

**PHARMACEUTICALS IN AUSTRALIA:
EQUITY, COST CONTAINMENT AND INDUSTRY
DEVELOPMENT**

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for
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1. Overview

The challenge addressed in this report, in a preliminary way, is how Australia can give real impetus to the growth of the pharmaceutical industry while maintaining a high quality, equitable and cost effective health system. This involves finding innovative ways of dealing with apparently irreconcilable objectives: ensuring that drugs remain accessible to all, providing better returns and incentives to pharmaceutical companies and containing the cost of a modern, high quality health system.

This report argues that there are in fact ways in which the Australian community can achieve these objectives, and hence boost the pharmaceutical industry while retaining the equity and cost efficiency of the Australian health system. These options arise in part from the dramatic changes which are occurring in both in the pharmaceutical industry and in health systems worldwide, so this is our starting point.

The options available to meet the overall challenge also depend on the reality of the industry in Australia, and on the particular form of its integration into the Australian health system. These matters are reviewed briefly in the report, where possible placing the Australian practice in an international context. The current settings of pharmaceutical industry policy and the performance of the Australian industry over the past 10-15 years are also reviewed. Finally, the report outlines a range of strategic options which could be employed to meet the desired objectives - rapid growth in the industry together with cost containment and continued equitable access to drugs.

The Global Context

Some of the relevant changes in the global pharmaceutical industry include the following:

- ***Pressure on prices.*** Pressure continues to mount on prices paid to pharmaceutical companies around the world, as governments and agencies representing consumers (such as Health Maintenance Organisations) strive to contain overall health costs.
- ***Effect of new technologies.*** New technologies – particularly genomics, combinatorial chemistry and high throughput screening technologies – are adding to the cost and complexity of R&D. They will in due course generate a large number of new drugs, which offer substantial long-term health benefits, in terms of both prevention and treatment.
- ***New round of patent expiries.*** Many major companies face a heavy round of patent expiries over the next few years, so that a new period of rapid growth in generics is widely anticipated. In countries such as USA and UK, generics

already account for 50% of scripts filled in the retail market, and this proportion is likely to rise further.

- ***Consolidation of majors, proliferation of small companies*** The corporate structure of the pharmaceutical industry is changing rapidly in several ways. Consolidation continues to occur among major companies, leading to a much smaller number of giant companies by 2005. These large companies are also expanding their field of operation, extending into health care more generally. At the other end of the scale smaller companies proliferate, providing specialist services or specific technological expertise. Outsourcing to these companies, or even alliances with them, are becoming increasingly central to even the largest companies.

Drawn by concern over costs and the pervasive impact of information technology, *health systems around the world are being reshaped*. With information more readily available, individuals are taking a more active role in their own treatment. Information systems also provide the basis for new programs of integrated care or disease management, through which effective treatment protocols can be identified and best practice approaches disseminated. In the longer term, the combination of integrated care programs and new drugs, targeted to the genetic basis of disease, offer new prospects for highly effective, cost efficient health care.

Health Spending and Drug Costs

Health Spending

Australia starts with a strong and cost effective health system by world standards. The quality of technology available and of care provided is generally high. Total Australian spending on health is 8.4% of GDP (1997-98), which is within the mid-range of OECD countries. It is well below the figures for 1997 for countries such as USA (13.9%) or Germany (10.7%) but above the spending levels of countries such as UK, Japan and New Zealand, which spend only some 7% of their GDP health care. Indeed it is notable that there can be such wide divergence in health costs across countries without equally apparent divergence in the quality of health care.

Pharmaceutical Spending

Spending on pharmaceuticals also differs widely across countries, and Australia is in the middle to lower end of the OECD range. Spending on outpatient pharmaceuticals (i.e. excluding hospital use) was about \$5 billion in Australia in 1996-97, or 1.0% of GDP. This is to be compared with OECD country figures (for 1996) in a range of 1.7% of GDP in France to 0.7% of GDP in Denmark, and with a figure for USA of 1.3%. There is evidence that the lower share for Australian than for some other countries reflects a combination of lower prices and lower use of prescription medicines in Australia.

Public Contribution to Drug Costs

There are also wide differences between countries in the extent to which the cost of outpatient drugs is met by individuals directly or through the public purse. In most European countries the public sector meets over 60% of these costs, and in some cases over 80%, while in the USA only about 15% is met publicly. In spite of the role of the Pharmaceutical Benefits Scheme (PBS), Australia is again in an intermediate position, with 54% of outpatient drug costs met by the Government in 1996-97. *The main concern for Australia is the rapid increase in this share in the 1990s – from 44.8% in 1990-91 to 54.0% in 1996-97.* This reflects the rapidly increasing cost to government of the PBS, which has continued since 1996-97.

The Pricing of Prescription Pharmaceuticals

Three sets of prices are particularly relevant for pharmaceuticals – the price paid directly by the consumer, the price received by the producer and that part of the price met by government subsidy. For prescription pharmaceuticals in Australia, each of these is directly influenced by the Government through the PBS.

Charges to Consumers

From 1 January 1999 a maximum charge for general patients of \$20.30 per prescription item applies, up to a limit of \$620.60 in any calendar year (after which a charge of \$3.20 applies). For persons holding a health card the charge per item is \$3.20 per prescription item, up to a maximum of \$166.40 per calendar year. In 1997-98 the cost of PBS pharmaceuticals to general patients was \$805 million, of which 36.6% was met by copayments and 63.4% by government subsidy, about one-fifth of the subsidy being due to the safety net limit. For concessional patients the total cost was \$2293 million, of which only 12.1% was provided by copayments and the remainder by the government. Again the safety net arrangements contributed about one-fifth of the total subsidy cost. One result of this system is that, for drugs listed on the PBS, there is little exposure of consumers to the actual prices of drugs as paid by the PBS.

Prices Paid to Companies

There are many complexities involved in comparing the prices received by pharmaceutical companies across countries, such as variations in medical practices and dosage levels, in patterns of drug use, in the role of generics and of original brand drugs, and in the availability of discounts against list prices. Studies such as APMA (1995), based on list prices for standard dosages of selected prescription drugs, suggest that Australian PBS prices for brand drugs are well below average OECD levels. For example, the APMA study found that for 38 leading products (accounting for about 50% of the Australian prescription market) PBS prices in 1995 were only about one-third of OECD average prices. For 19 new chemical

entities introduced since 1993, PBS prices in 1995 were about two-thirds of OECD average prices.

While there is no doubt that PBS prices for many drugs are significantly below those in some other countries, these studies must be treated with caution, for the reasons cited above. For example, the volume weights used in the APMA study give a strong weight to the USA, where listed pharmaceutical prices are relatively high. But the US has also seen very sharp growth in the generic market, in discounts and in contract purchasing, so that list prices for brand pharmaceuticals are only part of the story in that country. As we have seen, Australia is in the mid-range of OECD countries in terms of total outpatient spending on pharmaceuticals, measured as a share of GDP.

The Role of Generics

An important factor influencing the overall level of prices is the extent to which generics are used in place of the original brand drugs after the relevant patent expires. In some major countries generics account for over 50% of retail prescription drug sales by unit although, because of lower prices, the share of the market by value is much lower. Figures for the use of generics in Australia are difficult to obtain. The best measure appears to be the proportion of scripts filled at the benchmark level under the PBS Brand Pricing Policy.

In the year to May 1998 a total of 49.6 million scripts were filled under the Brand Pricing Policy, amounting to about 38% of all PBS prescriptions. But only 32% of these prescriptions, or about 12% of all PBS scripts, were dispensed at the benchmark level. The proportion of all PBS scripts filled at the benchmark level has risen quite strongly in recent years, growing from less than 5% in 1994 to 12% in 1998. These data suggest that the use of generics in Australia remains quite low by the standards of countries such as UK and USA, where about 50% of scripts are filled by generics. Little information is available on the level of benchmark pricing relative to overseas markets for generic drugs.

The PBS Approach to Price Setting

Over the past decade the Pharmaceutical Benefit Pricing Authority (PBPA) has led the world in the introduction and development of economic evaluation as part of the price setting process for drugs. In recent years, these techniques have also been more widely used within pharmaceutical companies, as they face the need to make complex choices between many different candidates in the drug development pipeline. This convergence on economic evaluation, in its various forms, as an analytical tool may provide the basis for a more transparent approach to PBS pricing in the future. However, the introduction of the Therapeutic Group Premium Policy in 1998, which is a form of reference pricing, is some of a retreat by the PBPA from the economic evaluation approach. The application of this policy in 1999 has also led to some real conflict between the drug companies and the authorities.

The Rising Cost of the PBS

While total health spending in Australia has stabilised, as a share of GDP, in recent years, the real cost to the Government of the PBS began to increase rapidly after 1993. Growth in the cost to Government of the PBS has risen sharply in real terms in each year since 1991-92, with average real growth of about 12% per annum between 1991-92. As a result, it has risen continuously as a share of GDP over this period. This rise in the cost to Government of the PBS has been a cause for concern, and attention has inevitably been given to ways of reducing that cost. Certainly, containing the growth in the cost to Government of the PBS is a central element of the challenge to be addressed.

The Efficiency of Drug Distribution and Use

The Efficiency of Drug Use

Many factors affect the value received by consumers, and indeed the effective benefit received by producers, for a given level of subsidy by government. One is the efficiency of the system for the distribution of drugs, an important aspect of which is the price received by manufacturers after a mark-up is paid to the wholesaler and the pharmacist. The share of the pharmaceutical sales dollar received by the manufacturer varies across countries, ranging from 77.1% in Sweden to 58.1% in Switzerland. The indications are that the share of sales going to manufacturers in Australia is in the middle of that range. For the total cost of PBS prescriptions for 1996-97, 67% was received by manufacturers, 26% by pharmacists and 7% by wholesalers. The share taken by pharmacists in Australia seems to be fairly high by world standards.

Compliance in Drug Use

Another aspect of the efficiency of drug use is the extent of compliance or non-compliance with prescription advice. After a medical consultation, often the patient may not proceed to obtain the medication from a pharmacist (*purchase non-compliance*) or, even though the drug is purchased, the patient may decide not to follow the prescribed regimen, either in whole or in part (*use non-compliance*). The two forms of non-compliance may lead to substantial inefficiencies in the use of pharmaceuticals to generate improved health within the community. We are not aware of evidence on the extent of non-compliance in Australia, but some overseas studies have suggested that it is of major importance. It is likely to be an important factor in the Australian situation also.

Information Technology and Integrated Care Programs

The revolution in information technology is having dramatic effects not only on practices within the pharmaceutical industry but also on the delivery of health services to individuals, and hence on the way in which the pharmaceutical industry is integrated to a given national health system. Three aspects facilitated by

information technology are the rise of managed care, the development by managed care organisations of new methods of cost containment and, perhaps most importantly, the development of new methods of disease management and of integrated care. These processes are most advanced in the US, although there have been important developments in other countries including Australia. In the US, for example, in 1996 about 80% of Americans in private sector employment were in managed care organisations, this being a sharp increase on the figure of only 23% in 1987 (PhRMA 1999). In 1997, 87.3 million Americans were enrolled in Health Maintenance Organisations (HMOs) and the top 10 HMOs had 48% of these enrollees (FTC 1999).

These and other factors have given rise to the increasing importance internationally of programs which:

- coordinate the delivery of health services to a group of patients;
- provide systematic knowledge on the most effective treatment strategies and drugs to participating professionals;
- use data on patient outcomes to monitor the effectiveness of treatment strategies and drugs, and to vary those treatments if necessary;
- monitor the adherence of professionals to best practice approaches and of patients to medical advice and prescriptions;
- control the cost of treatment, and ensure that least cost methods of treatment are used as appropriate, and
- more generally, encourage the use of evidence based approaches to all aspects of the health services process, so as to achieve better health outcomes for individuals at lower overall cost to the community.

In part these programs have been pioneered by the HMOs and similar organisations in the US, many of which have the scale, resources and incentives to develop quite new approaches to health care delivery.

The Australian Pharmaceutical Industry and Industry Policy

Recent studies such as the Industry Commission's 1996 report *The Pharmaceutical Industry* and the 1998 study *Pharmaceuticals and Australia's Knowledge Economy* by Australian Economic Analysis Pty Ltd have documented the recent performance of the industry in Australia, The Wills Report on health and medical research *The Virtuous Cycle*, released in December 1998 (Department of Health and Aged Care), has documented the research foundations of the industry in Australia. As a result, many of the broad facts about the performance of the industry are well known, and the present project does not seek to duplicate this work. We briefly document in the report some elements particularly relevant to the overall challenge and to policy responses to it.

The Structure of the Pharmaceutical Industry

It is important to note the unique structure of the research based pharmaceutical industry. On a global basis this industry is the most R&D

intensive of all industries, with a ratio of R&D to sales of over 20%. The industry is also one in which the level of capital expenditure in plant and equipment required is fairly modest, but in which marketing plays a very important role in total costs. With heavy sunk cost investment in R&D and marketing, the industry is thus one in which sunk costs are very large relative to variable production costs in spite of relatively low levels of capital spending, and hence one in which increasing returns prevail.

Estimates by Danzon (1997) bring out clearly these features of the global industry. For example, she shows that for a typical cohort of drugs, over 30% of the total lifetime costs of creating, producing and distributing those drugs is in the R&D expenditures. The discounted value of all manufacturing and distribution costs amounts to 25.3% of total costs, only a little more than marketing costs at 23.4%, whereas capital expenditure accounts for only 2.9% of total costs. Indeed, R&D and marketing alone account for more than 50% (54.5%) of the total costs. This fact is particularly relevant for the development of the industry in Australia, whose comparative advantage in the industry resides at the R&D end.

The Recent Performance of Industry

The performance of Australia's pharmaceutical industry was impressive in terms of value added, exports, R&D and investment from the mid 1980s to the mid 1990s. This performance includes growth in real value added of 22% per annum between 1985 and 1994, more than twice the OECD average; real investment growth of 11% between 1990 and 1995, at a time in which overall manufacturing investment was falling; real export growth of just on 20% per cent per annum between 1986-87 and 1995-96, slightly exceeding import growth and virtually a threefold increase in real industry R&D between 1986-87 and 1995-96 (Australian Economic Analysis 1998). Trends in the industry are somewhat more difficult to discern since 1995-96, but the signs are that the industry has continued to grow, although perhaps not at the earlier pace.

The Policy Framework

The achievements in building the Australian pharmaceutical industry since the mid 1980s have been heavily influenced by the settings of industry policy, and particularly the Factor (f) program. This program was introduced in 1988, providing payments by way of higher prices to drug companies. These payments were related to the increase in their value added and R&D activities. Agreements were negotiated on a company by company basis, with certain minimum participation requirements. Companies received payments as higher prices up to a maximum of 25% of increased value added and 25% of increased R&D spending (or 50% of the increase in after tax R&D spending), in all cases relative to the base year. Payments were not to bring the average level of prices above that prevailing, for the products in question, in the European Community.

The total cost to the Government over the six year period between 1991-92 and 1997-98 was \$550.9 million, or an average of about \$88 million per annum.

The cumulative increase in company outcomes over the base year (in most cases 1991-92) was \$2027.4 million for value added and \$272.5 million for R&D. The cumulative increase of just on \$2300 million in the two elements combined is just over four times the amount paid by the Government, consistent with the maximum payment of 25% of the outcome increase.

With the conclusion of the second phase of the Factor (f) the Government has established a new scheme, the Pharmaceutical Industry Investment Program (PIIP), to run from July 1999 to June 2004 and be similar in many respects to Factor (f). But it would be smaller, with its total cost capped at \$300 million over the five-year period, and the available funding would be allocated between companies on a competitive basis.

In spite of their evident impact, these programs contain certain limitations as guides to future policy, especially when viewed in the context of the massive changes which are taking place in the global industry and the challenges they pose for Australian policy. Some of these limitations are as follows:

- Both the second stage of Factor (f) and the PIIP program have provided benefits to only ten companies. With rapid structural change in the industry there are a much larger range of companies which either do undertake, or might consider undertaking, pharmaceutical activities in Australia. It would seem desirable, then, that the next generation of policy provide a framework applicable to all companies undertaking certain specified activities in Australia.
- Smaller companies providing specific services – in fields such genomics, combinatorial chemistry, automated screening, clinical trials and contract manufacturing – are becoming increasingly important in the pharmaceutical industry even as the majors consolidate. The next generation of policies should encourage the activities of such companies in Australia directly, as well as indirectly through support for pharmaceutical companies.
- With the industry being heavily driven by biotechnology, there is increasing overlap between development activities in pharmaceuticals and in other areas. It would thus be sensible for the next generation of pharmaceutical industry policies to dovetail closely with any policy initiatives developed for biotechnology.
- Finally, the choice of the basis period for measures which support *increased* activity is critical. If the period from the base year to the current year is too long, companies are effectively rewarded many times for increased activity in a given year. But if it is too short, benefits to companies become distorted by short-run changes in outcomes.

Meeting the Challenge: An Overall Strategy

As noted earlier, the central challenge with which this report is concerned is how to establish a regime which gives real impetus to the growth of the pharmaceutical industry in Australia, while maintaining a high quality, equitable

and cost effective health system. One example of success in meeting this challenge would be the following set of outcomes:

- the current level of equitable access to drugs, and especially to new drugs, is maintained;
- the overall level of spending by the community on drugs is held at the current share of GDP or, if spending rises as a share of GDP, this is due to higher prices for drugs which show clearly defined and quantifiable health benefits and hence at least offsetting reductions in health costs, and
- a new round of industry development takes place – in relation to value added, R&D and exports – comparable in terms of growth rates to that which took place during 1985-95.

A range of options which might be considered as part of an overall strategy to achieve these or similar outcomes are noted below. The general thrust of the overall strategy - *which is presented only as worthy of further, more detailed examination* - is as follows:

- a pricing regime which is more transparent, and based firmly on methods of economic evaluation, which provides higher prices for drugs with high social benefits and which rewards new drugs shown effective in disease prevention;
- a drug cost containment strategy involving a greater role for price signals in consumer decisions (through reform of the copayment arrangements), increased use of generics, improvements in the efficiency of the distribution system and programs to encourage greater compliance with prescription advice;
- vigorous development of integrated care programs, in appropriate Australian settings, which offer better health outcomes at lower overall cost through the systematic application of new knowledge, new technologies and new drugs on the basis of cooperation between industry, government and the health community, and
- a more powerful set of industry development policies, making available support for value added activity and R&D performed in Australia to a much wider range of companies than are currently supported by the PIPS program.

Some of the more specific options which might be considered as part of such a strategy are noted below.

PBS Pricing and Copayment Arrangements

PBS Price Setting – Sharing the Social Benefits through Economic Evaluation

If prices are to be set in a manner which makes Australia a more attractive location for pharmaceutical companies, higher prices might need to be paid for those drugs which offer substantial and clearly identifiable social benefits (and hence savings in health costs) relative to other treatments. For this to be

practicable it must be possible to identify those social benefits (and hence savings in health costs) relative to other treatments. This can be achieved through the economic evaluation approach. Thus such approach would allow the PBPA to generate price levels which share the net social benefits of a new product between the producer and the community. A strong emphasis on economic evaluation will also be important as new drugs proliferate over the next few years. Some of the new drugs will offer important social benefits, while others will be 'lifestyle' drugs, which provide benefits to individuals in quality of life rather than basic health outcomes.

Reforming the Copayment Arrangements – A Greater Role for Price Signals

The demands of equity have been well served over the years by the PBS copayment arrangements. But as they stand at the present time they have two limitations as a form of government subsidy for the purchase of pharmaceuticals – they insulate consumers almost entirely from the true prices for pharmaceuticals and the amount of subsidy an individual receives bears no relation to capacity to pay, being related only to drug usage. Cost containment is likely to be assisted by changes to address these limitations.

One way in which a greater role for market signals could be introduced is by setting the copayment as a fixed proportion of the drug cost, up to a maximum level and subject to safety net arrangements. For example, the following arrangement would provide a broadly similar overall level of subsidy to the present arrangements, but with a greater role for price signals:

- for general patients, a copayment of 50% of the drug cost up to a maximum of \$30 per prescription item, subject to current safety net arrangements, and
- for concessional patients, a copayment of 10% of the drug cost up to a maximum of \$6 per prescription item, subject to current safety net arrangements.

Such an approach would make consumers aware of the actual cost of different drugs, and provide some scope for the total level of copayments to rise as new, more expensive drugs are introduced.

On a social equity basis, the scheme could be made more equitable, as well as somewhat more cost effective, if the subsidy received (or for concessional patients some of the subsidy received) was treated as part of taxable income. In such a case, the individual would meet a further part of the subsidy at a rate determined by his or her marginal tax rate. Full analysis of the practical and financial implications of these or other suggestions is beyond the scope of this report.

An Increased Use of Generics

A more transparent pricing system based on economic evaluation is likely to provide higher prices for new, innovative brand drugs with high social benefits. An appropriate offset to this would be a much higher reliance on generic drugs, which may provide cost savings on drugs which are out of patent. As noted several times above, generics provide about 50% of the retail prescription market in both USA and UK, and this share is expected to rise sharply over the next five years as a new round of patent expiries takes place.

A range of actions would be necessary to increase the extent of generic use, and they cannot be explored here. But one necessary condition is likely to be the introduction of a greater role for price signals in the consumer purchase process, as suggested above.

A Special Focus on Prevention

With the rise of genomics and of techniques able to create and screen massive numbers of potential drug candidates, there is likely to be rapid emergence of a range of pharmaceutical products which can prevent rather than treat disease. These may operate by correcting genetic deficiencies which give rise to disease, by establishing treatment programs to reduce susceptibility to a particular disease, or in other ways.

Such products, when fully validated, offer major social benefits and substantial savings in costs. Special consideration should be given to pricing strategies which encourage firms to offer them quickly into the Australian market, and to ways of encouraging individuals and doctors to make maximum use of them.

Effective and Efficient Drug Use

Integrated Care Programs for the Australian Market

There is no doubt that an important part of the response to the overall challenge being considered here is to find ways – consistent with Australian institutions, practices and values – of realising in Australia the benefits of integrated care and disease management programs, and of evidence based care more generally. The issues involved in this matter take us far beyond the present report. We note only that systematic cooperation between governments, industry and health professionals is likely to be necessary if the potential benefits, both in terms of health outcomes and cost containment, are to be achieved.

In this context, programs such as the Integrated Care Program - a pilot program seeking to design, implement and evaluate a model of an integrated, comprehensive and evidence based approach to health care and service delivery – are likely to be of considerable importance. The stakeholders in this particular program are the Pharmaceutical Alliance (an alliance of six pharmaceutical

companies), three Divisions of General Practice (two in NSW and one in Victoria), the Commonwealth Department of Health and Family Services, Health Communication Network Ltd and the Health Insurance Commission.

Compliance with Prescription Advice and Distribution Costs

Other, and in some ways simpler, factors affecting the efficiency and effectiveness of drug use are also important in influencing the benefits received both by patients and by industry from a given level of public and private spending on pharmaceuticals. These include improved compliance of patients with prescription advice and increases in the share of total expenditure which finds its way back to the producer of the drug. We have not had the opportunity to investigate these matters in any depth, but there are indications that they may be areas in which significant improvements can be made in the Australian case. Certainly these matters are worthy of serious examination in the process of developing an overall strategy.

Industry Policies for the Future

In terms of industry policies for the future, it is not the role of this report to attempt to design specific policies which might respond to the varieties of factors considered. We simply highlight several characteristics which, in our assessment, the next generation of industries policies should possess and outline two broad approaches policy which would contribute significantly to the further development of the pharmaceutical industry in Australia in the 21st century.

Characteristics of Future Industry Policies

Policies for the future need to take into account both the lessons of past experience and an assessment of the future business context. On such a basis it seems appropriate to suggest that future policies for the pharmaceutical industry in Australia should have the following characteristics:

- they should a general framework applicable to all companies undertaking certain activities in Australia, rather than be based on agreements with a small number of companies, and hence provide a stable basis on which to encourage new or increased activity as circumstances change;
- they should encourage small but growing technology and services companies to undertake activities Australia, both directly as well as indirectly through support for pharmaceutical companies;
- they should the pervasive nature of biotechnology, and dovetail closely with any policy initiatives developed for biotechnology, and
- they should support companies in terms of increased activity relative to an appropriate base period.

Two broad suggestions for policies with these characteristics are noted below.

Support for Value Added

The first is a general payment to drug companies undertaking value added activities in Australia, related to the increase in their value added over, say, the average level of the past four years. The payments would be available to all companies undertaking such activities in Australia, perhaps subject to certain scale and commitment requirements. If the payment was at, say, 20% of the increase in value added over the average level of the past four years, this should provide a valuable and continuing incentive for both existing and emerging companies.

While given in general recognition of the impact on industry development of the low level of the prices paid for drugs in Australia, these payments need not be closely related to the actual prices received by a given company. Given the importance of economies of scale, spillovers and agglomeration effects in this industry, the disincentive effects for a given company of a low level of drug prices are much wider than the direct effects of the prices received by the company.

Support for Incremental R&D

The second suggestion is for a more general support program for R&D undertaken in Australia, which might apply to R&D in both pharmaceuticals and in biotechnology more generally. This could involve, for example, a support payment equivalent to a 200% tax concession on increases in R&D over the average level of the past four years. Again it should apply to all companies undertaking pharmaceutical and biotechnology R&D in Australia, subject to appropriate scale and commitment requirements. R&D in these areas would receive special treatment in recognition of Australia's comparative advantage in these areas, and of the strong contribution which they can make to long term industry development in this program.

Conclusion

An industry policy regime containing, for example, these two elements – a generally applicable 20% payment for increased pharmaceutical value added over a four year base period and a payment equivalent to a 200% tax concession on incremental R&D over a similar base period – would have a cost to the Federal budget comparable to the Factor (f) program rather than to the cheaper PIIP program which is currently in place. But recent Australian experience suggests that it would be a good investment in social cost benefits, especially if placed in the context of an overall strategy as sketched in this report.

2. The Changing Global Environment

In spite of some continuing discussion about whether or not the pharmaceutical industry is a competitive one, the broad structure of the industry in the 1990s as a classic case of monopolistic competition is quite clear. While there is intense product competition, through R&D and new products, prices received by companies for drugs within patent are widely set by governments or negotiated with other large agencies, and price competition is largely confined to out-of-patent drugs. Final consumers generally lack the knowledge to participate actively in the market and to respond to financial incentives, and decisions are largely taken for them by their agents, in most cases in Australia their doctors or pharmacists. The industry has been dominated by a significant number of large firms, with substantial market power within therapeutic groups. For example, the US Congressional Budget Office recently reported that in 35 of the 66 therapeutic groups which it examined the top three drugs constituted at least 80% of retail pharmacy sales in the US (CBO 1998).

While this image of an industry dominated by large firms and the agents of consumers engaged in various forms of strategic competition remains largely correct, it does seem clear that the industry is in the process of massive change which will shake the industry to its core. Indeed, while there are many differences between the two industries, the broad processes of change in pharmaceuticals are not dissimilar to those which have taken place in recent years in the computing and telecommunications industries. Some of the key aspects of this change are outlined below.

New Fundamental Technologies

It is a commonplace that over the past decade the process of drug discovery in the pharmaceutical industry has moved from one based on sophisticated trial-and-error to one increasingly using rational drug design based on biotechnology. But within this general trend three more specific developments are likely to change the face of the pharmaceutical industry: genomics, combinatorial chemistry and high throughput screening (PriceWaterhouseCoopers (PWC) 1998; Boston Consulting Group (BCG) 1999).

Vast efforts are currently being made to work out the sequence and structure of the human genome, which contains of the order of 100,000 genes, and this is expected to be largely completed by 2005. These efforts, and more generally work in genomics, offer an increasing capability to establish the link between specific genes and specific diseases. This in turn will enable the creation of drugs to target particular disease related genes, the preparation of preventative programs for individuals susceptible to a particular disease, and the customisation of health programs for individuals, having regard to their individual pattern of disease susceptibility.

New methods of combinatorial chemistry have dramatically increased the speed and reduced the cost of creating new chemical compounds, in each case by many orders of magnitude. The new combinatorial procedures allow companies to build libraries of several hundred thousand compounds for analysis in a short period of time. It has been reported that Pharmacoopia, a specialised combinatorial chemistry company, has built a library of 3.5 million compounds in only a few years (BCG 1999). This offers vast new opportunities for drug development but also threatens to bury companies in an avalanche of data.

In part this problem can be addressed through the third technology area, high input screening. Using both advanced molecular biology, automated screening processes and state of the art computing resources, firms can now screen 50,000 or more compounds per day, and further advances are likely in the near future. Thus not only can new compounds be created at an unprecedented rate but they can now also be screened for various active effects at a very rapid rate.

Rapid Expansion in Discovery of New Chemical Entities

One important result of these three new technologies will be a dramatic increase in the rate of discovery of new chemical entities, novel compounds with proven action which might lead to new drugs and which are ready for pre-clinical trials. Traditionally, the industry was constrained by the limited supply of potential drug candidates, and by high failure rates of those candidates in pre-clinical and clinical trials. BCG estimate that in the 1990s the typical large pharmaceutical company discovered about 12 new compounds per annum. Of these some 75% would fail in preclinical and early stage trials, and the remainder would be nursed carefully through the later stages, with only about one new compound reaching the marketplace on average per company per year (BCG 1999).

This situation is in the process of fundamental change. With genomics generating a rapid increase in potential treatment areas and combinatorial chemistry/high throughput screening throwing up an abundance of new compounds to address those needs, it is widely anticipated that the next 5-10 years will see a tenfold increase in new drug candidates. Thus the central challenge facing the industry will no longer be the discovery of compounds with drug potential but of accessing and evaluating a wide range of candidates for final stage trials.

Increasing R&D and Drug Development Costs

The advent of these new technologies, together with the increasing cost of taking a drug through from pre-clinical trials to the marketplace, have led to a rapid increase in R&D spending by major pharmaceutical companies. According to the PhRMA Annual Survey, R&D spending by the research based pharmaceutical companies covered increased by 60% in real terms between 1995 and 1998, reaching a total of US\$21.1 billion in that year. Company budgets

imply a further real increase of about 12% in 1999, to a current price total in excess of US\$24 billion. For these companies the ratio of R&D to sales has increased from 11.9% in 1980 and 16.2% in 1990 to an estimated 20.8% in 1999 (PhRMA 1999). Overall R&D spending by the global industry approached US\$40 billion in 1998. Thus the R&D intensity of the industry has increased sharply over the 1980s and 1990s, and this increase shows every sign of continuing for the foreseeable future.

The bulk of this R&D spending is concentrated not in new compound discovery and screening but in the stages from pre-clinical testing onwards to market launch. For the PhRMA companies in 1997 only 26.7% of R&D was devoted to synthesis, extraction, biological screening and pharmacological testing, with over 73% being devoted to later stages of the drug development process. With more and more new drugs candidates entering this costly evaluation cycle several things appear to be inevitable: continued rapid expansion of R&D spending by the pharmaceutical and related industries, a relentless search for new and more cost effective ways of undertaking that R&D and more rigorous selection of drug candidates, ensuring a higher success rate through the evaluation cycle.

One consequence of these pressures is the increasing importance within companies of the pharmacoeconomics, the application of methods of economic evaluation (such as various forms of cost benefit and cost effectiveness analysis) in firm decision making, and at an earlier stage of the drug development cycle (BCG 1999).

Increased Patent Expiration and the Role of Generics

One important change in the pharmaceutical market in many but by no means all countries has been the increasing reliance on generic substitutes for brand drugs, as the originator drugs have fallen out of patent. Generic drugs have much lower prices than the innovator drugs which they displace, as they do not have to bear the massive upfront development costs which are so central to the pharmaceutical industry. For example, the US Congressional Budget Office studied the impact of generic competitors to innovator drugs for 21 cases where the generic was introduced in the US between 1991 and 1993 (CBO 1998). They found that, on average, the generic drugs captured 44% of the market during the first calendar year and cost 25% less than the brand drugs at the retail level.

Given that, for compositional as well as direct price reasons, the average level of prices for generic drugs is much lower than that for drugs within patent, the share of generics in the total market is quite different in unit and in value terms. Consistent international data on either basis is difficult to obtain. Table 1 provides some data compiled by Lichtenberger for a number of mainly European countries in 1996, primarily from OECD, IMS and other sources. The data indicate the variation in the penetration of generics across countries in value terms, with figures as high as 22.1% in Denmark and 16.1% in Germany but with generics holding less than 5% of the total retail market in many countries.

Table 1: The Role of Generics in Retail Pharmaceutical Markets, 1996

Country	Total Retail Mark (US\$ billion)	Generic Market (US\$ million)	Generic Share (per cent)
Austria	1.67	145	8.7
Belgium	2.60	153	5.9
Denmark	0.79	173	22.0
Finland	0.94	73	7.8
France	14.3	415	2.9
Germany	15.5	2495	16.1
Greece	1.25	50	4.0
Ireland	0.37	45	12.2
Italy	8.90	67	0.8
Netherlands	2.50	365	14.6
Portugal	1.58	45	2.9
Spain	5.60	73	1.3
Sweden	1.73	75	4.2
UK	7.68	836	10.8

Source: Lichtenberger (1998).

Only limited data is available to us on the extent of the penetration of generics into total retail markets for prescription drugs in OECD countries. Two countries for which data are available, and which the penetration of generics is well advanced, are USA and UK. Following the changes brought about by the Hatch-Waxman Act of 1984 generics have increased rapidly in importance in the US marketplace. In 1984 generics provided 18.6% of all prescription units in the US, but this proportion has risen to 46.5% in 1996 and is likely to reach about 50% by 2000 (PhRMA 1999). The share of prescription dispensed generically has also be rising rapidly in UK, increasing from 36% in 1992 to 49% by 1997 (Scrip Yearbook 1999).

Another important influence on the role of generics is the substantial round of patent expiries likely to take place over the next few years. Because of variations in the nature of the drug portfolios of individual companies the extent of patent expiry differs markedly across companies, but is very heavy for companies such as Merck, Glaxo Wellcome, Lilly and Pfiser (Table 2). For the eight companies shown in Table 6 (since reduced in number by merger activity) drugs providing 36% of 1997 sales will be going out of patent over the 1998-2005 period. From the point of view of drug consumers, this provides an area of potential relief from the financial pressures inherent in the continual release of new drugs at higher prices. For many companies, however, it may intensify financial pressures arising from the costs of new drug development together with constraints on the pricing of drugs within patent.

Table 2: Leading Companies' Patent Expiries, 1998-2005

Company	Patent Expiries, 1998-2005 (Per cent of sales)	Total Sales, 1997 (US\$ million)
Merck and Co	63	11296
Glaxo Wellcome	45	10870
Lilly	44	6363
Pfizer	37	8333
SmithKlineBeacham	28	7227
Roche	22	6232
Bristol-Myers Squibb	17	9048
Pharmacia & Upjohn	8	4391
Total of the above	36.4	63760

Source: Scrip Yearbook (1999, vol. 1, p. 139).

New Models of Disease Management and Cost Containment

At the heart of technologies transforming pharmaceutical industry R&D lies the revolution in information technology. But this revolution is having equally dramatic global effects on the delivery of health services to individuals, and hence on the way in which the pharmaceutical industry is integrated to a given national health system. Any substantial documentation of these trends, which are most strongly evident in the US, is beyond the scope of the current report. But they are central to the opportunities available to Australia in health and pharmaceutical policy, so they must be touched on briefly here. Three aspects are noted: the rise of managed care, the development by managed care organisation of new methods of cost containment and, perhaps most importantly, the development of new methods of disease management and of integrated care.

In the US, for example, the consolidation of consumer power in the hands of a few large organisations is well advanced. In 1996 about 80% of Americans in private sector employment were in managed care organisation (health maintenance organisations (HMOs), preferred provider organisations or point-of-sale plans), this being a sharp increase in the figure of only 23% in 1987 (PhRMA 1999). In 1997, 87.3 million Americans were enrolled in HMOs and the top 10 HMOs had 48% of these enrollees (Federal Trade Commission (FTC) 1999).

Managed care organisations have developed a range of cost containment approaches, many of which make use of their size and market power and/or of the use on information technology to glean systematic information on resource use, the effectiveness of treatment strategies and other matters. For example, pharmacy benefit managers managed the drug benefits of 161 million Americans in 1998 (FTC 1999), and in the US these organisations have made use of techniques to control drug costs in some respects similar to those used by national agencies in other countries. These techniques include drug formularies, therapeutic interchange and generic substitution, treatment protocols such as step-care therapy

(such that high cost treatments are used only if low cost approaches are unsuccessful), and drug utilisation reviews (PhRMA 1999).

Medicine is a classic case of a knowledge based activity, as expert practitioners bring together knowledge drawn from a long history of medical and pharmaceutical research and from experience to treat individual patients. But as knowledge continues to expand rapidly, new methods need to be developed to gather that knowledge and to apply it to the treatment of patients. As knowledge grows it also becomes more diverse and specialised, so that coordination of a range of products and services becomes central to effective health care. The extraordinary power of modern information technology provides an enabling technology, and as a result new approaches – whether disease management, evidence based medicine or integrated care programs – are being pursued in many countries.

In the US, for example, an increasingly successful set of information technology and Internet based systems of disease management and integrated care are being put in place by these and other organisations. These programs make use of large scale patient data sets to analyse the efficacy of various treatments strategies and of drug use, coordinate the use of different types of hospital and medical services, provide advice and in some cases direction of treatment protocols, control drug use, and so on. Such programs have been rapidly taken up by the HMOs, with more than one half of all HMOs being involved in disease management programs in 1997, with special emphasis on chronic diseases such as asthma and diabetes.

New Businesses Structures

Several main trends have been evident in the business structure of the pharmaceutical industry in recent years. In one way or another they have each been responses to growing pressures on individual companies from the factors described above. These factors – fundamentally new and diverse technologies, implying an increase in R&D costs and a diversification in source expertise; a rapid increase in the number of new drugs over the next five years, competing in already crowded and price sensitive markets; heavy patent expiries and an increasing role for generics; and fundamental changes in national health systems – require vigorous responses at the individual company level. Some have argued that as a result of these factors pharmaceutical companies face a new term earnings squeeze which will force drastic change (PWC 1998; BCG 1999).

One way in which firms have responded is through a new wave of alliances between major companies, which has led to a consolidation, not yet completed, at the top of the industry. Major companies have also diversified their operations, purchasing generics companies and pharmacy benefit managers, for example, and extending into health care more generally. This combination of consolidation of ownership and diversification of activities is expected to continue. One observer has predicted a consolidation of the global industry into 'just three major

pharmaceutical-healthcare providers, each with a cloud of satellites' (Richmond, cited in PWC 1998).

The rise of new technologies and the deepening complexity of the industry have led to a diversification of expertise, both in terms of technology companies and service providers. Small companies are very much more important in the industry than ten years ago, and no major company can hope to assemble all the necessary expertise in-house. As a result there has also been a wave of alliances and outsourcing agreements between the majors and small companies, as the large companies seek access to the growing body of technologies, skills and services necessary to be competitive in the future. For example, it is anticipated that the major companies will outsource 50% of both their discovery and development activity by 2005 (BCG 1999).

One further result of these trends is that smaller companies – in fields such as genomics, combinatorial chemistry, automated screening, clinical trials and contract manufacturing – are becoming increasingly important in the industry even as the majors consolidate. This fact has important implications for industry policy.

3. Pharmaceuticals and the Delivery of Health Services in Australia

In global terms, Australia has a health system which is relatively effective, efficient and equitable. In spite of a few important exceptions and some disturbing trends, most Australians have access, on affordable terms, to hospital and medical services of high quality by international standards. This provides a firm basis from which to address the urgent challenges ahead, including those which are the focus of this report.

Total Spending on Health

Australia currently spends about 8.4% of its GDP on health, which places it broadly in the middle rank of OECD countries (Table 3). Thus Australia's level of expenditure is well below the figures for the USA, Germany and Switzerland (14.1%, 10.8% and 10.1% in 1996 respectively) but also well above those of countries such as New Zealand, Japan and the UK (7.3%, 7.1% and 7.1% in 1996 respectively). The pattern of change over the 1990s has been quite diverse. In many countries (such as USA, Germany, Japan, UK, France and Switzerland) total national spending on health as a share of GDP was substantially higher in 1997 than at the beginning of the decade, although in a number of these cases there has been some stabilisation since the mid 1990s.

It is apparent from Table 3 that massive differences in the cost of national health systems persist, without corresponding differences being apparent in the quality of those systems. In most other countries, including Australia, movements in this measure of health spending over the 1990s have been modest, in either direction. Indeed, with a few exceptions, total health costs seem to be stabilising or trending down as a share of GDP since about 1995. This seems to be in part associated with the impact of vigorous efforts to contain costs in many countries in the 1990s.

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Table 3: Total Expenditure on Health (per cent of GDP)

	1980	1985	1990	1995	1996	1997
	<i>(% of GDP)</i>					
United States	9.1	10.6	12.6	14.1	14.1	13.9
Germany	8.8	9.3	8.7	10.4	10.8	10.7
Switzerland	6.9	7.7	8.3	9.6	10.1	10.3
France	7.6	8.5	8.9	9.8	9.8	9.6
Canada	7.2	8.3	9.2	9.4	9.3	9.1
Sweden	9.4	9.0	8.8	8.5	8.6	8.6
Netherlands	7.9	7.9	8.3	8.8	8.7	8.5
Australia	7.3	7.7	8.2	8.4	8.6	8.4
Austria	7.7	6.7	7.2	8.0	8.0	8.3
Denmark	9.3	8.7	8.3	8.1	8.1	8.0
Belgium	6.5	7.3	7.5	7.9	7.8	7.6
Italy	7.0	7.1	8.1	7.7	7.8	7.6
New Zealand	6.0	5.3	7.0	7.3	7.3	7.6
Norway	7.0	6.7	7.8	8.0	7.8	7.5
Finland	6.5	7.3	8.0	7.7	7.8	7.4
Japan	6.5	6.7	6.1	7.2	7.1	7.2
United Kingdom	5.6	5.9	6.1	7.1	7.1	6.9
Ireland	8.7	7.9	6.7	7.0	6.4	6.3

Source: OECD Health Data, 1999.

Pharmaceutical Spending

For OECD countries expenditure on pharmaceutical goods accounts for only a modest share of spending on health, but this spending and its share of health spending varies significantly across countries. Data on pharmaceutical use within hospitals is difficult to obtain, and comparable data across countries is only available on a basis which excludes hospitals, that is on an outpatients basis. Pharmaceutical spending in 1996, so defined, ranged from 1.6% of GDP in France to 0.7% of GDP in Denmark, Norway and Ireland. As a proportion of total health spending, spending on pharmaceuticals (excluding hospital use) in 1996 ranged from 7.9% in Switzerland to 21.1% in Japan.

Australian individuals and governments spent just over \$5 billion on pharmaceuticals, again excluding spending within hospitals, in 1996-97. But by both of these measures spending on pharmaceuticals in Australia – 1.0% of GDP and 11.6% of total health spending of \$44 billion in 1996 – is towards the lower end of the range of OECD countries. There is some evidence that this reflects both lower prices paid to drug companies in Australia and a lower usage of prescription medicines in Australia than in OECD countries as a whole.

Table 4: Outpatient Expenditure on Pharmaceuticals (per cent of GDP)

	1980	1985	1990	1995	1996	1997
	<i>(% of GDP)</i>					
France	1.2	1.4	1.5	1.6	1.6	1.7
Japan	1.4	1.2	1.3	1.5	1.5	
Belgium	1.1	1.1	1.2	1.4	1.4	1.4
Italy	1.0	1.3	1.5	1.3	1.4	1.5
Canada	0.6	0.8	1.0	1.3	1.3	1.3
Germany	1.2	1.3	1.2	1.3	1.3	1.3
United States	0.8	0.9	1.1	1.3	1.3	1.4
Austria	0.8	0.8	0.9	1.1	1.1	1.2
Finland	0.7	0.7	0.8	1.1	1.1	1.1
New Zealand	0.7	0.7	1.0	1.1	1.1	1.1
Sweden	0.6	0.6	0.7	1.1	1.1	1.1
United Kingdom	0.7	0.8	0.8	1.1	1.1	1.2
Australia	0.6	0.6	0.7	0.9	1.0	
Netherlands	0.6	0.7	0.8	1.0	0.9	0.9
Switzerland	1.0	0.7	0.7	0.7	0.8	0.8
Denmark	0.6	0.6	0.6	0.7	0.7	0.7
Norway	0.6	0.6	0.6	0.7	0.7	
Ireland	1.0	0.8	0.8	0.7	0.7	

Source: OECD Health DATA, 1999.

There is some evidence in the tables above of an inverse relationship between the level of drug spending and of other health spending, especially if the USA is excluded from the sample. But further analysis of this relationship is complicated by price and volume effects at the aggregate level in the pharmaceutical industry, and the very limited information available about such variables. A country such as France may have a high level of spending on drugs because it has both high prices and high usage, whereas a country such as Denmark may have low spending on drugs because it has relatively low prices and low usage. High drug usage in turn may reflect either efficient use of drugs for health outcomes or a wasteful dependence on unnecessary drug usage. Thus it is impossible to draw any firm conclusions from aggregate data, but it remains possible that optimum use of drugs may lead to reductions in other health expenditures.

The Public Contribution to Health and Drug Costs

The health sector is one in which there remains a heavy emphasis on public provision. In all major OECD countries other than the USA, the bulk of spending on health takes place through the public purse. Even in the US nearly half of national spending (46.3% in 1996) is undertaken through the public sector. Of the 19 main OECD countries shown in Table 5, Australia has the lowest share of public spending in total health spending (66.3% in 1996) of any of the other countries. Spending on drugs is somewhat less concentrated in the public sector, but for 13 of the 19 countries more than 60% of drug purchases are undertaken

by the public sector. Again the Australian share (50% in 1996) is at the low end of the range.

Countries differ more substantially in the extent to which outpatient spending on drugs is funded by governments or individuals, than in the public share of total health spending. This reflects the wide range of different approaches to drug pricing and to the financing of spending on drugs in place in OECD countries. For most OECD countries the share of the outpatient drug bill met directly by governments ranges from about 40% to about 75%, although there are a number of outliers: the proportion is over 85% in Norway and Ireland, but only 30.8% in Canada and 15.4% in the USA. Again, in spite of the dominance of the Pharmaceutical Benefits Scheme, Australia is in a mid-range position, with 50% of the outpatient drug bill met by the public purse in 1996-97.

Table 5: The Share of Public Spending in Total Spending, 1996 (%)

	Total Health Spending	Outpatients Pharmaceutical Spending
Belgium	87.2	42.9
United Kingdom	84.5	63.6
Denmark	84.0	42.9
Sweden	83.7	72.7
Norway	83.3	85.7
Japan	80.3	66.7
Germany	78.7	76.9
Spain	78.4	73.3
New Zealand	76.7	63.6
Finland	75.6	45.5
Ireland	75.0	85.7
France	74.5	62.5
Switzerland	74.3	62.5
Austria	73.8	63.6
Netherlands	71.3	66.7
Italy	70.5	42.9
Canada	69.9	30.8
Australia	66.3	50.0
United States	46.1	15.4

Source: OECD Health Data, 1999.

Perhaps the most important feature of the Australian situation is the rapid rise in the reliance on government funding of drugs in the 1990s, the public share rising strongly over the 1990s. Later figures from the Australian Institute of Health and Welfare (Health Expenditure Bulletin No. 15, 1999) show a rise in the share of government expenditure in total outpatients pharmaceutical spending from 44.8% in 1990-91 to 54.0% in 1996-97. This proportion almost certainly has risen further since 1996-97. Thus while the reliance on the public purse to meet the outpatient drug bill is still lower in Australia than in most European countries, its rapid rise in the 1990s is giving rise to some difficulties.

The Role of Generics

A further factor noted as relevant above is the extent to which generics are used in place of the original brand drug after the relevant patent expires. As noted above, in some major countries generics account for about 50% of retail prescription drug sales by unit are supplied by generics although, because of lower prices, the share of the market by value is much lower. Figures for the use of generics in Australia are difficult to obtain. In 1990 the Australian Government introduced the Brand Pricing Policy, which involves subsidising a drug to the lowest price brand and allowing other brands to charge higher prices, with the consumer paying the price premium. Brand substitution by pharmacists was introduced in 1994. Transactions under this policy provide the best indication of the extent of the use of generics in Australia.

In the year to May 1998 a total of 49.6 million scripts were filled under the Brand Pricing Policy, amounting to about 38% of all PBS prescriptions. But only 32% of these prescriptions, or about 12% of all PBS scripts filled under the Brand Pricing Policy, were dispensed at the benchmark level. The majority of brand premiums were in the range \$1.00 to \$1.50, while the average brand premium was \$1.60 and the range was from \$0.22 to \$6.08. The proportion of all PBS scripts filled at the benchmark level has risen quite strongly in recent years, growing from less than 5% in 1994 to 12% in 1998. Nevertheless, these data suggest that the use of generics in Australia remains quite low by the standards of countries such as UK and USA, where 50% or more of scripts are filled by generics. Little information is available on the level of benchmark pricing relative to overseas markets for generic drugs, but the differential between the benchmark (generic) drug and the branded alternatives appears to be low by international standards.

The Costs of Distribution

Many factors affect the value received by consumers, and indeed the effective benefit received by producers, for a given level of subsidy by government. One is *the efficiency of the system for the distribution of drugs*, and hence the price received by manufacturers after a mark-up is paid to the wholesaler and the pharmacist. According to the Scrip Yearbook for 1999, the share of the pharmaceutical sales dollar received by the manufacturer ranges from 77.1% in Sweden to 58.1% in Switzerland. Data are not available from this source for Australia, but the indications are that the share of sales going to manufacturers in Australia is in the middle of that range. According to the Pharmaceutical Benefits Pricing Authority, for the total cost of PBS prescriptions for 1996-97, 67% was received by manufacturers, 26% by pharmacists and 7% by wholesalers.

Table 6: Shares of Retail Pharmaceutical Expenditure

Country	Manufacturer	Wholesale	Pharmacy
Sweden	77.3	2.7	20.0
Portugal	72.0	8.0	20.0
Denmark	69.4	5.5	25.1
Greece	68.7	6.3	25.0
Finland	68.5	2.5	29.0
France	67.8	6.3	25.9
Netherlands	67.2	11.4	21.4
Australia	67.0	7.0	26.0
Italy	66.9	7.6	25.5
Belgium	64.7	8.3	27.0
UK	63.4	9.1	27.5
Germany	62.3	9.9	27.8
Spain	61.7	8.4	29.9
Austria	59.0	10.0	31.0
Switzerland	58.1	8.4	33.5

Source: Scrip Yearbook (1999, vol. 1, p. 128), except for Australia. For Australia data refers to PBS sales only, and is drawn from the Department of Health and Aged Care, Canberra, www.health.gov.au/haf/branch/pbb/whopays.htm

Compliance with Prescription Advice

Another aspect of the efficiency of drug use is *the extent of compliance or non-compliance with prescription advice*. After a medical consultation, a doctor will often prescribe a drug as treatment for the condition diagnosed. What happens then is largely up to the patient, and one of two forms of non-compliance may be involved. The patient may not proceed to obtain the medication from a pharmacist (purchase non-compliance) or, even though the drug is purchased, the patient may decide not to follow the prescribed regimen, either in whole or in part (use non-compliance). The two forms of non-compliance may lead to substantial inefficiencies in the use of pharmaceuticals to generate improved health within the community. On the assumption that the doctor's decision is the best for health outcomes, patient non-compliance is likely generate less than optimal outcomes for the quantity of drugs actually sold, as well as to lead to lower sales drugs than is optimal for patient welfare.

There is an extensive international literature on non-compliance issues (for a review of some of that literature McGavock 1996). A study by SRI Consulting in the US is reported to have found that one-third of prescriptions written never get filled and that non-compliance costs the US health industry almost US\$100 billion per year (*Market Letter* 1999). The report argues that 10% of all admissions to hospital and 25% of admissions to nursing home are directly related to non-compliant behaviour. We are not aware of evidence on the extent of non-compliance in Australia, but some overseas studies have suggested that it is of major importance.

New Approaches to Integrated Care in Australia

We have noted briefly above the increasing importance internationally of programs which:

- coordinate the delivery of health services to a group of patients;
- provide systematic knowledge on the most effective treatment strategies and drugs to participating professionals;
- use data on patient outcomes to monitor the effectiveness of treatment strategies and drugs, and to vary those treatments if necessary;
- monitor the adherence of professionals to best practice approaches and of patients to medical advice and prescriptions;
- control the cost of treatment, and ensure that least cost methods of treatment are used as appropriate, and
- more generally, encourage the use of evidence based approaches to all aspects of the health services process, so as to achieve better health outcomes for individuals at lower overall cost to the community.

These programs draw heavily on, and have to some extent been made possible by, the revolution in information technology. In part they have been pioneered by the HMOs and similar organisations in the US, many of which have the scale, resources and incentives to develop quite new approaches to health care delivery.

While inevitably such programs can be abused, and used to reduce the effective health care provided to individuals in the name of reducing costs, it is clear that such programs offer major benefits if suitably applied. An important issue in Australia, then, is how the benefits of such programs can be captured in Australia, given the particular objectives, institutions and values prevalent in this country. This raises fundamental issues about the future structure of the Australian health system (see, for example, Scotton 199) which cannot be taken up here. But the successful introduction of such programs is likely to be an important part of meeting the central challenge being addressed in this report.

In this respect, the cooperation of a range of stakeholders in the Integrated Care Program is an important development which should be noted. This a pilot program seeking to design, implement and evaluate a model of an integrated, comprehensive and evidence based approach to health care and service delivery. It makes use of advanced information systems to provide information, training and decision support systems to participating GPs, to coordinate the use of resources and to provide outcomes data for evaluation on an aggregate basis. The stakeholders in the program are the Pharmaceutical Alliance (an alliance of six pharmaceutical companies), three Divisions of General Practice (two in NSW and one in Victoria), the Commonwealth Department of Health and Family Services, Health Communication Network Ltd and the Health Insurance Commission.

This project started in 1998 and it is too early for any extensive results to be available. But it is a potential example of the way in which various parties can

work together to use leading edge knowledge, products and services to achieve both better health outcomes and reduced costs.

4. The Pharmaceutical Benefits Scheme

Three sets of prices are relevant to the debate about pharmaceuticals in Australia – the price which the producer and/or the wholesaler of the product actually receives, the price paid by the final consumer and the effective price paid by government, as middleman between the producer and the consumer. In Australia, as in many other countries, these prices are not set by unfettered market forces but by strategic negotiation between the government and companies, and by government policy. At the heart of the determination of these prices is the Pharmaceutical Benefits Scheme, the PBS.

The PBS had its origin in the flurry of legislation, negotiation and constitutional change which took place in the late 1940s, and it has been involved in a process of controversy and adjustment since that time (Sloan 1995). There is no doubt that the PBS has generated major social benefits for Australia in terms of the cost and accessibility of drugs, nor that these benefits have been bought at some cost in terms of the development of the pharmaceutical industry in Australia. Governments have also shown a willingness to adjust the operation of the PBS to meet new challenges, and such a renewed process of adjustment may be necessary to meet the challenges outlined in this report. While the broad facts about the PBS are well known, some of the key elements are reviewed briefly below.

Charges to Consumers

For some decades, patient charges for drugs under the PBS have been divided into a charge for general patients and one for concessional patients. From 1 January 1999 a maximum charge for general patients of \$20.30 per prescription item applies, up to a limit of \$620.60 in any calendar year (after which a charge of \$3.20 applies). For persons holding a health card the charge per item is \$3.20 per prescription item, up to a maximum of \$166.40 per calendar year. In 1997-98 the cost of PBS pharmaceuticals to general patients was \$805 million, of which 36.6% was met by copayments and 63.4% by government subsidy, about one-fifth of the subsidy being due to the safety net limit. For concessional patients the total cost was \$2293 million, of which only 12.1% was provided by copayments and the remainder by the government. Again the safety net arrangements contributed about one-fifth of the total subsidy cost.

Two aspects of these arrangements which may be relevant to the broader issues are the limited role of price signals in consumer decisions and the nature of the link between the incidence of the PBS subsidy and capacity to pay. One result of this system is that, for drugs listed on the PBS, there is little exposure of consumers to the actual prices of drugs as paid by the PBS – for most prescriptions the price paid by the consumer is independent of the cost of the drug. While the split between general and concessional patients provides a general distinction in terms of assumed capacity to pay, there will still be marked differences in this capacity among general patients and among those holding health cards. The

present charging system gives no recognition to variations in individual circumstances within these categories.

Prices Paid to Drug Companies

There are many complexities in the process of comparing pharmaceutical prices across countries (Danzon 1997a, 1997b), such as variations in medical practices and dosage levels, in patterns of drug use, in the role of generics and of original brand drugs, and in the availability of discounts against list prices. Danzon (1997b) has argued, in a study of drug prices in nine main countries (not including Australia), that different assumptions on these matters may give quite different results in terms of the level of overall relative prices for the nine countries.

Emphasis on these difficulties has led the American pharmaceutical industry association PhRMA to argue that 'it is not possible to draw any conclusions about the general level of drug prices across countries' (PhRMA 1999 p. 82). In spite of this extreme view, it is widely held that prices paid in Australia to pharmaceutical suppliers are substantial lower than the average price received in OECD countries. In its 1995 submission to the Industry Commission inquiry APMA reported the results of a detailed analysis of prices relative to average OECD levels as follows:

- the weighted average Australian price of a basket of leading products represented 35.4% of average OECD prices, and
- the weighted average Australian price of a basket of new products represented 67.7% of average OECD prices.

This study was based on data provided by IMS on the list prices for a substantial sample of brand drugs. The Industry Commission's report into the pharmaceutical industry accepted this analysis as providing the best assessment of the overall level of prices paid in Australia available at that time (1995).

Nevertheless, and while there is little doubt that the prices paid by the PBS in Australia to manufacturers of pharmaceuticals are below average OECD prices, such studies must be treated carefully as measures of the overall cost of pharmaceuticals. They typically exclude the role of generics, by studying the prices for a selection of brand drugs; dosage levels and other factors differ significantly across countries, and results differ if different units are chosen; the pattern of drug use also differs across countries, so that comparative results vary with the weights used, and the level of drug use also varies markedly across countries. Further detailed work is necessary to form an accurate view of overall level of price paid to companies for drugs in Australia in 1999, relative to those paid in other countries.

Other indicative approaches to this issue are also worthy of consideration. For example, as noted in Section 2, the net effect of many factors is that total Australian expenditure on outpatient pharmaceuticals is, at 1% of GDP in 1996, about in the mid-range of OECD countries. While there is some evidence that

drug use in Australia may be lower than in some other countries, this fact also provides some indication of the overall level of relative prices.

Approaches to Price Setting

Over the past decade the Pharmaceutical Benefit Pricing Authority (PBPA) has led the world in the introduction and development of economic evaluation as part of the price setting process for drugs (for a comparative review see Drummond et al. 1997). Economic evaluation analyses became mandatory in pricing submissions in January 1993, and detailed guidelines are provided, and regularly revised, concerning the information required in those analyses. As noted in Section 2, in recent years these techniques have also been more widely used within pharmaceutical companies, as they face the need to make complex choices between many different candidates in the drug development pipeline. This convergence on economic evaluation, in its various forms, as an analytical tool may provide the basis for a more transparent approach to PBS pricing in the future.

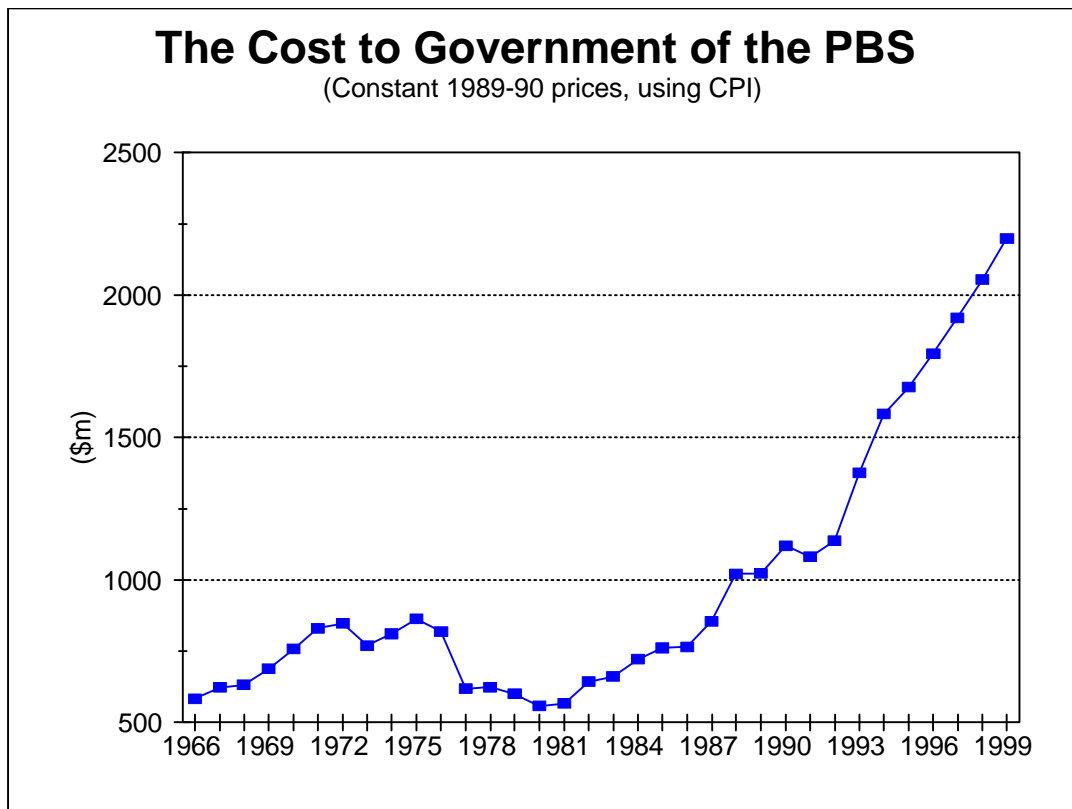
In the 1997 Budget, however, the Government announced that it would introduce a form of reference pricing. Reference pricing is used in a number of European and other countries (e.g. Germany, Netherlands and Sweden), and proceeds on quite different principles to economic evaluation. This was the Therapeutic Group Premium (TGP) Policy which came into effect in February 1998 and which implies something of a retreat by the PBPA from the economic evaluation approach. Under the TGP Policy the Australian Government subsidises drugs within broad therapeutic groups – drugs which have similar clinical activity – only to the level of the lowest priced drug in each group. The price difference between the more expensive drug and the benchmark price is paid directly by the patient, as an add-on to the relevant co-payment.

The introduction of the TGP Policy has led to reductions in prices paid by the PBS for a significant range of brand drugs, and to deepening concern among many pharmaceutical companies about the direction of drug pricing policy in Australia. The further application of this policy in 1999 has also led to some real conflict between the drug companies and the authorities.

The Rising Cost of the PBS

While total health spending in Australia has stabilised, as a share of GDP, in recent years, the real cost to the Government of the PBS began to increase rapidly after 1993 (see Chart 1). As is evident from Chart 1, growth in the cost to Government of the PBS has risen sharply in real terms in each year since 1991-92, with average real growth of about 12% per annum between 1991-92. As a result, the cost to Government of the PBS has risen continuously as a share of GDP over this period.

Chart 1



This rise in the cost to Government of the PBS has been a cause for concern, and attention has inevitably been given to ways of reducing that cost. Some of these initiatives, notably the introduction of Therapeutic Group Premiums, have had a hostile reception by the industry, as noted above. It has been claimed that they will have an adverse impact on the development of the local industry. Certainly, containing the growth in the cost to Government of the PBS is a central element of the challenge to be addressed.

5. The Australian Pharmaceutical Industry: Performance and Policy

The pharmaceutical industry in Australia has been the subject of extensive study in recent years. Notable examples are the Industry Commission's 1996 report *The Pharmaceutical Industry* and the 1998 study *Pharmaceuticals and Australia's Knowledge Economy* by Australian Economic Analysis Pty Ltd. The Wills Report on health and medical research *The Virtuous Cycle*, released in December 1998 (Department of Health and Aged Care), documented the research foundations of the industry in Australia. As a result, many of the broad facts about the performance of the industry are well known, and the present project does not seek to duplicate this work. Here we briefly review the structure of the pharmaceutical industry and its performance in Australia, as a prelude to considering the issues facing Australian industry policy in the broader context described earlier in this report.

The Structure of the Pharmaceutical Industry

Before examining industry performance data or policy issues it is useful to note the unique structure of the research based pharmaceutical industry. On a global basis this industry is the most R&D intensive of all industries, with a ratio of R&D to sales of over 20%. The industry is also one in which the level of capital expenditure in plant and equipment required is fairly modest, but in which marketing plays a very important role in total costs. With heavy sunk cost investment in R&D and marketing, the industry is thus one in which sunk costs are very large relative to variable production costs in spite of relatively low levels of capital spending, and hence one in which increasing returns prevail.

To give some quantitative expression to these aspects of the pharmaceutical industry, Danzon has undertaken an analysis in which, using data from the US Office of Technology Assessment, all lifetime costs for a cohort of drugs are expressed in discounted present value terms, after tax, at the time of launch (Danzon 1997a). This analysis assumes a corporate tax rate of 46% and a cost of capital of 10%. Different components of cost are then expressed as a share of total costs (see Table 7).

This analysis brings out clearly the central role of R&D, to the extent that over 30% of the total lifetime costs of creating, producing and distributing a typical cohort of drugs is in R&D expenditures. The discounted value of all manufacturing and distribution costs amounts to 25.3% of total costs, only a little more than marketing costs at 23.4%, whereas capital expenditure accounts for only 2.9% of total costs. Indeed, R&D and marketing alone account for more than 50% (54.5%) of the total costs.

Thus Danzon's estimates bring out clearly the unique cost structure of the pharmaceutical industry, and the extent to which it is dominated by R&D. This fact is particularly relevant for the development of the industry in Australia. With a relatively strong health and medical research base (producing 2.5% of global research output with 0.3% of global population – Wills (1998)) and a good health system in which to place clinical trials and related activities, Australia's comparative advantage in the industry resides at the R&D end. It is also worth noting that Danzon's estimates relate to the situation as at the early 1990s. The trends described in Section 2 suggest that the industry has become even more R&D intensive in the 1990s, and that this trend will continue in the foreseeable future.

Table 7: The Cost Structure of the Pharmaceutical Industry: Discounted Present Value of New Drug at Launch

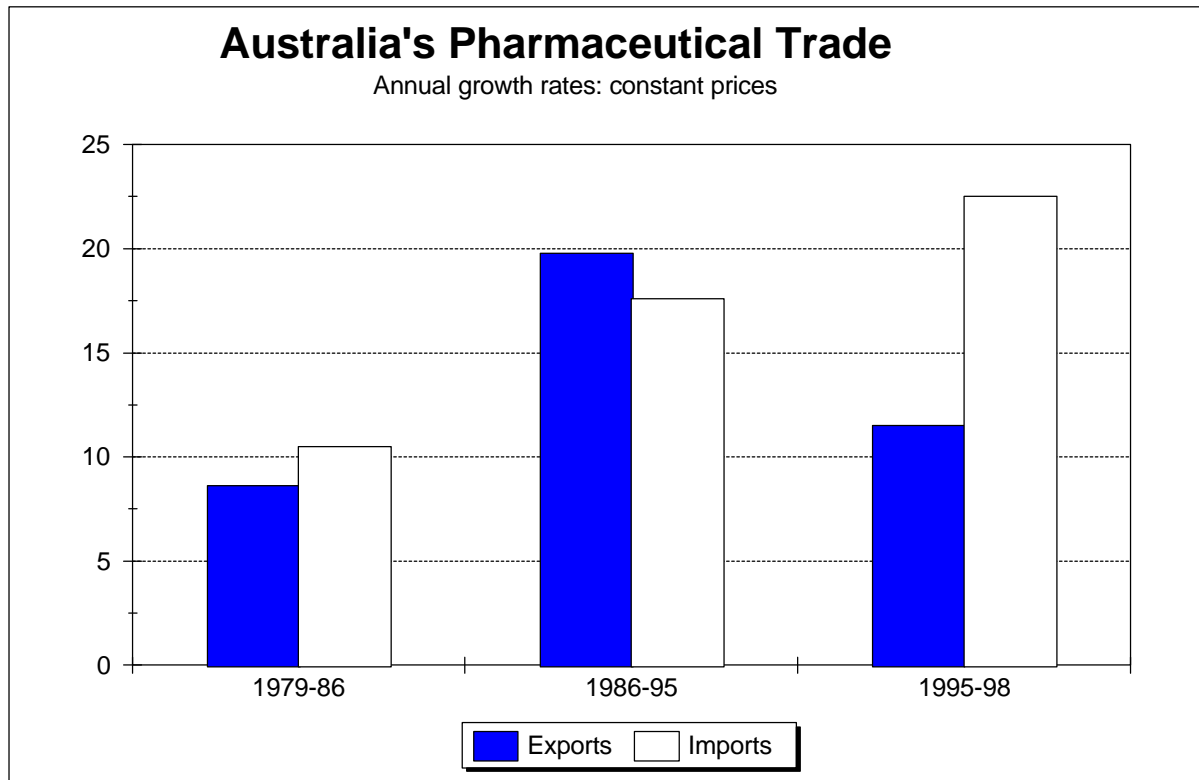
	Per cent of total cost, after tax (%)
Total R&D Cost	31.1
R&D	29.0
Ongoing R&D costs	2.1
Total Manufacturing Cost	28.2
Production and distribut	25.3
Capital expenditure	2.9
Other	40.6
Marketing	23.4
General and administrati	11.5
Other	5.7
Total	100

Source: Danzon (1997a).

The Recent Performance

The report *Pharmaceuticals and Australia's Knowledge Economy* documents the impressive performance of Australia's pharmaceutical industry in terms of value added, exports, R&D and investment from the mid 1980s to the mid 1990s, after a relatively poor performance in the preceding decade. These figures are indeed striking – they include growth in real value added of 22% per annum between 1985 and 1994, more than twice the OECD average; real investment growth of 11% between 1990 and 1995, at a time in which overall manufacturing investment was falling; real export growth of just on 20% per cent per annum between 1986-87 and 1995-96, slightly exceeding import growth (see Chart 2), and virtually a threefold increase in real industry R&D between 1986-87 and 1995-96 (Australian Economic Analysis 1998).

Chart 2



Trends in the industry are somewhat more difficult to discern since 1995-96, partly because of changes in the relevant industry classifications used by the Australian Bureau of Statistics. However, the signs are that the industry has continued to grow, although perhaps not at the earlier pace. Comparable figures on industry value added are difficult to obtain after 1995-96, but value added among the 10 Factor (f) companies, a substantial part of the local industry, has continued to increase, rising 22.1% in 1997-98 (PBPA Annual Report 1998). Exports grew in real terms by 11.5% between 1995-96 and 1998-99, a strong growth rate even though one below both the earlier export growth rate and rate of the growth of imports over 1995-96 to 1998-99 (Chart 2). Another important lesson of Chart 2 is the continued rapid growth, and indeed the accelerating growth, in pharmaceutical imports into Australia in real terms. Australia is an extensive user of advanced pharmaceuticals, and its trade deficit in this area will continue to grow unless there is another major round of expansion in the local industry.

We argued above that the global pharmaceutical industry is at a critical stage, with fundamental change underway as a result of new technologies, changes in national health systems and structural changes in the industry. The Australian industry also seems to be at a critical stage, after some fifteen years of rapid expansion. The global changes inevitably impact on the local industry, and require a response from health and industry policy makers in Australia. How these policies

are shaped over the next few years, and how companies respond to those new policies, will do much to determine the nature of the Australian industry which is built on the base created by the achievements since 1985.

The Policy Settings – The Factor (f) Program

Those achievements in building the Australian pharmaceutical industry since the mid 1980s have indeed been striking, especially since they have taken place at a time in which Australia has continued to enjoy prices for brand drugs well below those in many other developed countries. Central to those achievements has been the settings of industry policy, and particularly the Factor (f) program.

The Factor (f) program was introduced in 1988, providing payments by way of higher prices to drug companies. These payments were related to the increase in their value added and R&D activities. Agreements were negotiated on a company by company basis, with certain minimum participation requirements. Companies received payments as higher prices up to a maximum of 25% of increased value added and 25% of increased R&D spending (or 50% of the increase in after tax R&D spending), in all cases relative to the base year. Payments were not to bring the average level of prices above that prevailing, for the products in question, in the European Community.

Phase 1 of the Factor (f) program was closed to new entrants in May 1991, by which time 20 companies were involved. Phase 1 terminated in 1994-95, and a second phase was put in place, in which 10 companies were involved and which continued until 30 June 1999. As shown in Table 8, the total cost to the Government over the six year period between 1991-92 and 1997-98 was \$550.9 million, or an average of about \$88 million per annum. The cumulative increase in company outcomes over the base year (in most cases 1991-92) was \$2027.4 million for value added and \$272.5 million for R&D. The cumulative increase of just on \$2300 million in the two elements combined is just over four times the amount paid by the Government, consistent with the maximum payment of 25% of the outcome increase.

Table 8: Outcomes and Costs for Factor (f) Program

	Level for Participating Companies		Cumulative Increase
	1991-92	1997-98	Over Base (1991-92) Level (<i>\$million</i>)
Production Value Added	133.2	787.6	2027.4
R&D	15.5	99.0	272.5
Amount paid by Government			550.9

Source: PBPA Annual Report, 1998.

In assessing the effectiveness of the Factor (f) scheme the two key questions are the extent to which the additional expenditure was induced (that is, would not have occurred without the program), and the extent of the broader economic and social benefits deriving from these outcomes. While it is difficult to provide definite evidence, it seems high likely that a significant proportion of these cumulative outcomes were indeed induced by the program and that there were substantial social as well as private benefits from these induced outcomes. These judgements seem to lie behind the view of most industry observers, with which we concur, that this has been a very successful policy in social cost benefit terms.

The most recent detailed assessment of the impact of the Factor (f) scheme is that of the Industry Commission (1996), in large part based on the research carried out by the Bureau of Industry Economics (*The Factor (f) Scheme*, BIE (1995)). The BIE addressed these and other issues, although it was ultimately unable to quantify the social benefits to Australia of the Factor (f) program, to be assessed against the identified costs. But the BIE report found that the overall benefits, in terms of various types of spillovers and flow-on effects, would need to be at only a low level - about 5 cents per dollar of induced activity for Australian companies and about 23 cents per dollar for foreign companies - for the scheme to break even.

While it is difficult to quantify the spillover benefits for a particular industry in Australia, and hence to quantify the overall social returns to a given program, there is now a substantial body of literature about the spillover and flow-on effects of R&D and production in high technology industries. This literature suggests that much higher spillovers occur in most cases than are necessary on the BIE analysis to demonstrate the effectiveness of the Factor (f) scheme. We illustrate this point below with a brief review of some of the literature in relation to R&D.

One striking conclusion which emerges from a substantial body of econometric work, carried out both in Australia and overseas, is that the estimated returns to R&D generally are high in most advanced countries, including Australia, being very much higher than the cost of capital. (For a survey see Industry Commission 1995). This applies to both the private returns at the firm or industry level and the social returns at the economy wide level. Estimated social rates of return of over 100%, that is a *continuing* annual flow of social benefits in excess of the *once off* cost of the R&D, are quite common. Industry specific rates of return to R&D are also often quite high. For example, the unweighted mean of 23 studies of returns at the industry level for the United States and Japan was 26%, and for seven similar studies covering five other OECD countries was 54% (Industry Commission 1995).

Indeed, the returns to R&D in modern economies are richer and more diverse than those accommodated by conventional economic theory, and these are

captured by the high rates of return to R&D found in virtually all econometric studies. While few studies are available for the pharmaceutical industry alone, there is every reason to believe that pharmaceutical R&D, being in a very high technology industry with immediate consumer applications, has a higher than average social rate of return.

In terms of estimates of the private and social rates of return on pharmaceutical R&D perhaps the most relevant study is one by Odagiri and Murakami (1992), who have estimated such rates of return for Japan over the period 1967-1986. They find a private rate of return to this R&D of 19% and a social rate of return (to all firms in the industry) of 33%. The fact that the social rate of return is much higher than the private rate of return is interpreted as strong evidence of spillovers and related effects. These spillover effects themselves thus generate a social rate of return of 14%.

In an important recent paper, Cockburn and Henderson (1996) have investigated economies of scale and scope and the extent of intra-firm and inter-firm spillovers for the US pharmaceutical industry over the period 1960-1988. They found evidence of significant R&D economies of scale at the firm level and, in particular, significant intra-firm and inter-firm spillovers, giving rise to economies of scope both at the firm and national level. They also found evidence that the extent of both types of spillover has increased substantially after 1978, as the pharmaceutical industry changed with the advent of new and increasing complex technologies.

This is not the place to continue this discussion of the academic literature. But three things do seem clear:

- the economy wide social rates of return to R&D are very high, both in Australia and in other countries, implying very substantial spillovers from R&D;
- there is evidence of substantial spillovers from international studies in the case of pharmaceutical R&D, implying social rates of return well above private rates of return, and
- it is likely that the spillovers from R&D, and hence the social rates of return to R&D, in the pharmaceutical industry are at least as high as, those to R&D in the economy as a whole.

Thus the available evidence implies that the spillovers arising from the Factor (f) outcomes are very much greater than required for the program to break even on the BIE analysis, and hence confirms the common view that this has been a highly successful program.

The Policy Settings – The PIIP Program

With the conclusion of the second phase of the Factor (f) approaching, the Government announced in April 1997 that it would establish a new scheme, the

Pharmaceutical Industry Investment Program (PIIP), which would follow on from Factor the (f) program. The new scheme would run from July 1999 to June 2004 and be similar in many respects to Factor (f). But it would be smaller, with its total cost capped at \$300 million over the five-year period, and the available funding would be allocated between companies on a competitive basis. In December 1998 the Government announced that ten companies would participate in the first round of the PIIP program, effective from 1 July 1999.

Towards the Next Generation of Policy

It is clear that the Factor (f) program has had a significant impact on the rapid growth in the pharmaceutical industry in Australia over the past decade or so, and that the PIIP program will continue to deliver valuable benefits, albeit at a reduced level. But experience with these programs suggest that they contain certain limitations, especially when viewed in the context of the massive changes which are taking place in the global industry and the challenges they pose for Australian policy. Some of these limitations are as follows:

- Both the second stage of Factor (f) and the PIIP program have provided benefits to only ten companies. While this approach had real merits, with rapid structural change in the industry there are a much larger range of companies which either do undertake, or might consider undertaking, pharmaceutical activities in Australia. It would seem desirable, then, that the next generation of policy provide a framework applicable to all companies undertaking certain activities in Australia, and hence provide a stable basis on which to encourage new or increased activity in Australia as circumstances change.
- Part of the rationale for these policies is that lower than average world prices for pharmaceuticals in Australia discourages pharmaceutical companies from undertaking production and R&D activities. But a smaller pharmaceutical industry also discourages a range of other companies, drawing expertise from and providing services to the drug companies. As argued in Section 2, smaller companies – in fields such genomics, combinatorial chemistry, automated screening, clinical trials and contract manufacturing – are becoming increasingly important in the industry even as the majors consolidate. The next generation of policies should encourage the activities of such companies in Australia directly, as well as indirectly through support for pharmaceutical companies.
- With the industry being heavily driven by biotechnology, there is increasing overlap between development activities in pharmaceuticals and in other areas. Technologies relevant to human use products may, for example, have important applications to animal products. More generally, governments around Australia have identified biotechnology as a key priority area. The recent Ernst and Young report has documented the dimensions of biotechnology activity in Australia, in areas from human health and agriculture to food processing and environmental change (1999). It would thus be sensible for the next generation of pharmaceutical industry policies to dovetail closely with any policy initiatives developed for biotechnology.

- Finally, while the emphasis on rewarding *increased* levels of activity is an important focus of these programs, by comparison for example with the 125% R&D tax concession, the choice of the basis period is critical. If the period from the base year to the current year is too long, companies are effectively rewarded many times for increased activity in a given year. But if it is too short, benefits to companies become distorted by short-run changes in outcomes.

It is not the intention of this report to attempt to design specific policies consistent with these considerations and with the broader matters discussed in the body of the report. We wish only to highlight two broad approaches to policy which would, in our assessment, contribute significantly to the further development of the pharmaceutical industry in Australia.

The first is a general payment to drug companies undertaking value added activities in Australia, related to the increase in their value added over, say, the average level of the past four years. The payments would be available to all companies undertaking such activities in Australia, perhaps subject to certain scale and commitment requirements. If the payment was at, say, 20% of the increase in value added over the average level of the past four years, this should provide a valuable and continuing incentive for both existing and emerging companies.

While given in general recognition of the impact on industry development of the low level of the prices paid for drugs in Australia, these payments need not be closely related to the actual prices received by a given company. Given the importance of economies of scale, spillovers and agglomeration effects in this industry, the disincentive effects for a given company of a low level of drug prices are much wider than the direct effects of the prices received by the company.

The second suggestion is for a more general support program for R&D undertaken in Australia, which might apply to R&D in both pharmaceuticals and in biotechnology more generally. This could involve, for example, a support payment equivalent to a 200% tax concession on increases in R&D over the average level of the past four years. Again it should apply to all companies undertaking pharmaceutical and biotechnology R&D in Australia, subject to appropriate scale and commitment requirements. R&D in these areas would receive special treatment in recognition of Australia's comparative advantage in these areas, and of the strong contribution which they can make to long term industry development in this program.

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