The Pharmaceutical Benefits Scheme Under Threat

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In the lead up to the 2002 federal budget the escalating costs of the Pharmaceutical Benefits Scheme (PBS) attracted considerable attention. During the decade 1991-2001, the number of drugs prescribed under the PBS increased by 50%, the price per script rose by more than 120% and costs to the government soared from $1 billion to over $4 billion (Productivity Commission, 2001). This article summarises the 50-year history of the PBS, explains the drivers behind the recent cost escalation and comments on a number of policy options currently being proposed.

The History of the PBS

The PBS commenced over 50 years ago. At that time, there was concern that not all people could afford expensive but valuable new drugs such as penicillin. A committee of medical and pharmacy experts was set up to advise the Health Minister on the formulation of a limited list of drugs to be made available for prescription free-of-charge. Drugs on this list were to be life saving or disease-preventing and tailored to Australia’s health needs. This subsequently became the Pharmaceutical Benefits Advisory Committee (PBAC) (Sloan, 1995). The World Health Organisation subsequently adopted this Australian concept as a key mechanism of ensuring equity of access to necessary drugs.

The PBS evolved from a scheme that fully subsidised 139 drugs to one that now partially subsidises about 600. Over the years the cost of the PBS escalated and this issue became an ongoing concern. In 1948/1949 the PBS cost the government $298,074. It took 40 years for the costs to reach one billion dollars but only another 10 years for costs to pass four billion dollars. Between 1992-93 and 1999-2000, the government spending on pharmaceuticals rose from under 12% of public health expenditure to over 15% (Productivity Commission, 2001).

Ironically, at the same time as PBS costs were rising, pharmaceutical manufacturers were complaining about low returns. Successive governments introduced a number of incremental policy changes over the years to address these issues (Harvey & Murray, 1995).

Policy Measures to Restrain PBS Costs

1960 Copayments were introduced to provide a price signal and transfer some of the cost to consumers. Pensioners were initially exempt, but subsequently a lesser charge for pensioners was introduced; copayments were then progressively increased (now indexed to inflation).

1963 In response to evidence that Australia was being charged higher drug prices than the United Kingdom, a Pharmaceutical Benefits Pricing Tribunal (PBPT) was established. Subsequently, the health department acquired a reputation for stringent price negotiations.
1980s The cost of the PBS rose significantly due to increased per capita consumption of PBS drugs, population growth, increases in dispensing fees and useful new drugs such as oral contraceptives.

1990 ‘Safety-nets’ were added to preserve equity of access for people with chronic illness. After a ‘general’ (those not holding a health care card) copayment threshold was reached people were entitled to a lower ‘concessional card holder’ copayment and threshold; once the latter was reached prescriptions became free of charge for the remainder of the year.

1990 A minimum pricing policy was introduced. As is result, manufacturers were allowed increased PBS prices and only the lowest price brand (usually a generic) was made available to consumers at the cost of the copayment. If a more expensive brand was prescribed the consumer paid the difference (a brand premium). While this was good for manufacturers (and the PBS budget) it caused consumers considerable angst and ultimately led to a generic substitution policy whereby consumers could request cheaper bio-equivalent brands from pharmacists.

1993 When putting submissions concerning new listings and price determinations to the PBAC, pharmaceutical companies were now required include economic analysis. A case could now be made for adding an expensive drug to the PBS on the grounds that it can reduce global health care costs, for example the drug could be substituted for more expensive operation, reduce hospital admissions or produce fewer side-effects requiring medical intervention. However, it also became more difficult to obtain a listing for an expensive new drug with only marginal benefits over existing drugs (Birkett et al, 2001).

1998 The minimum pricing policy was extended to therapeutic group premiums for certain classes of drugs having ‘similar clinical activity’ such as the ‘statin’ group of drugs used for lowering blood cholesterol and the H2 receptor antagonists for the treatment of peptic ulcer.

Currently, the PBS purchases about 90% of all prescription medicines in Australia. This dominant or monopolistic power has produced Australian drug prices at least 160% lower than in the USA, 50% lower than in the Canada and Sweden and similar to the prices received in France, Spain and New Zealand (Productivity Commission, 2001). However, Australian prices for new innovative pharmaceuticals are much closer to those in the other countries. The largest price differences are observed for ‘me-too’ pharmaceuticals (minor chemical variations on an innovator brand that lack major benefits) and generic drugs (off-patent copies of innovator brands).

Policy Measures to Ensure Pharmaceutical Manufacturers a Fair Return

Over the years concerns about the PBS affects on the pharmaceutical industry and the development of new drugs have lead to a number of policy changes.

1. The Pharmaceutical Benefits Pricing Tribunal was transformed into an independent Authority (PBPA) and required to take into account an individual company’s Australian activity when making recommendations on price.
2. An industry assistance scheme was set up to provide additional payment to companies investing in local manufacture, Research and Development and increased exports. The current $300 million Pharmaceuticals Industry Investment Program (PIIP) commenced in July 1999, runs until June 2004 and involves nine pharmaceutical companies.

3. The Patents Act 1990 extended drug patent life from 16 to 20 years. It was amended in 1999 to provide an extension of up to five years for human use pharmaceutical patents. This measure puts Australian pharmaceutical companies on an equal footing with their competitors in the USA, Japan and Europe.

Why Increasing PBS Costs Despite Fair Drug Prices?

There are a number of reasons why PBS costs are increasing. These include:

1. An increased emphasis on diagnosing and treating chronic conditions such as mental illness, diabetes, and cardiovascular disease. Depression rose from the tenth most treated condition in general practice in 1990-01 to the fourth in 1998-9 and there was a corresponding three-fold increase in the dispensing of anti-depressant prescriptions (McManus, 2000). There has been a three-fold increase in the prevalence of diabetes in Australia in the last 20 years (Gan, 2001). A more aggressive approach to the prevention of cardiovascular disease has greatly increased the use of cholesterol-lowering drugs; these now account for about one fifth of the total PBS cost (Jackson, 2001).

2. Cost shifting between the Commonwealth and state governments, with hospitals limiting the supply of drugs to discharged patients and privatising outpatient clinics and pharmacies.

3. The eligibility for the highest level of PBS subsidy was relaxed. 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 per annum for a single retiree). In the 2001-02 budget it was estimated an extra 50,000 people would gain access to health care cards as a result. This relaxation, together with a measure to exempt superannuation from the social security means test for people aged over 55, is estimated to have caused an addition $70 million expenditure on the PBS in 2001-2002 (Senate Estimates Committee, 2002).

4. A shift towards prescribing larger volumes of newer, more expensive medication compared to older, cheaper drugs (Arnolda, 2001). This usage is not always in accordance with clinical best-practice guidelines and many of the prescriptions written for these drugs are for uses that have never been approved by the PBAC as cost-effective. If a drug is listed for subsidy on the basis of acceptable cost-effectiveness for severe disease then its cost-effectiveness in actual use will be diluted if there is widespread use or ‘leakage’ for less severe disease outside of the PBS restrictions (Birkett, et al, 2001). In this situation the price paid for the medication is higher than can be justified by the actual health benefit achieved.
There is concern that pharmaceutical promotion is contributing to PBS ‘leakage’ (Coulthart, 2001). According to the industry’s own figures, manufacturers spend up to one-third of sales revenue on marketing, twice as much as they spend on research. Marketing programs involve pervasive advertising directed to consumers and physicians, large numbers of sales representatives, physician hospitality and international trips, conference sponsorships, lavish drug launches, gifts and gimmicks (Moynihan et al, 2002).

In order to minimise ‘leakage’ the PBAC has recommended capping mechanisms such as price-volume agreements. This would see a drug’s price set according to the number of prescriptions estimated to treat a specific condition for which the drug is deemed cost-effective. If sales exceed the agreed volume then the price is reduced.

Not surprisingly, the pharmaceutical industry has opposed such arrangements. In 2000, the PBAC recommended that the arthritis drug celecoxib (Celebrex®) should initially be priced at $1.00 a day with the government negotiating a contract to halve the price once an agreed number of scripts had been issued. The PBPA was apparently unable to get the manufacturer to accept this and the government ultimately accepted the Pricing Authority’s recommendation to charge patients $1.20 a day with no cap on the numbers of scripts issued. It had been estimated that listing Celebrex on the PBS would cost about $50 million per year. However, following an extensive promotional campaign Celebrex cost the PBS $100 million in the first five months alone (Davies, 2001).

**Strategies to Improve Drug Use**

In 1992, the Commonwealth Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee recommended a quality use of medicines (QUM) policy as the final integrating arm of national medicinal drug policy. Strategies included independent information, drug audits and targeted education aimed at both consumers and health providers. PHARM argued that for successful projects to be continued they would need to come under the umbrella of an independent National Medicines Centre created for this purpose.

A subsequent government endorsed the QUM Policy (Commonwealth Department of Health and Aged Care, 2000) but created a National Prescribing Service (NPS) in addition to the existing PHARM initiative. The NPS primarily focused on educating prescribers by working with Divisions of General Practice. For an expenditure of about $5 million per annum NPS produced improvements in prescribing worth about $15 million per annum. While NPS activities are undoubtedly worthy, the savings achieved represent less than 2% of latest $650 million annual increase in the cost of the PBS.

The 2001 federal budget saw NPS funded for another four years at the same level and the allocation of $14.6 million (over four years) for ‘a consumer education strategy’. This has yet to be implemented but there is concern that this could lead to more fragmentation and duplication of effort, especially if yet another implementing body is set up. Regardless, given that independent educational activities continue to be
dwarfed by pharmaceutical industry promotion, there is doubt that the former will significantly impact on escalating PBS costs unless the latter are curtailed.

Possible PBS Policy Options

Recent PBS cost increases are unsustainable and many suggestions have been put forward as to how the increasing cost of the PBS might be reined in. A former Minister of Health, Peter Baume has argued that the number of drugs available on the PBS should be substantially reduced. The Australian Pharmaceutical Manufacturers Association proposed a flat $200 a year levy on all Australians to finance expensive new drugs (Kerin, 2002). The following policy options are divided into measures that could seriously damage the PBS and measures able to preserve the core values of the PBS. It draws heavily on the analysis by Goddard, Henry and Birkett (2001).

Cost-cutting Measures that Could Seriously Undermine the PBS.

1  Increasing patient copayments and/or safety net thresholds

Some pre-budget ‘leaks’ have suggested that copayments for pensioners and concession cardholders could increase from $3.60 to $4.75 and from $22.40 to $30.00 for general patients (Willacy, 2002). It has also been suggested that ‘safety-net’ threshold should be correspondingly increased. These are currently $686.40 for general patients and $187.20 for concession card-holders. Higher copayments and ‘safety-net’ thresholds are likely to substantially impact on equity of access, especially for people with chronic illness.

2  Higher copayments for ‘less essential’ drugs

Setting higher copayments for ‘less essential’ drugs or taking them off the PBS list is likely to have the same impact on equity of access as increasing copayments and safety net thresholds because ‘less essential’ drugs for some people can be absolutely essential for others.

3  Means Testing PBS

Reducing access to the PBS though a means test and encouraging others to take out private health insurance for pharmaceuticals is likely to result in a pre-Medicare situation. This would see people’s health suffering because they fall through the gap between the card-carrying poor and those who cannot afford private pharmaceutical insurance cover. In addition, reducing access to the PBS or the number of drugs subsidised will reduce the government’s power to negotiate good prices resulting in a fragmented US style pharmaceutical market and rising drug prices.

4  Provide Financial Incentives for Doctors to Prescribe Less Expensive Drugs

A Department of Health plan to financially reward Divisions of General Practice if their doctors prescribing ‘cheaper’ drugs runs the risk of providing doctors with a perverse incentive to prescribe cheaply rather than appropriately.
Measures Able to Preserve a Sustainable PBS.

1 Improved Transparency and Functioning of the PBAC

There is a need for more open scrutiny of the workings of the PBAC and its sub-committees and an end to the ‘commercial-in-confidence’ secrecy surrounding its decision making. This would improve public accountability, inform prescriber and consumer education programs, and allow educational campaigns to be coordinated with the listing of new drugs.

2 Multi-tiered Price-Volume Agreements

A greater use of legally binding, multi-tiered price-volume agreements would limit the promotional oxygen that currently drives PBS ‘leakage’. Differential prices need to be set for each drug based on the number of prescriptions estimated to treat the various conditions for which the drug is deemed cost-effective. Thus, a single drug with four major uses would have four different prices reflecting differing levels of cost-effectiveness, each with its own item number in the Schedule of Pharmaceutical Benefits. A doctor would specify this item number on the prescription. If sales exceeded the agreed volumes then the price would be substantially reduced.

3 Reviews of the Cost-Effectiveness of Listed Drugs

Regular reviews of the cost-effectiveness of drugs already on the PBS list are needed to consider subsequent clinical and utilisation evidence. This would lead to a drug’s price being changed if its actual patterns of use in the community were different than predicted or if post-marketing evidence showed that a drug worked better or worst in the community that it had in the original clinical trials.

4 Greater Control Over Pharmaceutical Promotion

Pharmaceutical promotion is a major driver of inappropriate drug use. It should be banned from doctors computerised prescribing packages. Pharmaceutical promotion is not allowed on government printed ‘script pads, why should it be allowed on the electronic variety? In addition, tax deductibility for drug company promotional expenses should be removed and the industries push for direct to consumer advertising must be resisted.

5 Increased Education for Prescribers and Consumers

Funding for the independent education of consumers and doctors must be substantially increased and aimed solely at providing quality care. QUM programs lose credibility if they are seen as a mere cost-cutting exercise. Much better integration, cooperation and rationalisation of various government branches and other agencies involved in QUM is required. These include the Therapeutic Goods Administration, the Pharmaceutical Benefits and Quality use of Medicines Branch, the Pharmaceutical Health and Rational Use of Medicines Committee, the National Prescribing Service and the newly proposed consumer education organisation.
Conclusion

The current debate over escalating PBS costs reflects the concerns of key players. The pharmaceutical industry argues that increased PBS expenditure represents value for money as expensive new drugs can keep people out of hospital and maintain their productivity despite health conditions. The industry is concerned that low Australian drug prices and other PBS restrictions have inhibited the development of the Australian pharmaceutical market and this in turn could slow the development and introduction of valuable new drugs. Other groups are more concerned about inappropriate and wasteful drug use and the role of pharmaceutical promotion in driving such use. Finally, although there is public commitment by all players to Australia’s national medicinal drug policy, including the role of the PBS, there is clearly tension between balancing competing objectives such as achieving equitable access to necessary drugs versus encouraging a profitable local pharmaceutical industry.

At the end of the day, value for money is more important than bottom line PBS cost. Cutting costs too far in the wrong way will produce poor value for the health system if people get sick because they do not have appropriate access to medicines and other parts of the health system end up bearing increased cost. The challenge is for government to find a policy mix that will curtail inappropriate prescribing while still preserving the core value of the PBS, that is providing all Australians with equitable and affordable access to necessary drugs.

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References


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