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## The Pharmaceutical Benefits Scheme: Options for Cost Control

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The Pharmaceutical Benefits Scheme: Options for Cost  
Control

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# Contents

Major Issues. . . . .	i
Introduction . . . . .	1
Background . . . . .	1
The PBS Drug Listing Process . . . . .	2
Eligibility for PBS Subsidies. . . . .	2
Patient Co-payments. . . . .	2
PBS Costs and Sustainability. . . . .	3
Sources of High PBS Costs. . . . .	3
Is the PBS <i>too</i> Costly? . . . . .	6
Are Current Rates of PBS Expenditure Affordable? (Is it too Costly in the First Sense?) . . . . .	7
Is Current PBS Expenditure Getting 'Value for Money' (When it Comes to Health Outcomes)? . . . . .	8
Cost Control Strategies . . . . .	10
Existing Cost Containment Measures . . . . .	10
Good Cost Containment Strategies: Some Broad Criteria . . . . .	11
Recently Proposed Cost Control Strategies . . . . .	12
Reducing Subsidised Access to 'Non-essential' Drugs . . . . .	13
Sharing the Burden of Subsidy with Private Health Insurers. . . . .	15
Drug Budget Holding. . . . .	17
Flat Monetary Levy on all Australians to Finance New Drugs . . . . .	17
Minimising Inappropriate Prescribing . . . . .	17
Managing 'Leakage' . . . . .	19
Other Targeted Measures . . . . .	19
Conclusion. . . . .	20
Endnotes . . . . .	20



## Major Issues

The Pharmaceutical Benefits Scheme (PBS) is currently the fastest growing area of health expenditure. In the 2001–2002 financial year it is estimated to cost \$4.837 billion, 13.6 per cent more than it did in the previous year. In the last decade it has experienced an estimated average annual expenditure growth rate of around 14 per cent. According to the fiscal projections of the *Intergenerational Report 2002–03*, the percentage of gross domestic product (GDP) government expenditure on the PBS will increase five-fold by 2041–42 (to approximately \$59 billion per annum). On the other hand, Australia is generally not out of step with other Organisation for Economic Co-operation and Development (OECD) nations in its public expenditure on pharmaceutical subsidies. Recent data indicates that the proportion of funding Australia devotes to pharmaceutical subsidies is lower than that of other OECD nations. However, the rate at which this proportion is growing is greater in Australia than these other countries.

The mission of the PBS is to make affordable to all Australians the medications they need, but at a responsible cost to the community. The currently growing cost to the community of the PBS is placing pressure on its future capacity to make available to Australians newly developed expensive medicines. The sustainability of the PBS is consequently an issue of some importance.

It is generally agreed that some of the factors contributing to PBS growth are to be expected (e.g. ageing population, advanced expensive drug additions). It is also agreed that some other drivers of growth are problematic. The PBS seeks to make available medicines that will have cost-savings effects on the use of other health-care and related resources (e.g. reduced GP visits, shorter or no hospitalisation, increased productivity, etc). A cost-effective PBS, even when it is costing more itself, will still be *reducing* expenditure in other areas. The problematic PBS growth drivers, therefore, will be those that detract from the PBS' capacity to deliver the greatest level of health-related cost-benefits. Cost control measures should target these factors.

One key factor in the increasing costs of the PBS is the rising prescription of expensive newly developed medicines, bolstered by community awareness and expectation. However, if those drugs are prescribed in accordance within their PBS cost-beneficial guidelines, the extra expense they constitute will be saving further costs elsewhere. It is when these drugs are prescribed outside their cost-effectiveness guidelines that the money the government pays to subsidise these drugs is being partly wasted. For example, the recently listed arthritis drug Celebrex was expected to cost the PBS \$40 million in its first

year, but ended up costing \$160 million, ostensibly through inappropriate prescribing. It has been estimated that between \$50 million and \$1 billion of PBS expenditure in the last year may have been due to inappropriate prescribing. A number of factors contribute to such prescribing, including primarily a lack of clear, accurate and timely information about cost-effective uses of these drugs, and misleading information and promotional incentives from manufacturers (It has been reported that the global pharmaceutical industry spends up to one third of sales revenue on marketing, twice as much as it spends on research).

Three objectives need to be negotiated in any response to PBS cost control—universal access, comprehensiveness in the medicines available, and responsible costs to the community. Reducing the cost to the community (i.e. reducing government expenditure on the PBS) can impact on the achievability of the other PBS objectives. How it impacts depends on how the costs are reigned in. Some of the more obvious cost-reduction measures may not, in the end, be as appropriate as they might seem. De-listing drugs from the PBS, for instance, may place undue burdens on groups who are least able to bear them. (80 per cent of PBS beneficiaries are concessional patients). The same may occur with increased co-payments, and this option may even cause people to avoid buying their medicines. Appropriate cost control strategies will address key weaknesses in PBS cost-effectiveness. This will primarily mean focusing on proper support for prescribers, controlling the prices paid to drug manufacturers, and addressing the promotional influences of the pharmaceutical industry.

An important point to remember is that high PBS costs, even increasingly high ones, do not necessarily translate into unsustainability. PBS sustainability is just as much a matter of public and political decision as it is a matter of finance and expenditure. It is a decision about how the three PBS objectives are to be weighed against each other, and what sort of balance between them seems best for Australia, in the circumstances of its limited health care resources.



## Introduction

The cost of the Pharmaceutical Benefits Scheme is currently high, and it is also growing at a very high rate. Question has arisen as to whether the PBS is sustainable at these costs, and there has been considerable debate as to what forms of cost control are appropriate to ensure its continued operation.

The discussion to follow presents a brief account of:

- trends relating to growth in PBS expenditure
- the major sources of high PBS costs
- the question of sustainability, and the sense in which PBS costs may be *too* high
- the existing cost containment measures relating to the PBS
- the considerations that may be relevant to deciding between different cost containment strategies
- the major strategies that have been proposed, viewed in the light of these considerations

## Background

The PBS has been in operation for 50 years with benefits first being made available from 1 June 1948. It has evolved from supplying drugs in the British Pharmacopoeia to pensioners and 139 life saving and disease preventing drugs for others, into a scheme which from 1 November 2001 covers 589 drug substances (generic drugs). These are available in 1458 forms and strengths (items) and marketed as 2459 different drug products (brands). Restrictions apply to 778 of the items, 290 of which require an authority prescription. The list of benefits is comprehensive, providing suitable therapy for most medical conditions in which medicine is an accepted form of treatment and diagnosis by a medical practitioner is appropriate.<sup>1</sup>

Most PBS prescriptions are dispensed through community pharmacies (as opposed to public hospital pharmacies). However, patients in private hospitals and people in residential care facilities also have access to PBS drugs (and pay the relevant co-payments). The Commonwealth also pays for several high cost drugs which can only be

supplied from hospitals to outpatients. These arrangements are known as the Highly Specialised Drugs Program or Section 100 drugs (after the relevant section of the *National Health Act 1953*) and include drugs used in the treatment of chronic conditions, for example, interferon for the treatment of hepatitis C and a range of drugs used in the treatment of HIV/AIDS. The PBS does not include drugs dispensed to patients in public hospitals (other than via the section 100 arrangements), which are generally the responsibility of State and Territory Governments.

## **The PBS Drug Listing Process**

Prior to listing on the PBS, a drug must first be assessed for its safety, quality and efficacy by the Australian Drug Evaluation Committee (ADEC). If ADEC recommends that the drug should be available for sale in Australia, a sponsor (usually the drug company) applies to the Pharmaceutical Benefits Advisory Committee (PBAC) for listing on the PBS. The PBAC assesses the evidence on the drug's effectiveness, particularly its cost effectiveness, and advises the Minister for Health and Aged Care if the drug should be listed on the PBS. If the Minister accepts the recommendation of the PBAC, the drug is then referred to the Pharmaceutical Benefits Pricing Authority (PBPA) which negotiates with the manufacturer on the price at which the drug will be listed on the PBS and advises the Minister accordingly.

## **Eligibility for PBS Subsidies**

PBS medicines are available to all Australian residents and to visitors from countries with which Australia has Reciprocal Health Care Agreements. People covered by certain temporary visas (refugees) may also be eligible for PBS medicines. Pensioners, Commonwealth Seniors, beneficiaries and some low income earners are eligible for health concession cards issued by Centrelink. These concession cards provide entitlement to concessional rate pharmaceuticals. Patients may be required to produce a current Medicare card and, where applicable, a Centrelink health concession card to establish their eligibility to receive PBS medicines. As of December 2001, the majority of government expenditure on PBS prescriptions was directed towards concessional cardholders (79 per cent of the total).

## **Patient Co-payments**

As of 1 January 2002 the costs patients pay for PBS listed medicines were set at the following rates:

- general patients pay up to \$22.40
- concession card holders pay \$3.60

A safety-net arrangement has operated since 1 November 1986 where no patient co-payment is required (i.e. pharmaceuticals are free) for concessional patients (and/or their families) if they pay more than \$187.20 per calendar year on pharmaceuticals. If general patients (and/or their families) pay more than \$686.40 a calendar year on pharmaceuticals

they are entitled to be charged at the concessional co-payment rate for further purchases in that year.

If the cost of a drug is lower than the patient co-payment, patients may pay less than the figures above. In some circumstances, however, patients may pay more. This may occur where the Commonwealth has set the PBS subsidy at, for example, the cost of a generic drug and if a brand name equivalent is prescribed, there may be an additional charge for the patient. In other cases the government and the drug manufacturer may not agree on the price of a particular drug. In these cases the patient would be required to pay the difference between the Commonwealth subsidy and the price of the drug.

General patient co-payments were introduced in 1960 at \$0.50 per prescription. The concessional co-payment increased from \$2.00 in 1983 to \$2.50 in 1990 (when pensioners were added to the concessional category), and then to the current level of \$3.60. Co-payment increases have been the result of government initiated increases, or routine Consumer Price Index (CPI) indexation increases. It has been proposed in the 2002–03 Federal Budget that these co-payments and safety-net levels be raised by 28 per cent to \$28.60 for general patients (safety-net \$874.90) and \$4.60 for concessional patients (safety-net \$239.20).

Pensioners receive a Pharmaceutical Allowance to offset the patient payment for PBS prescriptions. The Pharmaceutical Allowance is currently \$2.90 per week, paid fortnightly regardless of how many prescriptions are filled.

## **PBS Costs and Sustainability**

The PBS is currently a very high growth area of annual government expenditure. Since the early 1990s, the PBS has experienced an annual growth rate in expenditure of nearly 14 per cent.<sup>2</sup> Budget estimates have placed the 2000–01 financial year PBS expenditure at \$4.257 billion.<sup>3</sup> It is estimated that by June 2002, PBS expenditure will have increased by \$579.6 million to \$4.837 billion (a 13.6 per cent increase on 2000–01).<sup>4</sup> *The Budget Strategy and Outlook Paper* has also estimated that in 2004–2005, the PBS will cost \$5.457 billion (an additional \$1.2 billion per annum compared to the 2000–01).<sup>5</sup> This is a total increase of 28.2 per cent, and an average annual rate of increase of 6.4 per cent over the 4 years (somewhat less than the rate of increase for last year).

### **Sources of High PBS Costs**

PBS expenditure is not capped and is prescriber driven. Exact expenditure only becomes apparent at the end of the accounting period. The following factors are generally agreed to have been the major causes of PBS cost increases in recent years:<sup>6</sup>

- **Increasing numbers of aged people with chronic conditions that benefit from drug treatment.** There is suggestion that the role played by ageing is limited, however. A simulation of PBS expenditure to the year 2020, assuming a 5 per cent increase in the

price of medicines, indicated that expenditure was likely to be four times greater than the impact of population aging alone.<sup>7</sup>

- **The increasing availability of new and effective, but high cost, drug treatments on the PBS.** The Health Insurance Commission attributes a substantial proportion of the recent increase in PBS expenditure to doctors prescribing newer and more expensive drugs.<sup>8</sup> For example, one of the most frequently prescribed drugs in 2001—Atorvastatin for cardiovascular conditions (4.89 million prescriptions) cost \$59.61 per script on average. Similarly, the newly listed anti-smoking drug Zyban, costs \$249.51 per script on average. Celebrex, another heavily prescribed drug (3.56 million prescriptions), costs an average of 46.92, per script.<sup>9</sup>
- **The growth of preventive medicine.** There is a growing awareness of the benefits of primary and secondary prevention of diseases, and the potential role that drug treatments have in this. For example, the new Australian *Lipid Management Guidelines 2001* emphasises the importance of cardio-vascular disease prevention, and the central role of cholesterol-lowering drugs. In 2001, the serum-lipid reducing agents were the most heavily prescribed drug group, the major statins accounting for \$580 million in PBS expenditure.
- **National campaigns to improve detection and treatment of previously inadequately treated conditions** such as depression, high blood-cholesterol, and asthma. Depression, for instance, rose from the tenth most treated condition in general practice in 1990–01 to the fourth in 1998–99, and there was a corresponding three-fold increase in the dispensing of anti-depressant prescriptions.<sup>10</sup> Similarly, there has been a three-fold increase in the prevalence of diabetes in Australia in the last 20 years (7.2 per cent of adult Australians).<sup>11</sup>
- **Increasing community awareness of, and expectations of accessing, new, effective and often expensive drug treatments.** Often this occurs through media exposure, which can be seeded by pharmaceutical manufacturers.
- **Pharmaceutical costs that would otherwise be borne by the states (with capped health budgets) being shifted to the uncapped Commonwealth PBS.** This is brought about by hospitals (state) providing patients with only limited drugs on discharge, with the remainder being obtained by prescription on the PBS. The privatisation of hospital outpatient clinics and pharmacies, (and the corporatising of medicine through, e.g. multi-function medical clinics) as well as reclassifying in-patients as ambulatory, also shifts pharmaceutical expenditure to the Commonwealth.<sup>12</sup>
- **Increases in the number of people paying the lowest co-payment rate** through relaxation of eligibility for the concessional patient category. From October 2001, the income limits entitling self-funded retirees to a Commonwealth Seniors Health Care Card (with concessionary PBS benefits) were doubled (up to \$50 000 pa for a single retiree). In the 2001–02 Budget it was estimated an extra 50 000 people would gain access to the CSHCC as a result.<sup>13</sup> Commonwealth seniors health card holders, being older Australians,

are likely to be heavier than average users of medication. But they have also been identified as having the highest rate of PBS use of all concessionary PBS patient categories.<sup>14</sup> This relaxation, together with a measure to exempt superannuation from the social security means test for people aged over 55, will result in an estimated \$70 million in additional expenditure on the PBS in 2001–2002.<sup>15</sup>

- **('Leakage') The prescription (on PBS subsidy) of new and expensive drugs to patients with conditions that are not subsidised under the PBS restrictions for prescribing those drugs.** Leakage usually takes the form of *upward* prescription, where a more expensive new drug, designed (and listed on the PBS) to treat a serious condition is prescribed to treat minor conditions for which there are cheaper effective drug treatments. The new drugs Celebrex and Losec have been implicated in this. The former was authorised for chronic arthritis but has been prescribed on subsidy for e.g. sports injuries. The latter was authorised for serious ulcer conditions, but has been prescribed (on subsidy) for more minor reflux problems. At the time of its listing, it was estimated that Celebrex would cost the PBS \$40 million in its first year. However its actual cost was in the order of \$160 million.<sup>16</sup> It is difficult to determine the level of leakage that actually occurs. Some claim the cost of leakage to have been \$1 billion last year,<sup>17</sup> while others are reported to put the figure at \$50 million each year.<sup>18</sup> One source reports that it was originally estimated that proton pump inhibitor drugs (like Losec) should be used by less than 35 000 patients. But the actual number receiving this medicine was 177 000, costing an extra \$220 million per annum.<sup>19</sup>

There is emerging agreement about the sorts of factors that lead to and sustain leakage, most notably:

- a lack of timely independent information for doctors about effective, and cost-effective clinical application of new drugs.
- manufacturers' energetic promotion of their new drug products in a way that is not always clinically accurate,<sup>20</sup> and which canvasses a range of clinical uses, not all of which fall within PBS prescribing restrictions.<sup>21</sup> Some argue also that the pharmaceutical industry tends to 'medicalise' what might otherwise be considered ordinary physical/psychological processes and ailments, in order to broaden markets.<sup>22</sup>
- a professional impetus among doctors to give overriding priority to clinical need and the doctor-patient relationship, and therefore to make available to their patients what they consider the best treatments for their conditions.

Certainly, leakage contributes to high PBS costs because it usually involves high volume prescription of drugs that are expensive. But, it is costly in the perhaps more significant sense that it involves waste. An expensive resource is used to achieve health outcomes that could have been achieved much more cheaply (with cheaper existing drug treatments).

- **Prescriptions of drugs for conditions for which the drugs are not clinically indicated or appropriate.** Though this is not identified as a contributor to recent *increases* in PBS costs, it is still a significant contributor to maintained high costs. Antibiotic prescription is an example. Education campaigns have significantly reduced the rate at which antibiotics are unnecessarily prescribed. However, it is reported that \$100 million a year is still spent on antibiotics prescribed for conditions for which they are not effective.<sup>23</sup> It has been suggested that there is less than optimal adherence on the part of doctors to prescribing and clinical guidelines.<sup>24</sup> There is also an emerging tendency for doctors to prescribe defensively. That is, to prescribe a drug when there is only a low probability of it being effective, because 'you cannot afford to be wrong'. For example, prescribing antibiotics for a probably viral upper respiratory tract infection because there is some chance that it may be bacterial (albeit a low one). Evidence-based guidelines, however, would recommend that antibiotics not be used in this situation.<sup>25</sup>

These contributing factors are sometimes inter-related, and can be compounding in their effect. And arguably, some contributors seem more tolerable than others. (e.g. an increase in the use of preventive medicines seems, all things being equal, to be more acceptable as a cost factor than leakage and inappropriate prescribing).

Accordingly, some ways of containing PBS costs may be more appropriate than others. Just which will depend on the general sense in which PBS expenditure is too high (if it is), as well as the broad policy goals and constraints that ought to inform decisions/strategies concerning PBS expenditure control. These two things are taken up in the next sections.

### **Is the PBS *too* Costly?**

Clearly, the costs of the PBS are high. To a certain degree, this is perhaps predictable. Any system of providing high subsidy for medicines will remove price-barriers/signals for prescribers and users, and with this comes the risk of for example over-utilisation. However, some claim they are so high as to make the PBS unsustainable into the future. For example, there is continuing competition from expensive new drug developments to be listed on the PBS. But currently high and increasing levels of PBS expenditure impact on its capacity to subsidise them.

Nonetheless, whether the PBS is sustainable is not determined simply by its costs, but also by the public and political willingness to sustain it at those costs. So, high costs, and even increasingly high costs, do not inevitably translate into unsustainability. The crucial question is whether the money devoted to the PBS is well spent—in terms of what it buys in health-outcomes; and also in terms of what claim other competing budget priorities would legitimately have on that funding.

In line with this, the claim that the PBS is 'too costly' can be interpreted in two ways, and these interpretations are sometimes run together in the debate about PBS sustainability.

The PBS might be alleged to be too costly in the sense that:

- its large and increasing costs take away from other competing social programs and areas of budgetary concern that deserve sufficient Commonwealth funding. Here, PBS expenditure would be too high measured in terms of its (unfair) impacts on other funding priorities.<sup>26</sup> It cannot be afforded as is, given other priorities.

Completely independently of other funding pressures, the cost of the PBS might also be claimed too high in the sense that:

- the quality, and/or extent of the health outcomes achieved by the PBS are not the best that could be expected for the level of funding devoted to it. Here, the costs of the PBS would be too high measured in terms of (poor or less than optimal) 'health-value for money'.

### **Are Current Rates of PBS Expenditure Affordable? (Is it too Costly in the First Sense?)**

Can the Commonwealth afford current (and projected future) spending on pharmaceutical subsidies, given its other priorities?

Whether the PBS is getting more than its legitimate share of funding compared to other areas of social need is a question of policy priority. It is therefore, a matter for argument that lies outside the scope of this brief. Nevertheless, two quick observations can be made.

Firstly, as far as the broad philosophical arguments on this issue are concerned, it is generally agreed that health is a sufficiently important social good that it should be given a serious and ongoing degree of public priority. This agreement is grounded in the observation that adequate personal health is a necessary condition for people's full engagement in social life and responsibilities. Health programs, therefore, ought to be given significant weight in the competition for funding with other social programs. Moreover, those particular health programs, like pharmaceutical subsidisation, that have the capacity to reduce future health-care needs, should be given even greater priority.

Secondly, the available data indicates that Australia is generally not out of step with overseas nations in its public expenditure on pharmaceutical subsidies. Recent data from the OECD indicates that:<sup>27</sup>

- The proportion of public health expenditure Australia commits to pharmaceutical subsidy is less than the average of that spent by other comparable countries like Canada, France, NZ, Spain, Sweden, UK, and the USA.
- The proportion of overall national pharmaceutical spending that Australia publicly funds is the lowest compared to other similar nations having universal pharmaceutical cover (i.e. Sweden, France, Spain, NZ and the UK).

- In 1998, Australia's public expenditure on pharmaceuticals was 0.5 per cent of GDP, less than the average (0.7 per cent) for other OECD countries for which there is data for that year.<sup>28</sup>
- Between 1990 and 1997–98 or 1998–99 (depending on most recent available data), the rates of growth of Australia's total public expenditure on pharmaceuticals, and its per capita public expenditure on pharmaceuticals were above average compared to other OECD countries (12 per cent compared to 8.3 per cent; and 10.7 per cent compared to 7.85 per cent respectively).<sup>29</sup>

From these figures it seems that the proportion of funding Australia devotes to pharmaceutical subsidies is lower than that of other comparable nations. However, the rate at which that proportion is growing in Australia is not lower than other OECD countries.

Clearly, this information does not settle the question of whether the PBS is (or will be) taking too much from the overall public purse. But, to the extent that the data does have some bearing on that question, it suggests that the *level* of Commonwealth pharmaceutical expenditure might not be high, even if its recent rate of growth may be. What this indicates, of course, is subject to further analysis. However, on the face of it, it might be argued that Australia is in a process of 'catching up'.

There is one further observation that can be made about affordability. The provision of subsidised medicines seeks to reduce further costs in the health-care system or at a broader social level (e.g. productivity). It makes economic sense to pay for the PBS now (even if it currently costs a lot) if this avoids inevitably paying much more without it.<sup>30</sup> How much the PBS saves, and how efficiently it does, are questions about the value for money of PBS expenditure.

### **Is Current PBS Expenditure Getting 'Value for Money' (When it Comes to Health Outcomes)?**

As the previous outline of cost pressures suggests, there are weaknesses in the cost-effectiveness<sup>31</sup> of the PBS as it currently operates. However, there are also significant strengths. The PBS dollar is arguably being well spent in the following sorts of ways:

- Relatively low prices for drugs have generally been maintained through the PBS being the single buyer in a market with a number of pharmaceutical sellers.<sup>32</sup> (More medicines, and therefore health outcomes, are bought per PBS dollar.)
- Subsidies making medicines (including expensive ones) affordable to the public have ensured an ongoing market for manufacturers, and a strong incentive to invest in R&D for new advances (PBS dollar buys ongoing availability of medicines, and development of new advances, to achieve health outcomes).



- The subsidised availability of drugs with a primary or secondary preventive action (e.g. statins and coronary heart disease, zyban and cigarette smoking, etc.) can (if targeted properly) have cost-offsets in the way of averted health-care use, as well as quality of life enhancements. (Unfortunately, there is no ongoing evaluation of the overall cost-effectiveness of the PBS as a whole, although there are independently published cost-effectiveness studies for particular drugs or drug groups.)<sup>33</sup>
- Listing of newly developed drugs often involve cost-offsets for the PBS itself, via reduced use of other PBS drugs that the former are advances on, or that would have been used to treat side-effects the new drug controls more effectively.<sup>34</sup>

A number of the cost pressures mentioned above contribute to less than optimal health-value for the PBS dollar, and in some cases, very poor value.

- Most seriously implicated in poor value for the PBS dollar is leakage, and prescribing inappropriately (e.g. as with antibiotics for some conditions). In the latter case, money is simply being spent to no effect at all. It is completely wasted. In the former, the money is being spent to some effect. Celebrex, for instance, does treat sprain injuries. However, more money is being spent to get that effect than is necessary. There are cheaper options for the same outcome. So, expenditure associated with leakage is not completely wasted, it is partly wasted (just how much will depend on which particular drugs and minor conditions are involved).

There are also some other features of PBS operation, or the broader medication management context, that can reduce the value for money the PBS gets.

- Listings of drugs on the PBS, since 1993, have been based on assessments of their cost-effectiveness (cost-utility) in achieving health outcomes. More importantly, the prices agreed to be paid by the PBS to manufacturers for listed drugs are a function of their initially assessed cost-effectiveness. The Pharmaceutical Benefits Pricing Authority does review prices of listed drugs on cost-effectiveness criteria, but there is no ongoing system of regular reviews. It may be that some drugs are less cost-effective now than they would have been early in release (e.g. given new advances, etc.).<sup>35</sup> Drugs currently on the PBS that were listed pre-1993 have not been assessed for cost-effectiveness.<sup>36</sup>
- Sought health-outcomes are achieved only if patients make effective use of the medication the PBS has paid for. Patients non-compliance with their medication regimes can reduce effective health outcomes.
- Adverse drug interactions can be counter-productive, resulting in further healthcare resource use. It has been claimed that patients' inappropriate use of drugs results in an estimated 80 000 admissions a year and costs \$350 million per annum, and that adverse drug events account for 10–20 per cent of all adverse events.<sup>37</sup>

## Cost Control Strategies

### Existing Cost Containment Measures

There are some existing mechanisms within, or measures impacting on, PBS costs. These include:

**Patient co-payments:** Between January and December 2001 co-payments contributed 16 per cent of the cost of pharmaceuticals (amounting to \$770.1 million)

**Brand Premium Policy:** Prices paid by the PBS are set at the lowest priced brand of bio-equivalent drugs. If a patient is prescribed a brand which is not the lowest priced among bio-equivalents, the patient will be required to pay the difference (the brand premium), if any, between their level of co-payment and the brand's price. The aim is to stimulate price competitiveness and to encourage the development of generic pharmaceutical industry in Australia.

**Therapeutic Group Premium Policy:** Prices paid by the PBS for drugs in 4 therapeutic groups are set at the lowest priced drug within that group of (not necessarily bio-equivalent) drugs. Again, the patient pays the price difference (the therapeutic group premium) if the least expensive drug within the group is prescribed.

**Price Volume Agreements:** The PBS negotiates the prices it pays manufacturers for drugs partly on the basis of the anticipated utilisation of those drugs—generally the larger the anticipated market, the lower the price paid. In cases where there is question about the extent of the market for a drug (that is likely to be expensive), or where large volumes of sales are expected, the PBS has sought to establish agreements with manufacturers to vary the price it pays in the light of actual market variations. Price volume agreements enable a more accurate matching between the actual cost-effectiveness of a listed drug and the price paid for it.

**Quality Incentives for General Practice Programme (Quality incentives for prescribing pharmaceuticals):** A measure introduced in the 1999–2000 Department of Health and Aged Care Budget to encourage GPs to change their prescribing behaviour, particularly with respect to three high cost/high growth drug groups (antibiotics, peptic ulcer drugs, cardiovascular drugs). Half of the savings accruing from changes in prescribing behaviour were to be allocated to GPs. The measure expected to spend a total of \$187.4 million over 4 years. A pilot program was announced in April 2002 by the Department of Health to run in 30 Divisions of General Practice over 18 months. The divisions are to receive half the money saved through the prescribing changes of their GPs.<sup>38</sup>

**National Prescribing Service (Quality Use of Medicines initiative):** An organisation designed to inform and educate general practitioners about appropriate prescribing, and to propagate an evidence-based approach to medicine. The NPS receives funding in the order

of \$5 million per year, and it has been shown to have achieved improvements in prescribing in the order of \$15 million.<sup>39</sup> The 2001 Federal Budget has allocated \$14.6 million to the NPS (over 4 years) for a consumer education strategy.

**Improved monitoring of entitlements to pharmaceutical benefits:** A legislative change introduced to prevent those temporary residents in Australia (not subject to reciprocal medical arrangements) from accessing pharmaceutical benefits. Patients are now required (since January 2001) to produce their Medicare number when claiming pharmaceutical benefits.

**Simple price control measures** (applied by the Pharmaceutical Benefits Pricing Authority): Once drugs are PBS-listed, it is difficult for them to get price rises.

Although there may be occasional evaluations of some of these measures, there is no ongoing systematic evaluation of the cost-savings they achieve.

### **Good Cost Containment Strategies: Some Broad Criteria**

Costs can be reduced or controlled in any number of ways, for example, by simply capping the PBS budget. And just as clearly, different levels and loci of cost-reduction will have different impacts on the PBS program. There is an important question, therefore, as to what program impacts should be sought in the process of cost control, or at the very least, which impacts would be tolerable as a consequence of it.

Arguably, some clues about this might arise from looking at what the PBS is, at bottom, intended to do. In other words, its broad underlying objectives. These might provide some broad guidelines for judging the relative merit of different strategies for cost control.

The PBS operates under the umbrella of the National Medicines Policy, the aim of which, among other things, is to provide timely access to the medicines that Australians need, at a cost individuals and the community can afford. It also seeks to maintain a responsible and viable medicines industry. Within these policy goals, the overriding objective of the PBS is to help improve the health of all Australians by ensuring they have equitable access to necessary and lifesaving medicines at an affordable price.<sup>40</sup> Implicit in the National Medicines Policy and the PBS mission together are the following core defining elements:<sup>41</sup>

- *Comprehensiveness:* the range of medicines to be made available are the medicines that Australians need, at the time they need them
- *Universality:* all Australians are to have access (equity) on the basis of need, rather than capacity to pay (individual affordability)
- *Responsible Community Cost:* the costs to the community of pursuing the first two objectives should be as low as they can be.

It makes sense to assess cost containment options in terms of how well they respect these three broad PBS policy objectives. Determining this, though, is probably not straightforward. In circumstances of limited health-care resources, these objectives will be in tension. For example, making available new expensive medications (as per comprehensiveness) places pressure on community costs. And seeking low community costs might impact on universality. In fact, the whole issue of what will count as acceptable cost containment is essentially a question of what degree of compromise it is acceptable for the last objective to force on the first two. The acceptable strategies will be those that strike an acceptable balance between the three PBS objectives.

It would be fair to say that the least compromise that has to be made to save costs, the better. This suggests that good cost control strategies will address the cost weaknesses or pressures in the PBS, but also try to preserve PBS strengths (and some of these were identified earlier): Also such strategies will recognise that cost control or containment is not simply a matter of cost-reduction or cutting, but also of *benefit maximisation*.<sup>42</sup> Good cost control strategies will seek to make the program changes necessary to get the full health value per dollar of PBS expenditure. Greater efficiency achieved in this way will mean less needs to be spent to obtain the same health outcomes.

The following sections outline some of the major cost containment strategies that have been proposed for the PBS.

## **Recently Proposed Cost Control Strategies**

The strategies proposed fall into two classes: approaches that advocate system-wide modifications to PBS operation; those that involve measures targeted to specific areas of cost-pressure, (and those involving some of both). The following outlines the major systemic approaches.

**Increasing patient co-payments** (either at a flat rate for everyone, or in proportion to people's capacity to pay (means testing), or in proportion to the actual price of the medication purchased) Here, PBS costs to the Budget are reduced in so far as the PBS has to make up less by way of the difference in payment to companies for drugs, and to the extent to which higher co-payments moderate demand for drugs. Over the last decade there has been a steady decline in the proportion of the total annual spending on the PBS that has been contributed by patient co-payments. In 1991–92, patient co-payments accounted for approximately 20 per cent of the total cost of the PBS, and in 2000–01 accounted for about 15 per cent.

Increasing co-payments is probably the most direct way of substantially reducing PBS costs. Recent NATSEM modelling (on 1996–97 data) of a flat 25 per cent rise in co-payments for general and concessional patients indicated an annual saving to the PBS of \$181 million.<sup>43</sup> However, it was observed that this increase would place a burden on the lowest income earners among general patients (making expenditure on pharmaceuticals a high average of 8.6 per cent of disposable income). Furthermore, measures to partly

compensate the least well off—the concessional patients—by way of Government supplements to social security or pension payments (as was the case in 1986 and 2000 for pensioners) would serve to erode by half the net savings from the 25 per cent increase. The NATSEM analysis ends by observing that in view of the fact that 80 per cent of PBS beneficiaries are concessional, there would be limited potential to increase patient contributions—'alternatives other than the raising of patient contributions may need to be considered'.<sup>44</sup> There is also overseas evidence that increases in co-payments can result in patients not filling their scripts, and this, of course, involves the significant risk of deferred health care costs that will eventually be borne in other areas of the health care system.<sup>45</sup> In the case of people not purchasing drugs with a *preventive* action because of higher co-payments, this can have the effect of shifting health costs into the future, when the unprevented condition manifests.

A means tested increase in co-payments, where those above a certain income level pay higher co-payments, may avoid the above problem associated with low income earners. Only those capable of paying the extra would pay. However, as noted above, there is evidence that higher pharmaceutical co-payments may still have negative impacts on willingness to purchase. Care would need to be taken in setting the income-co-payment rates. Otherwise there may be pressure for people not to access needed pharmaceuticals, and the PBS goal of *universality* would be compromised to some degree.

It was observed earlier that the recent substantial cost increases in the PBS were due largely to the increasing prescription of more expensive drugs. Setting co-payments proportionate to the actual price of the drug might act to specifically offset that cost pressure. Proportional co-payments might also be argued to be effective in sending price-signals to patients to deter over consumption, and to encourage compliance with medication regimes. As well as this, such co-payments might provide incentives for GPs to prescribe cheaper alternatives, when they are viable.

However, there are concerns with this option as well. Chronic users of expensive drugs, for chronic conditions, are often concessional patients who would be least able to afford the extra payments. And it is not implausible to suppose that a smaller anticipated market for expensive drugs (because of the disincentive to purchase them) might contribute to further increases in their price on listing, and/or act as a disincentive for manufacturers to invest in their production in the first place.<sup>46</sup> The proportional co-payment option impacts on universality, and possibly the comprehensiveness of the necessary drugs available.

### **Reducing Subsidised Access to 'Non-essential' Drugs**

Cost reductions have sometimes been sought through the de-listing of certain groups of pharmaceuticals from the PBS Schedule.<sup>47</sup> A number of subsidised products have been de-listed as a result of recent Budget decisions:

- the 1996–97 Budget announced the de-listing of a range of topical anti-fungal medicines at a projected cost-saving of \$16 million over four years
- the 1997–98 Budget announced the de-listing of some anti-inflammatory products, medicines for common stomach problems and others for treatment of minor nail infections at an estimated cost-saving of \$112 million over four years
- the 2000–2001 Budget announced the de-listing of a range of nasal sprays, at an estimated cost-saving of \$61 million over four years

The products de-listed were considered treatments for minor or common conditions. In a number of cases the relevant Budget statements suggested that PBS funds could be better spent on medications to treat more serious illnesses.

Although the PBAC does not distinguish between essential and non-essential drugs, it does make a distinction (in its guidelines for listing) between drugs for the treatment of 'significant medical conditions' and the treatment of 'clinically minor or trivial conditions'. Discussions with the PBAC Secretariat indicate that PBAC does not employ any formal definitions or criteria for the distinction. Instead, it makes that judgement on a case-by-case basis when scrutinising submissions.

It is reasonable to assume that, all things being equal, subsidies for drugs that prevent or treat significant medical conditions will generally have greater cost-utility than subsidies for minor conditions. (Given that the former would likely have greater impact on resource use/quality of life loss/productivity loss if not treated). Given the increasing pressure for inclusion of significant new treatments, it makes sense to reserve PBS subsidy only for significant drugs.

Whether a medical condition is significant or not is always a clinical decision. Even within minor conditions, there will always be degrees of severity. Moreover a condition which in isolation is minor, might sometimes have more significant implications if not treated in the context of some other medical condition. With these qualifications in mind, the conditions for which the following drug groups are indicated might generally be considered minor. Drugs within these groups are currently subsidised on the PBS, without restriction as to prescribing conditions:<sup>48</sup>

- **mild antacids** (Mylanta, Gelucil, Sigma antacid)
- **mild analgesics** (paracetamol, codeine, aspirin)
- **anti-regurgitants** (e.g. Gaviscon)
- **anti-anaemics** (ferrous sulphate)

The following table provides an estimate of the cost to the PBS of mild analgesics over the next four years (based on their mean annual rate of increase in cost over the previous four years).

**Table 1: Estimated Cost to PBS of Certain Drugs 2002–2006<sup>49</sup>**

<b>Analgesics</b>	<b>Code</b>	<b>2001–2002*</b> <b>\$ 000</b>	<b>Projected cost b/w 2002–2006</b> <b>\$ 000</b>
Panadeine (Tabs)	1215Y	<b>20 312</b>	<b>95 799</b>
Paracetamol (Tabs)	1746X	<b>23 337</b>	<b>106 130</b>

Note: \* Estimated on July 2001–Dec 2001 costs multiplied by two.

The de-listing of drugs within these groups would achieve significant cost savings to the PBS. De-listing would also be broadly consistent with the PBS goal of providing (only) necessary medicines, and at a cost the community can afford.

However, it is important that this option is assessed in terms of its possible consequences, particularly the question of where the burden of costs associated with de-listing those drugs would then fall. Overwhelmingly the PBS subsidies for these drugs have been directed to concessional patients—99.5 per cent and 97 per cent in the cases of paracetamol tablets and paracetamol/codeine tablets respectively. If the subsidies are withdrawn, the greatest impact will be for them. They will either have to pay for the drugs themselves or do without. Whichever way, the costs will be borne by those least well-placed (economically and often health-wise) to bear them.

There is another potential consequence of de-listing in this context, the doctor's substitution of the de-listed drug for another, usually more expensive, (sometimes more toxic) one that remains subsidised. Given the doctor's overriding concern for the medical needs of his/her patient, the doctor has an incentive to prescribe a drug treatment that is affordable to the patient, even if it is actually more expensive to the PBS than the de-listed drug that would have been prescribed. This is exactly what happened with an earlier attempt to de-list mild analgesics. Doctors began to prescribe more expensive non-steroidal pain-killers.<sup>50</sup>

The upshot of these observations is that de-listing compromises the goal of comprehensiveness, and runs a substantial risk of increasing PBS costs. De-listing may also impose burdens on those least able to bear them.

### **Sharing the Burden of Subsidy with Private Health Insurers**

Currently in Australia, private health insurance schemes are prevented from playing a role in the subsidising of the medications listed on the PBS. Private insurers often cover non-PBS prescription medicines. In the three months to December 2001, private health insurers

paid out \$14.6 million in such benefits.<sup>51</sup> A mix of public subsidy and private insurance coverage in the Australian setting would probably take the form of either (a) public subsidy for all listed drugs for low-income/concessional patients, with higher-income earners requiring private subsidy, or (b) public subsidy for everyone for a very limited range of drugs (maybe life-saving ones), and private cover required for all other drugs.

Health insurance funds are extensively used in the US and Canada for drug subsidy. Most plans subsidise a formulary list of preferred pharmaceuticals for doctor and patient use. Often lower patient co-payments are required for these preferred pharmaceuticals, and higher co-payments for non-formulary drugs. Some funds offer no coverage for non-formulary drugs.

There are cost-related attractions of private coverage for pharmaceuticals. Clearly, it means less government expenditure on public subsidy. But also it allows private insurers the opportunity to negotiate cost-management conditions on prescribers/consumers. Brown and others note that the general attraction of private sector involvement consists in 'increasing consumer choice, responsiveness and price regulation through market competition'.<sup>52</sup> The market in other words, will produce good value for money. However, Brown and others also note that a mixed public private arrangement runs the risk of creating a two-tiered system, where there are people who can afford private insurance and those who cannot. Eighty per cent of PBS users in Australia are government beneficiaries. It is likely that either a large drug consuming population will be disenfranchised, or if they are still eligible for full concessionary PBS entitlements, only a significantly smaller cost-saving is likely to be achieved in reserving private cover for the remaining general patients.

The cost-management influence private insurers would have on GPs' prescribing may also have a downside. It may constitute a perverse incentive for GPs to prescribe in ways that may not serve their patients needs best. One further observation can be made. It was noted earlier that one of the strengths of the PBS was its monopsony power. Being the only buyer in a market with many sellers tends to keep the price low. Allowing private insurers into the drug market may create a tendency to increased drug prices.

Overall, this public-private mix cost control strategy has the capacity to put pressure on the universality and comprehensiveness of medicines cover. It is worth observing also, that until recently there was a continuing decline in Australian's voluntary subscription to health insurance, and recently a very substantial amount of government money was devoted to encouraging people to subscribe. In view of this, it is not clear how stable and sustainable a private insurance contribution to pharmaceutical subsidy would be over time, without itself being publicly subsidised.



## **Drug Budget Holding**

This involves setting 'budget' limits to GP prescribing. Drug budgets for GPs operate in the UK, France and Germany. Typically, cost-overruns are deducted from doctors' fees. On its introduction in Germany, there was an immediate 17 per cent reduction in drug volume and 24 per cent reduction in spending. These effects were short-lived, however. And it was not clear what impact this had on quality of prescribing, particularly given the strong incentive it would seem to provide to prescribe less than optimally (especially when the budget is reaching its limits).<sup>53</sup>

## **Flat Monetary Levy on all Australians to Finance New Drugs**

A \$200 a year levy is proposed by the Australian Pharmaceutical Manufacturers Association.<sup>54</sup>

There is an important observation to be made about all forms of cost-reduction that impact significantly on either universal or comprehensive access to pharmaceuticals. If people do not, or cannot, access the pharmaceuticals that address their health conditions, there is a strong chance that those health conditions will have cost impacts on other areas of the health or social system. To the extent that that would happen, such strategies are more cost-shifting than cost-reduction. They may even substantially increase costs.

The following list is of the major targeted cost control measures that have recently been advocated. Most of them have as their target one of the major sources of PBS cost pressure mentioned earlier—problematic prescribing. And, unlike the mostly *cost-reduction* options canvassed above, they largely seek to address cost-benefits or cost-effectiveness, to minimise waste and enhance value for money and the benefits of the PBS dollar. The targeted measures fall into two groups: those seeking to improve the source, accuracy and timeliness of information to practitioners about pharmaceuticals, and those seeking to improve the relationship between the prices paid to manufacturers for pharmaceuticals and the level and type of use those pharmaceuticals actually have. The former group of measures attempt to save costs by reducing the incidence of inappropriate prescribing. The latter recognises that leakage may still continue at some level, and seeks to reduce the waste it involves.

## **Minimising Inappropriate Prescribing**

- *Providing timely independent information to practitioners* The lack of accurate information about drug treatments (especially new and expensive ones) can result in inefficient use of medical resources (drugs) and can also compromise the treatment of patients.<sup>55</sup>

Commentators argue that independent and reliable information about the clinical effectiveness of drugs needs to be made widely available to GPs to reduce the clinically inappropriate use of PBS drugs (e.g. antibiotics). Not only this, some argue that information about the cost-effectiveness of PBS drugs should be made available also.<sup>56</sup> Even when it is clinically appropriate to treat a certain condition with a particular drug, that drug may not be a cost-effective way to treat the condition. There may be cheaper alternatives. This is particularly relevant with PBS listed drugs. If practitioners have access to this information, they would be in a better position to make cost-effective prescription decisions. In many cases, however, such information is available only through clinical trials conducted by the manufacturers (submitted as part of the PBAC listing decision process), and is treated as commercial-in-confidence. The PBAC would need to be more transparent in its listing process. It might be argued also that a drug should not be listed until the relevant information is made available to prescribers.

The National Prescribing Service has a useful mission in providing education and advice to prescribers. However, it is relatively under-resourced, given the extent of the problem it seeks to address.

- *Limiting manufacturers' influence on prescribing behaviour:* As indicated earlier, much of the information practitioners receive about newly listed drug treatments is via the promotional activities of the manufacturers. Moreover, the information is not always clinically accurate, nor clear and helpful in matters of cost-effective use. It can exacerbate increasing costs through the inculcation of inappropriate prescribing

Many commentators argue that these promotional activities should be regulated and limited. It has been reported that the global pharmaceutical industry spends up to one third of sales revenue on marketing, twice as much as it spends on research.<sup>57</sup> To some extent, marketing costs are likely to flow into the asking prices for drugs. Limiting promotions might have a two-fold impact on PBS costs—reducing the influence on inappropriate prescribing/leakage, and reducing asked for prices. One commentator suggests that tax deductibility for drug company promotional expenses should be removed.<sup>58</sup> Another option is to disallow promotional advertising on prescribing software.

- *Providing incentives for GPs to prescribe more appropriately* These may take the form of providing information for example on prescriptions, about the actual cost of medications. Also, monetary incentives may be of some use, as long as they are accompanied by appropriate education, and are sensitively introduced.

The options just mentioned may aid in reducing inappropriate prescribing. However, there are grounds to think that practitioners will continue to engage in 'leakage', to some extent. The following measures are intended to operate in that context.

## Managing 'Leakage'

- *Increased application of price-volume agreements* (so companies do not reap the benefits of leakage at the public expense). By definition, leakage involves the greater than originally estimated market uptake of a drug. Prices are agreed to between the PBS and manufacturers on the basis of estimated market uptake—a smaller estimated uptake generally arguing in favour of a higher price paid to the manufacturer. Manufacturers are doubly benefited by leakage in getting a higher price per unit than they should, and also greater volume of sales at that higher price. The more extensive employment of price-volume agreements would act as a check on unfair pricing and profiting at PBS expense. There is, however, some industry resistance to price-volume agreements.
- *Increased matching of a drug's price to the cost-effectiveness of the drug's use.* Goddard, Henry and Birkett have developed what they call a 'fair pricing policy' to address the health-value wastage associated with leakage.<sup>59</sup> Currently, prices paid to manufacturers by the PBS for listed drugs are based not only on anticipated sales, but also on the drugs' cost effectiveness as a treatment for specified conditions (its relative efficacy for the epidemiology of the conditions). If the drug is prescribed to treat more minor conditions for which there are cheaper treatments, its cost-effectiveness will be lower than the one at which the drug's price was agreed. The price the manufacturer gets on that occasion is thus not a fair one (it is too high).
- A fair pricing policy recommends that there be a multi-tiered pricing arrangement for drugs that turn out to have major uses other than the PBS specified one. A single drug with for example four major uses would have four different prices associated with it, reflecting the different levels of cost-effectiveness of those uses. Each indication would have its own item number in the Schedule of Benefits, and a doctor would specify this item number on the prescription. Or alternatively, prescribing software could require that the condition be specified for which the drug is prescribed (and the de-identified information sent to the HIC).<sup>60</sup> So, an anti-inflammatory drug used to treat rheumatoid arthritis would provide a higher price to the manufacturer than when it is used to treat more minor aches and pains. And manufacturers would get a higher price for proton-pump inhibitors when they are used for severe ulcerating oesophagitis compared to when it is used to treat less serious gastric problems, for which there are other equally good treatments.<sup>61</sup> Another possible benefit of this is that manufacturers would have less incentive to promote other clinical uses for PBS drugs, if they will end up getting less return for those uses.

## Other Targeted Measures

- *A system of periodic reviews of cost-effectiveness of listed drugs:* although not specifically associated with leakage, the fair pricing policy can be extended, to make sure that prices for drugs reflect their cost-effectiveness as an ongoing matter. Disease conditions change,

as do drug alternatives, and this can affect cost-effectiveness of existing drugs. Periodic reviews will ensure greater faithfulness over time to fair prices.

- *Encourage the prescription of generic drugs:* although prescription of generics account for about 25 per cent of all PBS expenditure, there is still opportunity to encourage their prescription instead of their more expensive brand-name alternatives.<sup>62</sup> The PBS also tends to pay manufacturers almost the same amount for a generic drug as it did when that same drug was listed under patent. This may have the effect of reducing price-competition between generics manufacturers, and therefore keeping generics prices higher than they could be. A revision of the pricing process for generics may be justified.

## Conclusion

The overview presented above does not exhaust all of the measures that might be employed in the service of PBS cost control. However, it does canvass the major candidates that have been put forth recently. The overview also does not enter fully into the question of which of those measures are more appropriate than others, nor which focus—PBS affordability as opposed to PBS cost-effectiveness—might be more sensible, all things considered. It does emerge however that the latter focus, unlike the former, has the potential to reduce the community cost of the PBS without significantly compromising that scheme's comprehensiveness and universality. That fact is perhaps a preliminary reason for giving priority to measures that can repair the cost-inefficiencies of the PBS. Whatever the measures employed, it is important that their impacts be carefully monitored and evaluated, lest they themselves simply contribute to higher expenditure without sufficient benefit.

The current discussion has also not entered into another fundamental but often overlooked issue—the cost-effectiveness of drug therapies compared to non-pharmaceutical and non-medical alternatives where they are available. (For example, with people at risk of cardiovascular conditions, the costs and benefits of adopting an ongoing exercise and diet regime compared to a regime of statin drugs). Ideally, assessing the cost-effectiveness of a drug should encompass not just other drug alternatives, but also viable non-drug and non-medical alternatives. It is really only in terms of this sort of comparison that we can gain a complete picture of the cost and value of the PBS to the community.

## Endnotes

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1. Pharmaceutical Benefits Scheme, *About the PBS*. <http://www.health.gov.au/pbs/aboutus.htm>  
Current provisions governing the operations of the Scheme are embodied in Part VII of the *National Health Act 1953* together with the *National Health (Pharmaceutical Benefits) Regulations 1960* made under the Act.  
<http://scaleplus.law.gov.au/html/pasteact/0/173/top.htm>

2. Budget 2002–03 *Health 1 Fact Sheet*. Some put the increase at 10 per cent however. See L. Brown, et al., *Funding of High Cost Biotechnology and Other Innovative Targeted Therapies under the Pharmaceutical Benefits Scheme*, NATSEM Position Paper, University of Canberra, 27 February 2002, p. 3. Though, the OECD puts this figure at 12 per cent between 1990 and 1998. See OECD Health Data 2001.
3. *Portfolio Additional Estimates Statements 2001–2002: Health and Ageing Portfolio: Explanation of Additional estimates 2001–2002*, p. 45
4. *ibid.*
5. 'Higher forecast Pharmaceutical Benefits Scheme (PBS) expenses (\$530 million in 2001–02, increasing to \$1.2 billion in 2004–05), reflecting an increasing trend towards the use of newly listed, high cost drugs such as Celebrex (used in the treatment of arthritis) and Zyban (an anti-smoking drug)', *Budget Strategy and Outlook 2001–02*, Budget Paper 1, pp. 2–8.
6. Because of the difficulty in determining just which contribute what degree to overall costs, these factors are not ranked in order of contribution to costs.
7. A. Walker, P. Percival & A. Harding, *The Impact of Demographic and Other Changes on Expenditure on Pharmaceutical Benefits in 2020 in Australia*, Discussion paper no. 31, NATSEM, University of Canberra, 1998.
8. Based mainly on the observation that overall PBS expenditure for 2001 increased by 17.4 per cent, but overall prescription volumes increased by only 5.6 per cent.
9. *Summary of PBS expenditure and prescriptions January 2001 to December 2001*, <http://www.health.gov.au/pbs/pubs/pbbexp/pbdec/index.htm>
10. P. McManus, A. Mant et al., 'Recent Trends in the Use of Anti-depressant Drugs in Australia, 190–198', *Medical Journal of Australasia*, no. 173, 2000, pp. 458–461. Currently, the volume and cost of prescriptions for one major class of anti-depressant drugs (selective serotonin reuptake inhibitors) is substantial: 8.24 million prescriptions in the eighteen months between July 2000 and December 2001, at a cost to the PBS of over \$254 million. (PBS data retrieved from the HIC website).
11. S. K. Gan and D. J. Chisholm, 'The Type 2 Diabetes Epidemic: A Hidden Menace', *Medical Journal of Australasia*, no. 175, 16 July 2001, pp. 65–66.
12. See Australian Health Care Association, Women's Hospitals Australia, and the Australian Association of Paediatric Teaching, 'Submission to Community Affairs References Committee, Inquiry into Public Hospital Funding', Community Affairs References Committee, Inquiry into Public Hospital Funding, October 1999.
13. *Family & Community Services: PBS 2001–02: Budget Papers*, p. 179.
14. P. McManus, D. J. Birkett and A. Mant, 'Prescription Use by Patients with Concession Cards', *Medical Journal of Australasia*, no. 169, 7 September 1998, pp. 285–86. As of June 2001, there were 4 957 984 (non-veteran) concession card holders (1 393 532 Health Care Card-holders, 353 562 Low-income Health Care Card-holders, 2 984 750 Pensioner Concession Card-holders, 226 140 Commonwealth Seniors Card holders). Source: Department of Family & Community Services.

15. Senate Estimates, Community Affairs Legislation Committee: Health & Ageing Portfolio, February 20 2002, p. 40.
16. *ibid.* It has also been suggested that the prescribing pattern for these expensive COX-II drugs has plateaued.
17. M. Goddard, D. Henry and D. Birkett, 'Implementing PBS Reform How to Make the PBS More Efficient Without Sacrificing Health', unpublished paper, 2002.
18. Reported in Ray Moynihan, 'Exploding the Drug Budget', *The Financial Review*, 18 March 2002. The Drug Utilisation Sub-committee of the PBAC tracks unexpected usage such as leakage. It compares the manufacturer's original estimates of a drug's projected usage rate (for the disease population it is approved for), and its actual usage rate after listing. This method, however, does not distinguish usage discrepancies that are due to over-prescription and those due to original underestimation on the part of the manufacturer. Manufacturers have an incentive to under-estimate because this allows them to argue for a higher price per unit from the PBS. (They also have an incentive to then promote heavily after listing to increase profits at the higher price).
19. Australian Medical Association, *PBS Discussion Paper*, 2002.
20. It has been reported that while sales reps told GPs that Celebrex had side-effects similar to a placebo, that drug was the subject of five or six times the adverse event reports that had ever been presented to the TGA. M. Goddard, *op. cit.*
21. Any use within Therapeutic Goods Administration guidelines for the drug can be promoted by companies. Drug company reps are a significant source of information for GPs, and a significant influence on their decisions to prescribe new drugs. That promotional information can also be misleading. See for example, Roughead, et al., 'Commercial Detailing Techniques used by Pharmaceutical representatives to Influence Prescribing', *Australia & New Zealand Journal of Medicine*, vol. 2, 1998 and M. I. Jones et al., 'Prescribing New Drugs: Qualitative Study of Influences on Consultants and General Practitioners', *British Medical Journal*, no. 323, 2001, pp. 378–381; 'Misleading Promotion', *Medical Journal of Australia*, 1997, <http://www.mja.com.au/public/issues/xmas/mansfield/manbox.html>.
22. See the selection of articles on medicalisation in the recent edition (vol. 324, 13 April 2002) of the *British Medical Journal*, particularly R Moynihan et al., 'Selling Sickness: The Pharmaceutical Industry and Disease Mongering', pp. 886–891. It has been estimated that internationally, the pharmaceutical industry spends approximately twice as much on promotion as it spends on research and development. (David Henry, in *How Do Decisions on the Listing of Pharmaceuticals Influence Health and Health Services in Australia*, Australian Health Policy Institute, University of Sydney, 2001, p. 28. One estimate places Australian pharmaceutical industry expenditure on promotion at \$1 billion per annum. (Ross Coulthart, *The Sunday programme*, Nine Network, 5 August 2001).
23. Report of National Medicines Symposium 2002 papers in Ray Moynihan, 'Australia could safely cut antibiotic use 50pc', *The Financial Review*, 23 March 2002.
24. There is evidence that GPs have a poor understanding of evidence-based decision-making. James Young et al., 'General Practitioners' Self-Rating of Skills in Evidence Based Medicine: Validation Study', *British Medical Journal*, no. 324, 20 April 2002, pp. 950–951.

25. Defensive medicine can sometimes be a response to concerns about litigation.
26. Given that the total health budget in Australia is capped as a proportion of GDP, it is likely that the opportunity costs associated with high PBS expenditure will be most immediately felt in the healthcare area, compared to other social programs. Thanks to David Henry for this observation.
27. Productivity Commission, *International Pharmaceutical Price Differences*, Research Report, 2001, Canberra.
28. OECD Health Data 2001.
29. *ibid.*
30. The estimated total Australian health expenditure on disease was \$31 billion in 1993–94. *Australia's Health 2000*, Australian Institute of Health and Welfare, 2001.
31. Unless otherwise indicated, the term 'cost-effectiveness' will here be used in the broad sense of cost-benefit or cost-utility, rather than in the more narrow sense involving comparisons between alternative drug treatments.
32. Productivity Commission, *op. cit.* The PBS purchases about 90 per cent of all prescription medicines.
33. Of course, measuring the cost effectiveness of the program as a whole would be very difficult. Most of the drug classes in the PBS schedule have been independently assessed by academics and consultants.
34. For example, the listing of selective serotonin reuptake inhibitors for depression resulted in a 25 per cent decrease in the use of tricyclic antidepressants. See P. McManus & A. Mant, *op. cit.* However, this can be offset by an 'add-on' effect, where the arrival of a newly listed drug increases total use of the whole group that the drug belongs to.
35. See Ken Harvey, 'The Pharmaceutical Benefits Scheme Under Threat', *unpublished paper*, LaTrobe University, 2002. Also, M. Goddard *op. cit.*
36. Australian Medical Association, *op. cit.*
37. Professor Bruce Barraclough, Chair, Australian Council for Quality in Health Care, speaking at an AMA forum. Thanks to Roger Kilham for this information.
38. David Wroe, 'Doctors rewarded for drug cutbacks', *The Age*, 10 April 2002.
39. Less than 2 per cent of the latest annual expenditure growth in the PBS. See Ken Harvey *op. cit.*, p. 6.
40. Department of Health and Aged Care, *Pharmaceutical Benefit Scheme: About PBS*, 2002. <http://www.health.gov.au/pbs/aboutus.htm>
41. The first two goals are often argued for on grounds of social justice, citizen equity and fairness. But they might also be given some justification in terms of their role in maximising the achievement of sought health-outcomes. All things being equal, the more medicines there are available for people to use when they need them, and the more people that can (affordably) use them when they need to, the better the level of health in society (and the fewer potential costs in other health-care areas).

42. M. Goddard, op. cit.
43. A. Walker, 'Distributional Impact of Higher Patient Contributions to Australia's Pharmaceutical Benefits Scheme', *Australian Health Review*, vol. 23, no. 4, 2000, pp.32–46.
44. *ibid.*, p. 45.
45. Two recent reports note the negative impact of increased co-payments on usage. S. Jacobzone, *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals*. Labour Market and Social Policy Occasional Papers, no. 40, OECD Section 2.1.1, 2000; Senate Standing Committee on Social Affairs, Science and Technology, *Interim Report on the State of the Health Care System in Canada*, vol. 2, January 2002, pp. 33–34.
46. As far as price-signals for consumers are concerned, demand is referred demand and price signals are of limited use in managing demand. See Australian Medical Association, op. cit.
47. For example, extensive de-listing is argued for by Peter Baume in *How Do Decisions on the Listing of Pharmaceuticals Influence Health and Health Services in Australia*, Australian Health Policy Institute, University of Sydney, 2001.
48. There are other drugs subsidised on the PBS for conditions which also appear minor—some vitamins and minerals, for instance. However, their subsidised prescription is restricted on the Schedule to significant circumstances or manifestations of the condition, e.g. serious vitamin deficiencies.
49. Health Insurance Commission, *PBS Statistical Reports*, [http://www.hic.gov.au/statistics/dyn\\_pbs/forms/pbs\\_tab1.shtml](http://www.hic.gov.au/statistics/dyn_pbs/forms/pbs_tab1.shtml)
50. See Michael Tatchell in P. Baume, op. cit.
51. PHIAC, *PHIAC Report, Quarter December 2001*, Canberra. <http://www.phiac.gov.au/statistics/phiacareports/index.htm>
52. L. Brown, op. cit.
53. M. Burstall, et al., 'Pricing and Reimbursement Regulation in Europe: An Update on the Industry Perspective', *Drug Information Journal*, no. 33, 2001, pp. 669–688. Cited in L. Brown, op. cit.
54. Reported in J. Kerin, 'Drug Levy a \$200 slug for taxpayers', *The Australian*, 6 March 2002, p. 3.
55. Ken Harvey, op. cit.
56. Most recently, M. Goddard, op. cit.; Ken Harvey, op. cit.
57. Ken Harvey, op. cit., also David Henry in P. Baume, op. cit.
58. Ken Harvey, op. cit.
59. M. Goddard, op. cit.
60. Of course, this arrangement may be time consuming.
61. Ken Harvey, op. cit., and M. Goddard, op. cit.
62. M. Goddard, op. cit.