

# **Department of Health and Ageing submission to the Productivity Commission:**

## **Impact of Advances in Medical Technology on Healthcare Expenditure**

### **Executive Summary**

Life expectancy in Australia has grown by 2½ years over the last decade. Expenditure on health has risen as a percentage of GDP at an average of 0.12% a year over this period. The IGR attributed 66% of the increased cost to emerging technologies. Technology appears to be reducing unit costs and increasing the range and quality of services that are delivered.

Other OECD nations have experienced similar patterns of growth with a correlation between growth in per capita GDP and health expenditure per capita. This is fuelled by increased demand and a growing number of services which can be provided. Demand is strong and Australians are choosing to expend more on health services. It is unclear whether this trend would continue should GDP growth slow or stop.

Uptake of new technology is influenced mainly by regulation, subsidies and private investment. With the strong economic growth of the last ten years, a well educated public is demanding rapid access to emerging technologies. The safety, cost effectiveness and efficacy of these are assured by a range of national regulators. In addition, the Australian Government actively influences the price of many new technologies to ensure that the public receive value for money.

The majority of health related research and development in Australia is funded by the Australian Government. The National Health and Medical Research Council has a lead role in setting research priorities. Investment is directed towards national health priority areas and general clinical research as well as encouraging the best Australian talent to work in Australia.

Technology already introduced has improved the range of preventative measures available, made possible earlier and more accurate diagnosis, moved many treatments formerly performed in hospitals out into the community, brought the unit cost down and enabled health treatments which were not previously available. This has come at a cost but without it Australians would require more time in hospital and have poorer health.

Information and Communications Technology (ICT) has potential to further improve the quality of health services and reduce the administrative load. Australia has a historically low investment in ICT compared with other industries and there is potential for some investment in extant technologies which would allow improvements to be realised.

Despite the strong influence of technology, healthcare remains people-centred. Australia is well serviced with healthcare professionals compared to similar OECD nations, although matching providers with areas of need remains challenging. Historic wage growth has increased both the willingness of Australians to invest in protecting and promoting their well-being and the cost of providing healthcare.

## Impact of Advances in Medical Technology on Healthcare Expenditure

Advances in technology have reduced the unit cost of delivering particular health services but increased the range and quality of services that can be delivered. Growth in demand for services, which is partially driven by availability of new and better technologies, has historically outstripped unit cost savings brought about by new technologies. This is expected to continue. The continuing demand for new and better health services will challenge our regulatory regimes, national finances and our health workforce but, if historical trends continue, will also result in better health outcomes for all Australians.

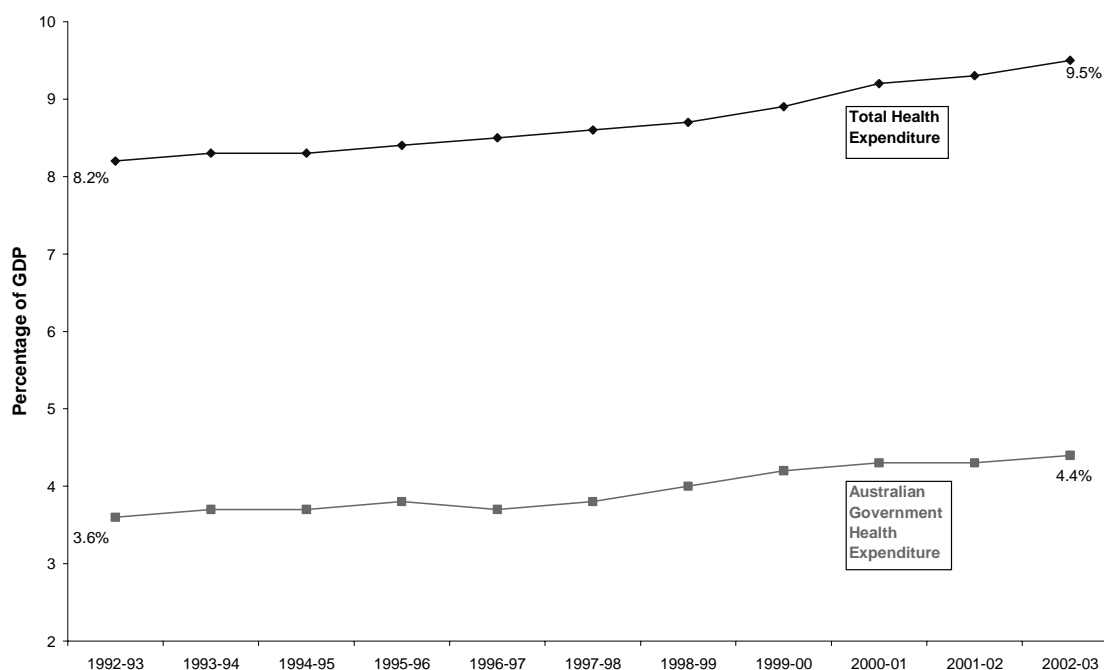
For the purpose of this submission we are using the Productivity Commission's definition of technology which encompasses physical equipment, instruments and pharmaceuticals, clinical procedures, knowledge and support systems. Within these terms advances in medical technology have been the strongest drivers of growth in healthcare expenditure over the last decade.

### *Expenditure Trends in Australia*

#### *Total Expenditure*

The total percentage of GDP spent on health has climbed by about 0.12% a year for the last ten years and was 9.5% in 2002-03<sup>1</sup>. This includes expenditure by all levels of government, private health insurers and individuals. Expenditure by the Australian government has tracked the increases in overall expenditure (Figure 1), but is slightly below growth in out-of-pocket expenses.

Figure 1 Total health expenditure as a percentage of GDP over time<sup>2</sup>



<sup>1</sup> Australian Institute of Health and Welfare (AIHW), 2004, Health Expenditure Australia 2002-03.

<sup>2</sup> Australian Institute of Health and Welfare (AIHW), 2004, Health Expenditure Australia 2002-03 and successive Department of Health and Ageing Annual Reports Australian Institute of Health and Welfare (AIHW), 2004, Health Expenditure Australia 2002-03.

Spending by the Australian government on healthcare has increased in nominal terms from \$11.5 billion in the fiscal year 1990-91, to \$27.2 billion in 2001-02. Expressed another way, the Government's spending on healthcare grew from 2.9% to 3.8% of the economy's GDP, growth of nearly a third in a little over a decade.<sup>3</sup>

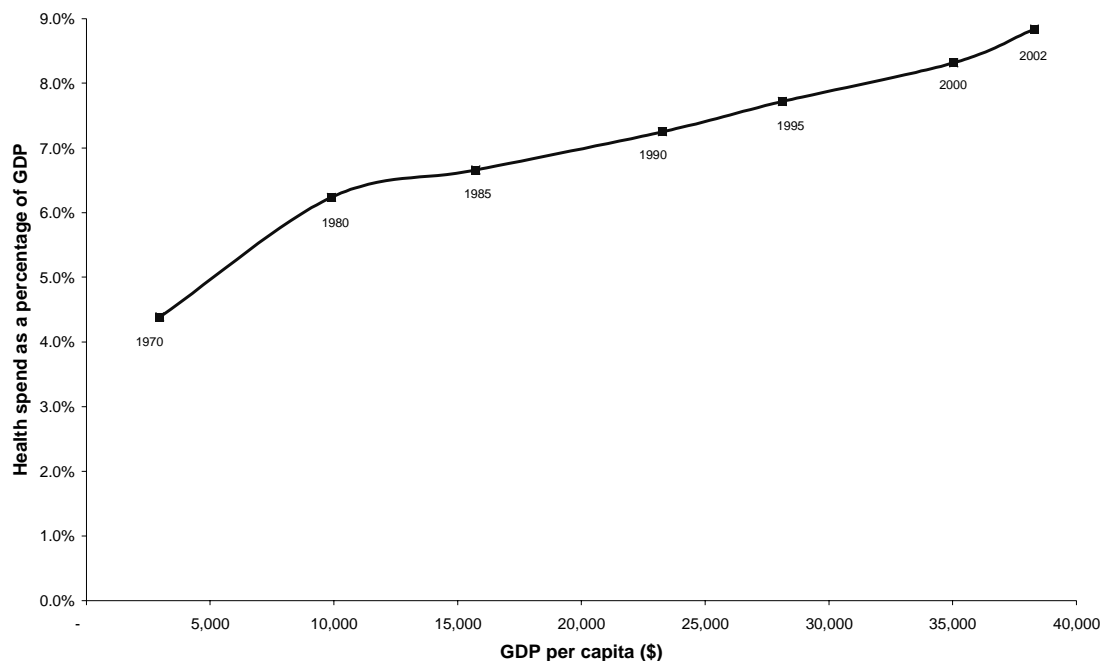
Treasury's *2002-03 Intergenerational Report (IGR)*<sup>4</sup> found that changes to the age structure of the Australian population accounted for only around 10% of the growth over the last decade, with population growth explaining another 24%. The IGR attributed the remaining 66% to advances in technology.

Since then the Department has undertaken more detailed modelling of the health and ageing components. This broadly supports the Treasury findings but is suggesting that the overall rate of growth may be less aggressive than first projected. For instance, following further analysis by the Department using comprehensive data, the Pharmaceutical Benefit Scheme (PBS) component seems to be growing in a manner more closely aligned to linear rather than exponential growth.

### *International Comparisons*

The growth in Australian healthcare costs has been mirrored in all OECD nations. There is a routine correlation between rising per capita GDP and rising healthcare expenditure. As Figure 2 shows, Australia has historically maintained a trend towards spending an increasing proportion of GDP on health as GDP has risen. Health expenditure has risen from 4.4% of GDP in 1970 to around 9% in 2002.

Figure 2 Relationship between rising GDP and health expenditure in Australia 1970 to 2002<sup>5</sup>



The picture is similar at the international level. Figure 3 shows that for selected OECD nations, the general trend in health spending has been the same as Australia's despite occasional discontinuities in funding related to policy decisions. Each nation chooses to adopt

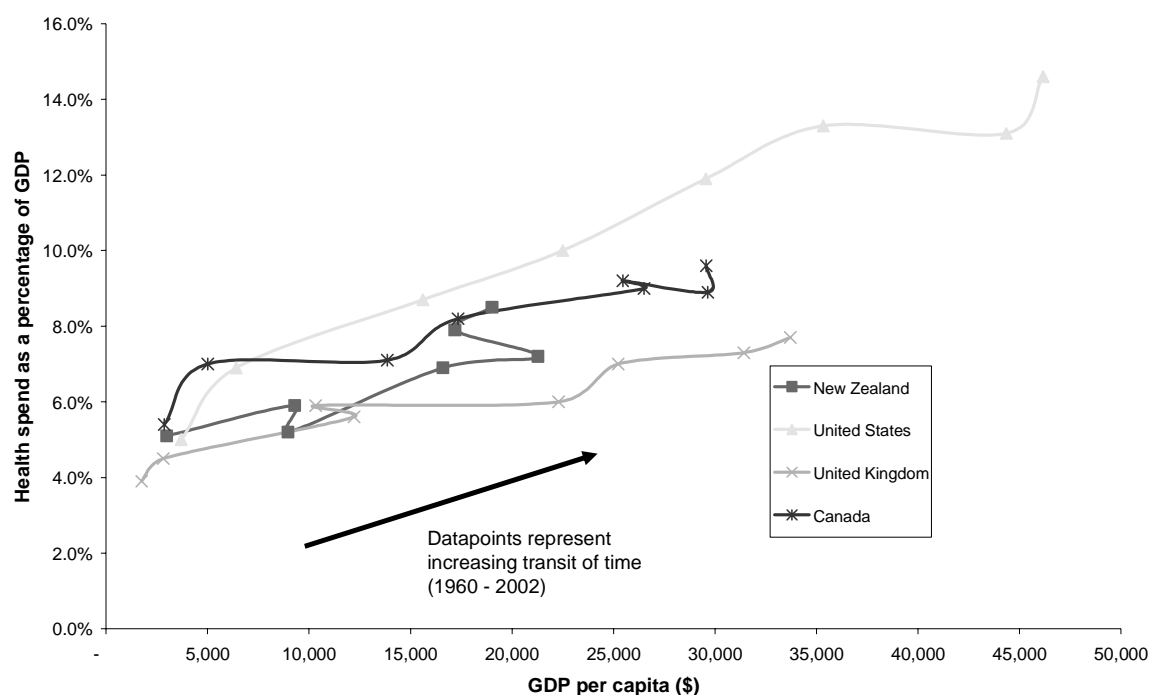
<sup>3</sup> Australian Department of Health and Ageing, 2004.

<sup>4</sup> 2002-03 Budget Paper No.5: The Treasury's Intergenerational Report, [www.budget.gov.au/2002-03/bp5/html](http://www.budget.gov.au/2002-03/bp5/html)

<sup>5</sup> Australian Bureau of Statistics, several sources.

differing models of public healthcare provision, which when aggregated with private health spending leads to different levels of expenditure as proportions of GDP.

Figure 3 Relationship between increasing per capita wealth, and health spending as a percentage of GDP (1960 – 2002) for selected OECD countries<sup>6</sup>



This correlation indicates that healthcare behaves as a *superior* good with demand rising in relation to income. In Australia this is illustrated by the rapid growth in out-of-pocket expenses, which, while still very small compared to investment by government, is growing faster than any other area of spending. The fastest real growth within the non-government area in the last ten years was pharmaceuticals. More than three quarters of the out-of-pocket expenditure on pharmaceuticals is on non-prescription medicines and alternative therapies.<sup>7</sup> Increasingly, Australians who can afford to, are making an investment in preventing illness or improving their general well-being above and beyond the spending on traditional medical care which is still about 70% funded by the governments of Australia.<sup>8</sup>

It is far from clear that by spending more on healthcare, the average health of a nation improves relative to others. The United States for example collectively spends 13% of its GDP on healthcare. This compares to around 9% in Australia, which is close to the norm for all other OECD member nations. However the corresponding life expectancies for those recently born are 74 years for males and 80 years for females in the United States, compared to 77 years for males and 82 years for females in Australia. Other measures which focus on morbidity rather than mortality statistics generally indicate a similar weighting in favour of Australia.<sup>9</sup>

We have no precedent to use in analysing whether a sustained downturn in per capita GDP would be accompanied by a reduction in health expenditure; a phenomenon which is usually

<sup>6</sup> OECD Health Data 2004, 1<sup>st</sup> edition. Comparative analysis of 30 countries (version 6/7/2004).

<sup>7</sup> Australian Institute of Health and Welfare (AIHW), 2004, Health Expenditure Australia 2002-03

<sup>8</sup> Percentage figure drawn from Australian Institute of Health and Welfare (AIHW), 2004, Health Expenditure Australia 2002-03.

<sup>9</sup> OECD Health Data 2004, 1<sup>st</sup> edition. Comparative analysis of 30 countries (version 6/7/2004).

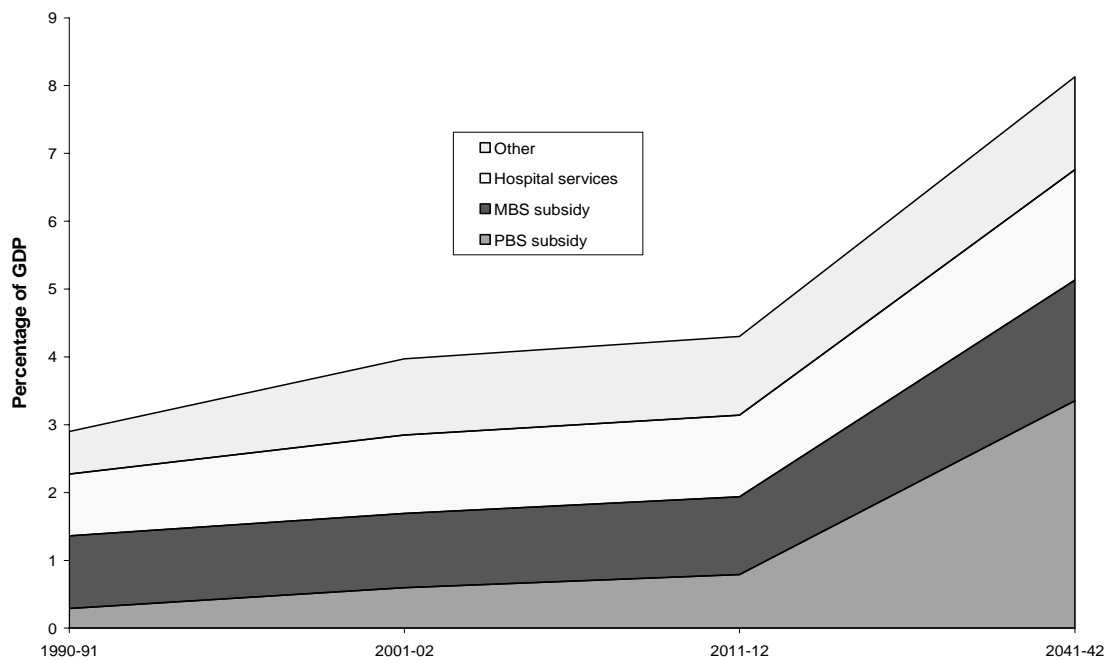
associated with superior goods. It is arguable that the rate of growth in health expenditure largely reflects the will of the electorate. US researcher Thomas Getzen<sup>10</sup> proposes that health care costs are a decision that a nation makes about how to spend its wealth, rather than something that is inflicted from the outside. When high government spending results in tax or debt levels that create concern, the weight of public, political and academic opinion moves towards controlling costs, even where this comes at the expense of services. Conversely, when under funded health systems are no longer meeting the (ever rising) expectations of their clients, the mood shifts and there is increased support for more spending.

The consequences of alternating periods of austerity and plenty in the broader economy provide natural ‘guard rails’ that keep the system in a sustainable equilibrium. Getzen’s research has supported this hypothesis and the history of health expenditure growth in Australia appears to reflect the same pattern. This suggests that it is possible that a downturn in GDP would be followed by a downturn in health expenditure.

### ***Expenditure Break-down***

The split of expenditure between its broad component parts is projected to change considerably over the next 40 years. As Figure 4 illustrates, at the beginning of the 1990s funding to the Medicare Benefits Schedule (MBS) and to public hospitals each comprised roughly one third of total expenditure, with subsidies for pharmaceuticals under the PBS comprising a further 10%. In 2001-02 this situation had shifted with the PBS subsidy growing to nearly 17%, while MBS and public hospital funding declined to 29% and 24% respectively. Projections differ, but by 2041-42 using Treasury figures, these trends are expected to result in MBS and hospital funding having both declined to around 20% each, whereas PBS subsidies will have grown to over 40% of Australian government health service expenditure.

Figure 4 IGR Projection of component parts of the Australian Health System<sup>11</sup>



<sup>10</sup> Getzen, T.E. Population aging and the growth of health expenditures. *Journal of Gerontology : Social Sciences* 1992; 47: S98-104.

<sup>11</sup> Department of Health and Ageing Annual Reports for 1990-1991 and 2002-02. 2002-03 Budget Paper No.5: The Treasury’s Intergenerational Report for 2011-12 and 2041-42.

Much of the recent growth in PBS spending has been due to the introduction of new pharmaceuticals which treat conditions that previously required surgery or were untreatable, and by the replacement of older pharmaceuticals with more effective, but more expensive alternatives. This has led to increases in both volume and unit cost. Measures have been implemented to maintain control of PBS costs such as the recent passing of legislation to increase patient co-payments for pharmaceuticals and the proposal by the government in the 2004 election to ensure an automatic 12.5% reduction in the benchmark price paid for generic versions of existing PBS pharmaceuticals. All new pharmaceuticals are subjected to a net-benefit analysis by the Pharmaceutical Benefits Advisory Committee prior to listing for the PBS.

### ***Summary***

The trend of spending an increasing proportion of GDP on health is likely to continue in line with growing per capita GDP. Advances in technology appear to be the primary drivers of this growth. This trend is shared with other developed nations and reflects the elasticity of demand for this superior good. Over time the proportion of health expenditure spent on pharmaceuticals will grow but less strongly than was indicated in the IGR.

### ***Maintaining public access to new technologies***

The uptake of new technology within the health system is driven by three main factors: regulation, subsidies and private investment by both providers and consumers. The Australian Government conducts most regulation and subsidisation within Australia.

Australians are well educated and can readily obtain information on emerging healthcare technologies. As a highly developed nation we expect to have access to this technology as it becomes available. Increasingly patients are empowering themselves through media such as the internet, which allows them to carry out their own research and then request particular treatments to be made available and to be subsidised through Medicare. In addition, it is argued<sup>12</sup> that private spending on new technologies leads to pressure for public spending to expand and to include these new advances.

### ***Regulation of New Technologies***

The role of regulators is to assure the efficacy, safety, net-benefit and timely introduction of new technologies. The last criterion ensures that any undue delay is avoided but is in tension with the others. New technologies are becoming available with increasing rapidity but they are often also more complex and difficult to assess. Managing this tension is at the heart of effective regulation.

The Australian government funds a range of regulators commensurate with the diversity and complexity of new technologies being developed. The majority of technology-oriented regulation in Australia is carried out at the national level which reduces the number of regulators needed and ensures consistency across the nation. The regulatory environment must change in response to changes in health technologies. Most recently, the Australian government created the Office of the Gene Technology Regulator to ensure that the appropriate expertise is brought to this new and challenging task.

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<sup>12</sup> Chronic Condition: Why Health Reform Fails - Sherry Glied, Harvard University Press, 1997

The following gives an overview of the responsibilities of the eight key regulators. More detail on each of these bodies is available on the internet. References to appropriate websites are included in Annex B. A governance chart for all these and a range of other health management and delivery organisations is provided at Annex C.

- Therapeutic Goods Administration - TGA is part of the Department of Health and Ageing, with responsibility for administering the *Therapeutic Goods Act 1989*. The TGA's key objectives in the regulation of therapeutic goods, which include medicines, medical devices, blood, tissues and cellular therapies, are to ensure that these goods;
  - meet appropriate standards of safety, quality and efficacy; and
  - are made available to the community in a timely manner.

Overall control of the supply of therapeutic goods is exerted through three main processes:

- the pre-market evaluation and approval of products intended for supply in Australia;
- the licensing of pharmaceutical manufacturers and certification of device manufacturer quality systems; and
- post market surveillance.

Annex D describes the activities of the TGA in regulating new technologies.

- Prostheses and Devices Committee - PDC is a Ministerially appointed Committee set up to make recommendations to the Minister for Health and Ageing on the listing of new prostheses, and the setting of benefit levels of new and existing prostheses and devices that health insurance funds will need to cover for their Members with private health insurance. These recommendations will be based on advice from the Clinical Advisory Groups (CAGs), primarily in relation to the clinical effectiveness and relative clinical effectiveness of prostheses and devices, and advice from benefit negotiators in regards to the establishment of appropriate prices for the different effectiveness categories of items.

The CAGs (which are comprised mainly of specialist clinicians) are required to address clinical effectiveness and in doing this will review data relating to:

- absolute clinical effectiveness of individual or groups of prostheses and devices;
  - relative differences in clinical effectiveness between prostheses and devices which are used for the same or similar purposes; and
  - the impact on patient outcomes of the prostheses or devices.
- Office of the Gene Technology Regulator - OGTR was recently established in response to the growing need for an independent, national body to formulate decisions and make rulings as to the legality of any technique which results in the modification of genetic material. This technology is at the cutting edge of science and there are no precedents for many of the decisions made by the OGTR. The Regulator is required to consider and make difficult judgements on a myriad of inter-related social, moral, ethical as well as clinical, financial and legal issues on behalf of the Australian people.
  - Food Standards Australia New Zealand – FSANZ core function is to develop, vary or review food standards, either in response to an application from an outside body or on

its own initiative. Among other duties it provides advice on the assessment of imported foods, provides food safety education and coordinates the recall of food.

- Australian Radiation Protection and Nuclear Safety Agency - ARPANSA was established to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.
- National Blood Authority – While not a regulatory body by definition (the TGA is responsible for regulating the blood sector), the NBA aims to improve the management of the Australian blood banking and plasma product sector at a national level, through the National Blood Agreement 2003 and the National Blood Authority Act 2003. The NBA manages supply contracts on behalf of the Australian, State and Territory Governments and promotes adherence to national safety and quality standards.

### ***Government Influence on Price of New Technologies***

Government influences the price of new technologies through a range of mechanisms including setting fee schedules for government subsidies, bulk-purchasing of goods or services, and incentive schemes. Government directly purchases some services, such as blood and vaccines, and negotiates a price for large volume services such as diagnostic imaging. The price signals sent through these mechanisms influence the pace of technological uptake. Decisions about funding health spending are, of course, constrained by competing priorities for public funds.

### **Medicare Benefits Schedule**

There are two distinct routes by which changes are made to the MBS. One route involves MSAC which strengthens the evidence base of the Schedule by advising the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures, and under what circumstances public funding should be supported for these services.

The second route relates to reviews of existing items on the General Medical Services Table (GMST) of the MBS. The Medicare Benefits Consultative Committee (MBCC) is charged with this role and comprises representatives drawn from the Department of Health and Ageing, the Health Insurance Commission, the Australian Medical Association and relevant craft groups of the medical profession. It is Government policy that reviews of Schedule items conducted under the auspices of the MBCC will be on a cost neutral basis, except for genuinely new items where consideration will be given to providing additional funding.

MSAC's activities complement the MBCC process. Accordingly, applications for the inclusion of new services in the GMST of the Schedule are referred to MSAC for independent evaluation. Following approval by the Minister of an MSAC recommendation for public funding of a new procedure, an appropriate MBS listing for the service will be negotiated through the MBCC process.

### **Medical Services Advisory Committee**

MSAC makes recommendations to the Minister of Health and Ageing about the safety, efficacy and cost effectiveness of new medical technologies and procedures. It is charged with overseeing a process where evidence and science are the only points of reference. It achieves this by ensuring that the results of new research are made widely available so that improved practices may be implemented quickly and universally. The rigorous MSAC process ensures that the gap between research knowledge and clinical practice continues to

narrow, ensures that the adoption of new procedures is not based on anecdotal evidence, and reduces the impact of aggressive marketing.

### Pharmaceutical Benefits Schedule

Listing a new drug or a new indication on the PBS requires preparation of a major submission to the PBAC which includes an economic evaluation. In line with international best practice, the PBAC appraisal process is evidence-based, with the highest level of evidence provided by well designed head-to-head randomised controlled trials against the relevant comparative therapy. However, PBAC will consider any form of clinical evidence.

A number of other relevant factors are considered by the PBAC. These include the clinical need, the severity of the disease, the availability of any alternative treatments, the number of patients affected, the cost to individual patients (in the absence of a subsidy) and the overall costs to the PBS and Government health budgets. A key aspect in this context is the consistency and defensibility of the decision-making.

Following each PBAC meeting, the Pharmaceutical Benefits Pricing Authority (PBPA), in considering the price of drugs, takes into account PBAC's advice on the clinical and cost-effectiveness basis of its recommendation, as well as a number of other factors including the prices of alternative brands, comparative prices of drugs in the therapeutic class, cost information from manufacturers, prescription volumes and overseas prices.

The PBPA interprets PBAC's consideration that the cost-effectiveness ratio of a recommended drug is "high", as an indication that a lower price than that proposed should be negotiated with the manufacturer. Price negotiations are undertaken by the Department of Health and Ageing and are based on PBPA's recommendations. Risk-sharing arrangements such as price/volume agreements, rebates or expenditure caps may also be considered where unit prices are high and/or the potential volumes are high and uncertain, and thus, where there is significant risk that the use of the drug may be outside the population in whom the PBAC considered it to be cost-effective.

The PBPA conducts annual reviews of the prices of all items listed on the PBS. Items are divided into therapeutic groups with drugs that are used for the same purpose being reviewed at the same time. Often manufacturers request pricing reviews, usually as a result of new clinical data becoming available. In addition, the PBAC may sometimes wish to review the evidence on cost-effectiveness and utilisation of certain drugs. Given that the PBS listing price is determined by the value of the incremental health outcome produced by a drug rather than by its on- or off-patent status, pricing reviews are not undertaken when patents expire unless there is a new generic entrant to the market at that time that has a lower price than the originator brand. In such cases the PBS subsidy is limited by the price of the existing product.

### Pharmaceutical Benefits Advisory Committee

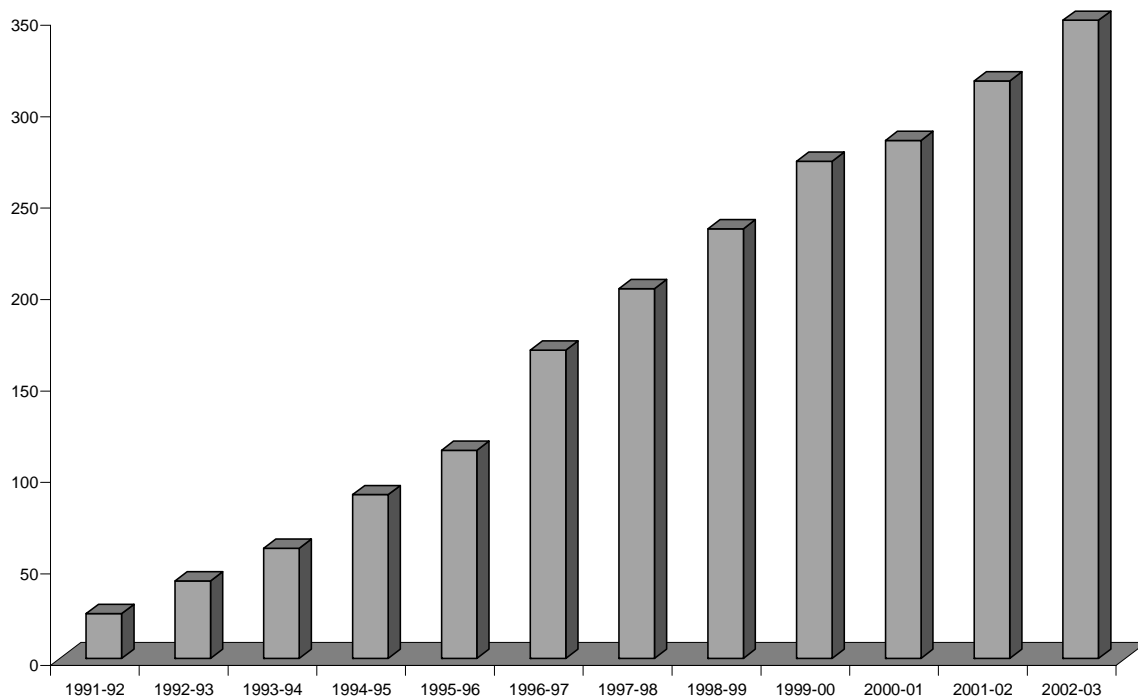
PBAC exists to make recommendations to the Minister for Health and Ageing as to which drugs and medicinal preparations should be made available as pharmaceutical benefits. The Committee is required to consider the effectiveness and, since 1988, the cost of a proposed benefit compared to alternative therapies. The overall goal of the PBAC's appraisal process is to recommend for subsidisation those interventions that provide "value for money" health outcomes. This means that a price higher than that of the therapy likely to be replaced in clinical practice can only be accepted if such price can be justified by the incremental health outcome produced by the new drug. In making its recommendations the PBAC, on the basis of community usage, recommends maximum quantities and repeats and may also recommend

restrictions on when the PBS subsidy should be available. The Minister for Health and Ageing may not add a drug to the PBS unless the PBAC has recommended its listing.

### Highly Specialised Drugs

In addition to medicines subsidized under the PBS, the Highly Specialised Drugs (HSD) Program exists to allow the funding of new medication technologies for chronic conditions that, because of their clinical use or other special features, are restricted to supply through hospitals which have access to appropriate specialist facilities. The process of selecting and reviewing medicines and procedures is the responsibility of the Commonwealth/States and Territories Highly Specialised Drugs Working Party, which subsidize them once a favourable recommendation has been made by PBAC. There were 50 drugs subsidized under the HSD Program during 2002-03 with the largest single class being HIV/AIDS antiretroviral agents which represented \$81 million of the total expenditure of \$349 million in that year. Figure 5 shows that there has been more than a ten-fold increase in expenditure on the program in the last decade.

Figure 5 Highly Specialised Drugs Program expenditure – constant \$ millions (1991-92 to 2002-03)<sup>13</sup>



### Vaccines

In an historical context, extremely cost-effective advances in public health were achieved through the enactment of government policies which made clean drinking water and sewerage services available to most Australians. More recently, national immunisation programs have yielded huge benefits by vaccinating large numbers of people against measles, smallpox, polio and whooping cough at relatively small cost.

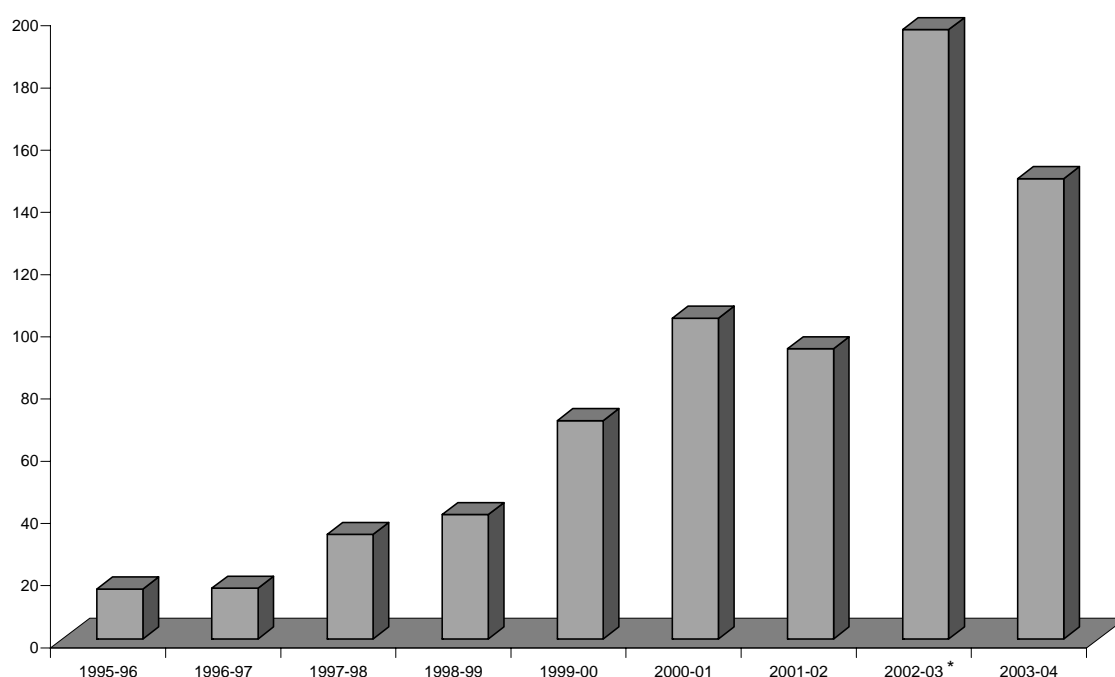
In the 21<sup>st</sup> Century however, many of these obviously cost effective measures have been exploited. The best use for the next dollar is now more difficult to discern. For example, vaccine funding cost the taxpayer an estimated \$13.3 million in 1995 and targeted common

<sup>13</sup> Department of Health and Ageing, 2004

diseases such as measles which had a significant impact on the community. This had escalated to \$148 million by 2003-04 (Figure 6) and now includes rarer diseases which were not previously vaccine preventable such as meningococcal C.

Future funding decisions about vaccines are likely to become progressively more difficult. The trend towards purchasing more and more expensive vaccines which target rarer conditions is not sustainable indefinitely. For example, emerging gene technologies may permit highly expensive individual genetic screening linked to personalised vaccination programs. The degree to which such programs will be funded from the public purse will need to be determined. Rapid development of new technologies will increasingly place this sort of decision before governments and ultimately before the Australian people.

Figure 6 Australian Government funding of vaccines – constant \$ millions (1995-96 to 2003-04)<sup>14</sup>



\* Expenditure in 2002-03 reflected additional catch-up spending on the National Meningococcal C Vaccination Program.

#### Australian Technical Advisory Group on Immunisation

ATAGI was established in 1997 by the Commonwealth Minister for Health to advise and make recommendations on the technical and scientific elements of the National Immunisation Program. Since this time, ATAGI recommendations have informed the development and implementation of every technical change to the Australian Standard Vaccination Schedule and the National Immunisation Program.

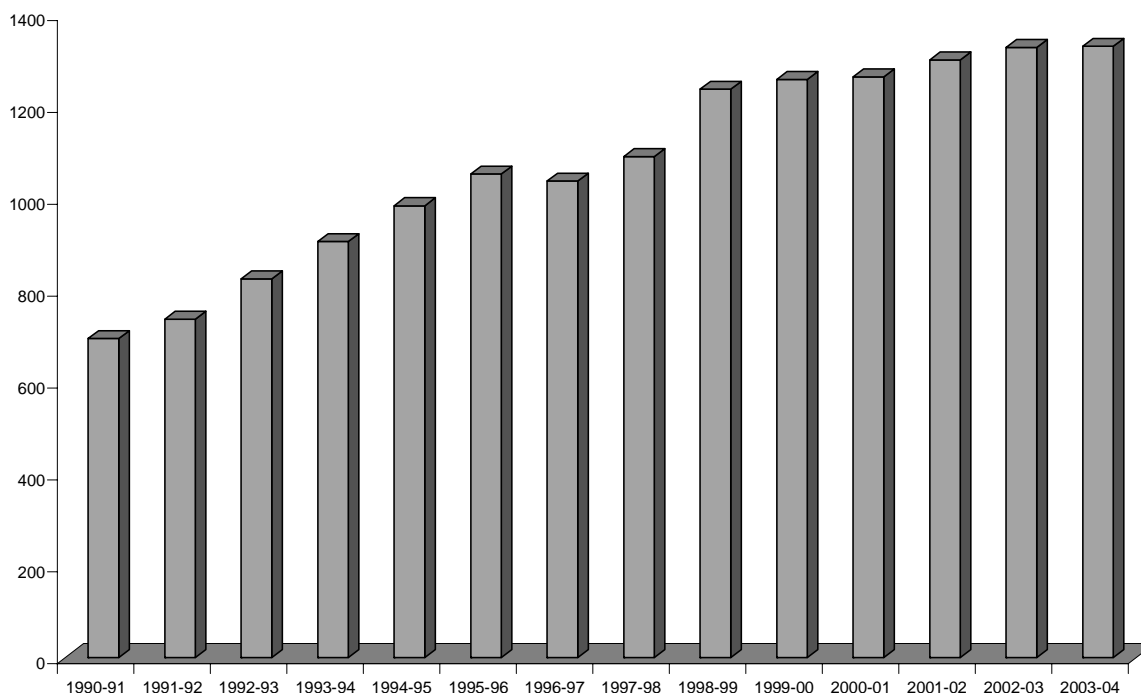
#### Diagnostic Tests

Memorandums of Understanding (MoU) for Medicare-funded diagnostic imaging services have been established between the Australian government and relevant peak bodies as a

<sup>14</sup> Department of Health and Ageing, 2004.

mechanism to promote access to quality and affordable services for patients. These MoUs cover radiology, cardiac imaging, nuclear medicine and obstetric and gynaecological ultrasound. Collectively they ensure that spending on diagnostic imaging services will remain within defined tolerances for given five-year target periods. The current agreement covers the period from mid 2003 to mid 2008 and is funded at \$7.5 billion. Figure 7 demonstrates how effective this mechanism has been in constraining cost growth.

Figure 7 Australian Government funding of Diagnostic Imaging services – constant \$ millions <sup>15</sup>



### Pathology Services

The latest in a series of MoUs between the Australian Government and the pathology industry was recently signed. It commits more than \$8 billion for pathology outlays under Medicare over the period 2004-05 to 2008-09. This provides for a growth rate of about 5 per cent a year over the five year term. Almost 85 per cent of pathology tests ordered by doctors under Medicare are bulk-billed. The MoU is designed to maintain this rate and keep out-of-pocket costs for patients down.

The agreement provides extra funds of almost \$4 million to train pathologists. It also provides \$10 million for the Quality Use of Pathology Program which will support research into consumer needs, increased use of IT and information for GPs.

### Blood Products

The blood sector faces unique challenges in terms of the ability of the Government to influence the price of new technologies, in that the 'starting material' for the blood supply is provided voluntarily, and unlike the MBS or PBS, blood products are provided free of charge to all Australians. Cost-effectiveness studies for new technologies in the blood sector also present particular challenges in that the safety, adequacy, security and consumer confidence of the blood supply, are often considered of greater importance than subsequent cost outlays, demonstrated by the frequent adoption of the precautionary principle in relation to national blood policy decision-making. In the blood sector, it is not unusual for governments to agree

<sup>15</sup> Department of Health and Ageing, 2004.

to take preventative action in the face of scientific uncertainty, for example, implementing more rigorous donor screening measures in relation to the potential for variant Creutzfeldt-Jakob disease to be transmitted through the Australian blood supply.

Despite the complexity and rapidity of technological change in blood products and services, much improved cost-effectiveness has been achieved by the NBA through more effective procurement arrangements such as competitive tendering and redressing the information asymmetry between Governments and suppliers of blood and blood products. The latter approach has been achieved mainly through significant, effective investment in developing negotiation and business strategies for large scale supply contract negotiations.

These procurement approaches have resulted in a range of fixed price blood product supply contracts which provide Governments with better tools to manage demand and cost escalation, through the NBA. These contemporary supply contracts have the capacity to assist in controlling government expenditure in future years, whereas in the previous environment Australian Governments were faced with ongoing, significant cost escalation in their financing of the supply of blood products in Australia.

Apart from the actual establishment of the NBA, the implementation of the tendering, contract negotiations and contracting approaches is the tangible implementation of the government-agreed reforms to the blood sector in Australia flowing on from the recommendations of Sir Ninian Stephen's *Review of the Australian Blood Banking and Plasma Product Sector, March 2001*.<sup>16</sup>

### Prostheses

For the major groups of prostheses, Clinical Advisory Groups, comprising of specialist clinicians, will be asked to examine existing products listed on the Prostheses Schedule and group them into like products. To date six major categories of prostheses have been examined. These are hips, knees, cardiac stents, pacemakers, defibrillators and intra-ocular lenses. Together, these account for about 65% of total benefit paid by health funds. A further six categories will be examined in 2005.

Benefit negotiators will liaise with individual suppliers and make recommendations on the appropriate level of benefits to apply for individual prostheses. It will take as its base advice provided by the Clinical Advisory Groups on the product groupings and, where available, clinical effectiveness and relative clinical effectiveness of products.

For each group of products listed above there will be at least one product that will have a listed benefit at a 'no gap' level. That is, the health funds will fully cover the products that are listed at 'no gap' for their members with appropriate cover. Where suppliers do not agree to the benefit level recommended, and there are alternatives available at the 'no gap' level, products will be listed with a 'gap'.

For products listed with a gap, the difference between the 'no gap' benefits for the alternatives and the price charged by the supplier, will need to be met by the patient or in some cases, the health funds may choose to fund but charge a higher premium.

Under the new arrangements, there will be some inclination for sponsors to list their products at the 'no gap' level in order to retain market share. However, the main impact of the new arrangements is expected to be on new products where sponsors requesting a higher benefit

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<sup>16</sup> <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-mediare1-yr2001-mw-mw01049.htm>

will be required to establish that their product(s) has clinical advantages over existing listed products.

Implementation of the new arrangements is subject to the passage of the National Health Amendment (Prostheses) Bill 2004 which is currently before Parliament.

Although the Bill is still before Parliament, the work already completed will be taken into account when issuing the next Prostheses Schedule. The Prostheses Schedule to be issued in February 2005 will list products in the groups recommended by the Clinical Advisory Groups but will not have benefit amounts assigned. Negotiations on benefit amounts are expected to be completed in time for a revised Prostheses Schedule with assigned benefit to be issued by June 2005.

### ***Challenges of managing technological growth***

In addition to exerting supply side control, it is also necessary to manage the ever increasing demand for health care services under Medicare in order to ensure our publicly funded health system remains viable into the future.

Over the period 1984-85 to 2001-02, the total number of medical services funded under Medicare grew in per capita terms by 55% from 7.2 to 11.2 services per person per year. A third of this increase arose in pathology items, up from 1.4 to 3.5 per capita. Other areas to experience strong growth included diagnostic imaging – up from 0.3 to 0.7, and ‘other services’, such as radiation oncology – up from 0.2 to 0.3. The majority of these increases have been strongly influenced by technological change.

Allied to the development of new tests and the automation of many existing ones has been the emerging trend towards treating many conditions outside the hospital setting. Collectively this has resulted in significant spending growth under the MBS. As Table 1 shows, growth rates for MBS expenditure in the new technology areas of ultrasound, computerised tomography, nuclear medicine imaging and radiation oncology have been significantly greater than the average.

Table 1 Real growth in contributions to Non-Hospital MBS services, 1984-85 to 2001-02<sup>17</sup>

	Commonwealth	Patient	Total
Unreferred Attendances	66%	65%	66%
Specialist Attendances	26%	158%	42%
Pathology	64%	-33%	57%
Ultrasound	318%	845%	363%
Computerised Tomography	246%	939%	270%
Radiology (X-Rays)	-6%	31%	-3%
Nuclear Medicine Imaging	643%	700%	646%
Radiation Oncology	305%	349%	310%
Total	64%	96%	67%

The table shows that patient contributions for out of hospital services increased by half as much again as Commonwealth expenditure over the period. The increase in patient contributions for these service types can be attributed to the shift from public institutional services to private non-hospital services, technological advances and changing consumer expectations. This trend is likely to continue as governments seek to restrain demand and so ensure ongoing affordability. However as more services are tending to be provided outside a hospital setting, without the financial protections available through public hospitals and private health insurance, there is an increasing need to safeguard vulnerable patient groups from accumulating out-of-pocket costs. This is especially the case for those who have chronic conditions or multiple health problems which require a combination of treatments. The *Strengthening Medicare* implemented by the Government in 2004 addressed this concern by introducing a safety net which covers 80% of out-of-pocket expenses above a specified threshold.

### **Summary**

The Australian Government through the Department of Health and Ageing funds a comprehensive range of regulators. Collectively they ensure the public continue to have timely access to new technologies which are proven to be safe and effective. Through a variety of mechanisms, the Government is able to influence the price of those new technologies to promote affordable healthcare provided by a sustainable healthcare industry.

### **Investment in Research and Development**

Research and development into new health technologies influences access to new technologies and supports the development of technologies needed by Australians. The majority of health research is funded by the Australian government. In 2002-03 the Australian government spent \$742 million on health research. A further \$175 million was

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<sup>17</sup> [http://www.aph.gov.au/Senate/committee/medicare\\_ctte/submissions/sublist.htm](http://www.aph.gov.au/Senate/committee/medicare_ctte/submissions/sublist.htm) Submissions 54, 54a and 54b.

provided by State, Territory and local government with non-government sources contributing \$373 million.

The key body in determining the national priorities for investment in health research is the National Health and Medical Research Council (NHMRC) which is part of the Department of Health and Ageing. The Council has played a pivotal role in providing independent, strong advice on all aspects of health and healthcare delivery in this country since 1937. This is done by managing the complementary functions of funding health and medical research, providing ethical guidance on health and medical research issues, and offering advice on health.

Considerable public funding is committed through the NHMRC for researching all forms of diseases and assessing how best to prevent, treat and cure them. The Australian government has boosted its commitment to Australian researchers by over \$220 million spread over the period 2004-05 to 2008-09. The funds are to be used to research the nation's major health problems, including cancer and heart disease. Projects are also to be funded which will tackle the obesity epidemic, including a study of the activity patterns of pre-school children. There will also be financial support for research to identify the genes responsible for high blood pressure, multiple sclerosis, anxiety and depression.

In addition to funding research for specific national health priority areas, commitments are made to encourage innovative clinical research of a more general nature. Funding for seven new Centres of Clinical Research Excellence has lately been announced which will provide excellent training opportunities for new researchers.

A recent innovation has been the funding of awards which allow our best expatriate researchers to undertake research here in Australia. In 2002 this program was successful in bringing home Nobel Prize winning scientist, Professor Peter Doherty who continues to make considerable contributions in the field of immunology. Further information about the NHMRC can be obtained in the supplementary reading at Annex B.

### ***Summary***

The Australian Government funds the majority of health research in Australia, sets priorities and distributes substantial funds to health researchers. Preference is given to projects which have the potential to reduce morbidity and mortality in the national health priority areas.

## ***Effect of Technology on the Health System***

### ***Health Outcomes<sup>18</sup>***

In the last ten years Australian life expectancy has increased from 74.5 to 77.4 years for men, and from 80.4 to 82.6 years for women, ranking Australia 4<sup>th</sup> highest in the world in 2002. This improved life expectancy should be considered in the context of overall disease prevalence and the latest measurements of health risk factors as reported by the Australian Institute of Health and Welfare.

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<sup>18</sup> AIHW Australia's Health 2004 publication

## Disease Prevalence

The major burden of disease nowadays arises from long-term conditions such as cardiovascular diseases, cancers, mental illness and nervous system disorders, with a much smaller contribution from infectious diseases. Cardiovascular disease is still the leading cause of death among older people despite a marked drop since the late 1960s. Cancer ranks second, although overall death rates dropped between 1992 and 2002. Cancer now kills more middle-aged Australians than cardiovascular disease. Diabetes prevalence has more than doubled over the past two decades and is estimated to affect more than one million adults in this country. Hepatitis C is the most frequently reported notifiable infection in Australia, affecting an estimated 1% of the population, or 150,000 to 200,000 Australians, with approximately 8,000 to 10,000 new cases each year. Around 15,900 people were living with HIV/AIDS in Australia in 2004, with an incidence of around 600 new cases per year<sup>19</sup>.

## Health Risk Factors

The prevalence of obesity among adults aged 25-64 years has doubled over the last two decades, with around 20% now regarded as obese. Over the same period, numbers of Australians suffering high blood pressure has more than halved, but this still amounted to 3.7 million people over the age of 25 years in 1999-2000. One in five adults smoked daily in 2001, compared with 70% of men and 30% of women in the 1950's. Around one in ten people drink alcohol at levels that risk harm in the short and long run. About one in six Australians aged 14 years and over in 2001 reported using an illicit drug during the previous 12 months, however there is no clear trend in overall illicit drug use since 1991.

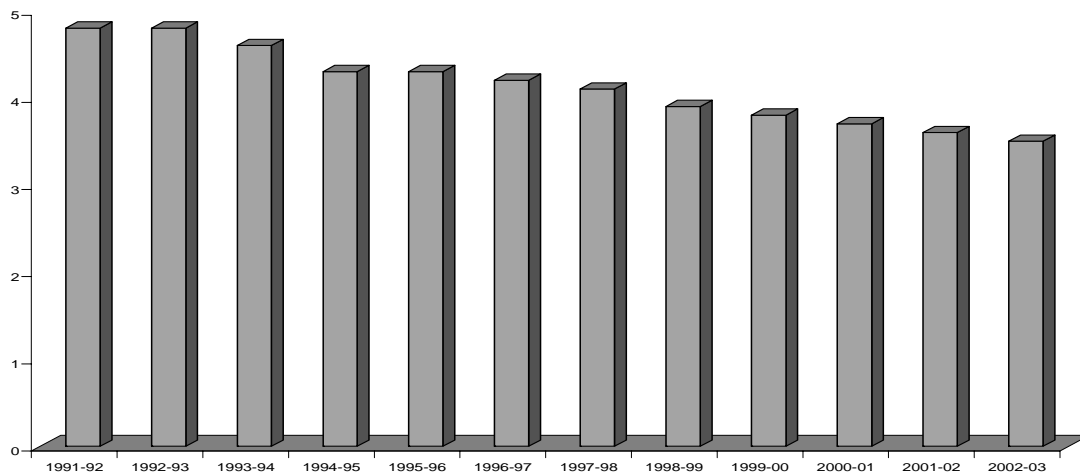
## ***Efficiency Improvements in Hospitals***

In general, technology in the broadest sense has served to reduce the unit cost of specific outcomes but also to increase the range of outcomes which are achievable. Historically the latter has outpaced the former in health care. Reduction in unit cost is clearly illustrated by the reduced average time spent in hospital (Figure 8) resulting from alternative models of care, better diagnostics, improved techniques such as keyhole surgery and better ambulatory care. All of these fall within the Productivity Commission definition of technological advancement.

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<sup>19</sup> June 2004, Senate Community Affairs References Committee: Hepatitis C and the blood supply in Australia, Commonwealth of Australia

Figure 8 Average length of stay (in days) in Australian hospitals (1991-92 to 2002-03)<sup>20</sup>



While no genuine counter-factual can be produced for what the requirement for hospital beds would be had no technological advancements occurred, the 27% reduction in average duration of a hospital stay indicates that substantially more bed days – with consequent workforce and infrastructure costs - would have been required if the changes of the last ten years had not occurred.

However many hospital episodes would not have occurred if there was not this technological advancement. For example same day endoscopes have become a major diagnostic and therapeutic procedure which results in hundreds of thousands of new hospital episodes. So while the average length of stay is decreasing, overall the total bed days has not changed greatly due to the increased volume of episodes. This is a further illustration of the trend for technology to reduce unit cost but increase the range and number of services.

Savings in unit cost of delivering services within a hospital are difficult to harvest. The introduction of new technology changes the pattern of expenditure in complex ways and queuing ensures that there is always pent-up demand. The introduction of new imaging techniques for example, has reduced the requirement for initial exploratory operation and supported the use of laparoscopic (or ‘keyhole’) surgery. The new technique is clearly beneficial from the patient’s perspective, and a cost saving is realised in terms of operating room time spared. However net savings are difficult to quantify since the new imaging equipment has purchase and maintenance costs, the time saved by the surgeon with that patient will generally be used to treat others who still remain on the waiting list, and as services continue to become less invasive latent demand is likely to emerge.

In addition to the direct benefits to patients through reduced time in hospital, many new technologies have reduced labour cost or enabled a single highly trained individual to effectively service more patients. The increasing use of automatic medicine dispensing carts in hospitals will, for example, reduce both the time taken to administer drugs and the incidence of patients who accidentally receive the wrong medication. Preliminary results from a recent early implementation of electronic medication management in hospital (Northern Territory 2004) was reported<sup>21</sup> as achieving a reduction of nurse drug round duration from 1 hour to 20 minutes.

<sup>20</sup> AIHW Australian Hospital Statistics (several editions)

<sup>21</sup> National Health IT Summit 2004

### *Accessing Treatment Outside Hospitals*

Ironically, although many new technologies are first introduced into the larger hospitals, the evolution of that technology often has the effect of making particular treatments more portable and widely available.

Today new information and communication technologies bring expertise out of hospitals to the wider community and have enabled teleconsulting by RFDS doctors using modern communications equipment to prescribe medicines which are made available at over 3,500 medicine chests located across the country. Innovative applications of technologies, such as medical alert call-out and incontinence management are enabling more older people to stay in their homes. In the future, Australia-wide accessibility of a patient's health record should enable people to achieve a high level of continuity in their health care even if they are highly mobile.

In some cases new pharmaceuticals provide alternatives to hospital treatment. Consider developments in the treatment of blood anti-coagulants. An operation involving surgical removal of potentially harmful blood clots was once the standard treatment. However with the development of anti-coagulant pharmaceuticals such as Warfarin, and more recently antiplatelet pharmaceuticals such as Clopidogrel, such technological advances have eliminated the need for invasive surgery for many patients who are judged to be prone to strokes and heart attacks.

### *Prevention*

Increasingly new medicines are being developed that can reduce the risk of some diseases before they become apparent. Over the decade to 2002, the number of Australians dying from cardiovascular disease has dropped from 54,912 in 1992 to 50,295 in 2002<sup>22</sup>, representing a decline in the age-standardised death rate by over a third (35.6%) during this period. This is at least in part attributable to the use of preventative pharmaceuticals. 2000-01 figures for the use of antihypertensive agents and lipid lowering drugs (primarily statins) indicated that in 87% and 80% of cases respectively the use was preventative rather than a treatment<sup>23</sup>. Statins are effective in reducing the mortality rate associated with cardiovascular disease but costs can be high, especially where treatment is of an extended duration (Table 2).

Table 2 Cost of the three most widely prescribed statins to the PBS, for the 12 months to October 2004

<i>Statin</i>	<i>Cost (\$ million)</i>
Atorvastatin	368.6
Simvastatin	333.7
Pravastatin	114.3

The use of information technology to estimate patient risk and follow up individuals could promote more effective treatment, reduce the number of people taking this medication unnecessarily and reduce costs.

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<sup>22</sup> AIHW GRIM Books Version 7 (2004) – All circulatory diseases (ICD10 I00-I99)

<sup>23</sup> AIHW Health system expenditure on disease and injury in Australia 2000-01, (May 2004)

Research in UK and Australia has shown up to 50% of patients with established heart disease are not being targeted with technology which can reduce the onset of recurrence by 30% over a five year period. Research in Australia on those undergoing preventive therapy, where there is no previous vascular disease, shows that upwards of 30% of treatment is unlikely to benefit the patient over a 5-10 year period. In other words prevention of vascular disease needs to be targeted at those with previous disease (to delay recurrence) and those at high risk due to a confluence of risk factors. Any decrease in the costs of medications achieved by improved targeting may well be offset by increased costs where under treatment occurs in high risk groups. The net result will certainly be improved patient outcomes, decreased costs to treat recurrence of vascular disease and most likely some decrease in the rapid growth of the use of these medications due to improved targeting of therapy.

### ***Early Detection***

General Practitioners make extensive use of pathology diagnostic tests. The utilisation rate of such tests has increased by 14% per annum in recent years. Pathology test efficiency has been affected by improvements in automation techniques and the application of technology to detect ever more diseases from a single sample submitted for analysis. Such technological improvements are not cheap to develop however, so they lead to expenditure increases for the MBS, PBS and our public hospitals. These are projected to easily outstrip the contributions to cost that will be made by population growth and the effects of an overall ageing of the population, which both imply a greater need for health services.

### ***Summary***

Technology has improved the range of preventative measures available, made possible earlier more accurate diagnosis, moved many treatments formerly performed in hospitals out into the community, brought the unit cost down, and enabled health improvement treatments which were previously not available. This has come at a cost, but without it Australians would have poorer health outcomes and require more time in hospital.

## ***Information and Communication Technology (ICT)***

Advances in information technology and allied data management are bringing improvements to healthcare support services, knowledge resources and to the understanding of healthcare.

Numerous reports have identified that the health industry is highly information dependent, yet this industry has low take-up of electronic information management when compared with other service industries such as banking and travel. Possible drivers for the low take-up include:

- Diffusion of market drivers (service providers are often at a distance from cost and quality control measures);
- The environment of scarcity and price control resulting in pent up demand for existing services; and
- The opportunity cost of investment in infrastructure at the expense of addressing immediate service provision needs.

The uptake of ICT has been patchy with great variability within and between specific health sectors. These differences are also mirrored internationally with comparable countries having different experiences with modernisation of information management systems. Australian General Practice has adopted computerised prescribing, results management and accounting

to a large extent. This has taken over a decade to accomplish with a Commonwealth investment in support and incentives of approximately \$520 million.

It is difficult to find many rigorous economic analyses of the costs and impact of electronic information management in healthcare. However based on some analyses Australia is lagging behind the US, Canada and the UK in terms of global investment in ICT. The United States General Accounting Office (GAO) in a review of “Information Technology: Benefits Realized for Selected Health Care Functions – Oct 2003”<sup>24</sup> has selected a dozen case studies demonstrating the costs and benefits of ICT. A salient feature is the global ICT expenditure level in the US, with organisations committing between 3% and 5% of total enterprise budget to ICT. Again it is difficult to obtain expenditure figures for Australian organisations however our assessment is that the expenditure does not exceed 1%.

### *ICT for Support Services*

Recognising that less than 10% of US hospitals have electronic clinical information systems, the GAO study examined early adopters and centres of excellence to ascertain the types and levels of benefits that can be achieved. The GAO report, covering 10 varied healthcare organisations, found 13 examples of cost savings resulting from use of ICT including reductions in medication errors, communication of documentation of clinical care, test reporting, staffing, records storage, and information processing. Other benefits related to improved quality of care, documentation, improved capture of charging codes, and improved communication between providers resulting in more responsive patient care.

While ICT may lead to direct savings or cost offsets, the major impact is likely to be seen in improved quality of patient care. There is ample evidence that good care is more cost effective care. Many complex and chronic diseases cannot be effectively managed without disease management support such as computerised records, reminders and client engagement systems.

### *ICT for understanding Healthcare*

The availability of large volumes of data in electronic format supports a more rigorous approach to healthcare planning and delivery. However, individual privacy must be protected in this process. The increasing digitisation of records and capacity to synthesise large bodies of data are challenging current data management regimes and privacy regulations. In recognition of this the Office of the Federal Privacy Commissioner has recently begun a review of The Medicare and Pharmaceutical Benefits Programs Privacy Guidelines.<sup>25</sup>

Advances have already been made with the storage of all forms of patient’s records in electronic format. Researchers, adhering to strict patient confidentiality criteria, gather statistics about general practice activity and use them to understand and interpret broad trends about the health of the nation’s population. One significant outcome of this work to date has been the compilation of a detailed analysis of medications prescribed by doctors. This will be used to assist with future planning of likely PBS expenditure trends. It could also allow universal standards and goals to be set; for example by using the prescribing regimes of doctors in the past to answer questions about the best antibiotic to prescribe once a particular

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<sup>24</sup> [www.gao.gov/cgi-bin/getrpt?GAO-04-224](http://www.gao.gov/cgi-bin/getrpt?GAO-04-224)

<sup>25</sup> 2004 Review of the Medicare and PBS Privacy Guidelines issued under section 135AA of the National Health Act 1953, <http://www.privacy.gov.au/consultation>

disease-causing pathogen has been identified. This support for better evidence based practice can reduce cost as well as improving health outcomes.

The Australian and State/Territory governments have also jointly contributed \$38.9 million towards a National Blood Management System (NBMS), a computer system designed for managing the national collection and supply of blood, and as a tool for future planning and monitoring. The NBMS is being implemented in stages over 2003 to 2005.

### ***ICT for Improving Healthcare Communication***

*HealthConnect* is a joint Australian, State and Territories Government initiative involving a network of electronic health records that aims to improve the flow of information across the Australian health sector. It involves the electronic collection, storage and exchange of consumer health information via a secure network and within strict privacy safeguards. It will give doctors and other health professionals quick and secure access to important and potentially lifesaving medical information.

Benefits are likely to include; rapid access to vital and accurate health information, reduced duplication of services, more time being made available for direct care, and more active participation by patients in decisions about their own healthcare. Work on a staged national implementation of *HealthConnect* has begun in coordination with the states and territories and in full consultation with consumer and healthcare provider groups. Tasmania, South Australia and the Northern Territory will be the first states to be involved in the implementation project.

While significant investment in interoperable clinical and administrative systems, together with significant changes to work practices, is required to reap these benefits the potential financial and health outcome gains outweigh the costs. For example, the estimated cost<sup>26</sup> of establishing and implementing *HealthConnect* is around \$30 million per annum over ten years, with recurrent costs thereafter in the order of \$160m per annum, while indicative benefits are estimated to be in the order of several multiples of these costs. The budget for the initial rollout of *HealthConnect* in two of the smaller states (Tasmania and South Australia) and the Katherine region of the Northern Territory, is in the order of \$130 million over 4 years.

### ***ICT – requirements for standards***

While some areas of health ICT expenditure will need to be sourced from capital and recurrent expenditure for health systems support, the development of core infrastructure for health IT systems such as coding and classification systems, standards for data architecture and messaging formats requires government leadership and central funding models. Given that there is an international and national market in health information systems, there is a critical role for standards to enable inter-system communication and to avoid duplication of expenditure on development of these types of system components.

In July 2004, Australian Health Ministers agreed to the establishment of a national e-health entity from mid 2005 to drive forward critical national priorities for information management and ICT in the health sector. The agreed national priorities focus on the critical standards and infrastructure required to support connectivity and interoperability of electronic health information systems. They include: clinical data standards; patient, provider and product

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<sup>26</sup> <http://www.healthconnect.gov.au/publications/#vol1>

identification standards; patient, provider and product directories; supply chain; consent models; secure messaging and information transfer; and technical integration standards.

In recognition of the urgency of this work, the National E-Health Transition Authority (NEHTA) was established for 12 months to take forward some of the most urgent priority work, and to progress the establishment of the new entity. The Australian, State and Territory governments allocated \$9.5 million to the work of NEHTA in 2004-05. Proposals for the structure, governance, funding and work program of the new national e-health entity are currently being developed for the consideration of Health Ministers in early 2005.

### **Summary**

Advances in health related information technology have and will continue to improve the quality of evidence based practice and provide better access to patient information. Both developments have potential to reduce costs and improve health outcomes in the longer term. However, there will need to be significant investment in the near term to redress historic low ICT investment levels and provide the level of patient service that existing technologies can already support.

### **Effect of Technology on Health Workforce**

In some health fields advances in technology are bringing productivity improvements by automating simple activities. For example, better design of data storage and retrieval systems is having a positive impact on the work of nurses. Current trials being conducted in the United States are finding that through the thoughtful application of new technology into the workplace, nurses are able to save an average of two hours per day currently spent on essential clerical work. This time is then available for direct patient care; yielding a favourable outcome for both recipient and nurse alike.

The work of radiologists and pathologists is also being revolutionised as more efficient ways are developed to support the preparation of large numbers of diagnostic reports by computers. All the radiologist need now do as they examine each patient image is to read out a set of codes which correspond to standard sets of words. Speech recognition software interprets these codes and converts them into correspondence detailing the findings from the diagnostic image, which is then sent directly to the patient's doctor. Pathologists already use computer aided interpretations of routine abnormalities arising in tests performed by automated test batteries.

However, technological advance has rarely replaced man with machine at the critical patient/carer interface. This is not surprising since patients look to healthcare professionals for consolation, care and understanding at times when they are unwell. As Table 3 shows, the finance and manufacturing industries have both experienced personnel growth rates slightly below population growth, but the number of health and community services staff has grown at almost twice this rate.

Table 3 Employed persons in selected Australian industries (1996 and 2001)<sup>27</sup>

Census Year	Health & Community Services	Finance & Insurance	Manufacturing	Total Australian Population
1996	725,178	296,456	965,036	18,310,714
2001	806,171	312,396	1,010,179	19,413,240
Growth	11.2%	5.4%	4.7%	6.0%

<sup>27</sup> Australian Bureau of Statistics

The real growth in health expenditure across this period was 27%<sup>28</sup>. The people-centred nature of healthcare partially explains the rate of health inflation. Australia's health inflation was above the general rate of inflation (CPI) for seven out of the ten intervals between 1991-92 and 2001-02. Over this period health inflation averaged 3.0% per annum where general inflation averaged only 2.4%. This means that the cost of buying the same basket of health goods and services rose faster than the cost of buying a more general basket of goods and services.

Given that the cost of employing people (as measured by the Wage Cost Index) rose by an average 3.3% per annum across a similar period and the cost of buying goods (as measured by CPI) rose by only 3.0%<sup>29</sup>, the excess health inflation can be partially explained by the greater emphasis on employment of people.

From an international perspective Australia ranks favourably in terms of numbers of health professionals relative to its population, compared to similar OECD countries. Table 4 shows that in 2001, Australia had more general practitioners and nurses for every 1000 people, than either the United States, the United Kingdom, New Zealand, or Canada. Despite the overall high numbers, Australia's unique geography poses particular problems and matching supply of health professionals with areas of need remains challenging.

Table 4 Number of Health professionals in selected OECD countries<sup>30</sup>

Occupation / year	Australia		New Zealand		Canada		United States		United Kingdom	
	Number	Rate*	Number	Rate	Number	Rate	Number	Rate	Number	Rate
<i>General Practitioners</i>										
1996	25,089	1.4	2,935	0.8	29,805	1.0	189,431	0.7	35,922	0.6
2001	24,307	1.3	3,166	0.8	31,115	1.0	215,225	0.8	37,837	0.6
<i>Medical Specialists</i>										
1996	20,209	1.1	2,319	0.6	32,033	1.1	358,597	1.3	78,284	1.3
2001	23,381	1.2	2,653	0.7	34,111	1.1	391,866	1.4	91,763	1.6
<i>Dentists</i>										
1996	8,000	0.4	1,364	0.4	15,819	0.5	160,400	0.6	22,928	0.4
2001	9,000	0.5	1,591	0.4	17,648	0.6	164,700	0.6	25,840	0.4
<i>Nurses</i>										
1996	197,500	10.8	36,303	9.7	307,209	10.4	2,161,700	8.0	475,000	8.2
2001	205,000	10.6	36,976	9.6	305,471	9.9	2,271,300	8.1	530,000	9.0

\* Number of workers per 1,000 population.

Latest New Zealand data relates to 2000, not 2001, latest United States data relates to 1999, not 2001.

According to census data, 450,792 people, or an estimated 4.9% of the Australian workforce were employed in health occupations in 2001. The range of pursuits is diverse ranging from workers with no formal qualifications who provide support services in home based settings, through retail pharmacists, environmental health officers, to dentists, nurses, general practitioners and specialist doctors working in technology intensive hospital environments.

<sup>28</sup> AIHW, Health Expenditure Australia 2001-02

<sup>29</sup> Australian Bureau of Statistics, Wage Cost Index table 6345.0, CPI table 6401.0. Time period refers to June 1998 to June 2004, as methodological changes implemented by the ABS preclude making a meaningful comparison using the period 1991-92 to 2001-02.

<sup>30</sup> OECD, reproduced in AIHW *Australia's Health 2004*.

## ***Summary***

Healthcare is an intensive user of human resources which partially explains why healthcare costs rise faster than the cost of most other goods. The number of healthcare professionals in Australia compares well to similar OECD nations on a population-adjusted basis with nearly 5% of Australians employed in health related jobs.

## ***Conclusion***

Growth in expenditure on healthcare services is to be expected into the future as advances in technology make new treatments available and as growth in national wealth increases our capacity to afford additional health services. Advances in technology have been the strongest driver of growth in the recent past and are likely to continue to be in upcoming years as the supply of new innovations is quickly embraced by the public who value healthcare services.

The Australian government actively manages and anticipates change, regulating new beneficial technologies in a timely manner while maintaining public health and safety standards. This ensures that improving health outcomes are constantly being realised and delivered to the Australian people. There is strong potential for improved patient outcomes through greater use of ICT in the future but this will require some catch-up investment.

Despite the strong influence of technology, healthcare remains people-centred. Australia is well serviced with healthcare professionals compared to similar OECD nations. Historic wage growth has increased both the cost of providing healthcare and the willingness of Australians to invest in protecting and promoting their well-being.

## **KEY AREAS OF ANTICIPATED TECHNOLOGICAL INNOVATION.**

MSAC assesses that the five most critical categories of new technology with the potential both to improve patients' health and to affect the cost of health care in the future are:

### ***More accurate diagnostic and screening technologies***

Tests that can be used to screen for, or diagnose, disease are becoming more accurate but also more expensive. Some of this change relates to incremental changes in existing technologies; higher resolution in diagnostic imaging equipment such as computed tomography is a case in point. The question for patients and insurers is whether greater accuracy changes the ways patients are managed, and thereby improves their health.

### ***Genetic testing***

The use of gene technology, particularly to as a means of diagnosing disease, may be an area of growth in the coming decade. Particularly interesting areas are the use of genetic tests for screening, and involvement of genetic testing in treatment using pharmacogenetic drugs.

### ***Cancer treatments***

Though age-standardised death rates from cancers are falling, the proportion of all deaths attributable to cancers is increasing. New technologies to diagnose and treat cancers are likely to continue to emerge over the coming decade.

### ***Device-dependent modes of treatment***

Procedures involving new medical devices are typically more expensive than the procedures they replace. While there might be some financial savings in clinicians' time, this is often more than offset by the additional expense of the device itself. The Department's experience has been that new health technologies are becoming more reliant on, or are more frequently made possible by, developments in or new applications of implantable devices in particular.

### ***Information and Communication technologies***

These support administrative and health care delivery, and based on current trends will have an impact on the introduction of many of the technology areas outlined above.

## SUPPLEMENTARY READING

### ***General References***

2002-03 Budget Paper No.5: The Treasury's Intergenerational Report  
[www.budget.gov.au/2002-03/bp5/html](http://www.budget.gov.au/2002-03/bp5/html)

Australian Institute of Health and Welfare  
[www.aihw.gov.au](http://www.aihw.gov.au)

Australian Bureau of Statistics (ABS)  
<http://www.abs.gov.au/>

### ***Key Health System Regulators***

Australian Technical Advisory Group on Immunisation (ATAGI)  
<http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/cda-pubs-cdi-2003-cdi2702-htm-cdi2702o.htm>

Food Standards Australia New Zealand (FSANZ)  
<http://www.foodstandards.gov.au/>

Medical Services Advisory Committee (MSAC)  
<http://www.health.gov.au/msac/>

National Blood Authority (NBA)  
<http://www.nba.gov.au/index.htm>

National Health and Medical Research Council  
<http://www.health.gov.au/nhmrc>

Office of the Gene Technology Regulator (OGTR)  
<http://www.ogtr.gov.au>

Pharmaceutical Benefits Advisory Committee (PBAC)  
[http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-outcomes\\_full.htm](http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-outcomes_full.htm)

Pharmaceutical Benefits Pricing Authority  
*Policies, Procedures and Methods used in the Pricing of Pharmaceutical Products.*  
*November 2004.*  
<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pbs-general-pricing-pbpamethods.htm>

Therapeutic Goods Administration (TGA)  
<http://www.tga.gov.au/>

***TGA Regulation***

<http://www.cmr.org/institute/pdf/RD40.pdf>

***Information Technology References***

HealthConnect

<http://www.healthconnect.gov.au/about/index.htm>

2004 Review of the Medicare and PBS Privacy Guidelines issued under section 135AA of the National Health Act 1953

<http://www.privacy.gov.au/consultation>

## GOVERNANCE CHART – HEALTH PORTFOLIO AGENCIES AND STATUTORY OFFICE HOLDERS

AGENCY	ACRONYM	CHAIR	CHIEF EXECUTIVE	AGENCY TYPE	CAC <sup>1</sup> / FMA <sup>2</sup>	ENABLING LEGISLATION	OTHER LEGISLATION	CLASSIFICATION	BOARD TYPE	CHAIR APPOINTED BY	CHIEF EXECUTIVE APPOINTED BY
Department of Health and Ageing	DoHA	-	Ms Jane Halton PSM	Department of State	FMA	Various	<i>Public Service Act 1999</i> <i>FMA Act 1997</i>	General Government Sector	-	-	Prime Minister
Aged Care Standards and Accreditation Agency Ltd	ACSAA	Mr James Harrowell	Mr Mark Brandon	Company Limited by Guarantee	CAC	Company Constitution	<i>Corporations Act 2001</i> <i>CAC Act 1997</i>	General Government Sector	Management	Minister for Ageing	Board
Australian Institute of Health and Welfare	AIHW	The Hon Peter Collins AMQC	Dr Richard Madden	Statutory Authority (Statutory Agency under <i>Public Service Act 1999</i> )	CAC	<i>Australian Institute of Health and Welfare Act 1987</i>	<i>Public Service Act 1999</i> <i>CAC Act 1997</i>	General Government Sector	Management	Governor-General	Minister for Health and Ageing
Australian Radiation Protection and Nuclear Safety Agency	ARPANSA	-	Dr John Loy	Statutory Office Holder (Statutory Agency under <i>Public Service Act 1999</i> )	FMA	<i>Australian Radiation Protection and Nuclear Safety Act 1998</i>	<i>Public Service Act 1999</i> <i>FMA Act 1997</i>	General Government Sector	-	-	Governor-General
Commissioner for Complaints	-	-	The Hon Rob Knowles	Statutory Office Holder	FMA	<i>Aged Care Principles 1997, Aged Care Act 1997</i>	<i>FMA Act 1997</i>	-	-	-	Minister for Ageing

AGENCY	ACRONYM	CHAIR	CHIEF EXECUTIVE	AGENCY TYPE	CAC <sup>1</sup> / FMA <sup>2</sup>	ENABLING LEGISLATION	OTHER LEGISLATION	CLASSIFICATION	BOARD TYPE	CHAIR APPOINTED BY	CHIEF EXECUTIVE APPOINTED BY
Food Standards Australia New Zealand	FSANZ	The Hon Rob Knowles	Mr Graham Peachey	Statutory Authority (Statutory Agency under <i>Public Service Act 1999</i> )	CAC	<i>Food Standards Australia New Zealand Act 1991</i>	<i>Public Service Act 1999</i> <i>CAC Act 1997</i>	General Government Sector	Management	Parliamentary Secretary	Board
General Practice Education and Training Limited	GPET	Ms Kate Carnell	Dr Bill Coote	Company Limited by Guarantee	CAC	Company Constitution	<i>CAC Act 1997</i>	General Government Sector	Management	Minister for Health and Ageing	Board
Gene Technology Regulator	GTR	-	Dr Sue Meek	Statutory Office Holder	FMA	<i>Gene Technology Act 2000</i>	<i>FMA Act 1997</i>	General Government Sector	-	-	Governor-General
National Blood Authority	NBA	Prof Richard Smallwood	Dr Alison Turner	Statutory Office Holder	FMA	<i>National Blood Authority Act 2003</i>	<i>FMA Act 1997</i>	General Government Sector	Advisory	Minister for Health and Ageing	Minister for Health and Ageing
National Health and Medical Research Council	NHMRC	Prof John Shine AO	Prof Alan Pettigrew	Statutory Authority	Neither CAC nor FMA	<i>National Health and Medical Research Council Act 1992</i>	<i>FMA Act 1997</i>	General Government Sector	Management	Minister for Health and Ageing	Minister for Health and Ageing
National Industrial Chemicals Notification and Assessment Scheme	NICNAS	-	Dr Margaret Hartley	Statutory Office Holder	FMA	<i>National Industrial Chemicals (Notification &amp; Assessment Scheme) Act 1989</i>	<i>FMA Act 1997</i>	General Government Sector	-	-	Governor-General
National Institute of	NICS	Prof Chris Baggoley	Dr Heather Buchan	Company Limited by	CAC	Company Constitution	<i>Corporations Act 2001</i>	General Government	Management	Minister for Health and	Board

AGENCY	ACRONYM	CHAIR	CHIEF EXECUTIVE	AGENCY TYPE	CAC <sup>1</sup> / FMA <sup>2</sup>	ENABLING LEGISLATION	OTHER LEGISLATION	CLASSIFICATION	BOARD TYPE	CHAIR APPOINTED BY	CHIEF EXECUTIVE APPOINTED BY
Clinical Studies Limited				Guarantee			<i>CAC Act 1997</i>	Sector		Ageing	
Private Health Insurance Administration Council	PHIAC	Mr Gary Richardson	Ms Gayle Ginnane	Statutory Authority	CAC	<i>National Health Act 1953</i>	<i>CAC Act 1997</i>	General Government Sector	Management	Minister for Health and Ageing	Board
Private Health Insurance Ombudsman	PHIO	-	Mr John Powlay	Statutory Authority	CAC	<i>National Health Act 1953</i>	<i>CAC Act 1997</i>	General Government Sector	-	-	Minister for Health and Ageing
Professional Services Review	PSR	-	Dr John Holmes	Statutory Office Holder (Statutory Agency under <i>Public Service Act 1999</i> )	FMA	<i>Health Insurance Act 1973</i>	<i>Public Service Act 1999</i> <i>FMA Act 1997</i>	General Government Sector	-	-	Minister for Health and Ageing

**Footnotes:**

<sup>1</sup>**CAC:** Commonwealth Authorities and Companies Act 1997

<sup>2</sup>**FMA:** Financial Management and Accountability Act 1997

PROFILES OF STATUTORY OFFICE HOLDERS AND AGENCIES



## **THE TGA REGULATORY CONTEXT**

TGA sets standards for the quality and safety of therapeutic goods in line with international best practice. The TGA achieves this through participation in a number of international fora that promulgate standards for medicines, medical devices and the manufacturing of these products and through its consideration and adoption of these standards in Australia. These international fora include:

- International Standards Organisations of Medical Sciences Working Groups;
- Pharmaceutical Inspection Cooperation Scheme (PIC/S);
- The Global Harmonisation Task Force (GHTF) group of regulators for medical devices;
- WHO Global Collaboration for Blood Safety;
- Centre for Medicines Research International Regulatory Advisory Board;
- WHO Consultation on Methodologies for Research and Evaluation of Traditional Medicines; and
- WHO Working Group on Harmonisation of Standards and Regulatory Framework for Herbal Medicines.

Prior to marketing, medical technologies are evaluated by the TGA and must be included on the Australian Register of Therapeutic Goods (ARTG). The level of evidence required to substantiate claims is dependent upon the risk classification of the products. Entry of a therapeutic product on the ARTG is required before a therapeutic product can be imported, manufactured, supplied, used within or exported from Australia. It is also the starting point for subsequent consideration of the question of reimbursement of costs of treatment to patients under either the Pharmaceutical Benefits Scheme (PBS), Medicare Benefits Scheme (MBS) or Prosthetic Benefits List.

However, there are mechanisms within the legislative framework for therapeutic goods that allow experimental (so-called “unapproved”) products to be supplied on a compassionate-use basis to single patients as well as in a clinical trial context, without them having first been included in the ARTG.

### **The interaction between emerging technologies and the TGA’s regulatory activities**

The number of therapeutic goods regulated by the TGA is continually increasing as new therapies evolve, new applications for existing therapeutic goods are found, and as international markets continue to expand. Manufacturing techniques are also continually changing and improving with new technology.

The TGA must be responsive to and able to meet the challenges of regulating products incorporating technological changes. There is a public and government expectation that such therapeutic goods supplied and used in Australia will be safe for the purpose, indication or therapeutic promise in the context of an overall risk benefit framework and that the TGA’s internal evaluation processes continue to be efficient, to ensure such goods continue to be made available for use in health care settings in a timely manner.

Staff must therefore keep abreast of advances in technology. To achieve this, the TGA uses a combination of international liaison activities, review of literature and conference proceedings for horizon scanning purposes and the consequent ongoing professional development of existing staff and/or recruitment of additional expertise in areas of technological advancement. The TGA also responds by reviewing and amending its quality

and safety standards. Thus, by necessity, there is a cost of regulating new technologies that, in a cost recovery setting, will be borne by sponsors and manufacturers of products, which may be passed indirectly to consumers and purchasers of health technology products.

By and large, the TGA is not a driver of technology change. However, in order to fully discharge its public health responsibilities, the TGA has had to play an important role in facilitating the speedy uptake of new technologies in the manufacturing of therapeutic products. This has been particularly so in the regulation of blood and emerging biological therapies, where advances in scientific understanding of new and emerging blood borne pathogens such as human immunodeficiency virus (HIV), hepatitis C virus (HCV) and variant Creutzfeldt Jakob Disease (CJD) has seen moves towards higher standards of safety and quality based upon evidence-based measures and appropriate precautionary steps when patient safety was threatened or compromised. Specific examples of TGA action in these areas are covered below.

In 2000 the TGA mandated the use of nucleic acid amplification tests for blood donations. The introduction of this highly sensitive technology for screening blood borne viruses has prevented the potential exposure of thirty Australian patients to infective blood components.

The TGA has required the plasma fractionator in Australia, CSL, to undertake studies to demonstrate the level of clearance of prions (the infectious agent responsible for variant CJD) in manufactured plasma products and to embark on measures, including the development of new testing systems, that will further enhance the safety of manufactured products with respect to the transmission of this agent.

The TGA is also continuously assessing the possible role of other emerging technologies, including blood filtration and chromatography, which have been proposed as possible candidates for prion removal processes.

Additional or more complex manufacturing steps are usually associated with increased manufacturing costs. Thus, there is a tension between the desire for safer products and the relative cost of these treatments. In the case of blood-derived, plasma-derived and tissue-based products, the requirement to have additional purification and viral inactivation steps increase cost. This is compounded by the fact that a number of these products are low volume and the manufacturing processes cannot take advantage of economies of scale to drive production costs downward. The resultant increase in costs juxtaposed with an improved safety benefit/cost ratio is met by the health care system.

Another important interface with new and emerging technologies is the TGA's regulation of mechanisms of access to "unapproved" products. As new life-saving technologies are developed that allow treatment of diseases that were previously untreatable or unresponsive to available treatment, terminally ill and seriously ill patients can access treatment through compassionate use programs (Special Access Scheme, Categories A and B) before such products are entered on the ARTG. This is an issue, of course, of personal choice about the risks involved in the context of informed consent. However, because products accessed in this way are not included in the ARTG, they are generally not included in the various Australian Government reimbursement schemes (blood-derived clotting factors are one notable exception). The resultant costs of treatment are borne by the patient and/or the treating institution.

The TGA also regulates clinical trials of experimental therapeutic products. The scope of this regulation includes:

- any product not entered on the Australian Register of Therapeutic Goods, including any new formulation of an existing product or any new route of administration, or in the case of an existing medical device, new technology, new material or a new treatment modality; or
- use of a product beyond the conditions of its marketing approval, including new indications extending the use of a medicine to a new population group and the extension of doses or duration of treatments outside the approved range.

From an historical perspective, Australia has had a strong clinical research environment that is well regarded internationally. This, coupled with the introduction of the Clinical Trial Notification (CTN) Scheme and resultant deregulation of clinical trials in Australia in the early 1990s has seen a dramatic and sustained increase in the level of clinical trials regulated by the TGA (in excess of 500 medicines trials at over 1500 sites and in excess of 50 medical device trials at approximately 100 sites each year). Furthermore, Australia is seen as a desirable country in which to undertake clinical trials of new and emerging technologies. Approximately 10% of all medicines trial activity regulated by the TGA relates to phase I trials, which involve the administration of new drugs to humans for the first time.

Clinical trials are expensive to run properly, especially if they are to comply with internationally accepted standards for “good clinical practice”. While the majority of these trials are undertaken by commercial companies who finance all trial-related activities, a significant proportion are sponsored by hospitals, specialist groups/networks and individual medical practitioners, who must find appropriate funding sources. Irrespective of the source of trial funding, there are other indirect costs to the health care system associated with the trial activity, such as administrative support activities, ethics committee involvement etc. (Note: there is also considerable additional clinical trial activity undertaken where products are used within the conditions of their marketing approval are not subject to TGA regulation but still need to be approved by a Human Research Ethics Committee (HREC) and participating institutions. These are usually undertaken by clinicians to establish the relative merits of alternative products in the treatment of a particular condition).

An important spin-off of this level of trial activity and the resultant “pre-exposure” of the new technology to the medical profession, is that rapid uptake of new treatments is likely once marketing approvals have been obtained, as well as enabling Australians with chronic, serious or terminal illnesses to have access to the latest experimental treatment modalities.

### **Future challenges for the TGA and the healthcare system**

The use of pharmacogenomics and pharmacogenetics has the potential to revolutionise the use of medicines. However, this may also present numerous challenges as products become highly specialised with use in an individual dependent on co-marketed pathology testing. Advances may lead to safer and more appropriate use of medicines in an individual, but will almost certainly lead to increased costs and to greater use of genetic information in the health care sector, with inherent privacy issues. The benefits to the individuals will have to be weighed against the costs to the health sector as a whole. Most major pharmaceutical companies are now investing resources in developing products using this technology. The WHO supported Council for International Organisation of Medical Sciences is about to publish a major document examining this trend. A copy of a briefing by the Institute for Regulatory Science entitled ‘Pharmacogenetics and Pharmacogenomics in Drug Development’ can be read by pursuing the reference in Annex B.

In the medical devices arena technology is expanding very rapidly. Older technologies are constantly being improved, for instance the estimated life of new types of heart valves is 3-4 years before newer more innovative products make previous products obsolete, while some newer technologies only have a six month life cycle. There are also moves into totally new areas such as:

- nanotechnology, including drug delivery systems able to target disease at cellular and molecular levels;
- combination products where medical devices incorporate a medicine or tissues to enhance the function;
- with the mapping of the human genome, the expansion in genetic testing using *in vitro* diagnostic devices (IVDs); and
- the use of bio-films to enhance the biocompatibility of implantable medical devices

At the innovative end of IVD development, there will be a continued trend toward the manufacture of in-house by pathology laboratories for niche diseases and genetic conditions.

In the area of tissue and cellular therapies, major changes are to be expected in the use of autologous vaccines to treat cancers, enhancements in the ability to bank various body tissues, use of cellular and subcellular transplants.