SUBMISSION TO THE PRODUCTIVITY COMMISSION STUDY INTO THE ECONOMIC, SOCIAL AND ENVIRONMENTAL RETURNS ON PUBLIC SUPPORT FOR SCIENCE AND INNOVATION IN AUSTRALIA

GLAXOSMITHKLINE AUSTRALIA PTY LTD

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CONTENTS

1. Introduction

GlaxoSmithKline Australia Pty Ltd (GSKA) welcomes the opportunity to contribute to this study by the Productivity Commission into the economic, social and environmental returns on public support for science and innovation in Australia. This study is both important and timely, in that it comes at a time when pharmaceutical innovation is continuing to move forward at a rapid pace, and is carrying with it the potential to radically change the current health system and the state of the pharmaceutical industry ('the industry') in Australia.

GSKA has over 120 years of shared history in Australia and as such has gained an in depth knowledge of the Australian operating environment. The company has invested considerably in capital infrastructure, people and skills, local communities and scientific endeavour in Australia. The company has also participated actively in various government programs aimed at encouraging local investment and innovation. Therefore, GSKA is ideally placed to provide insight to the Government on issues surrounding public support for science and innovation within Australia from an industry perspective.

Our submission is structured as follows:

- Chapter 2 – provides brief background information regarding GSK and the involvement of the company in research and development (R&D) activities.
- Chapter 3 – contains an overview of pharmaceutical use and its impact on health expenditure.
- Chapter 4 – outlines the research that has been conducted investigating the broad impacts of pharmaceutical innovation. This includes consideration of the impact on other forms of healthcare expenditure, as well as on the economic and health benefits.
- Chapter 5 – discusses the role of the Government in promoting medical R&D. It highlights what GSKA considers to be the positive elements of the government role in promoting R&D, as well as the current impediments in the existing system. It also discusses various reforms likely to have significant impacts on the investment of GSKA in domestic science and innovation.
- Chapter 6 – draws together the thoughts in this submission and provides an overall conclusion.

The issues raised in this inquiry are both complex and challenging, as it involves an increasingly dynamic and costly innovation environment, where the benefits are hard to quantify and may not be realised until years, even decades, after the initial investment of public funds. Regardless, it is an area that must be addressed in order to ensure that Australia does not fall off the map in terms of relevance in a world that "sees scientific research as the key to global leadership in opportunity and innovation".[1]

GSKA has demonstrated an ongoing ability to work with the Government to find mutually beneficial solutions and looks forward to continuing this productive relationship into the future.

[1] Address by Hon Julie Bishop MP to memfbers of the Federation of Australian Scientific and Technological Societies for "Science meets Parliament", 28th February 2006.

2. GlaxoSmithKline – Background

GSK is a world leading, research-based pharmaceutical company with a powerful combination of skills and resources able to meet the healthcare needs of people around the world in order to help them to do more, feel better and live longer. The company is a global leader in the research, development, manufacture and supply of prescription medicines, vaccines, over the counter medicines, oral care products and nutritional healthcare drinks. GSKA employs approximately 1500 staff and its contribution to Australia's export revenue through pharmaceutical and consumer healthcare exports totalled $A330million in 2004. Its manufacturing operations perform a key role as a global supplier of medicines, exporting 65% of pharmaceutical production to more than 80 countries throughout Europe, America, Africa, Asia, the Middle East and the Pacific Region.

As a predominately research based company, GSK is committed to sustaining its current R&D intensity and investment, with a global R&D budget of £2.8billion (A$6.8billion) annually. In recent years, GSK has re-designed its R&D operations through the creation of Centres of Excellence for Drug Discovery (CEDDs) (see Box 2.1). This innovative approach has helped GSK develop a significant product pipeline, with many new chemical entities (NCEs) and vaccines in clinical development.

At any one time, GSKA is conducting approximately 80 clinical trials in Australia involving approximately 250 investigating clinicians and 10,000 patients. In addition, our discovery research collaborations with respected Australian scientific institutions are targeting the increasingly important area of genetic research and investigating key health challenges including Alzheimer's, cardiovascular disease, diabetes, hepatitis B, immunology, migraine, metabolic pharmacology, respiratory medicine, oncology and rheumatology. As examples, two of the collaborative projects in which GSKA is involved are included in Box 2.2.

Box 2.1

GSK's Centres of Excellence for Drug Discovery (CEDDs)

The Creation of GSK's CEDDs

When GlaxoWellcome merged with SmithKline Beecham in 2001, the newly formed GlaxoSmithKline undertook a significant re-structure of its R&D operations. This re-structure involved a movement away from units formed on the basis of R&D functions (eg. Molecular Biology, Organic Chemistry etc.) to the creation of a number of CEDDs dedicated to particular therapeutic areas. Each of these research units contain the scientific expertise to take a new compound and develop it into a medicine able to be tested in human populations. However, the size of these research units has deliberately been kept small in order to raise both accountability and productivity.

Currently, there are eight CEDDs focussed on areas including respiratory diseases and inflammation, cardiovascular and urogenital disease, neurological and gastrointestinal research and psychiatry. The task of each of the eight CEDDs is to identify lead compounds with therapeutic potential and take them through proof-of-concept studies in order to produce a clinical candidate with strong evidence of efficacy. A significant part of the pre-clinical R&D GSKA conducts in Australia inputs into one or more of these CEDDs.

The importance of the GSKA's strong research base in Australia, and the company's ability to respond to the needs of Government, is demonstrated by GSKA's steps to scale-up its manufacturing capacity for the supply of the antiviral Relenza in response to a potential

pandemic flu outbreak. This initiative is part of a broader strategy to expand and enhance the company's manufacturing capacity and research capabilities in both vaccines and in antivirals, and demonstrates the ability of GSKA to work with Government so as to bring about solutions.

Indeed, GSKA works extensively with all levels of government and across the healthcare system, as well as the broader Australian community, to assist in building a strong local pharmaceutical industry which delivers better health outcomes for all Australians. The company's perspectives are underpinned by an understanding of future directions in pharmaceutical technology and commitment to the long-term sustainability of the industry in Australia.

Box 2.2

Examples of the GSK Early Stage R&D Collaborative Activities

Genetics screening laboratory – Perth

Supported by recurrent funding and capital support, the Perth laboratory of the Australian Neuromuscular Research Institute at the QE2 Hospital in Perth is one of a small number of sites around the world supported by GSK to undertake genetic screening work.

The Perth laboratory compares genetic samples of healthy and disease-state individuals in an attempt to find genes that are associated with the cause or susceptibility of major diseases. This effort includes the search for and use of single nucleotide polymorphism's (SNPs), a small number of which are already known to be markers for disease inheritance for conditions such at sickle cell anaemia and Alzheimer's. This information is then used to identify potential new targets that may be used to identify new medicines.

GSK supports the laboratory through the provision of financial support for expenses and staff, as well as funding the purchase of expensive, cutting-edge equipment to facilitate the laboratory's work.

Mimotopes – Melbourne

Mimotopes is a US-owned company focused on the custom manufacture of peptides and the supply of materials for the synthesis of peptides and small molecule compounds. The company has world leading expertise in the field of solid phase combinatorial chemistry and has enjoyed a long and extensive relationship with GSK, leading to the use of Mimotopes' propriety products in a number of GSK's research endeavours.

These research endeavours include a number of projects under which Mimotopes has applied its specialized combinatorial chemistry technology to manufacture libraries that are composed of thousands of related small organic compounds. These libraries are used by GSK in its high throughput screening efforts, the goal of which is to determine if any of the compounds might be potentially useful as new drug candidates.

The relationship between GSK and Mimotopes has been important for both companies. The research partnerships between Mimotopes and GSK and other large pharmaceutical companies are important to the growth of companies that service drug discovery. The work it undertakes also provides linkages into the global pharmaceutical industry that place Australia on the radar of global R&D decision-makers, thereby reducing the barriers to Australian involvement caused by a lack of decision maker awareness.

3. Pharmaceutical Use and Expenditures in Australia

Innovative medicines are an important product of progressive science and innovation activity with the potential to greatly enhance the quality of life for people around the world. Indeed, of all human endeavours, health and medical research has been described as offering "the greatest potential to improve human life".[2] However, recent discussions concerning pharmaceuticals have been predominantly focused on healthcare expenditure and containing the cost the pharmaceutical benefits scheme (PBS). This is due in part to the 2002 Intergenerational Report which projects that Government expenditure on healthcare will continue to grow, and a majority of the growth will be derived from pharmaceuticals.[3]

3.1 The Role of Medicines in Society

Medicines have played an increasingly important role in the prevention and treatment of diseases over the course of the last century. They save lives, relieve pain, cure and prevent disease. They keep families together longer, help improve quality of life for patients and caregivers, and enable employees to stay at work and remain economically productive.

Mass vaccination has effectively eliminated the risk of many diseases, such as polio, that previously caused substantial disability or premature death in Australia only decades ago. Modern medicine has also changed the way other diseases are treated, reducing their burden on patients, health systems and the wider community.

Medicines are an effective and economical means of treating and curing a disease. Research has consistently demonstrated expenditure on medicines as being associated with greater offsetting savings in hospital and other health expenditure.[4] However, medicines should not be viewed solely through the prism of reducing other healthcare costs. New medicines frequently address unmet medical needs, or improve outcomes for patients where current treatments are associated with adverse side effects, resulting in wider social benefits such as reduced mortality, improved quality of life and increases in the life-expectancy of patients.

Capturing the full societal and individual benefits of innovative medicines is a complex task involving the tracking of monetary savings through the health system over time and the evaluation of more intangible health outcomes such as impacts on longevity, productivity and quality of life.

3.2 Government Expenditure on Pharmaceuticals

Trends in Pharmaceutical Use

Australians are using more pharmaceuticals than ever before (figure 3.1). In 2004–05, 185 million 'subsidised' pharmaceutical scripts were prescribed in Australia under the Pharmaceutical Benefits Scheme (PBS) or the Repatriation Pharmaceutical Benefits Scheme (RPBS). This was 66 per cent (or 71 million) more than the number prescribed twelve years

[2] Vitale, MR and Bennett CC, "Australian health and medical research: Are we there yet?" *Medical Journal of Australia* (2005) **182(11):** 550-1.
[3] Commonwealth of Australia 2002, 'Intergenerational Report 2002-3', Budget Paper No. 5, Canberra.
[4] MEDTAP International, "The Value of Investment in Health Care: Better Care, Better Lives" (Bethesda, MD: MEDTAP, 2003).

earlier in 1992–93.[5] At the same time, the number of medicines listed on the PBS has risen, climbing by 255 medicines between 1996 and 2004. Today, the PBS subsidises about 650 different medications.[6]

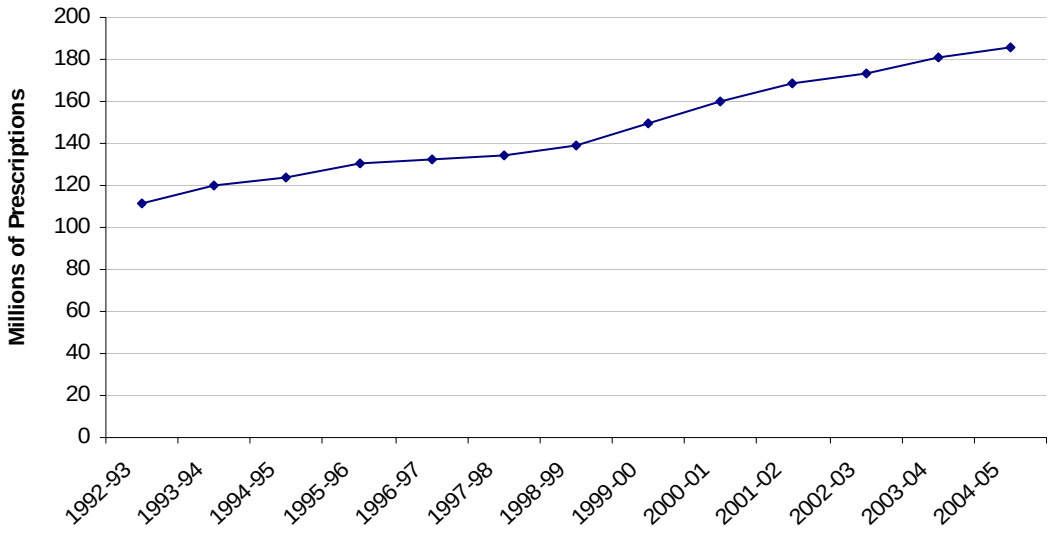
The rate of increase in subsidised pharmaceutical prescriptions has been much higher than the growth in the population, which rose 14 per cent over the same period. In 2004–05, about 9 prescriptions of subsidised pharmaceuticals were written for every Australian — almost three prescriptions per person more than in 1992–93.

The information available about prescriptions of non-subsidised pharmaceuticals, and those below the co-payment amount, is less extensive than that about subsidised pharmaceuticals. The Department of Health and Ageing has published estimates of prescriptions for non-subsidised pharmaceuticals, based on a survey of the pharmaceutical dispensing records of 150 pharmacies. These data indicate that the number of prescriptions of non-subsidised pharmaceuticals in Australia was reasonably constant at about 45 million prescriptions per year between 1995 and 2000. Over the same period, subsidised prescriptions grew by 21 per cent . In 2000, almost four of every five pharmaceutical prescriptions in Australia were subsidised by taxpayers.

There is no publicly available data on the pharmaceutical usage rates of different age groups in the population. However the Productivity Commission, using unpublished Health Insurance Commission data, recently reported that the per capita cost of PBS-subsidised pharmaceuticals are strongly age-related, with the average cost for a person aged 65-74 years more than 18 times the average cost for a person aged 15-24 years, and about five times the average cost of a person aged 40-50 years.[7]

Figure 3.1

Prescriptions of Pharmaceuticals in Australia, 1992-93 to 2004-05



Source: Medicare Australia, *Pharmaceutical Benefits Schedule Group Statistics*. www.medicareaustralia.gov.au/providers/health_statistics/statistical_reporting.htm, accessed on 23 March 2006.

[5] Medicare Australia, *Pharmaceutical Benefits Schedule Group Statistics*. www.medicareaustralia.gov.au/providers/health_statistics/statistical_reporting.htm, accessed on 23 March 2006.
[6] Department of Health and Ageing 2004, unpublished data.
[7] Productivity Commission 2004, *Economic Implications of an Ageing Australia*, Draft Research Report, Productivity Commission, Canberra, pp. 6.4-6.5.

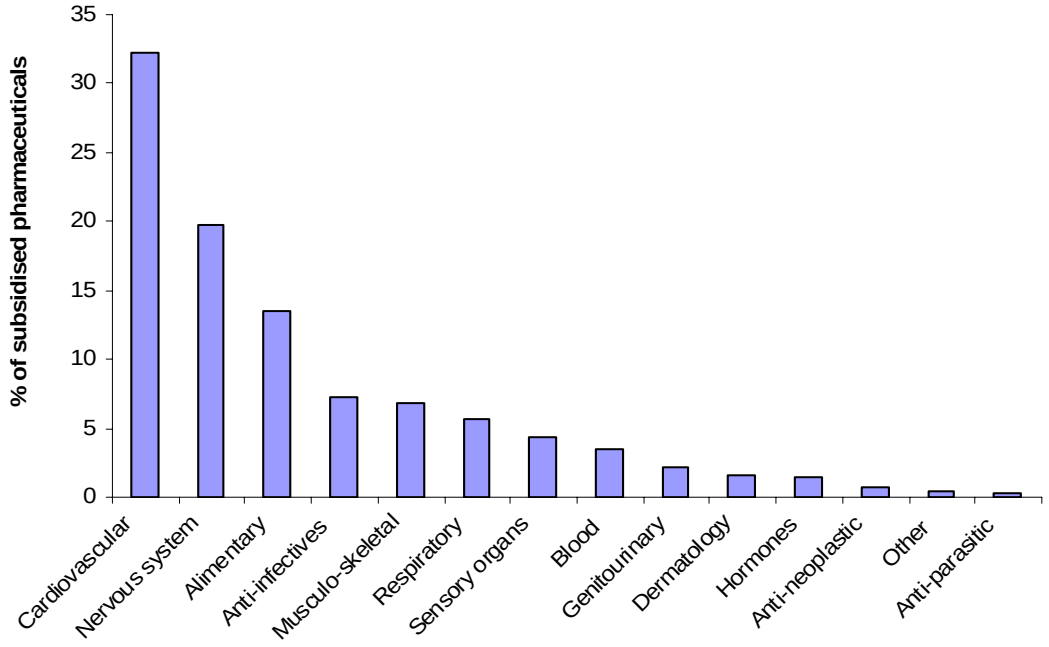
It is worth noting that the volume of subsidised pharmaceuticals is heavily concentrated into three main categories, which when combined contributed to 66% of subsidised prescriptions in Australia in 2004-05 (Figure 3.2):

- Cardiovascular system (32%);
- Central nervous system (20%); and
- Alimentary tract and metabolism (14%).

When combined with the musculoskeletal system, these categories of medications have accounted for 95% of the growth in total prescriptions from 1992-93 to 2004-05.

Figure 3.2

Proportion of Subsidised Prescriptions in each category of Pharmaceutical, 2004-05



Source: Department of Health and Ageing 2006, *Expenditure and Prescriptions Twelve Months to 30 June 2005.*

Trends in Pharmaceutical Expenditure

Accompanying the rise in use of pharmaceuticals has been an increase in total expenditure on pharmaceuticals. The Australian Government and individuals are the primary sources of funding for pharmaceuticals expenditures (Table 3.1). Government outlays arise largely through the Pharmaceutical Benefits Scheme (PBS), a universal scheme that provides subsidised pharmaceuticals. To obtain medicines listed on the PBS, individuals must contribute a co-payment, which varies according to an individual's family structure and concessional status.

These outlays are the main source of funding for subsidised pharmaceuticals, accounting for 81 to 85 per cent of total spending in this category. In real terms, expenditures on subsidised pharmaceuticals grew an average of 11.0 per cent per year from 1992–93 to 2003–04, with slightly lower growth experienced in the first five years (9.9 per cent) than in the second six years (12.4 per cent). Growth over the entire period was shared between the Government (11.3 per cent) and individuals (9.9 per cent).

Table 3.1

Expenditure on Subsidised Pharmaceuticals, constant price^, 1992-93 to 2003-04.

	Australian Government		Individuals		Total Expenditure	
	Amount	Growth	Amount	Growth	Amount	Growth
Year	($m)	(%)	($m)	(%)	($m)	(%)
1993-94	1,931	-	405	-	2,335	-
1994-05	2,126	10.1	470	16.2	2,596	11.2
1995-96	2,542	19.6	501	6.5	3,043	17.2
1996-97	2,745	8.3	557	11.2	3,331	8.8
1997-98	2,811	2.1	599	7.7	3,411	3.0
1998-99	3,102	10.3	629	5.0	3,731	9.4
1999-00	3,534	13.9	682	8.4	4,216	13.0
2000-01	4,320	22.2	776	13.7	5,096	20.9
2001-02	4,678	8.3	842	8.5	5,520	8.3
2002-03	5,166	10.4	951	12.9	6,116	10.8
2003-04	5,624	8.9	1,036	9.0	6,660	8.9
Average Annual Growth Rate						
1993-94 to 1997-98		9.9		10.3		9.9
1997-98 to 2003-04		12.9		9.7		12.4
1993-94 to 2003-04		11.3		9.9		11.0

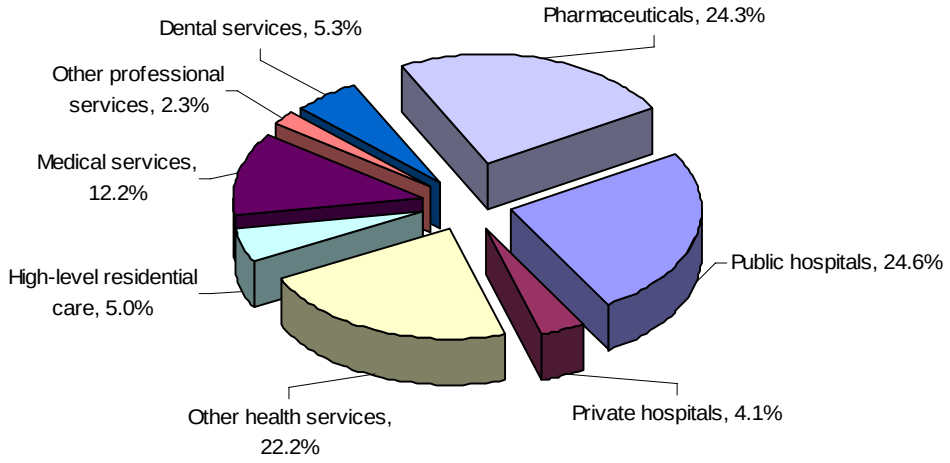
Note: ^ Constant price health expenditure for 1993-94 to 2003-04 expressed in terms of 2002-03 prices.

Source: AIHW, *Health Expenditure Australia 2003-04.*

Expenditure on pharmaceuticals represented the second largest proportion of real growth in recurrent health expenditure between 1993-94 and 2002-03 (24.3 per cent) – public hospitals represented the highest proportion (24.6 per cent).[8] Indeed, Australia demonstrated the fourth highest growth out of all OECD countries in public expenditure on pharmaceuticals, as a percentage of overall health expenditure between 1993 and 2003.[9]

Figure 3.3

Growth in Total Recurrent Health Expenditure, constant price^, 1993-94 to 2002-03.



Note: ^ Constant price health expenditure is expressed in terms of 2002-03 prices.

Source: AIHW, *Health Expenditure Australia 2003-04.*

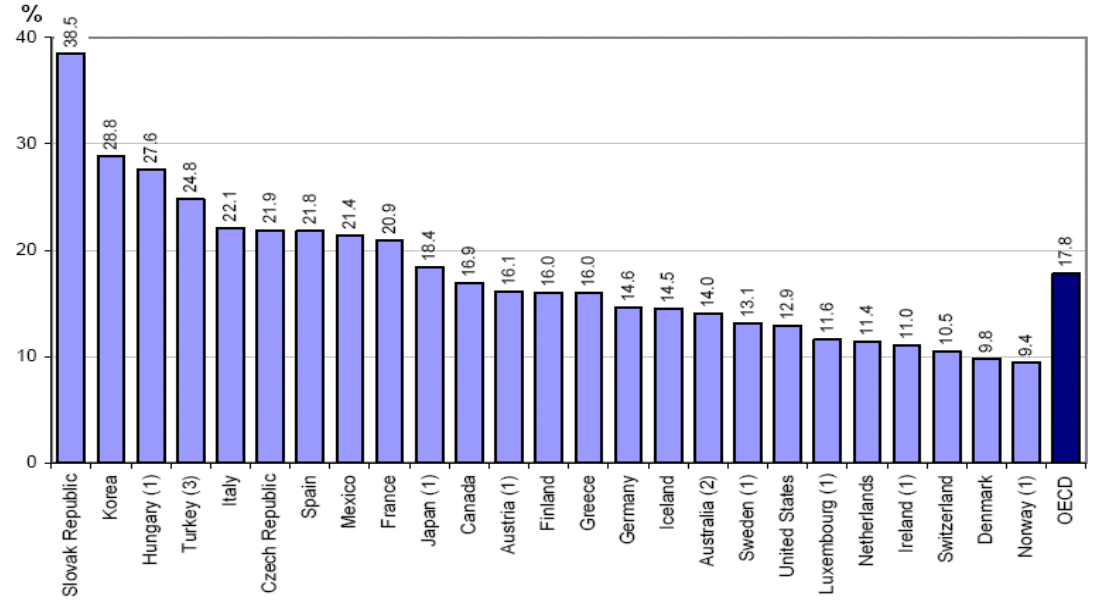
[8] AIHW, *Health Expenditure Australia 2003-04.*

[9] OECD 2005 Health Statistics.

The high growth rates that have been observed over the last decade must nevertheless be put into their broader perspective. All OECD countries for which there are data available have seen their expenditure on pharmaceuticals grow. Furthermore, over the previous ten years (1981-1991), at least seven OECD countries have had higher annual growth rates than Australia. Indeed, the proportion of total health expenditure spent on pharmaceuticals within Australia is still well below the OECD average (Figure 3.4). However, Australia is following an international trend whereby pharmaceutical expenditure continues to absorb an increasing proportion of national health budgets (Figure 3.5).

Figure 3.4

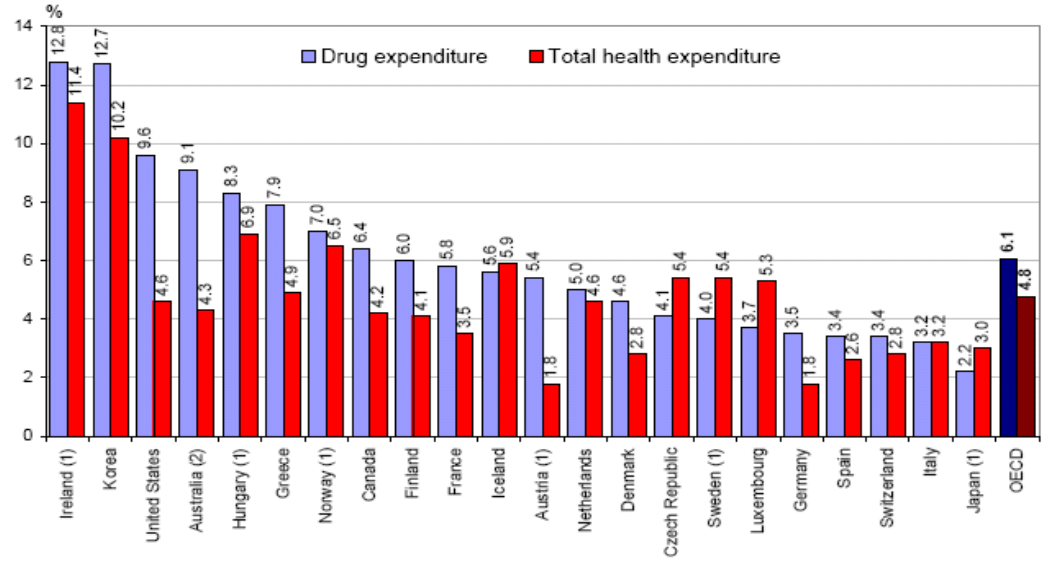
Pharmaceutical Expenditure as a Percentage of Total Health Expenditure.



(1) 2002. (2) 2001. (3) 2000.
Source OECD HEALTH DATA 2005, June 05

Figure 3.5

Annual Growth in Pharmaceutical Expenditure and Total Health Expenditure, 1998 to 2003.



Note: Countries are ranked from left to right by annual growth of per capita pharmaceutical expenditure.
(1) 1998-2002. (2) 1997-2001.
Source OECD HEALTH DATA 2005, June 05

Factors Influencing the Increase in Pharmaceutical Expenditure

Rising expenditures on pharmaceuticals are the result of a number of factors, including:

- Population growth and ageing;
- Increases in the number of pharmaceuticals per person;
- Introduction of new therapeutic agents;
- Changes in the mix of existing therapies towards more costly and often better agents; and
- Increased identification, prevention and treatment of medical conditions.

The trend in Australia can be better understood by an analysis of these different factors.

Although population growth and ageing contributed to the increasing expenditures, both the number of prescriptions and expenditures per person per year rose over time:

- For example, the number of prescriptions per person per year increased from three to nine between 1992–93 and 2003–04;
- Likewise, real per capita expenditures on subsidised pharmaceuticals rose an average of 9.2 per cent per year between 1992–93 and 2002–03 to a high of $306.77 in 2002–03;
- Per person expenditures on non-subsidised pharmaceuticals increased by an annual average of 6.6 per cent during the same time period, reaching $190.98 in 2002–03;
- Per person rates of growth are slightly lower than growth rates for aggregate expenditures on pharmaceuticals (10.4 per cent for subsidised items and 8.3 per cent for non-subsidised items). The difference between the growth rates in each category is the result of growth in the overall size of the Australian population.

3.3 Implications of Innovation on Pharmaceutical Use and Expenditure

Innovation and technological advances are largely responsible for the increasing cost of pharmaceuticals in the last two decades, and this is a trend that will certainly continue into the future. The pharmaceutical industry is experiencing a period of rapid change, and with this change comes the potential to transform the future role of pharmaceuticals in the delivery of healthcare. However, the ultimate impact of pharmaceutical innovation on public funding and healthcare delivery will also depend on changes in the demographic composition of Australia and interactions between the factors underlying the use of medicines.

Future Directions in Pharmaceutical Discoveries

In the medium term, the application of *pharmacogenomics* is likely to create the greatest range of new possibilities for pharmaceuticals. This involves the study of how a person's genes affect the way they respond to medicines. By identifying and characterising genes in this way, scientists will be able to design simple genetic tests that determine in advance which medications will work for a given individual and which will not — both in terms of the avoidance of adverse events and increased efficacy.

The refined understanding of how medicines interact with individuals' genetic compositions learned through pharmacogenomics can also be used to identify which medications are the best candidates for clinical trials. Applications could also identify and exclude from research trials those individuals who are less likely to respond or are at risk of adverse reactions at later stages of clinical trials. Better targeting in this field could increase the reliability of scientific findings by using smaller groups of genetically similar participants in clinical trials, as well as shorten the average time to develop a medication, potentially reducing R&D costs.

In the longer term, pharmacogenomics may allow researchers to tailor medicines to different segments of the population with a particular type of genetic composition. The incorporation of this type of development into clinical practice has the potential to improve efficacy and reduce toxicity by allowing the choice of the 'right medication for the right patient in the right disease at the right dose'.[10] Some predicted developments from pharmacogenetic research are set out in Box 3.1.

Box 3.1

Examples of the Predicted Use of Pharmacogenomics

- Establishment of prescribing guidelines, based on clinical studies, for medications that are subject to substantial polymorphic metabolism.
- Prescribing advice will relate dose to genotype and will highlight the possibility of medication interactions when multiple medications are prescribed concomitantly.
- Establishment and recording of individual patient genotypes — that is, 'personal pharmacogenetic profiles'.
- Pharmacogenetic testing will reduce the need for hospitalisation, and its associated costs, because of adverse medication reactions.
- Development of new medications for patients with specific genotypes — that is, 'medication stratification'.

Source: C. Wolf, G. Smith and R. Smith 2000, 'Science, medicine, and the future: Pharmacogenomics', *British Medical Journal*, vol. 320, 8 April, p. 987.

In addition to pharmacogenomics, there are many other research fields being explored by scientists to discover new and innovative medicines. Projects investigating bioinformatics, stem cell technology and therapeutic vaccines are believed to carry the potential to significantly change current clinical practice and improve overall health outcomes. Indeed, predicted pharmaceutical discoveries from these types of innovations include:

- Medicines that prevent the HIV virus from entering a cell at the outset;[11]
- Medications that slow the progression of Alzheimer's disease;[12]
- Combinations of treatments that cut off the blood supply to cancerous tumours;[13]
- Medicines that prompt the heart to grow new blood vessels, providing the same benefits currently delivered by bypass surgery;[14] and
- Multi-component fixed dose combination medicines that prevent cardiovascular disease.[15]

[10] M. Pirmohamed and G. Lewis 2004, 'The implications of pharmacogenetics and pharmacogenomics for drug development and healthcare', in. E. Mossialos, M. Mrazek and T. Walley (eds), *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*, Open University Press, Berkshire, p. 281.
[11] *Time* 2001, 'The Hunt for Cures', 15 January.
[12] Ibid.
[13] Ibid.
[14] *The Wall Street Journal* 2000, Next Milestones in Human Genetics', 26 May.
[15] World Health Organization (WHO) 2004, *Priority Medicines for Europe and the World*.

Impacts of Pharmaceutical Advances

Pharmacogenomics is likely to become increasingly important in the discovery and development of medicines as knowledge of the relative importance of genetic or generic factors in responsiveness helps to identify which sub-sets of the population will be best treated by particular medicines. However, pharmacogenomics may make the task of medicine discovery more complex, time-consuming and costly, as the research processes involved are more advanced and the sub-set of patients from whom R&D costs can be recouped is smaller. For example, one reason for the high-cost of the breast cancer drug, Herceptin, is that the potential market is only one seventh of that available for other breast cancer medications.

In addition, as consumers become more aware of therapies under development, accustomed to having access to improved therapies and continue to enjoy rising incomes, expectations will rise as to the medicines that should be available to them. This will continue to pose a challenge to Government in an environment of limited and competing resources.

Drug discovery and manufacture will also continue to be an increasingly costly industry. Current predictions place the cost of bringing a prescription molecule to market at US$897 million, and increasing at 2.5 times the rate of inflation.[16] Furthermore, only five of every five thousand pharmaceuticals developed are tested in clinical trials, and of those five only one on average is approved for patient use, meaning many compounds are the subject of substantial investments but only a small percentage of these will ultimately generate any sort of return.

These challenges, and their interaction with other factors such as a changing demographic and the evolving standards of medical care, will significantly influence the future medicines landscape within Australia and the consequent direction of science and innovation within this area.

3.4 Conclusions

This chapter began by noting the important benefits, both societal and economic, that pharmaceutical innovation has had through the treatment and prevention of disease within Australia. Understandably, these benefits have accompanied a significant increase in the usage of medicines in Australia, with a consequent increase in public expenditure through the pharmaceutical benefits scheme. Factors further underpinning the increase in usage and expenditure – including developments in technology, the ageing population and consumer expectations – are likely to continue, even strengthen, as innovation leads to the development of more advanced techniques such as pharmacogenomics.

It is not simple to assess the appropriateness of the increasing expenditure on pharmaceuticals in Australia. It is not simple to judge whether the expenditure is too little, too much or just right. It depends on the nation's preferences, the opportunity costs of the expenditure, and in particular, the cost effectiveness of the expenditure — taking into account the total (net) effects on costs across the health system as a whole, not simply the cost of pharmaceuticals in isolation. This requires a comprehensive understanding of both the costs and the benefits of pharmaceuticals. This issue is discussed in chapter 4.

[16] TUFTS Centre for the Study of Drug Discovery, May 2003. Accessed 22 April 2006.

4. Impact of Innovative Advances in Pharmaceutical Research

Recent discussions about the impact of advances in pharmaceuticals have tended to take a fairly narrow approach to the assessment of their costs and benefits. Considering the expenditure on pharmaceuticals separately instead of as part of overall resource use in the healthcare system has been criticised as reflecting a 'silo mentality'.[17] One disadvantage of such a narrow approach to the assessment of the costs of pharmaceuticals is that it could result in inefficiency because pressure to reduce the consumption of pharmaceuticals could lead to increased consumption of other healthcare resources.

Similarly, the benefits of pharmaceuticals are often described in terms of direct health outcomes, whereas a broader appreciation of the benefits, including, for example, the impact on workforce participation due to healthier employees, allows a more comprehensive view. This chapter takes a more comprehensive approach to the assessment of the costs and benefits of pharmaceuticals by looking at the economic benefits and gains in health outcomes offered by modern medicines, and the particular benefits offered from innovative pharmaceutical interventions.

4.1 Economic Impacts of Pharmaceuticals

Advances in pharmaceuticals have had significant impacts on economies around the world through their impacts on public health expenditure and other factors influencing economic growth, namely increased worker productivity and participation.

Health Expenditure Reductions

Several researchers have evaluated the cost-effectiveness of pharmaceuticals in light of their substitution for other medical services. For example, a 1996 study by Lichtenberg in the *American Economic Review* found an increase of 100 prescriptions was associated with 16.3 fewer hospital days. In monetary terms, this translated into a saving of US$3.65 in hospital expenditure for every US$1 increase in pharmaceutical expenditure.[18] In the United Kingdom, medicines have helped to halve the number of hospital beds used in 12 major disease areas and reduce the average hospital stay from 45 to eight days. The related savings have been estimated at £10 billion a year.[19]

Box 4.1 summarises the results of a sample of studies that seek to quantify the relationship between the use of pharmaceuticals and reduced health expenditure in other areas.

Box 4.1

~~Impact of Pharmaceuticals on~~ Reducing Health Expenditure

[17] M. Drummond 2003, Moving beyond the drug budget silo mentality in Europe. *Value in Health*, volume 6, supplement 1, S74-S77, p. S74.

[18] Lichtenberg F, Do (more and better) drugs keep people out of hospitals. *American Economic Review* (1996); **86:** 384-388.

[19] Association of the British Pharmaceutical Industry (ABPI) 1997, White Paper: ABPI Statement. Available at http://www.abpi.org.uk/press/press_releases_97/971210.asp accessed on 9 May 2006.

Cholesterol Lowering Therapy The use of a cholesterol-lowering statin provides a clear example of how the use of pharmaceuticals can reduce overall hospital expenditure. The use of this medication reduced hospital admissions by a third during the five years of treatment, as well as reducing the number of days patients stayed in hospital once admitted and reducing the need for bypass surgery and angioplasty.[20]
Alzheimer's Medicine A study of the effects of the Alzheimer's medicine, donepezil, on costs in a Medicare managed care plan showed that the use of the medicine reduced overall medical costs by US$4,000. These savings of one third were the result of reduced costs in other areas, such as hospital and skilled nursing facility costs.[21]
Depression A study published in the Journal of Clinical Psychiatry found that per-patient spending on depression fell by 19 per cent over the course of a decade as the method of treating these patients changed from hospitalisation to medication.[22]
Stomach Ulcers Medicines now successfully combat stomach ulcers caused by bacterium *helicobacter* and prevent future peptic ulcer problems. Studies have shown this to have both decreased endoscopies of the stomach by 50% and saved $250 million each year in associated health costs.[23]

Increased Worker Productivity and Participation

The Federal Treasurer, the Hon Peter Costello, has stated that economic growth is driven by:[24]

> *How many people you have, their participation level in the workforce and the productivity of that participation.*

Medicines have a significant impact on each of these areas identified as influencing economic development. The impact of pharmaceuticals on the population will be discussed in section 4.2 in terms of their role in increasing the overall life expectancy of the general population and in reducing the mortality associated with numerous diseases. However, beyond these benefits, medicines have also been demonstrated to have significant impacts on workforce participation and productivity.

Health researcher, Paul Gross, has shown that better health outcomes obtained through modern innovative medicines lead to higher gross domestic product (GDP) by increasing both

[20] "Cholesterol Pill Linked to Lower Health Costs" *The New York Times* 7 March 1995.
[21] Hill JW *et al.* The effect of Donepezil therapy on health costs in a managed care plan. *Managed Care Interface* (2002):63-70.
[22] Greenberg PE *et al.* The economic burden of depression in the United States; how does it change between 1990-2000. *Journal of Clinical Psychiatry* (2003) **64(12):** 1465-75.
[23] Access Economics, 'The value of investing in health R&D in Australia' September 2003.
[24] The Hon Peter Costello, 'Celebrating 20 000 000: The future that lies before us' ABS House, Canberra, 4 December 2003.

workforce participation and productivity.[25] Similarly, Professors David Bloom, David Canning and Dean Jamison found that better health has significant benefits for GDP growth.[26] These authors found that good health raises per capita incomes through improvements in labour productivity. In an earlier article by these authors published in *Science*, Bloom and Canning found that health influences GDP per capital in several ways.[27] Healthier populations tend to have a higher labour productivity, suffer fewer lost work days from illness or the need to care for family members that become ill. People have stronger incentives to invest in their education because they enjoy the benefits over a longer time frame and tend to save for the longer term because of improved longevity. There is also a demographic dividend where lower infant and child mortality leads to a larger workforce.

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. Indeed, a U.S. study demonstrated substantially lower absenteeism amongst workers on prescription medications and estimated the net benefits to employers from having chronically ill workers on these medicines amounted to $286 per employee with hypertension, $633 per employee with heart disease, $822 per employee with depression and $1475 per employee with type II diabetes under medication.[28] Other studies have shown that poor health has a substantial impact on a person's earnings, workforce participation and productivity. Some examples of the positive impact of pharmaceutical intervention on participation and productivity are shown below:

- Individuals who received an influenza vaccine had 18 to 43 per cent fewer lost workdays and 18 per cent fewer days of reduced effectiveness than individuals receiving a placebo.[29-30]
- Migraine medications were shown to reduce productivity loss by 49 percent per headache during the workday.[31]
- For individuals with diabetes, individuals taking the medicine glipazide lost 5 days per 500 workdays in comparison to their counterparts taking a placebo who lost 24 days during the same length of time.[32]
- The employment rates of persons with schizophrenia doubled with the use of a new atypical antipsychotic medication.[33]
- In a study of employees with depression, anxiety, migraines, or hypertension, researchers found that employees who received pharmaceutical interventions for their condition were able to significantly increase the number of hours worked after treatment from their pre-treatment level.[34]

[25] Gross P. The economic value of innovation: Measuring the linkages of pharmaceutical research, use of innovative drugs and productivity gains. *Institute of Health Economics and Technology Assessment: Dee Why.*
[26] Bloom D *et al.* Health, wealth and welfare. *Finance and Development* (2004) **41(1):** 10-15.
[27] Bloom D *et al.* The health and wealth of nations. *Science* (2000) **287:** 1207-9.
[28] Rizzo JA *et al.* Labour productivity effects of prescribed medicines for chronically ill workers. *Health Economics* (1996) **5(3):** 249-65.
[29] Rubin H. Influenza vaccination: not just for those at high risk. *Healthcare Productivity*, National Pharmacy Council, 2003 pp5-6.
[30] Nichol K *et al.* Cost benefit of influenza vaccination in healthy, working adults: an economic analysis based on the results of a clinical trial of trivalent live attenuated influenza virus vaccine. *Vaccine* (2003) **21(17-18):** 2216-2226.
[31] Cady R. Reduction of labor costs associated with treating migraines in the workplace [editors correspondence], *Archives of Internal Medicine* (1999) **159(2):** 197.
[32] Testa MA and Simonson DC. Health economic benefits and quality of life during improved glycemic control in patients with type 2 diabetes mellitus: a randomised, controlled, double-blind trial. *JAMA* (1998) **280(17):** 1490-1496.
[33] Glazer WM. Formulary decisions and health economics. *Journal of Clinical Psychiatry* (1998) **59(19):** 23-29.
[34] Berndt E *et al*. Illness and Productivity: Objective Workplace Evidence. Massachusetts Institute of Technology (MIT), Working Paper #42-97 (1997).

4.2 Broader Impacts of Pharmaceuticals on Health Outcomes

Disease imposes burdens on people that extend well beyond direct financial costs. Pharmaceutical innovation has led to increased life expectancies, improved health status and a higher quality of life for people. As mentioned, these factors have an impact on an economy through their ability to influence workforce participation and productivity. However, they also represent broader societal benefits that carry a value beyond any potential economic benefits.

Reduced Mortality

Innovation in asthma medication is one of many examples in Australia demonstrating the broader impact that pharmaceuticals can have on overall health outcomes for a particular disease. Asthma currently affects around 10 per cent of the population[35], causing limited social function, poor general health, hospitalisation, lost time from work and premature death. However, medicines for asthma have resulted in a 28 per cent decline in mortality associated with this disease in Australia over the last decade.[36] This impact on mortality is not unique to asthma, a recent study by Lichtenberg found that cancer medications have accounted for 50-60 per cent of the gains made in cancer survival rates since 1975.[37] Indeed, over 45 per cent of the variation in mortality across diseases between 1970 and 1991 has been attributed to the use of new pharmaceuticals to treat those diseases.[38]

Studies by the Battelle Institute further suggest that pharmaceutical innovation will continue to be a major factor contributing to mortality reductions into the future. By 2015, pharmaceutical advances are predicted to account for:[39]

- 19 to 40 per cent of the projected reduction in coronary heart disease;
- 28 to 65 per cent of the projected reduction in breast cancer;
- 15 to 40 per cent of the projected reduction in cerebrovascular disease.

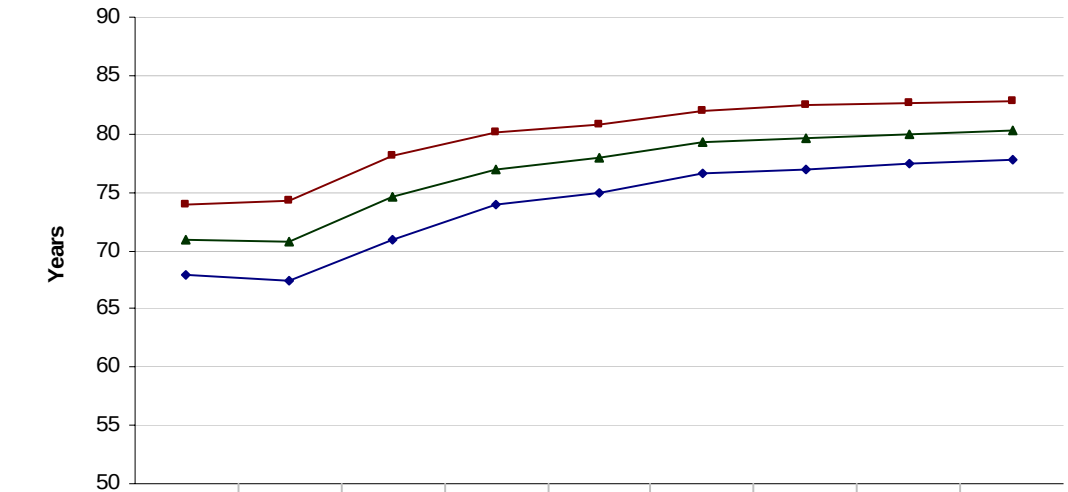
Increased Life Expectancy

Disease-related mortality is closely linked to average life expectancy which has been steadily increasing in Australia over recent decades (Figure 4.1).

[35] National Health Survey 2004-05. Australian Bureau of Statistics. Feb 2006.
[36] Woolcock AJ *et al.* The burden of asthma in Australia. *MJA* (2001) **175:** 141-45.
[37] Lichtenberg FR. The expanding pharmaceutical arsenal in the war on cancer. NBER Working Paper No. 10328 (Cambridge, MA: NBER, February 2004).
[38] Lichtenberg FR. Pharmaceutical innovation, mortality reduction and economic growth. NBER Working Paper No. 6569 (Cambridge, MA: NBER, February 1998).
[39] Hall M. The impact of behavioural advance on health trends over the next 25 years. *Office of Health Economics Briefing* No. 31, London, UK: Office of Health Economics.

Figure 4.1

Average Life Expectancy in Australia (Years) from 1960 to 2003



	1960	1970	1980	1990	1995	2000	2001	2002	2003
Male	67.9	67.4	71	73.9	75	76.6	77	77.4	77.8
Female	73.9	74.2	78.1	80.1	80.8	82	82.4	82.6	82.8
Overall	70.9	70.8	74.55	77	77.9	79.3	79.7	80	80.3

Source: OECD Health Statistics 2003.

While a number of factors contribute to increases in average life expectancy, such as improvements in nutrition, increased health awareness, public health awareness campaigns and better health services, the value of pharmaceutical innovation needs to be appreciated.

For example, a study which measured the relationship between launches of innovative pharmaceuticals and life expectancy in 52 nations over the period between 1982 and 2001 attributed 40 per cent of the gain in life expectancy over that time to the impact of new medicines.[40] A wider study involving 21 OECD countries also investigated the link between pharmaceutical expenditure and life expectancy. This study estimated that doubling pharmaceutical consumption would raise remaining life expectancy by 2% for the average 40 year old, and 4% for the average 60 year old.[41]

Economic research has indeed linked longer life expectancy with economic growth. In a study comparing two nations identical but for one nation having a five year longer life expectancy, it was found that the healthier nation experienced economic growth at a rate 0.3 to 0.5 per cent faster. Another study used international data relating to the period between 1960 and 1990 to conclude that *"…a one year improvement in a population's life expectancy contributes to a 4% increase in output."*[42] However, the impact of pharmaceuticals on better health outcomes extends beyond economic returns alone and translates directly into an

[40] Lichtenberg FR. The impact of new drug launches on longevity. *International Journal of Health Care Finance and Economics* (2005) **5(1):** 47-73.
[41] Frech HE and Miller RD. 'The productivity of health care and pharmaceuticals: An international comparison' *UCLA Research Program in Pharmaceutical Economics and Policy.* (1 December 1996) Paper 97-1.
[42] Bloom D *et al.* The effect of health on economic growth: Theory and evidence. Working Paper 8587 (2001) Cambridge, MA, NBER.

improved quality of life for countless individuals. A sample of case studies illustrating the effect medications have had on certain populations in contained in Box 4.2.

Box 4.2

Impact of Pharmaceuticals on Disease-Specific Health Outcomes

HIV/AIDS

Although a cure for HIV/AIDS has yet to be discovered, new medicines have lengthened life expectancy for individuals with the virus and dramatically improved the quality of their lives by enabling them to remain in good health. A recently developed class of medications in this area known as 'fusion inhibitors' effectively prevents the virus from infecting certain components of the immune system. As a result, the amounts of the virus in the bloodstreams of individuals taking these medicines have been reduced to undetectable levels.[43]

Cancer

Advances in pharmaceuticals have improved the quality of lives for individuals with cancer by ameliorating some of the adverse effects of chemotherapy. There are now medicines to prevent the associated nausea, restore the energy that is frequently lost with the therapy, and stimulate the often-weakened immune systems of individuals undergoing treatment. At the same time, researchers are discovering medicines that can target cancer cells without damaging healthy cells. An individual involved in a clinical trial of one of these medicines noted:[44]

> *From crawling across the floor on my knees to go to the bathroom, I'm now back at work … This drug is the magic pill people have dreamed of. It's given me the ability not just to survive, but to have my life back.*

Mental illness

Pharmaceutical advances have helped transform mental illness from a misunderstood cause of shame into an easily treatable condition. Medicines for depression help individuals with this disease be productive at work, care for their families, and engage in life. Breakthrough advances in pharmaceuticals for schizophrenia have enabled most patients to be treated outside the hospital, not only reducing medical costs, but also lessening the burden of treatment on the patient and family members.[45]

This underscores the advantages to individuals of pharmaceutical innovation that accompanies societal benefits and the immense value of public support in this area. Indeed, there is a continuing need for public investment into health and medical research focussed on the development of new medicines. For it has been shown that investment into new innovative medicines produce better health outcomes and much greater economic returns than older medicines, which is discussed below.

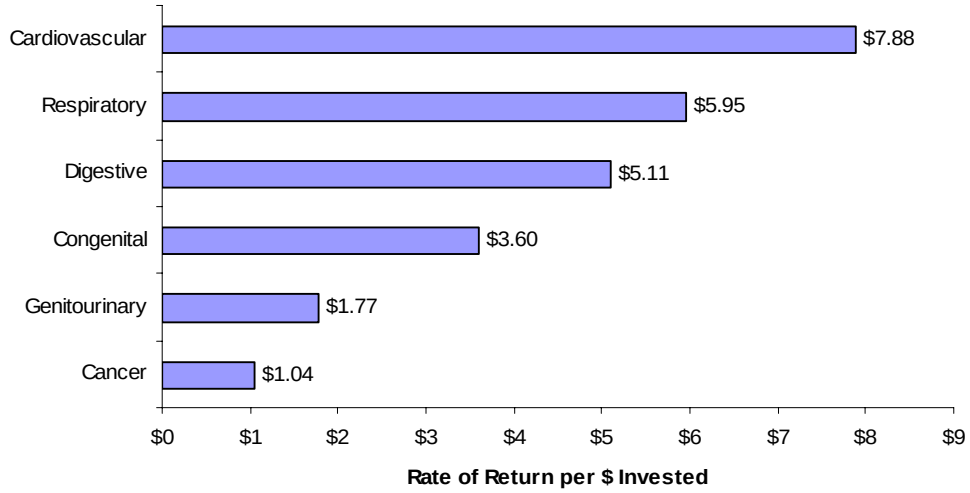
[43] Pharmaceutical Research and Manufacturers of America (PhRMA) 2003, *A Decade of Innovation*. Available at www.phrma.org/files/Decade_of_Innovation.pdf, Accessed 24 May 2006.
[44] Lemonick M and Park A (2001), 'New Hope for Cancer', *Time*, 28 May.
[45] Pharmaceutical Research and Manufacturers of America (PhRMA) 2003, op. cit.

4.3 Cost-effectiveness of Health & Medical Research on Newer Medicines

The societal and economic benefits of pharmaceuticals all stem from an initial investment into health and medical research. Indeed, public support of health and medical research has been described as the best investment of public funds a government can make due to the significant returns it offers society. Research by Access Economics determined that Australian health medical research brought about a rate of return of up to five times R&D expenditure.[46] Figure 4.2 provides a further breakdown of the rates of return for some of the major areas of medical research within Australia. In addition to this research, the Allen Consulting Group demonstrated the cost-effectiveness of public support for programs designed to stimulate medical research in a recently released study finding that every $1 invested in a Commonwealth Cooperative Research Centre caused GDP to be 60 cents higher than it would have been if allocated to general government expenditure.[47]

Figure 4.2

Rates of Return by Major Health Area from Australian R&D, 1999



Source: Adapted from Access Economics, 'Exceptional returns: The value of investing in health R&D in Australia' Canberra, September 2003.

The significant return associated with health and medical research is largely attributable to the development of new, more innovative, pharmaceuticals. Lichtenberg has carried out a number of studies comparing the benefits of newer pharmaceutical agents against old pharmaceuticals. These studies are summarised in Box 4.3 and demonstrate innovative medicines to have a far greater impact on health outcomes, productivity and life expectancy than older medicines. Such findings highlight the importance of ongoing public support for medical research into more innovative and cost-effective pharmaceuticals.

This research illustrates the importance of ongoing public support sufficient to encourage innovative health and medical research with the potential to produce *new* pharmaceutical entities. For these agents carry with them the potential to offer savings above and beyond

[46] Access Economics, 'Exceptional returns: The value of investing in health R&D in Australia' Canberra, September 2003.
[47] Allen Consulting Group, 'The economic impact of cooperative research centres in Australia: Delivering benefits for Australia' Report for the Cooperative Research Centres Association Inc, 2005.

those already significant savings enjoyed by Australia through the use of existing medicines. Future advances in this area would carry significant implications for public spending:[48]

- R&D that could reduce deaths from cancer by one fifth would be worth $184 billion to Australians.
- R&D reducing cardiovascular events by 15 per cent would be worth $34 billion.

This shows even relatively small future advances in the prevention and treatment of chronic disease would carry with it tremendous value. Consequently, these issues reinforce the need for a comprehensive strategy that ensures adequate public support for innovative medical research into the future.

Box 4.3

Benefits of Newer vs Older Pharmaceuticals

Impact of Newer Medicines on Health Outcomes.

People who use newer medications have been shown to display better post-treatment health than people who used older medications for the same condition, controlling for pre-treatment health, age, gender, race, marital status, education, income and insurance coverage. In particular, individuals on newer medications reported higher perceived health status and quality of life, fewer social limitations and more substantial improvements in physical ability.[49]

Impact of Newer Medicines on Productivity

Research has also suggested that those on newer medications are significantly less likely to miss workdays than those on old medicines.[50]

Impact of Newer Medicines on Life Expectancy

A recent study measuring the relationship between launches of new medicines and life expectancy in 52 nations over the period between 1982 and 2001 found 40 per cent of the gain in life expectancy over this period to be attributable to the impact of new medicines. Older medicines were held to have little impact in this regard.[51]

4.4 Conclusions

Although increases in pharmaceutical expenditures have attracted a great deal of attention recently and has been an ongoing concern for the Government for several years, it is the view of GSKA that it is misleading to consider the expenditure on pharmaceuticals separately instead of as part of overall resource use in the healthcare system. This chapter has taken a broader view of the costs and benefits of pharmaceuticals. This leads to a more comprehensive appreciation of the costs and benefits involved, which includes the impact on other forms of healthcare expenditure, and the benefits associated with increases in productivity as well as improvements in general wellbeing and quality of life. Altogether, this

[48] Access Economics, 'Exceptional returns: The value of investing in health R&D in Australia' Canberra, September 2003.
[49] Lichtenberg FR, Pharmaceutical embodied technical process, longevity and quality of life: Drugs as "Equipment for your health" *NBER Working Paper* No. 9351, 2002.
[50] Lichtenberg FR, Are the benefits of newer drugs worth their cost? Evidence. *Health Affairs* (2001) **20(5):** 241-51.
[51] Lichtenberg FR, The impact of drug launches on longevity: Evidence from longitudinal, disease level data from 52 countries, 1982-2001. *International Journal of Health Care Finance and Economics* (2005) **5(1):** 47-73.

chapter highlights the value of innovative pharmaceutical development and leads on to the issue addressed in the next chapter, that is, the current problems with and future potential for public support of pharmaceutical innovation.

5. Promoting Innovative Advances in Pharmaceutical Research

5.1 Current State of Public Support for Research and Development

Advances in pharmaceuticals, which offer the promise of new and more effective medicines to prevent and treat disease, are dependent on continual investment in R&D. From the perspective of pharmaceutical companies, this R&D is complex, carries high risk and comes at a high cost to developers. Developing, testing and gaining approval for a new medication is time consuming and extremely risky as it takes 12 to 15 years on average to bring a therapeutic compound to market at a cost of approximately one billion dollars to the manufacturer. Given the risks involved with these kinds of outlays, it is important that government continues to invest in medical R&D to ensure sufficient incentives exist to encourage industry to continue to undertake innovative health and medical research.

Globally, health and medical research is indeed a growth industry. The Honourable Julie Bishop MP recently described it as a "race to the top… in which you have to run just to stay in the same spot"[52]. Many countries are now acting on the realisation that investment in R&D is a critical component of the economic prosperity of any nation. India and China have recently made significant investments into the R&D sectors of their countries, the European Commission is aiming to increase investment in European R&D to 3% of GDP by 2010 and the United States have declared an intention to double their federal commitment to research programmes over the next ten years and make permanent their tax credit research expenditures. In this context, it is important that Australia's investment in science and innovation keeps pace with international trends.

Initiatives in the Federal Budget 2006-07

In light of the need to keep pace with the level of support internationally for science and innovation, GSKA welcomes the recent announcements made as part of the 2006-07 Federal Budget to increase funding for health and medical research. The investment of $500 million over four years for the provision of additional grants through the National Health and Medical Research Council (NHMRC), and the $170 million over nine years to establish a research fellowship scheme through the NHMRC, are positive initiatives that will help to boost the level of medical research undertaken in Australia. Similarly, the $235 million provided for the development of Australia's physical R&D infrastructure will act as a further incentive for more researchers to become involved in R&D within Australia and will provide them with the facilities and equipment necessary to develop the medical break-throughs of tomorrow.

Such increases in public support act as an indirect stimulus for business investment in this area, as more significant and large scale projects encourage collaboration with industry and innovative companies seek to invest in emerging research in order to ensure the full economic potential of any discoveries are captured.

Whilst these announcements were a positive step forward, more clearly needs to be done in order to lift the level of support in Australia for science and innovation back up to international standards.

[52] The Hon Julie Bishop MP, Address to members of the Federation of Australian Scientific and Technological Society (FASTS) for "Science meets Parliament". 28 February 2006.

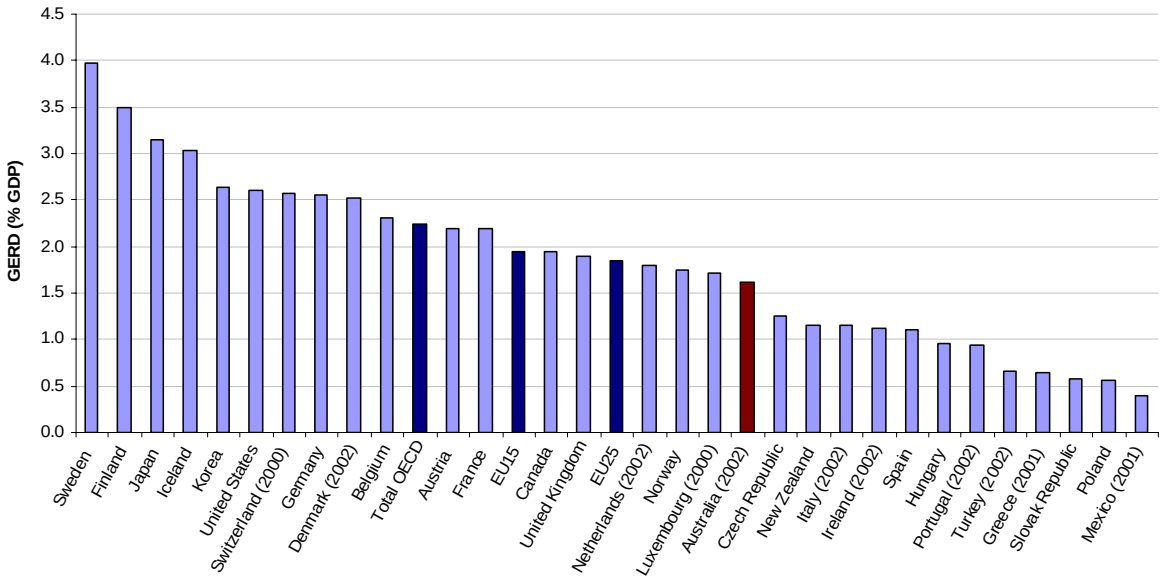
The Current Level of R&D Funding in Australia in an International Context

Gross domestic expenditure on R&D (GERD) is an important indicator as to where Australia is placed as a nation in terms of investment in science and innovation. GERD has increased in Australia as a percentage of GDP from 0.93 per cent in 1980-81 to 1.7 per cent in 2002-03. This rise in GERD has been largely due to increasing levels of business expenditure on R&D (BERD) which has grown from 23.9 per cent of GERD in 1981-82 to 51.2 per cent in 2002-03.

However, this increase in BERD has been largely offset by decreasing government expenditure on R&D (GOVERD) which has fallen from 45.8 per cent in 1981-82 to 19.3 per cent in 2002-03. Therefore, GERD within Australia still currently sits below both the OECD and European averages for this indicator (Figure 5.1). Similarly, between 1995 and 2003, the average annual growth rate of GERD in Australia has also been below average at 3.3 per cent, compared to the OECD average of 3.7 per cent.[53]

Figure 5.1

Gross Domestic Expenditure on Research and Development (GERD) as a percentage of GDP – by OECD country, 2002



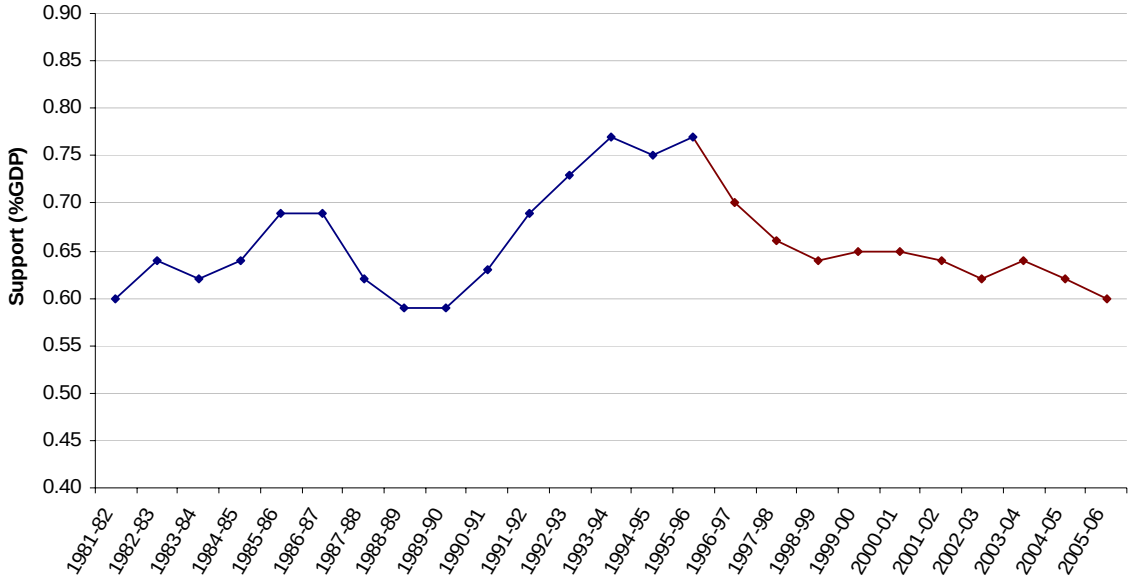
Source: OECD Science, Technology and Industry Scoreboard 2005.

Recently released government data looks more specifically at Government support for science and innovation and tracks changes in the level of this support between 1981-82 and 2005-06 (Figure 5.2). These figures reveal that Government support for science and innovation in Australia increased through the 1980s to a peak level of 0.77 per cent of GDP in 1995-96, but has since declined to the same level recorded in 1981-82 of 0.60 per cent of GDP. With other countries continuing to make significant investments in this area, the lack of expenditure growth in this area in real terms should be of particular concern to decision makers within Australia.

[53] OECD Science, Technology and Industry Scoreboard 2005.

Figure 5.2

Australian Government Support for Science and Innovation as a percentage of GDP, 1981-82 to 2005-06.



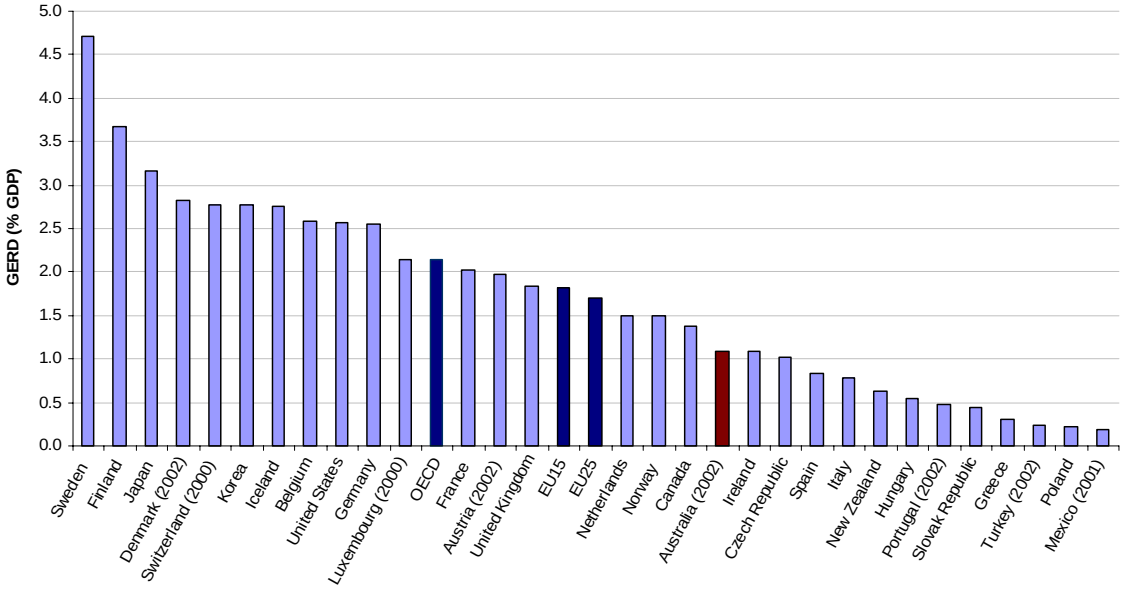
Source: Adapted from DEST publication, *Australian Science and Technology at a Glance 2005.*

5.2 The Need for Initiatives Driving Innovation in the Pharmaceutical Sector

Government programs designed to stimulate business investment in science and innovation are an important means of ensuring Australia remains competitive in terms of its R&D intensity and realises the substantial economic benefits that stem from an active research sector. As mentioned, BERD in Australia has risen over the past two decades, but it still remains below average as a percentage of GDP (Figure 5.3).

Figure 5.3

BERD as a percentage of GDP – by OECD country, 2003



Source: OECD Science, Technology and Industry Scoreboard 2005.

Part of the reason for low BERD in Australia is in part due to the low level of Government incentives in Australia when compared internationally. For example, in 2003 the percentage of BERD financed by government was 4.1 per cent. This is significantly lower than the OECD average of 7.3 per cent and further behind the level of support observed in countries such as the United States and United Kingdom where government finances 10.0 and 10.9 per cent of BERD respectively.[54]

A number of programs have been put in place to encourage investment in R&D activity in Australia (see Box 5.1). However, these programs generally exclude larger companies from accessing the funds or have other requirements that can reduce their value to industry. Indeed, the Innovation and Incentives Working group established in 1999 stated:

> *There has been a significant change in the focus of government incentives to encourage industrial R&D, with much greater emphasis being placed on R&D start grants…the effect of this shift has been to focus greater attention on the R&D efforts of small firms…whilst the Working Group commends this increased focus on smaller firms, we believe the policy pendulum has moved too far towards the granting side.*

The Honourable Kim Beazley MP echoed similar thoughts in his speech on the 10th July 2006, during which he stated:

> *In the past, governments of all persuasions have emphasised the discovery side of innovation - the work that goes on in research institutions and universities. I believe what's been overlooked is the adoption and dissemination of innovation in individual businesses. I'm not saying we have to choose one over the other, but our future innovation strategy must have a stronger focus on what business and industry need.*

There are strong reasons for Government to adopt a stronger focus on the needs of business and industry when considering public support for science and innovation. Firstly, the competition for international R&D investment has made significant Government incentives a necessity for attracting investment from the head office of multinational companies. Secondly, public support encourages additional expenditure on R&D activity above a company's baseline level, leading to more projects which are larger in scale and which involve a greater chance of success. Thirdly, it will help Australia avoid becoming a production 'labour pool' that supplies skills and knowledge to other countries rather than accessing the potential benefits of these skills and employment opportunities through R&D involvement. Lastly, increasing the focus on the needs of industry will begin to ensure that the strong knowledge-base being developed in Australia has the capacity to both deliver ideas to Australian firms and to drive these firms into the future.

Various initiatives have been put in place by the Federal Government in order to encourage BERD. The programs that have had the most significant impact on the pharmaceutical industry in this regard have clearly been the R&D tax concession, co-operative research centres and the Pharmaceutical Industry Investment Program (PIIP), later replaced with the Pharmaceuticals Partnerships Program (P3). However, these initiatives have enjoyed varying degrees of success.

Therefore, the following section will contain a focussed discussion on the effectiveness of the above initiatives as mechanisms of public support more directly targeted at larger firms involved in innovative research.

[54] OECD, Science, Technology and Industry Scoreboard 2005.

Box 5.1

Example Australian Government Initiatives for Stimulating Research and Development

Commercial Ready A program providing $200 million per year in competitive grants to small and medium-sized businesses. These grants support activities ranging from initial R&D, to proof of concept studies and early stage commercialising activities. The size of the grants range from $50,000 to $5 million for up to three years duration. This program is only available to companies with an annual turnover of less than $50 million.
Commercialising Emerging Technologies (COMET) A program designed to support early-stage growth and spin off companies commercialise their innovations. Financial assistance is provided through a two-tier system – the first involving a grant of up to $64,000 and the second making available an additional $56,000 for eligible applicants. Eligible companies must not have a turnover of greater than $5 million.
Industry Cooperative Innovation Program (ICIP) ICIP is a $25 million competitive grants program aimed at supporting cooperative innovation. The program has two funding streams: Stream A is for small scale projects aimed at scoping potential innovations; and stream B is for more extensive collaborative projects. The applicant must lead a consortium of at least three members, two of which must be businesses. Early stage commercialisation is not covered under this scheme.

5.3 Improving the Value of Current Public Support for Pharmaceutical Innovation

Research and Development Tax Concession

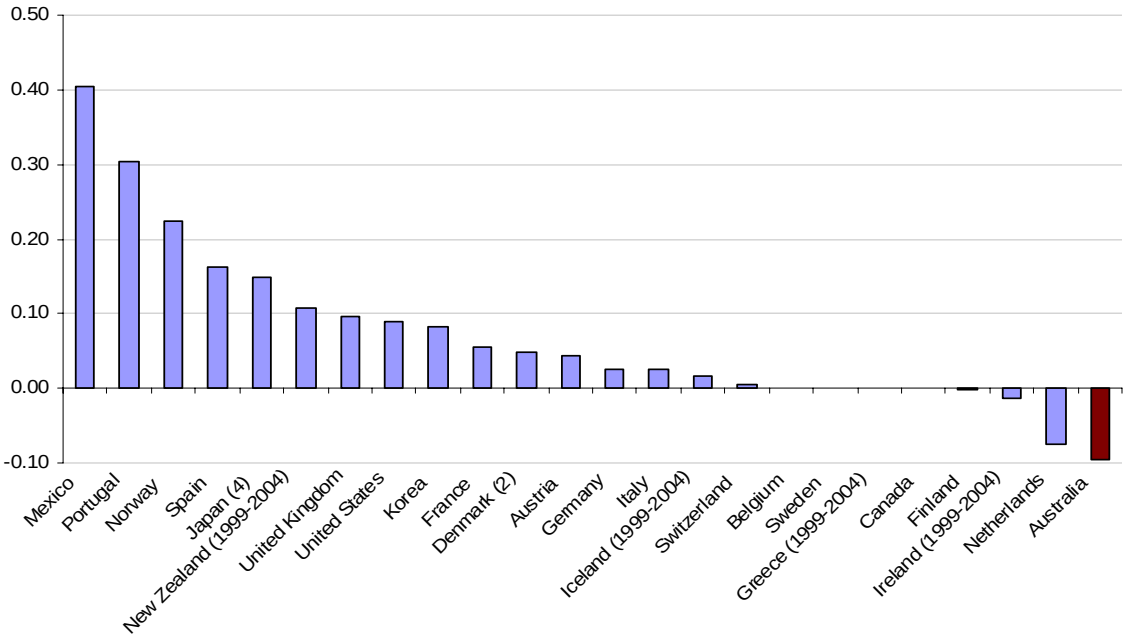
The R&D tax concession is currently the principal initiative to increase the amount of R&D undertaken in Australia. In the 2006-07 Budget, the programme was estimated to provide $414 million in tax concessions to Australian businesses for their R&D activities each year.[55] It is a well-accepted incentive with low compliance costs, which therefore has had a demonstrable effect on increasing BERD within Australia.

However, it should be noted that such tax incentives are not unique to Australia but rather could be considered a minimum standard for an active R&D sector when compared to other international benchmarks. Many competitor nations now offer their own types of tax incentives to stimulate both local and international investment in science and innovation (Box 5.2). In fact, Australia is one of only three OECD nations that has been decreasing tax subsidies for large firms over the past decade, whilst 16 OECD nations have been increasing tax incentives and five have remained stable (Figure 5.4).

[55] The Hon Ian MacFarlane MP, Media Release, 'R&D Tax Concession – A Winner for Business' 9 May 2006.

Figure 5.4

Change in rate of tax subsidies for large firms for US$1 of R&D, 1995-2004



Source: OECD Science, Technology and Industry Scoreboard 2005.

This trend suggests that the tax environment within Australia may not be the most favourable for stimulating science and innovation. Indeed, this is particularly the case in the context of health and medical research due to the "beneficial owner" requirements in place for accessing the tax concession. Under the *Income Tax Assessment Act* and the *IR&D Act* the concession is limited to those entities that hold the intellectual property associated with the R&D domestically. This effectively prevents subsidiaries of multi-national entities, for which head office requires intellectual property to be held centrally, from accessing the benefit and means that a significant proportion of the R&D carried out by members of the pharmaceutical industry is without any significant public support by way of tax incentives. For this reason, overall the tax concession appears to facilitate the mining industry and provide significant support to the information technology sector, but has "strikingly low impact upon the fields of research associated with the medical and bio-science areas".[56]

The Productivity Commission considered the economic value of removing the beneficial ownership requirement for the pharmaceutical industry during their evaluation of PIIP. It was acknowledged as an issue that warranted government action, but that action was recommended as being in some other form of industry assistance oriented to R&D rather than through the creation of an exception to the eligibility requirements unique to the pharmaceutical industry. The implementation of P3 could in part be described as Government's response to that recommendation.

In addition, a House of Representatives report released on 19 June 2006 by the Standing Committee on *Science and Innovation* again considered the case for expanding the eligibility requirements of the R&D tax concession. This report recommended that the Government "assess the revenue implications and potential economic returns of extending R&D tax concessions eligibility to include Australian-based subsidiaries of multinational companies".

[56] Howard Partners, 'A study of government R&D expenditure by sector and technology', Emerging Industries Occasional Paper #3, February 2000.

GSK believes this recommendation should be followed and indeed encourages open and direct consultation on this issue.

Box 5.2

Examples of International Research and Development Tax Incentives

Canada	Offers a permanent 20 per cent flat R&D tax credit. Many provincial governments also offer various incentives for research conducted in their provinces.
China	Offers foreign investment enterprises a 150 per cent deduction for R&D expenditures, provided that spending has increased by 10 per cent from the prior year.
France	Allows a 50 per cent R&D tax credit, including a 10 per cent flat credit and a 40 per cent credit for R&D expenditures in excess of average spending over the two previous years.
India	Allows companies a 100 per cent deduction for 10 years for scientific R&D.
Ireland	Offers a 20 per cent tax credit plus a full deduction, as well as a low 12.5 per cent corporate income tax rate.
Japan	Offers a flat 10 per cent R&D tax credit in addition to other incentives.
United Kingdom	Allows a 125 per cent deduction for R&D expenses, plus a 175 per cent deduction for expenditures exceeding a base amount.
United States	Allows a maximum 10 per cent incremental credit for qualified R&D expenditures in excess of a base amount, as well as an "Alternative Incremental Research Credit" formula.

Factor (f), PIIP and P3

Government initiatives directed at industry such as Factor (f), PIIP and P3 offer significant potential to enhance innovative R&D within the Australian pharmaceutical sector. They offer a practical incentive for firms to make substantial R&D investments that will ultimately bring about economic gains for Australia. However, the design of these programs is clearly critical to them having this desired effect.

From an industry perspective, the design elements present in Factor (f) and PIIP offered a far greater incentive to increase current levels of R&D investment than that offered by its successor, P3. Some of the key differences between these programs and P3 are highlighted in Table 5.1. This shows that overall P3 offers smaller financial incentives which are open to a far greater number of participants. Programmes of this nature are of more benefit to the smaller biotechnology firms due to their greater ability to significantly increase their R&D expenditure from a smaller base, the lower compliance costs experienced by smaller firms and the greater attractiveness of smaller grants for their early-stage research.

There are a range of other funding options open to smaller companies involved in pharmaceutical research such as Commercial Ready and COMET. Therefore, GSK submits

that allowing smaller companies to access funding under P3 has only diluted the effectiveness of this mechanism of public support for innovative research by those members of the pharmaceutical industry which are precluded from accessing other forms of financial assistance. This opinion accords with previous statements made by the Productivity Commission in their review of PIIP, including the recommendation that "participation in any modified PIIP should, therefore, be restricted to firms supplying the PBS".

Table 5.1

Comparison of PIIP and P3

	Factor F	PIIP	P3
Company eligibility	Restricted to companies that: 1) Achieved an export:import ratio of one half within three years. 2) Increase exports of by 33 per cent within three years. 3) Spend a minimum of 3 per cent of turnover on R&D. 4) Increase spending on R&D by 33 per cent within three years.	Confined to companies with products listed on the PBS	Open to all members of the pharmaceutical industry with three years track record in pharmaceutical R&D activities in Australia.
Government allocation	$1 billion over 11 years (approx. $90 million per year)	$300 million over 5 years (approx. $60 million per year)	$150 million over 5 years (approx. $2 million per year)
Entitlement	Payment rate of 25% of increased value added activity and 50% of the increase in post-tax expenditure on R&D above a base level	Payment rate of 20% for expenditure above a baseline level	Payment rate of 30% for expenditure above a baseline level
Max Payment	10 per cent of total PBS product sales	$60 million over 5 years	$10 million over 5 years
# of Participants	10 in phase I and 11 in phase II	9 across phases I and II	18 over two rounds (with one round yet completed)
Avg grant size	Not publicly available	$27 million	$7.4 million

A government initiative that offered more substantial incentives, targeted towards the larger firms in the pharmaceutical sector, would be a more effective addition to current public support initiatives for science and innovation. It would compensate those currently unable to access the R&D tax concession and various other programs available to smaller firms; it would combat the perception of price suppression flowing from the operation of the PBS; it would stimulate larger scale investments in R&D offering real economic benefits through increased employment and commercialisation opportunities; and it would indirectly assist smaller firms through increasing collaborative projects.

Cooperative Research Centres

Cooperative Research Centres (CRCs) are another important means by which Government supports science and innovation within Australia. GSK is currently involved in the Cooperative Research Centre (CRC) for Asthma and Airways. In its current form this CRC consists of a joint venture between GSK, Pharmaxis, the Garvan Institute, Woolcock Insititute of Medical Research and four partnering universities. Our participation in the asthma CRC

has provided access to top researchers and new research, and of course to government funding in an area of research that is in the public interest.

The role of CRCs in encouraging collaboration and partnership is increasingly important in the pharmaceutical sector due to the rising investment in extra-mural research by pharmaceutical companies. Increasing the utilisation of external expertise and resources, particularly for discovery research, is a global trend in industry, as companies turn more of their focus towards the clinical testing of compounds.

However, whilst CRCs are an effective use of public funds for ensuring collaboration in research, it should be understood that the challenge of commercialising research is often more effectively done through other means. For example, the commercialisation of a particular innovation from a CRC can often be undermined by the role of industry partners being limited to the provision of funds. In addition, when many industry partners are present in a CRC, competitive and confidentiality concerns may compromise their ability to assist significantly in the research program. The need for exclusive rights to intellectual property (IP) also hinders the value to individual companies of large CRCs with many industry partners from the pharmaceutical sector. This sets the pharmaceutical industry apart from other sectors (such as the wine industry) in which mere production of technology for use by all parties is of value. However, for the development of medicines exclusivity of rights over a new innovation is critical to its commercialisation, and this hinders the ultimate value of many CRCs in this area. Indeed, this was the experience of GSKA during the first incarnation of the Asthma CRC (see Box 5.3).

GSK submits that whilst CRCs are a positive initiative, they represent just one link in a longer 'supply chain' of R&D. As such, CRCs should not detract from the need for further industry specific programs – such as PIIP/P3 – that can offer further public support for the commercialisation of innovative products. Indeed, better coordination between these types of programs could enable the objectives of increased collaboration and more effective commercialisation to come together.

Currently, there are a large number of collaborative research programs in existence. These include programs administered by the Australian Council (linkage grants, centres of excellence and special centres of excellence), the NHMRC (Centres of Clinical Research Excellence and program grants for broadly based collaborative research), DEST (CRC Program), AFFA (the Rural Research and Development Corporations), and CSIRO (the flagship program). The Australian Stem Cell Centre and the National Information and Communication Technology Centres of Excellence are also examples. There are also some individual offerings which are too small to achieve meaningful outcomes and are unlikely to generate interest.

Collaborative research programs should return value to the Australian tax payer and all collaborating partners. For research intensive firms such as GSKA, that are highly research-intensive, fully global and operate with very long cycle times from discovery to commercialisation, collaborative programs must:

- be of a size and scale to attract critical mass of researchers and industry funding;
- be of a size and scale to attract international attention - this will serve to generate additional investment and attraction of skills;
- encourage the creation of research centres with capabilities that are truly globally competitive;
- conduct quality research that is world class and novel;

- have funding that is long term i.e. ten years;
- be commercially focussed and industry driven;
- have few industry partners to ensure exclusive access to research results;
- be sensitive to commercial partner needs regarding rights and ownership to the outcomes from the research (mainly IP); and
- have application and reporting requirements which are not overly complex or disproportionate to the value of the program.

Most of the collaborative programs listed above do not meet such criteria. The Australian Stem Cell Centre is a good example which is creating some critical mass in a defined area of medical research. It is recommended that the Government undertake work to review the suite of collaborative research programs to ensure they are meeting both the needs of the research base and industry.

Box 5.3

Asthma Cooperative Research Centre

GSKA's Experience in the Asthma CRC

The CRC for Asthma and Airways (CRCAA) has recently undertaken a significant re-structure. In its original form it involved multiple industry partners including GSKA, AstraZeneca, Boehringer Ingelheim, Merck Sharpe & Dohme and Aventis Pharma. Whilst this collaboration generated much high quality 'public good' research, with so many industry partners it meant that the benefit to GSKA, which relies on exclusive ownership of IP to generate returns, was significantly diluted. In addition, the ability of GSKA to engage in high priority competitive commercial research projects which have the highest possible downstream commercial return for the parties was difficult.

In contrast, the CRCAA was re-launched in September 2005 with GSKA acting as the main industry partner in this new collaborative. The Centre now has three main areas of research: advanced diagnosis and monitoring; developing new and superior treatments; and assessing the consequences of adverse air quality. Whilst it has only been in operation for a short period of time, GSKA is confident that the new governance and administrative arrangements will assist in generating better outcomes and providing significant returns to Australia.

5.4 Conclusions

Investment within Australia in R&D remains well below OECD averages. Public support initiatives aimed at lifting both government and business expenditure on innovative research is needed in order to keep pace with a rapidly moving and fiercely competitive international community. A number of publicly funded programs currently exist to support the smaller biotechnology sector. However, it is time to swing the policy pendulum back towards the centre through programs that more effectively target industry investment in cost-effective health and medical research. Each of the tax concession, P3 and CRC programs could be reformed in this regard and it is the belief of GSK that this is necessary in order to ensure the most effective use of funds for supporting science and innovation within Australia.

6. Overall Conclusions

Medicines have clearly had an increasingly important role in society. Past advances have made significant contributions to the overall health, well-being and longevity of society, and future innovations have the potential to take these health and economic benefits to a new level.

Recent discussions regarding medicines have been predominantly focused on the increasing costs of health care, and particularly increasing proportion of Government expenditure needing to be committed to the pharmaceutical benefits scheme. Certainly, with emerging technologies and scientific advances in areas such as pharmacogenomics, treatment costs are likely to rise into the future and present challenges for health care providers.

However, discussions on this point must not omit the significant benefits offered by innovative pharmaceuticals; both direct economic benefits, through reduced health expenditure and worker productivity, and broader societal benefits, including reduced mortality, increased life expectancy and improvements in quality of life. When these benefits are taken into account, the evidence confirms that public support of health and medical research into innovative pharmaceuticals is amongst the most cost-effective investments available to government.

Significant public funds are currently committed to a number of programs directed at assisting the biotechnology sector, yet larger scale investment into health and medical remains to an extent neglected. Each of the major sources of public support for larger scale investment in science and innovation (the tax concession, PIIP/P3 and the CRC program) could be better designed to target the activities of members of the pharmaceutical industry. Indeed, there is a pressing need for industry-specific programs that can stimulate investment in science and innovation in a real way within Australia.

Health and medical research is a growth industry, and one with an outstanding record of achievement in both monetary terms and through returns to our society. New discoveries are now our best defence against the future challenges facing society such as the ageing population and the increasing burden of chronic disease. Therefore, it is critical to ensure that adequate public support is in place to enable Australia to bring these discoveries to the world.