has increased considerably, particularly in 1999-00 and 2000-01. This increase has been driven by a combination of the introduction of new drugs and a continuing strong demand for drugs which have been within the PBS for some time.

The Government has sought successfully to bear down on prices within the PBS, by encouraging competitive pricing from so-called "follower" drugs and generics, and by its regular pricing reviews[15]. The impact of this however has been overwhelmed by the consistently strong growth in demand for both for new and established drugs.

About 75% of the cost of the PBS is incurred by patients covered by concession cards. This means that over 85% of the population of retirement age have access to drugs at very low prices.

Medicines are consumed disproportionately by older age groups, particularly for the more expensive types of drugs which make up much of the PBS and which have exhibited the strongest growth. This includes the drugs to lower blood pressure and cholesterol, treat peptic ulcers and diabetes, the antiinflammatories and antirheumatics, and antidepressants.

Most of these are included in the top 30 or so drugs which account for about half the cost of the PBS, so actions to contain costs must concentrate on this collection of drugs. Perhaps more importantly, these 30 drugs account for 69% of the increase in costs.

Part of the cost increase is driven by rapidly growing new blockbuster drugs. These drugs are largely for conditions for which there has been no treatment, or where the treatment is greatly enhanced.

This means that the effect of these new drugs is to increase overall costs and not to reduce cost by displacing other drugs.

While the government has been successful in keeping down the prices of drugs, this has not been the case for some of these new drugs, which in any case tend to be more expensive than the drugs that have been in the PBS for some time.

The use of drugs included within the PBS broadly reflects Australia's disease burden and the Government's National Health Priority Areas. The exceptions are drugs for treating dementia and cancer. These areas lack truly effective drugs although anti-cancer drugs are the most rapidly growing group of drugs within the PBS.

[15] Sweeny, Kim, ibid.

APPENDIX A

Analysis Of Pbs Cost For 2000-01

Table A1 Calculation of PBS Cost Changes 1999-2000 to 2000-01

	Number of Items	Scripts	Government Cost	Patient Cost	Total Cost
		millions	$ millions	$ millions	$ millions
Total in 2000-01	1,975	148.1	3,820.6	744.2	4,564.7
Total in 1999-00	1,908	138.1	3,187.2	651.8	3,839.0
Total increase		10.0	633.3	92.4	725.7
New drugs in 2000-01	153	5.6	315.5	43.0	358.5
Drugs dropped prior to 2000-01	86	0.1	1.3	0.3	1.6
Increase due to net new drugs	67	5.6	314.2	42.8	357.0
Drugs in common 2000-01	1,822	142.4	3,505.1	701.1	4,206.2
Drugs in common 1999-00	1,822	138.0	3,186.0	651.5	3,837.4
Increase due to common drugs		4.4	319.1	49.6	368.7
Cost in 2000-01 at 1999-00 prices			3,569.4	697.8	4,267.3
Effect of prices			-64.4	3.3	-61.1
Effect of volume			383.5	46.4	429.8
Summary					
Total increase			633.3	92.4	725.7
Increase due to net new drugs			314.2	42.8	357.0
Increase due to common drugs			319.1	49.6	368.7
Effect of prices			-64.4	3.3	-61.1
Effect of volume			383.5	46.4	429.8
As a percentage					
Total increase			100.0	100.0	100.0
Increase due to net new drugs			49.6	46.3	49.2
Increase due to common drugs			50.4	53.7	50.8
Effect of prices			-10.2	3.5	-8.4
Effect of volume			60.5	50.2	59.2

Table A2 PBS Cost Changes 1992-93 to 2000-01, $m

	1992-93	1993-94	1994-95	1995-96	1996-97	1997-98	1998-99	1999-00	2000-01
Government Cost									
Total increase	285.5	281.8	196.1	310.1	140.9	193.2	254.2	391.6	633.3
Increase due to net new drugs	6.7	16.4	45.6	21.4	36.8	93.6	27.7	117.4	314.2
Increase due to common drugs	278.9	265.4	150.5	288.7	104.0	99.6	226.5	274.2	319.1
Effect of prices	44.5	59.6	0.8	37.6	-81.5	-65.4	-72.6	-46.4	-64.4
Effect of volume	234.3	205.8	149.7	251.0	185.6	165.0	299.1	320.6	383.5
Patient Cost									
Total increase	51.7	35.8	48.9	33.6	52.1	40.6	30.5	50.4	92.4
Increase due to net new drugs	2.3	3.3	5.9	5.0	3.2	16.8	3.6	16.3	42.8
Increase due to common drugs	49.4	32.5	42.9	28.5	48.9	23.8	27.0	34.1	49.6
Effect of prices	-13.5	-12.2	21.3	-4.4	38.8	16.5	-16.5	-18.5	3.3
Effect of volume	62.9	44.7	21.7	32.9	10.1	7.3	43.5	52.7	46.4
Total Cost									
Total increase	337.2	317.6	245.0	343.6	193.0	233.8	284.7	442.0	725.7
Increase due to net new drugs	9.0	19.7	51.5	26.4	40.0	110.3	31.2	133.7	357.0
Increase due to common drugs	328.2	297.9	193.5	317.2	153.0	123.4	253.5	308.3	368.7
Effect of prices	31.0	47.3	22.1	33.2	-42.7	-48.9	-89.2	-65.0	-61.1
Effect of volume	297.2	250.5	171.4	284.0	195.7	172.3	342.7	373.3	429.8

APPENDIX B

PBS COST BY ATC CATEGORIES

Table B1 PBS Cost by ATC Categories ($m)

		1991-92	2000-01	Share in 2000-01	Change 1991-92 to 2000-01
		$m	$m	%	%
A	Alimentary tract and metabolism	198.3	639.4	14.0	13.9
B	Blood and blood forming organs	11.1	76.8	1.7	23.9
C	Cardiovascular system	472.3	1,409.7	30.9	12.9
D	Dermatologicals	37.0	80.2	1.8	9.0
G	Genito urinary system and sex hormones	52.1	131.6	2.9	10.8
H	Systemic hormonal preparations	13.9	27.9	0.6	8.1
J	General antiinfectives for systemic use	167.0	264.3	5.8	5.2
L	Antineoplastic/immunomodulating agents	28.7	270.0	5.9	28.3
M	Musculo-skeletal system	70.5	293.7	6.4	17.2
N	Nervous system	156.2	839.3	18.4	20.5
P	Antiparasitic products, insecticides etc	7.8	11.9	0.3	4.7
R	Respiratory system	155.7	345.4	7.6	9.3
S	Sensory organs	39.5	96.1	2.1	10.4
V	Various	15.0	41.0	0.9	11.8
	Total	1,442.2	4,564.7	100.0	13.7

Table B2 PBS Cost by Selected ATC Sub-categories ($m)

		1991-92	2000-01	Share in 2000-01	Change 1991-92 to 2000-01
		$m	$m	%	%
	Alimentary tract and metabolism				
A02	Antacids, drugs for treatment of peptic ulcer and flatulence	104.7	380.3	8.3	15.4
A10	Drugs used in diabetes	46.4	143.2	3.1	13.3
	Cardiovascular system				
C08	Calcium channel blockers	102.0	186.0	4.1	6.9
C09	Agents acting on renin-angiotensin system	136.6	408.2	8.9	12.9
C10	Serum lipid reducing agents	98.9	642.3	14.1	23.1
	Antineoplastic/immunomodulating agents				
L01	Antineoplastic agents	5.1	101.2	2.2	39.2
	Musculo-skeletal system				
M01	Antiinflammatory and antirheumatic products	60.1	238.9	5.2	16.6
	Nervous system				
N02	Analgesics	43.4	122.4	2.7	12.2
N05	Psycholeptics	43.6	199.6	4.4	18.4
N06	Psychoanaleptics	27.7	327.9	7.2	31.6
	Respiratory system				
R03	Anti-asthmatics	153.4	334.9	7.3	9.1
	Total of above	821.9	3,084.9	67.6	15.4
	All other drugs	620.3	1,479.8	32.4	10.1
	All drugs	1,442.2	4,564.7	100.0	13.7