

SUBMISSION NO. 42

AUTHORISED: 30-05-05



MEDICINES
Australia

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

**Medicines Australia
Submission to the
House of Representatives Health and Ageing
Committee**

Inquiry into Health Funding

May 2005



Table of Contents

1. Introduction.....	4
2. Overview of PBS funding mechanisms and subsidy decision processes in Australia.....	4
3. Australia’s use of medicines.....	12
4. Future growth of the PBS.....	15
5. Potential for further changes in patient co-payments.....	19
6. Other options for funding arrangements.....	22
7. The role of new medicines in transforming healthcare.....	22
8. New medicines likely to appear on the market.....	23
9. The effect of the PBS on productivity and participation.....	26
10. Conclusion.....	32

Medicines Australia Inc
Level 1, 16 Napier Close Deakin ACT 2600
Ph: 02 6282 6888 Fx: 02 6282 6299 E: info@medicinesaustralia.com.au
Website: www.medicinesaustralia.com.au

Key Points

- Pharmaceuticals are a major medical technology influencing Australia's health system and an essential pillar of national health policy.
- The PBS is a key part of Australia's health system and a major component of health funding in Australia.
- Technological advances are giving rise to a whole new generation of medicines to cure major diseases which could be funded under the PBS.
- Currently 579 medicines are under clinical trials to cure diseases covered by Australia's National Health Priority Areas.
- The challenge is to ensure that Australia has a system in place that provides Australians with timely access to new medicines into the future while ensuring the system is sustainable from a fiscal and health policy perspective.
- Australia's system of ensuring access to pharmaceuticals is a complex mix of evaluation, subsidy, pricing and reimbursement where the price Australia pays for new, high technology medicines is low by international standards.
- Pharmaceuticals are likely to continue to grow as an area of health expenditure in Australia. However, the overall pattern of growth needs to be better understood, defined and appreciated.
- Expenditure on pharmaceuticals, particularly newer, high technology pharmaceuticals, can be demonstrated in many instances to be accompanied by substantial and real cost-offsets within other areas of the health system. These deserve greater recognition in government policy than is currently the case.
- Spending on new, innovative medicines provides broader economic and societal benefits such as enhanced quality of life, increased productivity and workforce participation. This is not always sufficiently recognised.
- The growth in health expenditure on pharmaceuticals in Australia should be viewed more favourably given Australia's relative level of spending, international trends, and the benefits that accrue to the health system and the broader community.
- Various options to reform co-payments and develop alternative funding vehicles, such as medical savings accounts and private health insurance, could be considered. This would maintain the long term financial sustainability of Australia's spending on medicines and guarantee that Australians have access to the latest medicines into the future.

MEDICINES AUSTRALIA SUBMISSION TO HOUSE OF REPRESENTATIVES INQUIRY INTO HEALTH FUNDING

1. Introduction

Medicines have played a pivotal role in improving the health of humanity. Technological improvements in medicines have led to increased life expectancy, improved quality of life, increased productivity, enhanced workforce participation and made a more efficient health system. Medicines have eliminated diseases that in times past were major threats to human health.

The challenge, now and into the future, is to ensure that Australians have access to the latest medicines available. This is likely to become particularly important with the ageing of the population. Medicines have a key role to play in improving the health of Australians in the future. Growing health expenditure as result of advances in medical technology, such as in new, innovative pharmaceuticals, may not be detrimental given the range of benefits for health and broader society from that technology. The issue may be in adequately recognising and rewarding such improvements in medical technology and ensuring that Australians will gain access to them into the future.

A number of factors will help to ensure that Australians will have access to the new medicines being developed. Ensuring the long-term sustainability of the Pharmaceutical Benefits Scheme (PBS) – both financial and health outcome sustainability – will provide certainty of future access for patients. Allocating sufficient resources to the PBS will ensure Australians can access to new medicines as they become available. A better understanding of the role of the PBS in delivering sustainable health outcomes and its benefits for the health system, the economy and society will allow more informed decisions to be made about accessing new pharmaceutical technology.

2. Overview of PBS funding mechanisms and subsidy decision processes in Australia

Federal Government funding of prescription medicine costs is administered through the Pharmaceutical Benefits Scheme (PBS), a comprehensive centralised formulary listing reimbursable products. The Pharmaceutical Benefits Branch of the Department of Health and Ageing (DoHA), along with the Pharmaceutical Benefits Advisory Committee (PBAC), administers the scheme. The PBAC is a statutory body that makes recommendations on product listings to the Minister for Health and Ageing, based on an assessment of the cost and effectiveness of a medicine. This requires submission and assessment of economic evaluations of the medicine in question.

Overall the PBS (government and patient contributions) accounts for around 90 per cent of total prescription of pharmaceutical expenditure. Government spending on prescription medicines under the PBS rose by 9.3 per cent in 2003-04 to \$5 billion. Patient contributions added a further \$938 million, thereby taking total prescription medicine costs to \$5.9 billion. The number of prescriptions dispensed under the PBS grew in

2003-04 by 4.3 per cent to 156 million. Processing and payment of PBS claims to pharmacists is the responsibility of the Health Insurance Commission (HIC).

The prescribing of new, higher-priced, products is one of the main components driving PBS expenditure.

In 2003-04, the therapeutic categories accounting for the largest share of PBS spending were:

- Cardiovascular medicines (\$1.89 billion);
- Nervous system agents (\$1.07 billion);
- Alimentary tract/metabolic products (\$870 million); and
- Musculo-skeletal products (\$435 million)¹.

The four most costly products reimbursed under the PBS in 2003-04 were:

- Atorvastatin (\$427 million). This is a medicine in the 'statin' group that lowers cholesterol and improves the balance of various lipids in the body, thereby reducing the risk of cardiovascular disease;
- Simvastatin (\$373 million), another a medicine in the 'statin' group;
- Omeprazole (\$209 million). This is a proton pump inhibitor, which suppresses the production of acid in the gastric system, thereby assisting healing of duodenal and gastric ulcers, or reducing the symptoms of gastro-oesophageal reflux; and
- Salmeterol/fluticasone (\$177 million). This is a combination therapy for asthma².

The substances generating the most prescriptions under the PBS during 2003-04 were:

- Atorvastatin (6.6 million prescriptions, costing \$427 million);
- Simvastatin (5.5 million prescriptions, costing \$373 million); and
- Paracetamol (4.1 million prescriptions, costing \$32 million)³.

Each of these medicines represents an advance in medical technology and each of these, except for the statins, are more expensive than the previous technology that they replace. Where the products are more expensive they will have justified their higher price through the process of economic evaluation. For example, the statins (represented here by simvastatin and atorvastatin) have generally replaced bile acid sequestrants in the treatment of hypercholesterolaemia. On current prices there is no difference between the two classes although the statins are more convenient to take and more tolerable which partly explains the significantly higher usage of the statins relative to the bile acid sequestrants.

The Government has introduced a range of measures in place that control PBS spending. Prominent among these are:

- Restricted and 'Authority required' listings;
- Restrictive pricing policies;
- Imposition of cost effectiveness requirements;

¹ DoHA 2004 *Expenditure and prescriptions twelve months to 30 June 2004*, Pharmaceutical Pricing Section: Canberra, p. 7.

² DoHA 2004 *Expenditure and prescriptions twelve months to 30 June 2004*, Pharmaceutical Pricing Section: Canberra, p. 21.

³ DoHA 2004 *Expenditure and prescriptions twelve months to 30 June 2004*, Pharmaceutical Pricing Section: Canberra, p. 23.

- Generic substitution;
- 'Quality use' initiatives; and
- Patient co-payments.

PBS listing

While most prescription medicines are listed on the PBS, many are not reimbursed freely, and even when reimbursed, this is usually much narrower than the indications for which medicines are approved by the Therapeutic Goods Administration. Three listing categories define the conditions attached to reimbursement of individual medicines. These are:

- **General listing:** Reimbursement applies to all prescribed indications. This typically applies to older, low-cost medicines, such as early-generation antibiotics;
- **Restricted listing:** Reimbursement is offered for indications where the product has demonstrated cost-effectiveness (see Cost Effectiveness Requirements). For example, Losec (omeprazole) is reimbursable when prescribed for reflux oesophagitis, but not for the treatment of milder gastric conditions; and
- **Authority required listing:** Reimbursement is restricted to a specific disease classification, often with associated eligibility criteria. Doctors must obtain prior approval from the HIC before completing prescriptions for medicines in this category.

An independent analysis by the Centre for Strategic Economic Studies found that almost two thirds of items listed on the PBS in 2002 had some form of restriction (Table 1).

Table 1: Restrictions on PBS items

	Number of Items	Cost in 2000-01 \$m	%
Authority required	500	1,092.4	24.5
Restricted benefit	669	1,913.0	42.9
No restriction	1,134	1,449.0	32.5
TOTAL	2,303	4,454.5	100.0

Source: Sweeney, K. 2002 *Trends in the Use and Cost of Pharmaceuticals under the PBS*, Working Paper 5, Centre for Strategic Economic Studies, Victoria University of Technology: Melbourne.

Restricting the listing of a medicine is one strategy that is increasingly being used as a means of controlling the cost of PBS reimbursement to the Government. Companies are also required to demonstrate that new products are cost effective in comparison with established medicines or therapeutic regimes.

Hospital sector

There are around 730 public hospitals in Australia, with a total bed capacity of close to 57,000. Hospital funding is provided from the Federal Government's healthcare budget

and the GST payments to the States, but responsibility for managing the public hospital infrastructure lies with State administrations.

Pressure on the public hospital sector has increased as a result of declines in private health insurance and the impact of high-technology procedures. Funding and staffing shortages are widespread in the system. This has prompted recent increases in hospital waiting lists, and has forced hospitals to focus more closely on spending. Some in the public hospital sector have suggested that the failure to address the waiting list problem is part of a broader strategy, designed to push the patient population back into the private sector.

The PBS provides limited coverage of public hospital medicine costs. Under recent reforms, some States have agreed to PBS cover of discharge prescriptions dispensed at hospital pharmacies in exchange for efforts related to continuity of care. In-patient use of pharmaceuticals is funded directly from individual hospital budgets. Patients receiving treatment in private hospitals, however, can access the scheme.

In addition to medicines listed under the PBS, a number of 'Highly Specialised Medicines' are listed under Section 100 in the PBS schedule. These medicines are for the treatment of highly specialised, usually chronic conditions, such as HIV/AIDS, rheumatoid arthritis and hepatitis C and B. They are often administered at special clinics and are subsidised by the Commonwealth Government.

Cost shifting to the primary care sector is a means for hospitals to cut pharmaceutical costs. Earlier patient discharges also reduce hospital pharmacy costs, since primary care prescription costs fall under the remit of the PBS. Other efforts by public hospitals to reduce pharmacy spending include the use of formularies, increased generic prescribing and purchase tenders.

One issue that has not received sufficient attention to date is the potential for advances in pharmaceutical technology to provide savings to other parts of the health system, such as reduced use of hospital services. This is discussed later in the submission.

Private health insurance

The proportion of the Australian population covered by private health insurance declined dramatically from the late 1980s, from almost 50 per cent to a level of about 30 per cent in the late 1990s but has risen again to around 45 per cent as a result of various government incentive programs. Employee health insurance schemes are relatively rare, and most private insurance is on an individual basis. Most people with private insurance have both hospital and ancillary cover. Pharmaceuticals coverage by private health insurance is generally limited in Australia. The scope for the private sector to play a greater role in funding medicines in Australia is discussed below.

Pricing system

Pharmaceutical price control is an established focus of the Federal Government's efforts to control PBS spending. This approach to pricing has had the effect of pushing prices down below average levels of other leading industrialised markets, over time reducing the real value of the reward paid for the development of new medicines. The current system

of price control is likely to remain a priority issue into the future, particularly with an increased focus on the cross national price differentials as a result of the impact of the Internet on cross border purchasing, greater public awareness of price differentials and growing use of economic evaluation.

Significant changes, introduced during the 1990s, have had significant impacts on medicines prices:

- Cost effectiveness comparisons have been mandatory since 1992 for new products listed on the PBS, and are being applied retrospectively to older products. This has had the effect of reducing price differentials for many new products in the initial period of introduction;
- The subsequent application of reference pricing through methods such as weighted average monthly treatment costs across groups. This creates a pricing link between the price of off-patent products and patented products so that the post-patent price reduction of a product can be extended to patent protected products, and yet remain within the bounds of TRIPs⁴; and
- The therapeutic group premiums (TGP) reference pricing policy introduced in four key therapeutic areas during 1998. This is an extension of reference pricing that allows premiums to be applied to a reference priced product.

Process of PBS listing

Having gained marketing approval for a new product from the Therapeutic Goods Administration (TGA), companies submit a request for listing on the PBS, which must be supported by cost effectiveness data. Requests are submitted to the Pharmaceutical Benefits Advisory Committee (PBAC), which then makes a recommendation on listing to the Minister of Health and Ageing, subject to agreement on the price of the new product.

The PBAC is required by legislation to consider both the effectiveness and cost of therapy in making its recommendations. Since 1992, recommendations by the PBAC to list an item on the PBS are based on an assessment of whether the medicine is an effective complement to existing items on the PBS and is cost effective.⁵

For the past two years PBAC recommendations have been made public on the PBAC website. Only limited details of recommendations are posted on the site. Arising out of the United States-Australia free trade agreement, there will be greater levels of transparency over PBS procedures and information about the recommendations it makes.

According to Professor Lloyd Sansom, Chair of the PBAC, while 'comparative cost effectiveness forms the basis of [a] decision', other factors are taken into consideration including:

- The severity of the condition being treated;
- The ability to target therapy to those likely to benefit most;
- The presence of effective alternatives; and
- The financial implications for the PBS.⁶

⁴ Agreement on Trade-related Aspects of Intellectual Property Rights.

⁵ Stephen J Duckett, 2004, "Drug Policy Down Under, Australia's PBS", *Health Care Financing Review*, Vol 25, No.3, p 59.

⁶ Lloyd Sansom, 2004, "The subsidy of pharmaceuticals in Australia: processes and challenges", *Australian Healthcare Review*, vol 28, No.2, p198.

Negotiations on new product prices are conducted between manufacturers and the Pharmaceutical Benefits Pricing Authority (PBPA). The PBPA guidelines recommend that nine factors be considered in recommending new prices and reviewing existing prices. The first, and most dominant, is the advice provided by the PBAC on clinical and cost effectiveness. Other factors include:

- Prices of alternative brands;
- Comparative prices of medicines in the same therapeutic group;
- Cost data information;
- Prescription volume, economies of scale, expiry dating, storage requirements etc;
- Level of activity being undertaken by the company in Australia including R&D activities; and
- Overseas prices⁷.

The PBPA notes that ‘new medicines are most commonly recommended by the PBAC on the basis of cost-minimisation or acceptable incremental cost effectiveness ratios’.

The PBPA uses several mechanisms “to contain the price of products listed on the PBS”⁸ including:

- The therapeutic group premium (TGP) policy; and
- Price volume arrangements.

New products expected to incur significant PBS costs (more than \$10 million in any of the first 5 years of listing), having been recommended by the PBAC and the price having been negotiated by the PBPA, are also subject to approval by Federal Cabinet. The Department of Finance and Administration may also at times impose additional demands for price-volume agreements where concern exists over ‘leakage’ (where the PBS subsidy is paid for an indication which is prescribed by a medical practitioner and is outside the PBS indication).

Delays can also sometimes occur in listing a new products during price negotiations with the PBPA. The recently completed ‘Post PBAC Review’ produced a series of recommendations to improve on the timeliness and processes required to list a product on the PBS after the PBAC makes a recommendation. While these measures were introduced to help manage healthcare expenditure, they can delay or unduly limit Australians access to new pharmaceutical technologies.

Cost effectiveness data

Proof of the ‘cost effectiveness’ of a new medicine is a key requirement of PBS listing. New products must be shown to be cost effective in relation to both products already listed and alternative treatment regimes. Stringent cost effectiveness requirements have been compulsory for new products since 1992, and are being applied retrospectively by the PBAC to older products wherever possible. By 1998, cost effectiveness reviews had been applied to 31 per cent of all products listed on the PBS.

⁷ Pharmaceutical Benefits Pricing Authority, *Procedures and Methods*, November 2003, viewed 25/11/04.

⁸ Sansom, p200.

One of the industry's concerns about cost effectiveness reviews is the choice of 'comparator' products against which new medicines are gauged. A comparator is the alternative therapy used as a basis for comparison when a new medicine is being considered for listing on the PBS. While a new product may offer significant advances over existing therapies, its cost effectiveness is very often judged in comparison with an established, often generic product, which is listed at a lower price. As a result, companies often find it difficult to demonstrate the value of new medicines and technologies in the context of Australian healthcare expenditure.

Guidelines on the presentation and assessment of cost effectiveness data have been updated periodically since 1992. A further review of the guidelines is currently under way which could be completed in 2005. The industry is seeking more flexibility in the guidelines, particularly with respect to the selection of the comparator product, and the methodology including the treatment of indirect costs and use of monthly treatment costs. A range of other issues covered in this submission, such as recognition of broader social and economic benefits of new medicines, the potential for less invasive treatments that provide savings in other parts of the health system could be considered in the guidelines review.

Brand premiums and therapeutic group premiums

Where a generic product exists in a therapeutic class, the subsidy level will be set at the lowest generic price. Manufacturers of off-patent products are permitted to apply a brand price premium to their off-patent products that face competition from generic medicines listed on the PBS. Patients who wish to use the original branded product, rather than bioequivalent generics, pay price premiums. While innovator companies are free to determine price premium levels, most apply relatively modest increases in the knowledge that patients will otherwise switch to cheaper generic equivalents.

In 1997, the Federal Government announced its intention to introduce another price control policy, the Therapeutic Group Premium (TGP) pricing system. Originally slated for application to six therapeutic groups, it was intended to generate PBS savings of \$560 million over a four-year period. The Government committed \$4 million to a public education campaign undertaken by pharmacists following the introduction of this system.

Two of the six product groups (Beta-blockers and Selective Serotonin Reuptake Inhibitors - SSRIs) were omitted from the TGP system when it was introduced in February 1998. The groups subject to the TGP policy were:

- Statins;
- Calcium channel blockers;
- Ace inhibitors; and
- H2 receptor antagonists.

TGPs are essentially a form of reference pricing. Reimbursement under the PBS is reduced to the level of the lowest-priced product (usually a generic) in each of the affected therapeutic groups. Manufacturers of other products in the group are free to apply a 'therapeutic group premium' to the price of their product, but patients must pay the difference between the PBS reimbursement ceiling and the 'premium' price. Technically, a mechanism exists under which doctors can obtain authority for individual

patients to remain on a particular therapy without losing reimbursement status. The process, however, is complicated and is not widely deployed.

The PBPA calculates reference-price 'benchmarks' in TGP groups by comparing the monthly treatment costs of medicines in a particular therapeutic group. The imposition of reimbursement ceilings at these price benchmarks has had a significant effect on prices in the four therapeutic areas to which it has been applied. Prices of more than half of all branded products affected by the system have been reduced to the reimbursement 'benchmark'. About a quarter of the remaining products now carry a therapeutic premium ranging from 70 cents to \$4.50, but companies are loath to levy significant premiums since, by doing so, they risk dramatic reductions in market share.

Co-payments

One major factor that affects future healthcare expenditure, through both additional funding as well as influencing the demand for medicines is patient co-payments. Co-payments for medicines are well established in Australia. Co-payment levels are linked to movements in the consumer price index, but have also been increased at regular intervals by the Government during the past decade. Co-payments towards the cost of prescription medicines on the PBS take the form of prescription fees and on 1 January 2005 were levied at:

- \$28.60 per prescription for the general public; and
- \$4.60 per prescription for concession card holders (pensioners, the unemployed and other welfare recipients).

The maximum payment or 'safety net' threshold for the general public is \$874.90 per annum and \$239.20, or 52 scripts, a year for concession card holders. Concession cardholders account for around 80 per cent of all PBS prescriptions. PBS co-payments increased on 1 January 2005 with general patients' co-payments increasing from \$23.70 to the current \$28.60, and concession cardholders' co-payments increasing from \$3.80 to \$4.60.

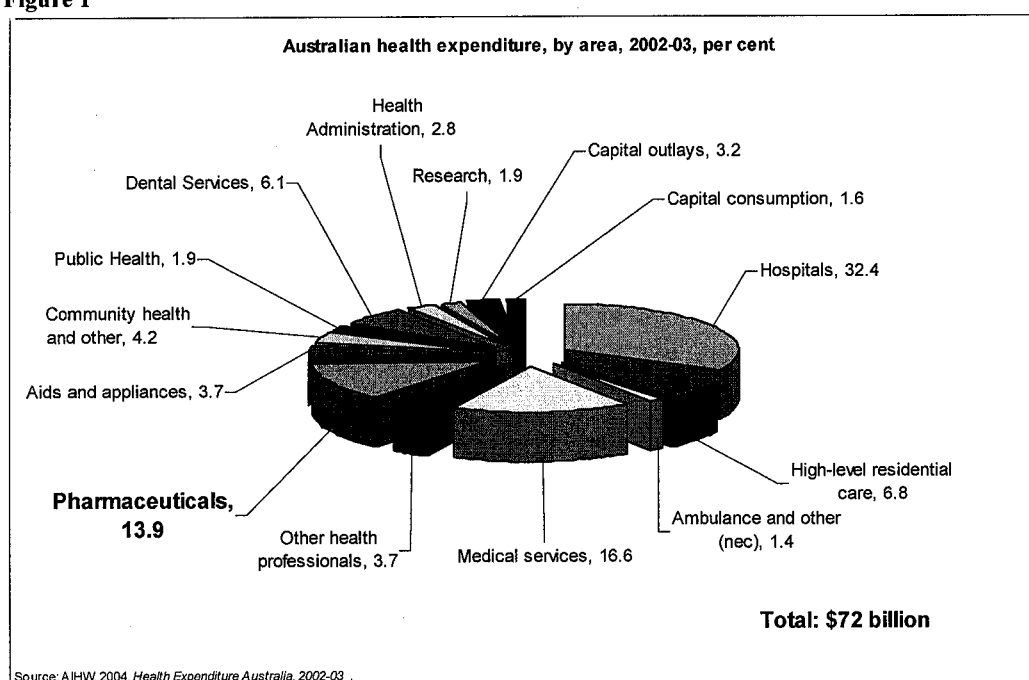
It should also be remembered that patients who wish to take an original branded product rather than a cheaper, bioequivalent generic must pay the relevant price premium, or the therapeutic group premium (TGP) for products affected by this system in addition to the co-payment.

Medicines Australia supports the co-payment increases and the development of a responsible co-payment system, provided that the health and wellbeing of those that can least afford the increases is not compromised. Co-payments help to ensure the future financial sustainability of the PBS. Discussion of the potential for further reform of co-payments is discussed later in this submission in the context of future PBS sustainability and the range of new high technology medicines being developed now.

3. Australia's use of medicines

Australia currently spends \$72 billion on health, or 9.5 per cent of GDP⁹. Of this \$72 billion, the single largest component is hospitals which account for 32.4 per cent (Figure 1). This includes public, private and psychiatric hospitals. The next largest category of spending is medical services (16.6 per cent), representing doctors and specialists. Pharmaceuticals is third largest at 13.9 per cent, the bulk of which is accounted for by the PBS and is less than half of what Australia spends on hospitals. Other categories of Australian health expenditure include high-level residential care – including aged care facilities (6.8 per cent), dental services (6.1 per cent), community health (4.2 per cent) and aids and appliances (3.7 per cent).

Figure 1



Some concerns have been raised about the rate of growth in pharmaceuticals spending in Australia. Over the period 1991 – 2001, Australia has had a relatively high rate of growth in per capita spending on total pharmaceuticals (government and private) (Table 2). In fact, after adjusting for inflation, the growth in Australia's per capita spending on pharmaceuticals doubled. In the ten years to 2001, Australia's per capita expenditure on medicines grew by an average eight per cent each year in real terms, compared with 4.3 per cent in the previous ten years.

⁹ AIHW 2004 *Health Expenditure Australia 2002-03*: Canberra.

Table 2: Growth in OECD countries' per capita spending on pharmaceuticals¹⁰, national currencies, 1995 GDP prices.

	Average annual growth rate (%)	
	1981-1991	1991-2001
Australia	4.3	8.0
Belgium	3.0	-
Canada	6.8	5.3
Czech Republic	-	7.0
Denmark	3.9	3.3
Finland	4.6	4.5
France	-	4.3
Greece	0.3	4.4
Hungary	-	3.3
Iceland	1.9	4.4
Ireland	3.0	6.1
Italy	-	2.3
Japan	-	1.7
Korea	-	6.8
Luxembourg	5.1	1.1
Netherlands	4.6	3.6
New Zealand	5.5	-
Norway	2.2	-
Portugal	8.0	-
Sweden	3.4	7.2
Switzerland	-	3.5
United Kingdom	4.2	-
United States	5.7	6.2

Source: OECD Health Data 2004.

However, the high rate of growth in the decade to 2001 should be put into perspective. Over the previous ten years (1981 – 1991) there were at least seven OECD countries that had higher annual growth rates than Australia. Three countries, Greece, Ireland and Sweden, also saw their average growth rate at least double in the period 1991 – 2001, compared to 1981 – 1991, much like Australia. Finally, all OECD countries for which there are data available have seen their spending on pharmaceuticals grow. Thus Australia is not unusual in having growth in pharmaceuticals spending, per se.

Compared to other OECD countries, Australia devotes a smaller share of its health spending to medicines. If the substitution of more labour-intensive medical treatments, such as hospital visits, for more cost-effective capital-intensive treatments like newer medicines represents a shift to greater efficiency, then Australia has some way to go to matching the performance of other industrialised countries. Australia's spending on pharmaceuticals is relatively low compared to other OECD countries (Figure 2, Figure 3).

¹⁰ Total expenditure on pharmaceuticals and other medical non-durables comprises pharmaceuticals such as medicinal preparations, branded and generic medicines, drugs, patent medicines, serums and vaccines, vitamins and minerals and oral contraceptives. This classification is used throughout this section using OECD data and includes non-durables. Pharmaceuticals represent around 80 per cent of this expenditure, with non-durables accounting for 20 per cent.

Figure 2

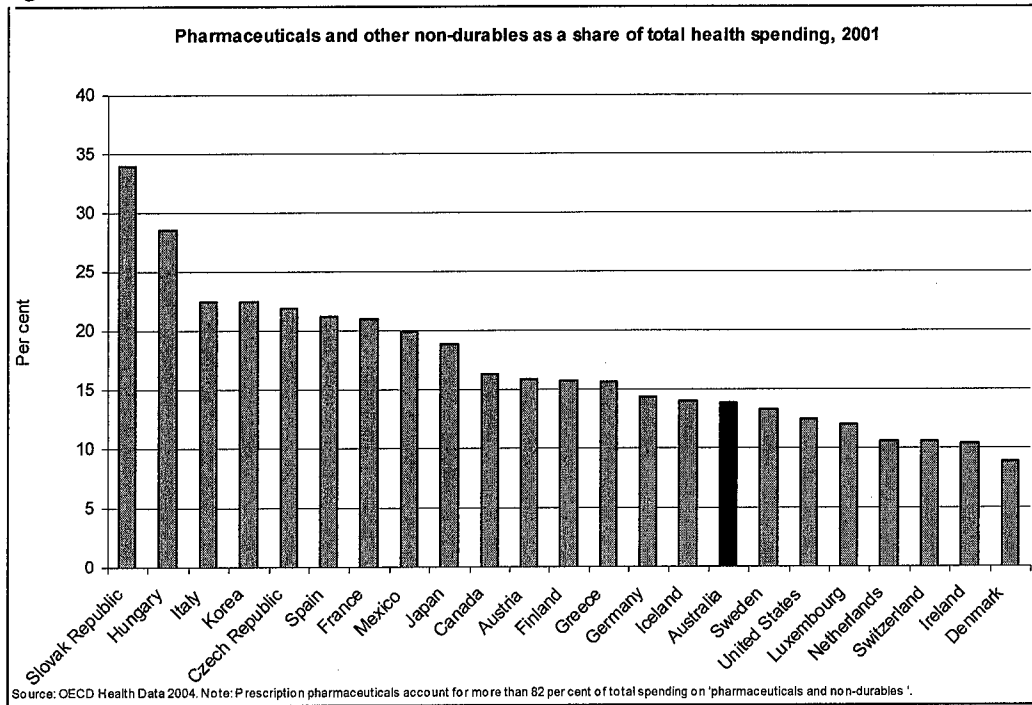
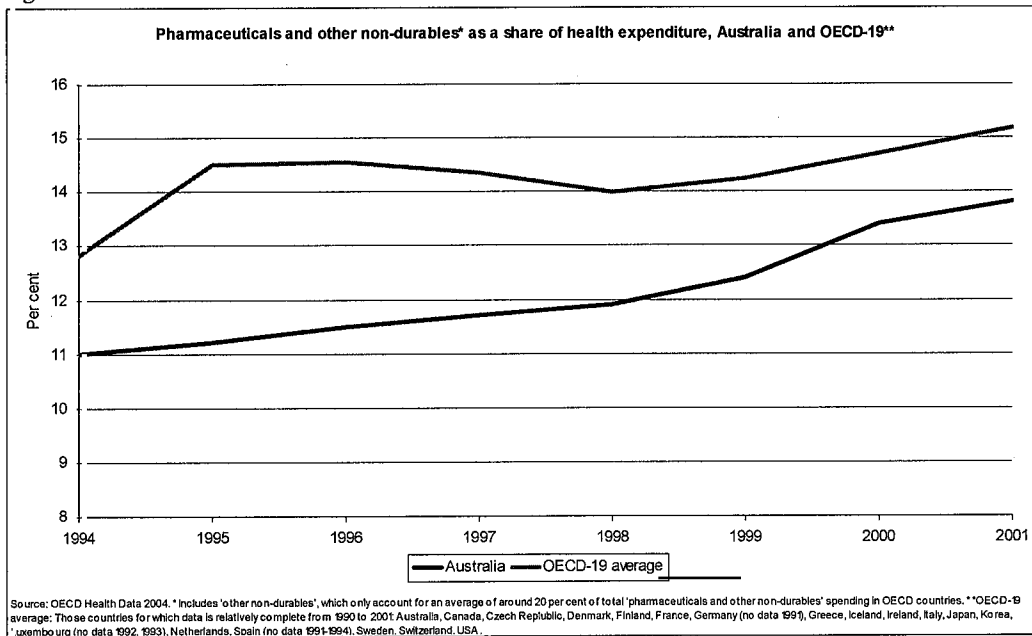


Figure 3



Interestingly, the role of medicines in countries' health spending varies. At one extreme, only 8.8 per cent of health expenditure in Denmark is spent on medicines in 2001¹¹. On the other hand, the Slovak Republic spends more than one-third of its health budget on medicines. By comparison, Australia spent 13.8 per cent of its health expenditure on medicines in 2001. While this is more than several industrialised countries, including the US, it is well below a range of countries that spend in excess of 15 to 20 per cent of their health budget on pharmaceuticals.

While some might view the growth in spending on medicines as a concern, the fact is that Australia spends relatively less on medicines than many other OECD countries. Moreover, if indeed the switch to using medicines instead of hospitals delivers overall savings in health care expenditure, as some of the literature on health outcomes suggests, Australia's current level of spending on medicines could perhaps be a concern.

Added to this is the fact that in Australia, pharmaceuticals are rigorously evaluated for cost effectiveness before being listed on the PBS. By and large, prescription medicines available have demonstrated cost-effectiveness through the PBS listing process, administered by the PBAC. The same cannot be said for most other treatments in Australia's health system, although applications for subsidy under the Medical Benefits Scheme (MBS) now require an economic evaluation.

The key point is that just because the cost of medicines, and the PBS, is increasing, albeit at a faster rate than other components of the health system¹², this should not necessarily be a cause for concern. More spending on medicines in Australia has the potential to provide net savings in other more labour-intensive parts of the health system, particularly hospitals. If more costly treatments are being replaced by newer, more effective innovative medicines, the overall impact on the health budget is actually a good thing. *"High-price new medicines may be the cheapest weapon we have in our struggle against rising overall medical expenses"*¹³.

4. Future growth in the PBS

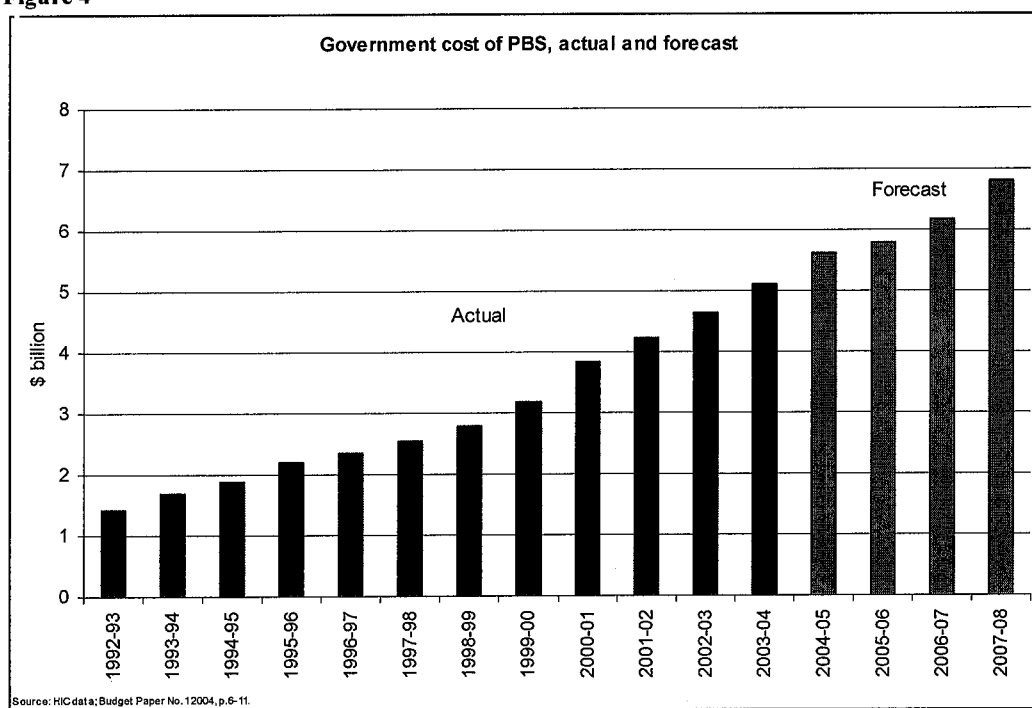
Expenditure on the PBS is likely to grow over the next five years. This is due to a range of factors including an ageing population, the identification of new treatments, latest technology medicines developed to treat a range of health conditions and the demand from consumers for access to the latest treatments. Estimates of future PBS spending vary.

¹¹ OECD Health Data 2004.

¹² PC 2004 *Economic Implications of an Ageing Australia: Draft Research Report*, November: Canberra, p. 6.6.

¹³ Kleinke, J. 2001 "The Price of Progress: Prescription Drugs in the Health Care Market", *Health Affairs*, 20(5), Sept-Oct

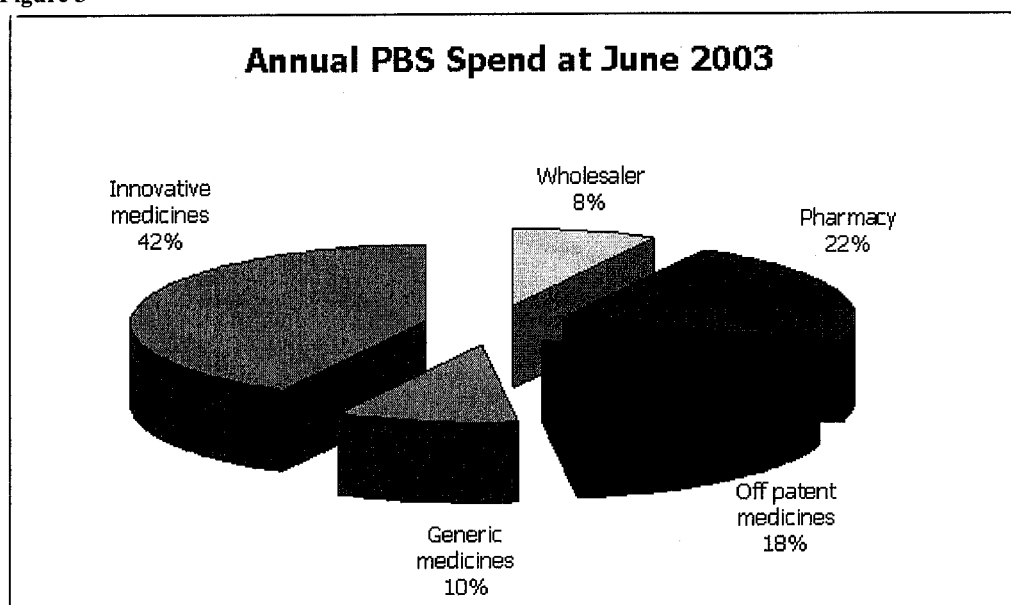
Figure 4



The 2004-05 Federal Budget papers suggest growth in the PBS will continue until 2007-08 (Figure 4). Since 1992-93, growth in Government spending on the PBS has averaged 12.5 per cent per annum, not adjusted for inflation. From 2004-05 until 2007-08, the Government's forward estimates forecast a growth rate for the PBS of 7.5 per cent per annum. In particular, in 2005-06, Government spending on the PBS is forecast to grow at 3.4 per cent, probably in part due to an expected fall in usage related to the introduction of higher co-payments from 1 January 2005.

The PBS funds a range of activities devoted to delivering medicines to the end-user: the patient. It is not always recognised that the cost of the PBS is not only the cost of the medicines themselves, but the services provided by wholesalers and pharmacists in delivering the medicines manufactured by pharmaceutical companies to patients. Around 70 per cent, or less than three quarters of the PBS is actually spent on medicines themselves (Figure 5). Innovative medicines account for 42 per cent of PBS spending, off-patent medicines 18 per cent and generic medicines 10 per cent. This means that patented medicines account for less than half of the cost of the PBS. The remaining 30 per cent of the PBS is spent on distribution through wholesalers' margins, pharmacists' fees and other marketing costs.

Figure 5



Source: Medicines Australia.

While the price of medicines themselves are obviously one driver of the growth in PBS spending, so too are these other components of the PBS. For example, the payments made to pharmacists out of the PBS are indexed to the CPI, protecting the real value of these against inflation. This is in contrast to the price of prescription medicines on the PBS which have failed to keep pace with inflation due to the system of reference pricing and cost effectiveness evaluation.

The result is that aggregate prices for PBS medicines have shown little increase and have fallen since the mid-1990s. *"The tendency for price falls to be concentrated in the new medicines is a particularly notable feature of the Australian system"*¹⁴.

In terms of future influences in PBS growth, a number of components are likely to contribute to the growth in the PBS. Medicines themselves will be a contributor to the PBS, although the prices of these are not keeping pace with inflation, while other components in the supply chain that deliver the medicines to the consumer will also be a contributor, particularly as they are indexed to grow with inflation.

Much of the previous policy reform of the PBS has focused on the beginning of the distribution chain. There may be scope for reducing transaction costs and achieving efficiency gains through a review of the operation of the whole value chain.

While concerns are sometimes raised about the growth in the PBS, international comparisons reveal that Australia's level of spending on pharmaceuticals is not unusually high. In 2001, Australia spent 1.3 per cent of GDP on pharmaceuticals, around the mid-

¹⁴ Sweeney, K. 2004, *Review of Findings: Australian Pharmaceutical Pricing in a Global Context*, Working Paper No. 19, Pharmaceutical Industry Project, Centre for Strategic Economic Studies, Victoria University of Technology: Melbourne, p. 2.

to lower-range of spending compared to other OECD countries (Table 3). Moreover, its level of overall spending on health (9.1 per cent) is higher than many other OECD countries.

The result is that the ratio of Australia's pharmaceutical spending to its total health spending is not especially high and, if anything, is towards the lower end of the scale.

This suggests that Australia has elected to spend less of its resources on innovative medicines and more on other health treatments compared to many other OECD countries.

Table 3: OECD Countries' spending on pharmaceuticals & health as a share of GDP 2001

Country	Spending as a share of GDP (%) on ...		Ratio pharmaceuticals to health spending
	Pharmaceuticals	Health	
Slovak Republic	1.9	5.6	0.34
Hungary	2.1	7.4	0.28
Italy	1.9	8.3	0.23
Korea	1.3	5.9	0.22
Czech Republic	1.6	7.3	0.22
Spain	1.6	7.5	0.21
France	2.0	9.4	0.21
Mexico	1.2	6.0	0.20
Japan	1.5	7.8	0.19
Canada	1.5	9.4	0.16
Greece	1.5	9.4	0.16
Austria	1.2	7.6	0.16
Finland	1.1	7.0	0.16
Australia	1.3	9.1	0.14
Iceland	1.3	9.2	0.14
Germany	1.5	10.8	0.14
Sweden	1.2	8.8	0.14
United States	1.7	13.9	0.12
Luxembourg	0.7	5.9	0.12
Switzerland	1.2	10.9	0.11
Netherlands	0.9	8.5	0.11
Ireland	0.7	6.9	0.10
Denmark	0.8	8.6	0.09

Source: OECD Health Data 2004.

Projected lower growth rates in PBS spending through the second half of the 2000s do not take into account patent expiries set to happen in the next few years. With patent expiry, several major therapeutic areas in the PBS, such as statins for cholesterol lowering and selective serotonin reuptake inhibitor inhibitors for mental illness, will see the entry of generic versions of patented medicines, with likely consequent price reductions. The Government's forward estimates for the PBS do not take this impact into account. In evidence to Parliamentary Senate Estimates hearings, DoHA officials made clear that the estimates do not account for medicines going off patent¹⁵. Nor do the

¹⁵ Senate Community Affairs Legislation Committee 2004 *Hansard: Budget Estimates*, 2 June, <http://www.aph.gov.au/hansard>, p. 110.

forward estimates take account of new molecules coming on stream in individual therapeutic areas. The PBS is an important area of public expenditure and should continue to grow with Australia's development and community expectations about access to the latest innovative medicines. However, it could be that the actual spending levels could be quite different from the Government's forecasts.

5. Potential for further changes in patient co-payments

With all of these changes taking place, the sustainability of the PBS is a key issue for the future. There is a range of options available to Government to reform PBS funding arrangements through changes to the co-payments that patients pay for PBS medicines. More immediately, the co-payment increase on 1 January 2005 provides lessons on how co-payment increases might be handled in the future to enhance sustainability while ensuring the best health outcomes.

2005 co-payment increases

PBS co-payments increased by 21 per cent on 1 January 2005. General patients' co-payments increased from \$23.70 to \$28.60; concession card holders' co-payments increased from \$3.80 to \$4.60. Medicines Australia supports the co-payment increases and the development of a responsible co-payment system, provided that the health and wellbeing of those that can least afford the increases is not compromised.

Nevertheless, Medicines Australia believes that there is a risk that patients, facing a significant increase in co-payments, will choose not to have their prescription(s) filled, at least in the short-term. The size of the increase scheduled for 1 January 2005 could have a disproportionate impact on concession card holders, in particular the poor and elderly, who may respond by not dispensing or delaying prescriptions recommended by their doctor. This could have potentially serious implications for their own health and for the broader effectiveness of the health system, with added stress on the health system. For these reasons, Medicines Australia suggested to the Government in its most recent budget submission that the proposed 2005 increase could be phased in over a period of time, say one year.

In the future, the Government could consider phasing in co-payment increases to ensure that the increase does not unduly impact on patient health and the efficiency of the health system.

Longer term co-payment options

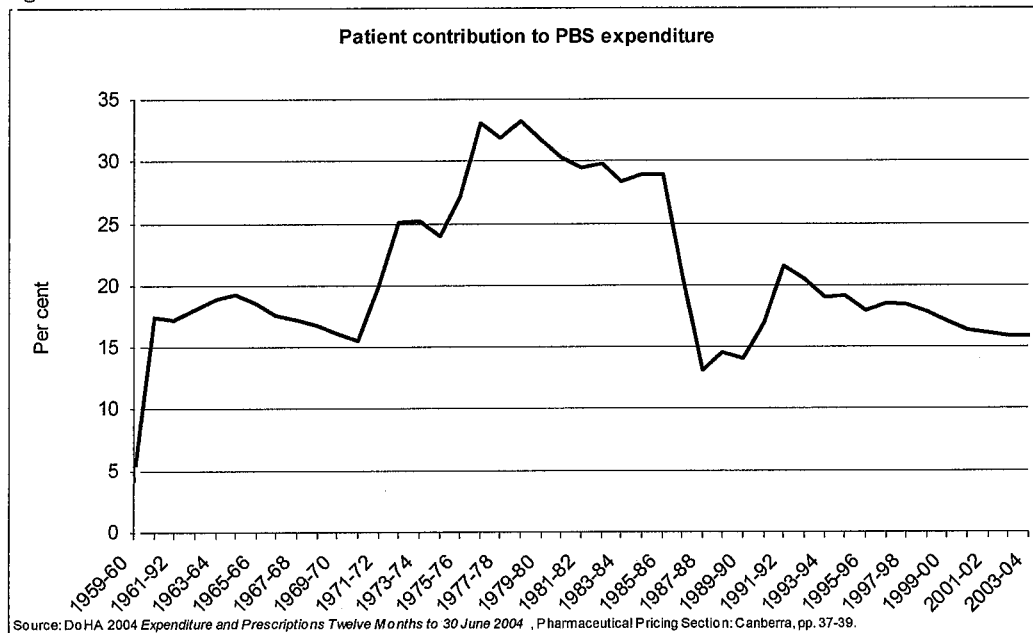
In the longer term, the Government could consider a range of options with respect to PBS co-payments to ensure a sustainable PBS. Both the flat rate co-payments and fixed Safety Net thresholds are inconsistent with horizontal and vertical equity principles. In other words, high income earners (such as a 'millionaire') are subject to the same co-payment and Safety Net threshold as a person earning less than \$30,000 a year with dependent children.

This impact will become starker following the extension of concession cards to self-funded retirees with an annual income of up to \$50,000. As a result, a family with one

breadwinner on an annual income of, say \$30,000, will pay more for medicines than a self-funded retiree on the same or much higher superannuation and investment incomes.

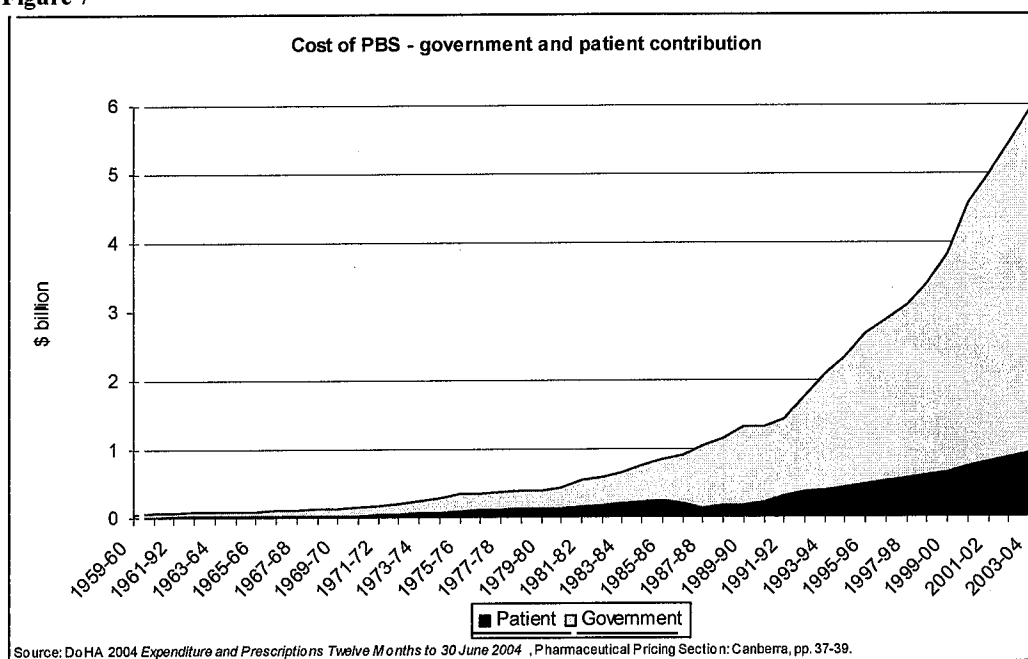
Co-payments are adjusted for movements in CPI. However, the slower growth in co-payments, compared to average medicine costs, and increased demand as reflected in the growth in volumes, has placed a greater cost burden on the Government. Patients' contribution to the PBS has declined from around 30 per cent in the 1970s to just 15.8 per cent in 2003-04 (Figure 6). Thus in times past the contribution by patients to the PBS has been double what it is today.

Figure 6



The falling patient contribution is further illustrated when compared with what the Government contributes to the PBS. In nominal terms, while the patient contribution to the PBS has slowly increased to \$938 million over the last four decades, the Government's contribution has grown to \$5.0 billion (Figure 7). Most of the growth in the PBS over this time has been met by the Government.

Figure 7



In light of the above, there are merits in reviewing the co-payment and safety net policies to address the following issues:

- To differentiate between lifesaving medicines and less essential medicines so that the PBS would give greater support to 'essential' medicines;
- To re-balance the distributional impact between different income groups;
- To ensure that those who can afford to pay assume greater individual responsibility; and
- To provide greater market signals in consumer choice.

Australia is one of few countries to require a flat co-payment. Other countries including France, Belgium, Italy and Denmark, have utilised a variety of co-payment systems for their medicine reimbursement systems.

There are at least several co-payments options available for consideration. One option could involve patients paying different levels of co-payments based on priority. Alternatively, co-payments could be means-tested, where they increase with income, such that low income earners pay a lower co-payment than those on high incomes. Another option could be to have a proportional co-payment where the patient pays a fixed percentage of a medicine's cost, say 10 per cent. This policy would adopt a standard patient contribution to the cost of medicines available on the PBS. However, there should also be a floor (a minimum co-payment level) and a ceiling (a maximum payment level) to ensure no undue hardship or a further reduction in patient contribution to the PBS budget. The design of the new co-payment and Safety Net system and the rates of co-payments would need to be targeted carefully to minimise significant impacts on disadvantaged groups.

In the context of the challenges facing the health system, Medicines Australia argues that the Government should develop a comprehensive White Paper on the National Medicines Policy and in particular the future ability of the PBS to deliver affordable medicines when Australians need them. It should examine PBS policy options to ensure the delivery of the desired health outcomes through equitable, timely access of medicines, with an assessment on the impact of these options on other parts of the health system, community expectations and intergenerational equity considerations.

6. Other options for funding arrangements

There are other funding options available to ensure that the community has access to the latest innovative medicines. Future sustainability may be served if the community takes greater direct responsibility for funding access to medicines. There may be a need to investigate alternative private sector funding arrangements for access to medicines. Two particular options in this area are medical savings accounts (MSAs) and greater pharmaceutical coverage by private health insurers.

MSAs operate in a similar way to superannuation, whereby people invest some of their savings to fund their future health and pharmaceutical costs as they get older. They could be attached to people's superannuation accounts. Singapore is a notable example where MSAs held by individuals are used to fund a portion of that country's health spending.

An alternative is to have private health insurance play a greater role in covering the cost of people's prescription medicines. While some health insurers now cover prescription medicines, the overall coverage of medicines in Australia is low, and health insurers are prevented from offering co-payment coverage. Some countries have a greater proportion of their pharmaceutical costs borne by private health insurance. For example, in Canada, private health insurance plans account for around 34 per cent of prescription medicine costs¹⁶. Private health insurance could potentially play a larger role in Australia in encouraging private funding of prescription medicines in the future, including the funding of individual expenditure in co-payments.

7. The role of new medicines in transforming healthcare

Throughout history, the development of new medicines has transformed health care, saved lives and improved peoples' quality of life. Life expectancy across the world has increased dramatically over the last half a century and this has been due, in no small part, to technological developments leading to the development of new medicines. For example, diseases such as small pox, polio, tuberculosis and measles that once killed many and cost society millions to treat are now eradicated or being controlled by new vaccines developed by the pharmaceutical industry.

¹⁶ Commission for the Future of Health Care in Canada 2002 *Building on Values: the Future of Health Care in Canada*, (Commissioner: Roy J. Romanow QC), November, http://www.hc-sc.gc.ca/english/pdf/care/romanow_e.pdf (accessed 24 November 2004), p. 195.

Twenty years ago the life expectancy for a patient with HIV/AIDS was not long and quality of life was severely hampered. Through various anti-viral treatments developed by the pharmaceutical industry, today a person diagnosed with HIV/AIDS can expect a much longer life expectancy and higher quality of life than if that person had been diagnosed 20 years ago. Currently there are 82 AIDS medicines available, with an additional 79 currently undergoing clinical trials¹⁷.

Examples such as this highlight the major contribution that medicines make to life. As discussed elsewhere in this submission, medicines make a major contribution to health, economic and social outcomes, as well as offset costs in other parts of the health system.

8. New medicines likely to appear on the market

A range of new medicines are currently undergoing clinical trials, meaning that at least some of these are likely to come on to the market over the next five to ten years. Generally, only one in five medicines that begin clinical trials make it to market¹⁸, although some research suggests that the success rate in more recent years could be as low as one in nine¹⁹.

An appreciation of the scope of developments likely over the next five to 10 years can be obtained by an analysis of the website developed by the Pharmaceutical Research and Manufacturers of America (PhRMA), www.innovation.org. This website has details on the individual medicines currently being developed for particular health conditions.

Although the site is based in the United States, it does include products where the development is based in other countries and the information still provides a useful insight into the range of medicinal treatments currently in the pipeline. In this data there may be some small double counting as the same medicine may be being developed for more than one condition. However, the information still provides an indication of where much of the activity in future medicine development is occurring.

New medicines relevant to the Australian Government's National Health Priority Areas (NHPAs) have been summarised below. Although hundreds of conditions are listed in detail on the www.innovation.org website, only those relevant to the NHPAs are examined here. All of the potential new treatments are in clinical trials in humans at the time of writing. This means that by and large all of the earlier stages of research have been completed. The overall results of this analysis are presented in Table 4.

¹⁷ PhRMA 2004 "Researchers are Testing 79 Medicines and Vaccines for HIV and Opportunistic Infections" *Medicines in Development for HIV/AIDS 2004*, <http://www.phrma.org/newmedicines/resources/2004-11-30.146.pdf> (accessed 2/12/04), p. 1.

¹⁸ PhRMA 2004 *Why Do Medicines Cost So Much and Other Questions About Your Medicines*, <http://www.phrma.org/publications/publications/brochure/questions/questions.pdf> (accessed 2/12/04), p. 2.

¹⁹ Gilbert, J., Henske, P. & Singh, A. 2003 "Rebuilding Big Pharma's Business Model" *In Vivo: the Business and Medicine Report*, 21(10), November, p. 4.

Table 4: New medicines currently in development, by Australia's National Health Priority Area, by stage of development, November 2004.

Condition	Phase			Apply*	Other	Total
	I	II	III			
Asthma	8	20	4	5	1	38
Cancer	56	122	62	4	1	245
Cardiovascular	18	35	20	0	2	75
Mental health	9	16	12	6	3	46
Diabetes	18	20	9	6	3	56
Injury prevention	1		3			4
Arthritis	24	27	17	9	4	81
Dementia	13	6	9	6	0	34
<i>Total</i>	<i>147</i>	<i>246</i>	<i>136</i>	<i>36</i>	<i>14</i>	<i>579</i>

Source: Derived from www.innovation.org (PhRMA website). Accessed 24/11/2004. * FDA application.

Cancer clearly has the highest priority in terms of new medicine development. Table 4 shows that of an estimated 579 new therapies being developed for different health conditions, 245 are for one form or other of cancer. Around half of these, 122, are currently at Phase 2 stage of clinical trials, while 56 and 62 treatments are in Phases I and III respectively. Arthritis is the next highest with 81 new treatments currently in the pipeline, closely followed by cardiovascular health with 75 new medicines in the pipeline.

Based on the number of molecules in Phase I, an estimate of the likely number of new medicines making it on to the market can be calculated, using the figure that one in five, or 20 per cent, of medicines that enter clinical trials make it to the market. For example, it could be expected that of the 56 cancer treatments currently at Phase I of clinical trials, around 11 will make it to market over the next five to 10 years. However, with 122 cancer treatments already in Phase II, one would expect that a larger number of these will enter the market sooner. For example, based on Gilbert, Henske and Singh's view that one in five medicines at Phase II will make it to market²⁰, one could speculate that of the 122 cancer medicines currently at Phase II of clinical trials, 24 could be expected to be on the market over the same time period.

Table 4 also provides some insight into the relative stages of development of different therapies. For example, while treatments for arthritis are reasonably evenly spread across the three phases of clinical trials, in cancer treatments there are twice as many molecules at Phase II than at Phase I or III, suggesting, that there could be a wave of new cancer treatments five to 10 years away.

More detailed results on medicines in the pipelines related to Australia's NHPAs are contained in Table 5. On an individual health condition basis, lung cancer has the most prospective treatments with 52 medicines in the pipeline. The next highest are Type 2 diabetes (48), breast cancer (45), rheumatoid arthritis (42) and prostate cancer (41).

²⁰ Gilbert, J., Henske, P. & Singh, A. 2003 "Rebuilding Big Pharma's Business Model" *In Vivo: the Business and Medicine Report*, 21(10), November, p. 4.

Table 5: New medicines currently in development, by Australia's National Health Priority Area, by stage of development, November 2004.

Condition	Phase			Apply*	Other	Total
	I	II	III			
Asthma	8	20	4	5	1	38
<i>Total asthma</i>	8	20	4	5	1	38
Cancer, breast	12	23	9		1	45
Cancer, cervical	6	5	2			13
Cancer, cervical - prevention		1	1			2
Cancer, Colon	6	3	2	1		12
Cancer, colorectal	7	19	10			36
Cancer, Colorectal Adjuvant Therapy			2			2
Cancer, Colorectal Metastatic		1				1
Cancer, lung	11	28	12	1		52
Cancer, prostate	7	25	8	1		41
Cancer, Prostate, Early-Stage		2				2
Cancer, skin	3	6	9	1		19
Cancer, Skin, Non-Melanoma			1			1
Cancer, Lymphoma, Non-Hodgkin's	4	9	6			19
<i>Total cancer</i>	56	122	62	4	1	245
Cardiovascular disease	4	1	1			6
Heart disease, other			1			1
Heart failure, acute			1			1
Heart failure, chronic		1	2			3
Heart failure, diastolic		1				1
Stroke	6	8	3			17
Stroke, Acute Ischemic	1	5	2			8
Stroke, Hemorrhagic		2				2
Stroke, Ischemic	1				2	3
Stroke, Prevention in Atrial Fibrillation	2	1	1			4
Peripheral Vascular Disease	1	4	2			7
Peripheral Arterial Disease		5	1			6
Arteriosclerosis	1		1			2
Cardiac disease	1					1
Congestive Heart Failure	1	5	5			11
Congestive Heart Failure (Outpatient Study)		1				1
Congestive Heart Failure, Acute and Chronic		1				1
<i>Total cardiovascular</i>	18	35	20	0	2	75
Depression	7	10	2	3	1	23
Depression, Major Depressive Disorder		2	1			3
Anxiety	1					1
Anxiety, acute	1					1
Anxiety, Generalized Disorder		2	2			4
Bipolar depression			1	1	1	3
Bipolar disorder					1	1

Condition	Phase			Apply*	Other	Total
	I	II	III			
Bipolar maintenance				1		1
Schizophrenia		2	6	1		9
<i>Total mental health</i>	9	16	12	6	3	46
Diabetes - type 1		1		1		2
Diabetes - type 2	18	16	8	3	3	48
Diabetes - type 1 & 2		3	1	2		6
<i>Total diabetes</i>	18	20	9	6	3	56
Injury prevention	1		3			4
<i>Total injury prevention</i>	1		3			4
Arthritis		1	1			2
Arthritis, psoriatic		1	1			2
Arthritis, rheumatoid	12	19	7	2	2	42
Osteoarthritis	2	3	1	3		9
Osteoporosis	9	2	7	4	2	24
Osteoporosis, post menopausal	1	1				2
<i>Total arthritis</i>	24	27	17	9	4	81
Dementia			1	1		2
Dementia, Vascular	2		2			4
Alzheimer's Disease	11	6	6	5		28
<i>Total dementia</i>	13	6	9	6	0	34
<i>Total for NHPAs</i>	147	246	136	36	14	579

Source: Derived from www.innovation.org (PhRMA website). Accessed 24/11/2004. * FDA application.

A proportion of the new medicines being developed will provide patients, governments and the health system new tools to treat some of the most serious health conditions in our community today. In some cases, these will be medicinal treatments that treat illnesses which previously needed to be managed by other parts of the health system. For example, an effective medicine for prostate cancer could remove the need for patients to have radiation therapy or prostatectomy surgery. Or if one of the 28 treatments currently being developed for Alzheimer's Disease proves effective, as well as treating a major illness of an ageing population, it could save much money in other parts of the health system such as aged care costs.

9. The effect of the PBS on productivity and participation

The Commonwealth Treasury's *Australia's Demographic Challenges* report from 2004 correctly points out that improvements in workforce participation are affected, at least in part, by the health of the workforce. The report states "Poor health often leads to early retirement, spells out of work, and lost productivity through sickness or injury"²¹.

²¹Commonwealth Treasury 2004 *Australia's Demographic Challenges*: Canberra, p. 6.

However, while it is recognised that medications can improve Australians' health and workforce participation, there is not sufficient recognition in either this report or the 2002 *Intergenerational Report*²² of the value that medicines can bring to improving the health of Australians. The reports make little mention of the fact that increased PBS spending, while obviously needing to be funded, can positively contribute to health, labour productivity and economic growth.

As well as treating symptoms and extending life, innovative medicines improve peoples' activities and functions in daily life, including their physical, social, emotional and cognitive well being. These all contribute to a person's ability to participate in the community and the economy.

It could well be that increased PBS spending may improve economic growth and should be seen as an investment, not just a cost, for the community. As a case in point, several of the examples of key health conditions affecting Australians highlighted in *Australia's Demographic Challenges*, such as circulatory diseases and depression, are now directly treatable by innovative new medicines available on the PBS.

It is likely that one factor that causes an increase in workforce productivity and participation may actually be an improvement in Australians' health, attributable in part to access to innovative medicines via the PBS. This improvement in health then has all the flow-on benefits of greater GDP growth, lower budget deficits and so on.

In his paper *The Economic Value of Innovation: Measuring the Linkages of Pharmaceutical Research, Use of Innovative Drugs and Productivity Gains*, Australian researcher Dr Paul Gross of the Institute of Health Economics and Technology Assessment, confirmed that higher levels of national health expenditures are associated with better health outcomes. Moreover, better health outcomes obtained with modern innovative medicines lead to higher gross domestic product (GDP) by increasing both workforce participation and productivity.

A 2002 Access Economics report on schizophrenia, *Schizophrenia Costs: an Analysis of the Burden of Schizophrenia and Related Suicide in Australia*, found that improved outcomes, dependant in part on access to newer antipsychotic medications, could reduce a projected \$1 billion health burden associated with the illness. In 2001 the lost earnings from people unable to work due to schizophrenia was \$488 million.

A more recent Access Economics report, *The Dementia Epidemic: Economic Impact and Positive Solutions for Australia*, notes that in Australia there were over 162,000 people with dementia in 2002. The prevalence of dementia is growing rapidly and will reach the 500,000 mark around 2040. Dementia cost over 117,000 years of healthy life in 2002 and will become the largest cause of disability burden in Australia by 2016. By mid-century, according to Access Economics, dementia costs may exceed 3 per cent of GDP – unless we can find effective treatments.

In a 2002 National Bureau of Economic Research paper, *The Effect of Changes in Drug Utilization on Labor Supply and Per Capita Output*, Frank Lichtenberg confirmed that

²²Treasurer 2002 *Intergenerational Report*, Budget Paper No. 5: Canberra.

pharmaceutical technical progress has increased per capita output via its effect on employment rate and hours worked per employed person. Each successive vintage of innovative medicines has produced a progressive increase in per capita output. The research concluded that the use of new medicines reduces the rate of human capital depreciation.

A study in the United States by MEDTAP International, *The Value of Investment in Health Care*, released earlier this year showed that spending on medicines has substantial health gains. For example, it showed that every dollar spent on medicines that lower a diabetic's cholesterol produces \$3 in health gains, each additional dollar spent on hormonal treatments for breast cancer results in at least \$27 of health gains, each dollar invested in beta-blockers to treat heart attacks produces \$38 in health gains, and every dollar spent on therapies to prevent strokes in high-risk patients has delivered health gains valued at \$2 to \$6.

The World Health Organisation has established that access to new knowledge-medicines and vaccines was substantially more important in achieving the dramatic decline in mortality rates throughout the twentieth century than income growth, improved educational levels and improvements in nutrition and sanitation.

Further academic studies have shown that the use of prescription medicines reduces absenteeism of chronically ill workers and increases their productivity by a value far greater than the cost of the medications. Other studies have shown that poor health has a substantial impact on a person's earnings, workforce participation and productivity.

Newer, innovative medicines can reduce overall health costs

As well as their broader social, economic and health benefits, spending on medicines can also provide offsetting savings in other parts of the health system. Illnesses that once required expensive hospitalisation, nursing homes or surgery such as diabetes, heart attacks, depression and schizophrenia, are now increasingly being treated by new medicines developed by the pharmaceutical industry. In the future, conditions like Alzheimer's Disease, which currently cost the community much in terms of residential care, family and carer costs, may be treatable with new medicines currently being developed. While in some cases the newer generation of medicines themselves are more expensive, in many cases this is more than offset by falling costs in other parts of the health system.

For example, the four most costly products listed on the PBS (see above) all help to reduce costs in other parts of the health system. Atorvastatin and simvastatin, the two most costly products, help reduce the risk of heart attacks and strokes which are treated in hospitals. Similarly, omeprazole assists in healing stomach ulcers, reducing the need for surgery, and salmeterol/fluticasone helps manage asthma which also reduces hospital costs.

Unfortunately, broader Government policy does not seem to recognise the impact that new, innovative medicines can have by reducing cost pressures in other parts of the health system. The overriding concern in the 2002 *Intergenerational Report* and the more

recent *Australia's Demographic Challenges* documents is that spending on the PBS is simply a cost. The Government's additional concern is the cost of the PBS is growing and that measures must be taken to curtail that growth.

There is insufficient acknowledgement in these statements that such pharmaceutical spending can, in fact, help reduce overall health expenditure. There is a growing body of evidence to suggest that increased spending on medicines can and does lead to greater offsetting savings in other parts of the health system. Treating conditions like high cholesterol, mental illness and cancer with medicines now can reduce the need for more expensive options such as hospitalisation and surgery.

The result is savings in other parts of the health system. The Chair of the Productivity Commission has flagged the fact that spending on medicines could give rise to savings in other parts of the health system²³. However, the *Intergenerational Report* makes no allowance for the interactions between different parts of the health system like the PBS and hospital costs²⁴.

Medicines Australia strongly argues that any future consideration of the effects of ageing on the PBS should consider the positive impacts that spending on medicines has on both workforce productivity and participation, and the potential for such spending to provide offsetting savings in other parts of the health system.

Most studies of cost offsets are from other countries where health systems have linked data sets, such as in the US managed care environments. Unfortunately, few equivalent studies are available at this point in Australia due to a lack of data linking patient use of hospitals, medical services and pharmaceuticals.

International research suggests that a general increase in spending on medicines is more than offset by greater savings in other parts of the health system. A 1996 study by Lichtenberg in the *American Economic Review* found that for every US\$1 increase in spending on medicines there was a US\$3.65 saving in hospital care expenditure²⁵.

Freund and Smeeding in their discussion of future health care costs in an ageing society argue that governments often do not take the benefits of spending on medicines into account. "*By far, the most important lesson to be learned here is that governments and policy analysts consider only the costs of new treatments and new medicines, and ignore the benefits*"²⁶. Making a full assessment of the impact of medicines can only be made once the benefits of those medicines, both for productivity and for other costs in the health system, are taken into consideration. Nobel laureate, Professor Gary Becker, makes the point that new medicines can potentially cut overall health costs.

²³ Banks, G. 2004 "An Ageing Australia: Small Beer or Big Bucks?" *Presentation to the South Australian Centre for Economic Studies, Economic Briefing*, 29 April: Adelaide, p. 24.

²⁴ Dowrick, S. & McDonald, P. 2002 "Comments on Intergenerational Report, 2002-03", Australian National University: Canberra, p. 10.

²⁵ Lichtenberg, F. 1996 "Do (More and Better) Drugs Keep People Out of Hospitals?," *American Economic Review* 86, May, 1996, 384-388.

²⁶ Freund, D. & Smeeding, T. 2002 "The Future Costs of Health Care in Aging Societies: Is the Glass Half Full or Half Empty?" Prepared for the Seminar *Ageing Societies: Responding to the Policy Challenges*, 8 April, University of New South Wales, p. 18.

“The share of drugs in future medical spending is likely to increase sharply. But even without full cures, drugs that greatly delay the onset and severity of major diseases will reduce expensive and unproductive time spent in hospitals, nursing homes, and under the care of family members ... New drugs have the potential to cut the growth of medical spending sharply. It is crucial to take much better advantage of this potential”²⁷.

In his review of studies into the impact of rising medicine costs on overall health budgets, Kleinke concluded that new, more expensive medicines save costs in other parts of the health sector. The shift to more capital-intensive forms of treatment gives rise to increased efficiencies and represents the health sector moving towards the ‘new economy’.

“In the aggregate and in the short term, ‘expensive’ new drug technologies are a bargain for society. Increased spending on drugs that specifically manage disease, preclude or delay surgeries, or reduce hospital admissions and lengths-of-stay pay for themselves many times over. Added pharmacy costs that offset other medical costs represent the economics of progress. They reflect a profound, permanent movement in our health care system away from medical labor and toward medical technology - a belated catching-up of health care with the rest of the ‘new economy’. The added costs associated with breakthrough drugs represent a major structural shift from the provision of traditional medical services to the consumption of medical products, a systemic rotation from labor to capital”²⁸.

The change from expensive, labour-intensive health treatments such as hospitalisation and surgery, in favour of capital-intensive treatments such as medicines is a major structural shift in healthcare towards a more efficient kind of health expenditure.

Kleinke’s review highlights several studies that identified the effect of how the switch to more capital-intensive treatments in using newer, innovative medicines have reduced the overall costs of treating HIV/AIDS and psychiatric illness. This occurred because the increased cost of new, more effective medicines was more than offset by falls in hospitalisation rates²⁹. Other studies found that restricting the re-imburement of three medicines in the US Medicaid program *“increased the rates of institutionalization in nursing homes, emergency mental health visits, and full-day or half-day hospitalizations in community mental health centers - all at costs far in excess of the medicine savings”³⁰.*

The Value of Medicines: Longer and Better Lives, Lower Health Care Spending, A Stronger Economy

Over the last few decades, scientists have made substantial progress in discovery of new medicines. Even more dramatic advances are anticipated in the years ahead through research in new fields such as genomics and proteomics.

In the last decade alone, over 300 new medicines have been approved by FDA. These advances are improving the treatment of common diseases like heart disease, diabetes and cancer, as well as rare disorders like Fabry’s disease, cystic fibrosis and sickle cell anemia.

²⁷ Becker, G. “New Drugs Cut Costs, And Medicare Can Help”, *Business Week*, 22/3/04, p. 32.

²⁸ Kleinke, J. 2001 “The Price of Progress: Prescription Drugs in the Health Care Market”, *Health Affairs*, 20(5), Sept-Oct.

²⁹ Ibid.

³⁰ Ibid.

As a result of these new discoveries, medicines are taking on an increasingly important role in patient care. As a result, we are spending more on pharmaceuticals. In return, more patients are living longer, better lives; overall health care costs are restrained as patients avoid invasive surgeries and costly hospital and nursing home stays; and the economy is strengthened through improved worker productivity.

A growing number of studies are confirming the increasing value of new medicines to patients and society. For example, a study by Frank R. Lichtenberg, the Courtney C. Brown Professor of Business at Columbia University, finds that patients using newer drugs were significantly less likely to die and lose workdays than those using older drugs. Lichtenberg also found that the use of newer medicines increased drug costs by US\$18, but reduced hospital and other non-drug costs by US\$129.^[i] meaning that for each additional US\$1 spent on newer pharmaceuticals, US\$6.17 is saved in total health care spending, US\$4.44 of which comes from savings in hospital spending.

New Medicines Save and Improve Lives

New medicines have made a major contribution to the decline in the death rate from HIV/AIDS in the U.S. over the last 10 years. Since the mid-1990s, when researchers developed a new wave of medicines to treat HIV/AIDS, the U.S. death rate from AIDS dropped about 70 percent.^[ii]

Several studies have found that use of statin therapy to treat people with high cholesterol reduces hospital admissions and invasive cardiac surgeries. For example, a study of one statin showed that it reduced hospital admissions by a third during five years of treatment. It also reduced the number of days that patients had to spend in the hospital when they were admitted, and reduced the need for bypass surgery and angioplasty.^[iii]

A study sponsored by the Agency for Health Care Policy and Research concluded that increased use of a blood-thinning drug would prevent 40,000 strokes a year, saving US\$600 million annually.^[iv]

A February 2004 study by Lichtenberg finds that new cancer drugs have accounted for 50-60 per cent of the gains we have made in cancer survival rates since 1975. Since 1971, when the U.S. declared war on cancer, our arsenal of cancer medicines has tripled. During that time, the survival rate rose from 50 per cent to 62.7 per cent. Overall, new cancer drugs have contributed a remarkable 10.7 per cent of the increase in life expectancy at birth in the U.S.^[v]

New Medicines Help Control Health Care Costs

A January 2004 study by Duke researchers found that "beta-blocker therapy improves the clinical outcomes of heart failure patients and is cost saving to society and Medicare." The study, which was written before enactment of the Medicare drug benefit, notes: "If medication costs were completely reimbursed by Medicare, program savings from beta-blocker therapy would remain positive."^[vi] Looking at the overall societal perspective, the researchers found that five years of treatment for heart failure without beta-blockers cost a total of US\$52,999. With beta-blockers added to treatment, total treatment costs fell by US\$3,959, patient survival increased by an average of about three-and-a-half months, and patients needed fewer overnight hospital stays.

New studies are showing how newer, better medicines reduce the cost of treating people with depression. "The cost of treating a depressed person fell throughout the 1990s, largely because of a switch from hospitalization to medication," the Wall Street Journal said in a December 31, 2003, story on the study. The study, published in the Journal of Clinical Psychiatry in December 2003, found that per-patient spending on depression fell by 19 per cent over the course of the decade.^[vii]

New diabetes medicines are helping patients avoiding serious complications and death, and can reduce overall health care spending. One recent study found that effective treatment of diabetes with medicines and other therapy yields annual health care savings of US\$685 - US\$950 per patient within one to two years.^[viii] Another study corroborated these results, finding that use of a disease management program to control diabetes with medicines and patient education generated savings of US\$747 per patient per year.^[ix]

A study of the effects of a new Alzheimer's medicine, donepezil, on costs in a Medicare managed care plan showed that, although the prescription costs for the group receiving the drug were over US\$1,000 higher

per patient, the overall medical costs fell to US\$8,056 compared with US\$11,947 for the group not receiving drug treatment. This one-third savings was the result of reduced costs in other areas, such as hospital and skilled nursing facility costs.[x]

New Medicines Strengthen the Economy

New medicines also benefit the economy by increasing worker productivity and reducing absenteeism. One study, which evaluated the effect of migraine treatment on productivity, found that more than 50 per cent of workers who received a triptan drug injection for a migraine attack returned to work within two hours, compared with 9 per cent of workers who received a placebo.[xi]

A study in the *Journal of Occupational and Environmental Medicine* found that patients taking a non-sedating antihistamine for allergies experienced a 5.2 per cent increase in daily work output in the three days after receiving the medication, compared with a 7.8 per cent reduction in work output for workers receiving sedating antihistamines.[xii]

The National Committee for Quality Assurance says that "if every American with depression received care from a health plan or provider that was performing at the 90th percentile level, employers would recover up to 8.8 million absentee days a year." [xiii] NCQA also reported that only 40.1 percent of patients with depression "received effective continuation phase treatment."

[i] Frank R. Lichtenberg, "Benefits and Costs of Newer Drugs: An Update," (Cambridge, MA: National Bureau of Economic Research, June 2002).

[ii] CASCADE Collaboration, "Determinants of Survival Following HIV-1 seroconversion after introduction of HAART," *The Lancet*, 362 (2003):1267-1274

[iii] "Cholesterol Pill Linked to Lower Hospital Costs," *The New York Times*, March 27, 1995.

[iv] D. B. Matchar, G. P. Samsa, Secondary and Tertiary Prevention of Stroke, Patient Outcomes Research Team (PORT) Final Report - Phase 1, AHRQ Pub. No. 00-N001, Rockville, MD: Agency for Healthcare Research and Quality, June 2000.

[v] Frank R. Lichtenberg, "The Expanding Pharmaceutical Arsenal in the War on Cancer," National Bureau of Economic Research Working Paper No. 10328 (Cambridge, MA: NBER, February 2004).

[vi] PA Cowper, et al., "Economic Effects of Beta-Blocker Therapy in Patients with Heart Failure," *The American Journal of Medicine*, 116 (2004): 2, 104-111.

[vii] PE Greenberg, et al., "The Economic Burden of Depression in the United States: How Did It Change Between 1990 and 2000?" *Journal of Clinical Psychiatry*, 64 (2003): 1465-1475.

[viii] E. H. Wagner, et al., "Effect of Improved Glycemic Control on Health Care Costs and Utilization," *Journal of the American Medical Association*, 285 (2001): 2, 182-189.

[ix] J. Berger, et al., "Economic Impact of a Diabetes Disease Management Program in a Self-Insured Health Plan: Early Results," *Disease Management*, 4 (2001): 2, 65-73.

[x] J. W. Hill, et al. "The Effect of Donepezil Therapy on Health Costs in a Managed Care Plan," *Managed Care Interface*, (March 2002): 63-70.

[xi] R. C. Cady, et al., "Sumatriptan Injection Reduces Productivity Loss During a Migraine Attack: Results of a Double-Blind, Placebo-Controlled Trial," *Archives of Internal Medicine*, 158 (11 May 1998).

[xii] I. M. Cockburn, et al., "Loss of Work Productivity Due to Illness and Medical Treatment," *Journal of Occupational and Environmental Medicine*, 41 (1999): 11, 948-953.

[xiii] National Committee for Quality Assurance, *State of Health Care Quality: 2002* (Washington, DC: NCQA, 2003).

Source: Adapted from PhRMA, <http://www.phrma.org/publications/policy/24.04.2004.983.cfm> (accessed 24/11/2004).

10. Conclusion

New medicines offer a variety of benefits for productivity, participation and the efficiency of the health system. New medicines have the potential to treat a range of conditions associated with an ageing population. In many cases these new medicines are likely to be expensive and need to be funded. These medicines can potentially offer a range of new treatments to Australians.

If Australians are to ensure that they have access to these new medicines into the future, particularly in the context of an ageing population, the appropriate funding levels and systems for medicines need to be in place. Ensuring sufficient resources are put into the PBS to pay for new, innovative medicines is one key strategy. Recognising that such medicines have benefits for productivity and participation is another. It is also important that reimbursement decisions for individual medicines, and Government policy more generally, recognises the potential that medicines have for providing offsetting savings in other parts of the health system, such as in hospitals. A range of alternative funding options such as changes in co-payments, medical savings accounts and private health insurance could also be considered.

More generally, Australia needs to have a more general policy debate about the future of the PBS and the funding of medicines which recognises the benefits, as well as the costs, of medicines. Medicines Australia would be very willing to take part in such a wide-ranging review. Such a process would help maintain the financial *and* health outcomes sustainability of the PBS and Australia's funding of medicines more generally, as well as guaranteeing that Australians had access to new medicines into the future.