Pharmaceuticals, Health and Industry Development: Strategic Issues and Options

Working Paper No. 13

Peter Sheehan

Pharmaceutical Industry Project
Equity, Sustainability and Industry Development
Working Paper Series

August 2002

Centre for Strategic Economic Studies
Victoria University of Technology
PO Box 14428 Melbourne City MC VIC 8001 Australia
Telephone +613 9248 1340
Fax +613 9248 1350

Email: csesinfo@vu.edu.au
Website: http://www.cfses.com

Pharmaceuticals, Health and Industry Development:

Strategic Issues and Options

At the present time, the biomedical industries are probably the main focus of global technological change. Progress in basic science and in the application of new technologies – from high throughput screening and computational chemistry to genomics and proteomics – offers a wide array of new drugs and treatments. Massive resources are being devoted to these new products, especially in the centre of this revolution, the USA. US pharmaceutical companies spent US$30.3 billion on R&D in 2001, a level 3.6 times the 1990 figure of US$9.4 billion. This represents a sustained average annual increase in real terms of over 10% per annum.

These changes, together with rapid innovation in other parts of the health system, are generating what Kleinke (2001) refers to as a systematic rotation from medical labour to medical technology, from labour to capital. While the trends are obscured by many other factors, it seems clear that we are experiencing a rapid shift from reliance on labour intensive procedures to a much greater reliance on technology, as embodied in drugs, equipment and procedures. This basic shift has been occurring for a long time, but it has accelerated markedly over the past decade.

For all countries, including Australia, these two facts raise important issues on several fronts. One relates to science, technology and industry policy, and hence to Australia's ability to participate in the emerging pharmaceutical industry. Another relates to health policy, and how the institutions and policies of the health system can be adapted to ensure that Australians benefit as much as possible from these changes, while containing costs. The challenge to health policy is widely seen as accentuated by the population ageing that is taking place in many developed countries.

These issues are crucial for Australia, both in terms of health outcomes and economic structure. Australia's health system is one of the best in the world, in terms of the three criteria of health outcomes, equity and cost effectiveness. But it remains vulnerable to continuing financial pressures and to its dependence on other countries for advanced technologies. Having largely missed the boat in terms of production capability in the information and telecommunications industries and in aerospace, Australia's ability to be a significant player in advanced knowledge-intensive industries is heavily dependent on her performance in biotechnology in general and the biomedical industries in particular. But these industries are moving very fast, and Australia's current position is limited, so that the policy challenge is urgent.

The objective of this paper is to examine some of the issues that Australia faces in this area, and to explore some of the options available to policy makers in responding to them. I deliberately adopt a strategic, long term and exploratory approach. That is, I seek to define and discuss the main strategic issues that emerge, rather than to get immediately into the details. The intention is very much to open up issues and explore options, rather than to attempt to reach definitive conclusions at this stage of the research.

1. Institutional, Information and Policy Structure

Segmentation in the institutional and policy structure

The origins of the current institutional and policy structure in relation to the pharmaceutical industry lie deep in the nation's history, going back especially to the *Pharmaceutical Benefits Act 1947*, which was passed soon after the national referendum of 1946 gave the Commonwealth Government significant powers in the area of health. Reflecting that history, there is a high degree of segmentation in the structure, the key elements of which are as follows:

- dedicated institutions, separate from those influencing other parts of the health system, for determining prices and supported indications for most drugs in widespread use outside the hospital system;
- direct government payment through the Commonwealth Budget for the vast bulk of these costs;
- prices determined within these institutions entirely on grounds of health and cost containment, rather than industry policy, grounds; and
- industry policies directed at offsetting the impact on firms of lower prices resulting from these arrangements, in the context of increased activity in terms of production, exports and R&D.

Thus two forms of separation lie at the heart of this structure – the separation between pharmaceuticals and the health system and that between drug prices and industry policy. Pharmaceuticals are treated differently from other inputs to the health system, being managed by specific institutions and as a high profile cost item in the Government Budget. In spite of the well-known inclusion of the factor (f) criterion in the legislation, drug price setting by the PBS is entirely divorced from industry policy considerations, even though price-related assistance is provided through the Department of Industry, Tourism and Resources.

International experience shows that there are many other possibilities, though not necessarily more effective ones. As is well known, processes in the USA are different in many of these

respects, partly because of the much lower role of governments in paying for drug costs. There are no special institutions in the UK for setting drug prices, and drugs are not treated differently from other inputs to the health system. In Germany in the 1990s the decision to exempt drugs within patent from the reference pricing system seems to have been heavily related to industry policy considerations, but perhaps also to health issues.

The growing complexity of the pharmaceutical market

Developments in recent years – such as the rising cost of the PBS, disputes about the listing of drugs, increasing co-payments, attempts to confine the use of PBS subsidised drugs to designated uses and concern about industry development – suggest a system under strain. In exploring whether a high degree of segmentation matters for the future, I start from the presumption that, under the influence of fundamental technological changes, the pharmaceutical market is becoming very much more complex. This involves not only growth in the number of major new drugs becoming available, but also an increasing number of smaller drugs, targeted to more specific conditions or risks. Both types are expected to proliferate over the next decade, as the effects of recent scientific developments begin to be felt. In short, the presumption is that the pharmaceutical industry now is in a position similar to the computing industry in about 1990. That is, that it is at the beginnings of technology-driven change that will shake the industry, and the sectors that it serves, to the core.

It should be noted that this presumption, while common in some circles, is still controversial. There is a significant literature on the 'innovation deficit' – the limited output of new chemical entities from major company R&D programs during the 1990s – and concerns about extent and quality of the drug pipeline in some companies. Nevertheless, it is widely held that is we are seeing, and will see increasingly during the next decade or so, a proliferation of new drugs. Many of these will be potential 'blockblusters' with widespread application, but others will be more targeted to particular elements within the population. Newhouse (2002), for example, pointed out that during the 1990s over 1000 new drugs were introduced to the US market, with over 300 new molecular entities. He also noted that, for example, since 1990 the number of cancer drugs in the pipeline has increased from 28 to 402, and that the number of cancer agents in Phase I trials rose from 6 to 150-200. Publications such PhRMA (2002) also highlight the large number of new medicines under development in different therapeutic classes.

Even so, it is difficult to get clear aggregate data on trends in drugs in the pipeline, and hence on the extent and timing of the introduction of new drugs. Tables 1 and 2 and Chart 1 provide some initial information relevant to this question. When a company or an individual researcher or physician wishes to develop and trial a new drug in the USA, that drug must be registered with the Food and Drug Administration (FDA) as an Investigational New Drug (IND). The registrations may be either commercial, that is filed by companies whose ultimate aim is to develop a new drug, or for non-commercial or research purposes, which is

normally done by practicing physicians. Table 1 provides some data on the stocks and flows of these registrations over the period 1987-95.

Table 1. Trends in number of investigational new drugs, FDA, 1987-2001

	Commercial registrations				Non-commercial registrations				Commercial share of total registrations
Year	New	Closures	Change in stock	Stock at year end	New	Closures	Change in stock	Stock at year end	
									(%)
1987	302	344	-42	2,675	1044	1461	-417	7,434	26.5
1995	358	364	-6	3,280	1566	942	624	8,175	27.5
2001	425	205	220	3,883	1447	2632	-1185	6,990	35.7
Per cent change									
1987-1995	18.5	5.8		22.6	50.0	-35.5		10.0	
1995-2001	18.7	-43.7		18.4	-7.6	179.4		-14.5	

Source: FDA.

These data show steady growth in the number of new commercial INDs between 1987 and 2001 (an overall increase of 40.7%), together with a reduction in the rate of closures. The result was that active commercial INDs were 45% higher in 2001 than in 1987, with 2001 being a particularly strong year, with a 6% increase in active INDs. The position with non-commercial registrations is quite different, especially after 1995. Between 1995 and 2001 new registrations fell and closures jumped, so that the stock of non-commercial INDs fell 14.5% between 1995 and 2001. These data seem to be indicative of an industry in company activity is growing rapidly, and is becoming more efficient and focused, while non-commercial activity is becoming more difficult.

Table 2 provides another window on this issue, by drawing on the IMS Lifecycle database to identify the number of drug candidates in the development pipeline in 2002. The database identifies 10,397 such candidates, of which 2,875 or 27.7% were in clinical trials or post-clinical registration processes. Using estimated success rates from a study of the experience of major companies, this data implies that over 1500 drugs are in the pipeline. It is not possible to infer anything directly about either the size or the specific timing of these emerging new drugs, although the fact that over 500 drugs are in the phase III trials or in the pre-registration phase is noteworthy.

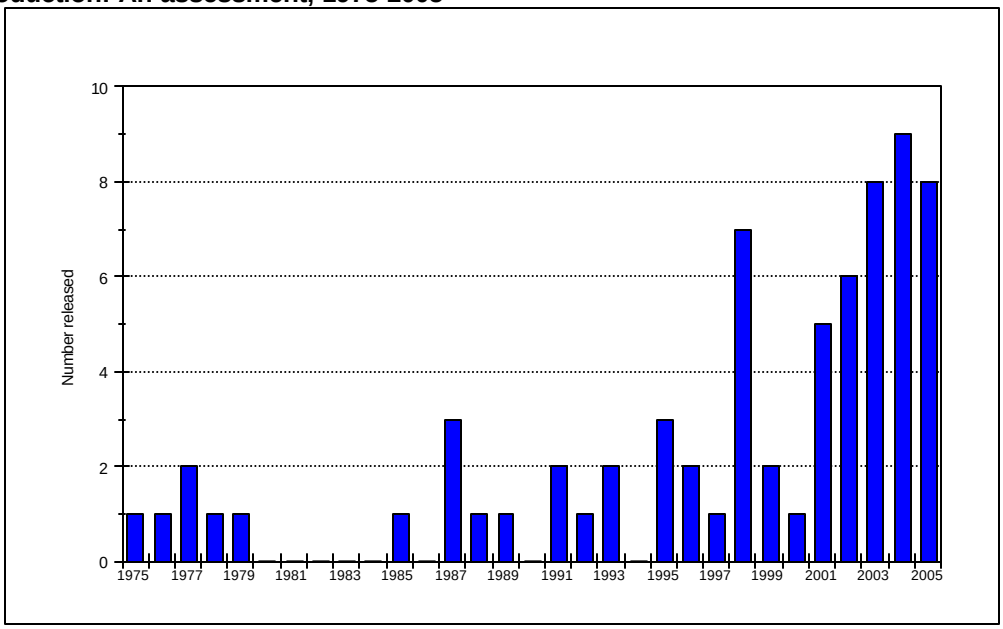
Table 2. Drugs in Pipeline, 2002, and Projected New Drugs

Development phase	Number June 2002	Estimated success rates (%)	Projected new drug outcomes
Preclinical	7522	10.3	775
Phase I	1288	18.4	68
Phase II	1253	28.1	352
Phase III	403	65.8	265
Pre-registration	130	90.6	118
Total	10397		1578

Source: Numbers in pipeline – IMS *LifeCycle Database* (2001); estimated success rates – PARAXEL (2001).

A third piece of evidence is provided in a review by Credit Suisse First Boston of major new drugs driving growth in the global pharmaceutical market over 1975-2005 (Chart 1). It shows a jump in such drugs in 1998, and sustained high levels in each year from 2000 to 2005. However, we have not had a chance to review the underlying data, and in particular to check how well this study documents the pre-1998 experience. Overall, however, there would seem to be sufficient evidence to lead one to pursue policy issues on the presumption of rapidly increasing complexity in the pharmaceutical market, driven above all by scientific and technological change.

Chart 1. Major innovative new drugs driving growth in the pharmaceutical market, by date of introduction: An assessment, 1975-2005



Source: Credit Suisse First Boston (2001).

Does segmentation matter?

Given this presumption, does the high degree of segmentation and regulation in Australia's institutional and policy structure matter? It is argued that there are a number of reasons for thinking that it does matter, and that the continuing attempt to manage the key focus of this technological revolution through segmented regulation and financial control is fraught with danger.

In terms of *management*, in most organisations the contemporary focus is on managing in an integrated fashion all the resources required to achieve a given output, or to solve a particular problem. The Australian health system at the national level is still mainly about managing inputs rather than, for example, about managing in an integrated way all the resources necessary to achieve better cancer outcomes. We have identified national health priorities, for example, but have not put in place coordinated management systems to make the best use of our resources to achieve particular goals.

In *financial* terms, concentrating on a particular drugs line within the Federal budget seems certain to introduce pressures extraneous to the optimal management of health outcomes, just as would have a national computer budget line during the 1990s. The economic and social pressures to balance the Federal budget do not necessarily mesh either with the health needs of the community nor with their willingness to pay for health products. As noted elsewhere, the Commonwealth is meeting an increasing proportion of total non-hospital spending on drugs (now about 70%) and under present arrangements this is likely to rise as costly new drugs become available. But the central point remains that cost effective outcomes for the health system as a whole are what matters, not managing any particular line.

In terms of *economic evaluation*, the benefits (and in some cases the costs) of innovative drugs flow in diverse ways through the health system, and indeed through the society as a whole. Attempts to recognise and measure these benefits through a single submission, concentrating on directly quantifiable health benefits, seem likely to become increasingly difficult. In my assessment we need more economic evaluation, not less, but this needs to be properly resources, transparent and focused on optimal community outcomes, not on government cost control.

In terms of *information*, one of the major limitations of present arrangements is that there is no regular flow of objective information about innovations to the various participants in the health system. As technologies proliferate, access to high quality information becomes increasingly critical. While not a segmentation problem per se, much of the information that needs to be more widely available is of a system-wide nature, involving the impact of new drug or other technologies across health services and outcomes.

In terms of *regulation*, the common response in a highly regulated system to growing complexity and cost pressures is a further tightening of the regulations. But increasing

regulation often becomes dysfunctional, and a vicious cycle of rising cost and complexity matched with tighter and more restrictive regulation can develop. This dilemma is inherent is many economic sectors in an increasing globalised knowledge economy.

This is not intended to give a one-sided story, nor to play down the real benefits that have been achieved, in terms of health outcomes and cost containment, by the present arrangements. But it is intended to suggest that we should give serious attention to other options in terms of the institutional, information and policy structure for pharmaceuticals in Australia.

Some strategic responses

More Independence for the Pharmaceuticals Authority, with Assignment of the Medicare Levy

At the present time, the Australian Government's health budget is managed in terms of three main items – medical services and benefits (estimated to cost $11.9 billion in 2002-03, of which $2.3 billion is for the Private Health Insurance Rebate), hospital services and health care agreements ($8.7 billion) and pharmaceutical benefits ($5.4 billion). Pharmaceutical benefits, the most rapidly growing item, thus accounts for about 18.5% of Commonwealth health spending but for only about 10% of total national health costs.

By accident, expected revenue from the Medicare levy ($5.2 billion in 2002-03) is very close to the current cost of the PBS. One option, which would go part of the way to addressing the structural problems, is to establish the Pharmaceuticals Authority (PA - a label used to describe the parts of the PBPA, PBAC and so on relevant to this task) with real statutory independence and with responsibility for managing pharmaceuticals for the welfare of the Australian community. The Medicare levy could then be assigned to the PA as a funding source to meet those costs. The levy could then be adjusted over time, up or down, to meet the actual costs of the PBS without being a direct charge on the health budget. The criteria on which the PA would act would be defined in the enabling legislation.

This change would make the PA an independent body established by legislation similar to worker's compensation or social security commissions in some countries. While it would remove pharmaceutical issues from the direct cut and thrust of Federal Budget debates, it would not necessarily generate greater integration between pharmaceuticals and health policy. But a more adequately resourced PA might have a charter to link more closely with health policy, for example in national priority areas, and to facilitate the dissemination of drug information.

Integration into the Medicare Process

In the majority of cases, a bout of illness leads to a visit to a doctor and the prescribing of a drug. But those two transactions are handled by entirely separate mechanisms, linked only

through the Department of Health and Ageing. Another option, which would give priority to greater integration of pharmaceutical and health decision-making processes, would be to integrate both transactions into the Medicare system.

How this might work would need to be thought out in detail, and many issues would arise. These would include the possibility of a single co-payment arrangement covering both transactions, and of insurance to cover this co-payment. Such integration, of whatever form, would not remove the need for an expert body such as the PBAC to advise on pharmaceutical pricing. But it should generate better incentives and structures for managing health costs and outcomes as a whole, in particular target areas, rather than managing particular inputs. It would not be a substitute, of course, for more fundamental reform of health management processes, to enable resources to be more effectively managed to achieve national priorities.

Regulation and Price Signals

It seems highly likely that, as the number, complexity and cost of the drugs becoming available increases rapidly, the regulatory authorities will find the task increasingly difficult to manage. This will be especially so if the cost pressures on the budget continue to be a key issue. One standard response to such an increasing regulatory burden is increased use of price signals to influence allocation. Two key social considerations have traditionally limited the use of price mechanisms in the health sector in Australia – the fact that allocating access to resources by price may often in practice mean rationing them by price, and that the need for medical care is not evenly distributed across the community, but is concentrated in particular groups. Nevertheless, some increased use of price signals seems to be highly likely in Australia in the future, hopefully with appropriate safety nets.

There are three obvious ways in which price signals could be allowed to play a greater role in pharmaceuticals in Australia. One is by a shift from flat rate to a proportional pricing system for consumers, so that co-payments are set as a proportion of the wholesale price, with two or more bands and subject to safety nets and other limitations. A second could be in terms of the prices set by the PBAC for preferred and other indications of a given drug. A lower reimbursement price, and hence a higher price to the consumer, might be set for a non-preferred indication. A third, which is already occurring to some extent, is to allow the coverage of the PBS system to fall over time, relative to what would otherwise be the case, as an increasing number of 'non-core' drugs are available for sale without reimbursement. In a proportional co-payment system, some of these drugs might be available with a much higher co-payment rate.

The Information Structure and the Use of Medicines

In a knowledge-based economy the information structure – the institutions, systems and processes by which the various participants obtain the information they need to take fully informed decisions – is crucial. There seems to be widespread agreement that, in Australia,

the information structure in relation to pharmaceuticals is far from optimal, and that further action is necessary. This relates both to the fact that, given current systems, little public information can flow from the PBAC process and to the effectiveness of the Quality Use of Medicines program. Some have argued that this program is currently uncoordinated and ineffective (e.g. Harvey 2002). This issue is beyond the scope of the present paper, except to reiterate the crucial role of the information structure in any knowledge intensive economic or social system.

The Pricing and Access System

The Social Objective

In my view, the social objective of the pharmaceutical pricing system should be: *to maximise the use of the most effective medicines to support the health of the population as a whole, at prices which minimise the cost of those health outcomes as a whole and which provide adequate rewards for innovation.*

The following comments are relevant to this proposed statement of the social objective. First, the health of the whole population is the central goal. Thus equity considerations, and the provision of the most effective medicines as necessary to all of the population, are vital. Second, what matters is health outcomes, and the cost of those health outcomes, rather than any intermediate targets such as drug use or the cost of pharmaceuticals. Third, adequate rewards for genuine innovation are also necessary. There are, in my view, a number of reasons for this: there needs to be a climate within the Australian health system that encourages and rewards innovation; there will be increasing limits to the ability of any country to 'free-ride' on the innovation carried out in other countries; and it is important that Australia involves international companies, both large and medium sized, in the development of its pharmaceutical industry and health system. Innovation here does not mean anything that is new, but drugs or other therapies that generate new and additional therapeutic benefits.

The discussion below looks briefly at aspects of the pricing and access system in the light of this social objective.

Interpreting the PBS

In another project paper, our attempt to provide an economic interpretation of the current operations of the PBS led to the following very tentative conclusions.

1. ***Increasing Role of Benefit Paid Pharmaceuticals.*** As the importance of new, higher priced drugs increases, benefit paid pharmaceuticals are taking an increasing share of the total ex-hospital pharmaceutical market. This means that the share of the market regulated by the PBS, and the cost to the Commonwealth of subsidy payments, is increasing over time.
2. ***Highly Regulated Prices, with Administered Competition.*** From an economic point of view, the PBS appears to be a system of highly regulated prices, with very little price competition between suppliers and few avenues for price signals to have any effect within the system. At the same time the system makes use of competitive forces in negotiating and setting prices, and hence to some degree mimics the operation of the marketplace.
3. ***Extensive Non-Price Competition between Suppliers.*** In spite of the tight regulation of prices, there appears to be considerable non-price competition between suppliers for many, but perhaps not all, drugs.
4. ***Low and Short-Lived Returns to Innovation.*** While the PBS system ostensibly makes extensive use of cost effectiveness, the hypothesis is that the returns to proven, innovative health effectiveness are low in Australia, and are quickly eroded over time.
5. ***Relatively High Price, Low Volume Approach to Generics.*** While there has to date been little reliable information available in regard to the usage and pricing of generics within the PBS, the hypothesis is that, at least relative to some other countries, the usage of generics is relatively low and their prices are relatively high.
6. ***Duopoly Situation for Many Post-Patent Drugs.*** A final hypothesis is that, in many important cases in the PBS, two drug companies come to dominate the market for a particular drug after its patent has expired – the originating company and a single generics supplier. This further limits effective competition in the PBS.

In some respects this assessment differs from that of the Productivity Commission (2001) in its July 2001 study on *International Pharmaceutical Price Differences*. This study found that Australia had lower prices, relative to those in a selection of other countries, for generics than for innovative drugs. It also found that Australia had lower prices for generics relative to innovative drugs than in the USA, Canada, UK and Sweden. Broadly speaking, then, it found that Australia was a relatively low price user of generics. The reasons for this difference are explored in another paper.

The return to innovation

Most governments of developed countries recognise the importance of good returns to pharmaceutical innovation, and the existence of an elaborate system of patent protection is a sign of this fact. But most are also committed to the goal of cost containment, and in pursuit of this goal many have introduced complex processes of price regulation. In these processes the return to innovation becomes obscured, and the extent to which the resulting prices do in fact provide an adequate reward for innovation becomes a matter of public debate.

The returns to innovation achieved by a given product are affected by outcomes at several stages of the product's history:

(i) the initial patent stage, when the drug competes only with pre-existing drugs and therapies;
(ii) the 'me-too' stage, when the drug competes not only with follower drugs with very similar chemical effects but with new drugs or therapies in any relevant area of the therapeutic class; and
(iii) the generic stage, when the drug initially competes with one supplier of the same molecule but in due course may compete with many such suppliers.

These stages exist both in competitive systems (such as the USA and to some degree the UK) and in highly regulated systems such as Australia. Their impact on the pricing of drugs and on the return to innovation is likely to be quite different in different systems, even though regulators may set out to mimic market forces in their attempt to keep prices down. There is evidence that the dynamics of these stages is changing in both competitive and regulated systems, as competition intensifies in the US and as some reference pricing systems are tightened.

This issue becomes a particularly serious one in regulated pricing systems (such as in Australia) in which reference pricing is used, with regular price reviews and with both patented and generic drugs included in the reference schedule. This can mean that generic copies of other molecules act to reduce prices for a given drug in stages (i) and (ii), as well as in stage (iii). In Australia the issue is highlighted further by the prominence given to cost effectiveness evaluation in setting original prices – the dynamics of the reference pricing system may quickly erode the return to innovation embodied in the original price.

There seems to be evidence that, in spite of our adherence to a strong intellectual property regime, the returns to innovation in the Australian pricing system are very low, and in some cases are eroded quickly over time. In my view, if Australia is to be guaranteed regular supplies of new drugs and is to participate in future industry development, this issue needs to be addressed. Options include using a higher value per unit of benefit (e.g. for a quality adjusted life year gained) or allowing a more inclusive definition of benefits in economic evaluation processes, and excluding some innovative drugs with proven cost effectiveness from the reference pricing system for a specified period. Consideration could also be given to allowing some companies, with substantial investment in Australia, to set prices freely subject to a rate of return cap (the UK model, which integrates pricing and industry policy objectives).

The use of generics

In common with some other countries with a reference pricing system covering both generics and innovator drugs, Australia has a low usage of generic drugs, and seems to pay higher

prices for those generics than in some other countries, both relative to the price of innovator drugs and (to a lesser extent) absolutely. A more active and competitive generics market could lead to significant cost savings, without affecting the incentives for new industry development. Investment and related decisions by research based pharmaceutical firms are based primarily on returns achieved during the within-patent period, while access to a larger market may stimulate activity in Australia by generics firms.

The central issue here is the link between prices for innovative, within-patent drugs and generics, through the reference pricing system. In my assessment, pricing systems in place in OECD countries can be divided into two main groups along this axis. One consists of those countries, such as USA, UK and Germany, which do not have a reference pricing system including within-patent drugs. In these countries, prices for generics are low, especially relative to prices for innovator drugs, and the usage of generics is high. The benefit of generics is realized by high use at low prices after the expiry of the patent.

A number of other countries, especially in Europe, have a reference pricing or similar system that includes both within-patent drugs and generics across therapeutic groups. These systems tend to have relatively lower prices for within-patent drugs, to maintain broad parity between innovator drugs post-patent and generics, and to have a low use of generics at a relatively high price. They realize the benefit of generics substantially through the price effects on innovator drugs, both before and after the expiry of the patent.

As far as I can tell, only in New Zealand is an attempt being made to realize both the price and quantity benefits of generics simultaneously, through aggressive action on generics (such as tendering processes) in the context of a reference pricing system covering both types of drugs. This appears to be leading to very low within-patent prices for many drugs, to a progressive withdrawal of the industry from New Zealand and some restrictions on the availability of drugs.

In my view, there is a strong case to be made to increase the use of generics in Australia, and perhaps in that context to achieve lower generics prices, but only if the link between prices for within-patent and generic drugs through the reference price system is broken. There are a number of ways in which these two goals could be achieved, especially if there was a greater role for price signals within the PBS.

Price signals in the PBS

At the present time there is virtually no role for price signals in the selection of prescription drugs for use by consumers, and hence little incentive for doctors to take account of price considerations in their prescribing behaviour. In my view, a pre-condition for change is that the co-payment made by most consumers for most drugs bears some relation to the cost of the drug provided.

The most obvious way of achieving this result would be to move to a proportional rather than flat-rate co-payment system. This could be done at no overall additional cost to the consumer, although there would inevitably be winners and losers. There also seems to be little rationale for the division of the population into only two groups, with very different co-payment rates (from 1 September 2002, $4.60 and $28.60), and the rapid growth in the concessional group in recent years has been an important contributor to the growth of PBS costs. Thus a move to a proportional system should perhaps involve a move to three or four co-payment rates.

Non-preferred indications

When prices to the consumer are heavily subsidised, the regulatory authorities will rightly be keen to ensure that the use of subsidised drugs is confined to those uses for which their cost-effectiveness has been demonstrated. They can seek to achieve this either by tighter regulation or by greater resort to price signals. If the PBAC were to determine lower prices for non-preferred indications, and these were reflected in higher consumer charges, the option for prescribing for non-preferred use would remain, but consumers would bear more of the cost of such use. This may be more effective in reducing the cost of highly subsidised use for non-preferred indications than intensified regulation, or be a reinforcement of such regulations.

Rationales for pricing in the PBS

In another project paper (Paper 12), I have suggested that there appear to be two ideas about drug pricing, potentially competing, implicit in the operations of the PBS:

- drugs should be priced in terms of the their incremental contribution to human welfare, relative to other drugs and therapies achieving similar effects; and
- drugs should be priced at the lowest price at which any comparable drug within the relevant reference group can be delivered.

The first is a concept that seeks to reflect economic principles in terms of administered prices (prices are related to marginal productivity), while the second is a use of market power in the national interest. In a case such as the pharmaceutical market, in which sunk costs and

market power are pervasive, these concepts are likely to give quite different pricing outcomes. It may be possible to respond to some of the issues discussed above by giving each of these ideas more thorough and complete application in the distinct areas in which they are each at home – economic evaluation methods for drugs within patent and market based approaches to achieve the lowest available price in the post-patent market.

The Industry Development Framework

The pharmaceutical industry is a knowledge intensive, oligopolistic one, driven by heavy sunk costs, information asymmetries and other features of knowledge, and hence subject to strategic competition rather than to traditional market competition. As a response to these characteristics, features of the industry include:

- a continuing reliance on patent protection, although the value of that protection is falling in many markets as there is increased competition from follower drugs and from alternative therapies;
- clustering of knowledge intensive activities in firms and locations with critical mass and the strongest capabilities, which in practice has meant an increased concentration of the global industry in the USA;
- the segmentation different parts of the value chain, with increasing contracting out of important elements (such as aspects of R&D, clinical trials and manufacturing) to a variety of specialist firms;
- increasing reliance on alliances, networks and other non-market forms of cooperation (in the sense of involving transactions not mediated through the market); and
- heavy reliance on publicly funded R&D and research support.

For such an industry there seems little doubt that the various dimensions of policy – pricing and health policy, industrial policy and science and technology policy – play an important role in the growth and location of the industry.

The pharmaceutical industry is both an important one for Australia and one in which Australia is seen as having substantial opportunities that have not been realized. The importance arises from several factors. These include the failure to achieve any substantial role in other high tech industries (such as ICT and aerospace), which has placed increased emphasis on the biomedical and biotechnology industries; the long term implications of this failure for the balance of payments and/or the exchange rate; the recent inability of the national economy to generate increases in the supply of high value jobs, and the level of investment by different sections of the community in health sector R&D, estimated at $1.26 billion in 1998-99.

It is worth dwelling briefly on the issue of the quality of jobs. For a decade of strong growth, the quality of the jobs generated during the 1990s was very disappointing. As shown in Table 3, all of the net increase in jobs during the 1990s (1.13 million) was in jobs paying less

than $600 per week, mainly because they were part-time and/or casual jobs. While there was a significant increase in jobs paying over $1400 per week, there was a net decline of 16,300 in jobs paying $600 or more over the decade. While the data are not available to make the same calculations for recent years, the signs are that this trend has continued since 2000. Between July 2000 and July 2002 the number of full-time jobs in Australia fell by 81,600, while the number of part-time jobs rose by 243,700. Thus there are strong social as well as economic imperatives for the development of industries, such as the pharmaceutical industries, that can generate high quality jobs.

Table 3. Job creation in Australia, 1980–2000, by earnings level

Weekly earnings level (2000 values)	('000 persons)			Change 1980–1990		Change 1990–2000	
	1980	1990	2000	No.	%	No.	%
Under $300	517.3	939.5	1482.6	422.2	81.6	543.1	57.8
300–600	1388.0	1857.4	2460.2	469.3	33.8	602.8	32.5
600–900	1997.9	2232.4	2108.5	234.5	11.7	–123.9	–5.5
$900–1400	955.7	1266.9	1243.9	311.2	32.6	–23.0	–1.8
Over $1400	272.7	269.7	400.3	–3.0	–1.1	130.6	48.4
Total	5131.6	6565.8	7695.4	1434.2	27.9	1129.6	17.2

Source: Estimates of the authors, based on ABS various issues, cat. no. 6310.0.

The position of the industry in Australia

Consistent and reliable data on the Australian pharmaceutical industry for any length of time is particularly difficult to obtain. But a number of facts seem reasonably clear. One is that, in spite of some good growth over the past decade or more, the Australian industry remains small by most measures. Given global trends, and in spite of the degree on publicity in Australia about biomedical developments, its position is precarious and much needs to be done if an industry of sufficient scale to be viable in the long term is to be created. Another is that, after stagnation and in some respects decline in the late 1970s and early 1980s, the industry has shown strong growth on most measures in the late 1980s and throughout most of the 1990s.

The current position of the industry is less clear, and the figures assembled in Table 4 (from different sources and on somewhat different bases) provide a mixed message. Exports, R&D and employment have continued to grow strongly after 1998-99, but industry value added and fixed capital expenditure were both lower (in current prices) in 2000-01 than in 1998-99. Further work is being done on the meaning of these divergent trends.

Table 4. The pharmaceutical industry in Australia: Recent indicators

	1995-96	1996-97	1997-98	1998-99	1999-2000	2000-01	Average annual per Cent change 1995-96 to 1997-98	Average annual per Cent change 1997-98 to 2000-01
	('000 persons, end June)						(%)	
Employment	15403	16195	16385	16931	15507	17517	3.1	2.3
	($ million, current prices)							
Industry value added	1527.6	1764.8	1914.6	1850	1965.7	1780.1	12.0	-2.4
Fixed capital expenditure	223.4	350.1	229.8	236.7	342.2	228	1.4	-0.3
R&D	122.8	121.7	130.2	157.8	182.5	198.6	3.0	15.1
Exports	940.1	1104.3	1174.3	1371.5	1769.1	2305.9	11.8	25.2

The firm structure of the industry in Australia is split to an unusual degree into two main components: the local branches of the major international pharmaceutical companies and Australian owned firms, many of which are small and relatively new firms. Thus the industry policy task must address these two distinct components. Further, with the changing structure of the global industry, a wide range of other companies, providing a range of specialised services or a more specialised product portfolio, are becoming increasingly important in the industry.

The environment for innovation

In terms of creating an environment conducive to increased innovative activity in the pharmaceutical industry in Australia two matters seem to be particularly important. One is a drug pricing system which provides an adequate return to innovation, and which sustains that return over a period of time. This has been discussed above. The second is adequate incentives through the tax system for investment in R&D.

In its *Backing Australia's Ability* statement of January 2001, the Australian Government put in place a new R&D tax concession scheme, to replace the 150% R&D concession that had been in place the 1980s, and the Syndicated R&D Scheme, which was closed down in 1996. The new scheme involves a general deduction of 125%, which can be increased in certain circumstances to 175% on increased spending over a base period, and a provision for cash refunds in circumstances in which a company does not have sufficient income to

claim the concession. The total estimated cost of these concessions in 2002-03, on an accrual basis, is $415 million ($310 million for the 125% deduction and $105 million for the 175% concession. This is less than half the cost of previous arrangements in 1995-96, when the Syndicated R&D scheme was in full flight, and also less than half the cost, as a share of GDP, of these arrangements in the first half of the 1990s.

In economic terms, the move towards an incremental basis for the scheme is welcome, as the main economic imperative is to provide the strongest possible incentive, within the limited funds available, for incremental R&D. A number of problems have, however, been raised about the operation of this scheme as it applies to the pharmaceutical industry:

- Consistent with the long-term approach to the R&D concession, the Australian company claiming the concession must be the beneficial owner of the intellectual property. But for most multinational companies this condition cannot be fulfilled, as the parent company will always remain the beneficial owner.
- It has also been argued that the conditions on eligibility for the 175% reduction are too restrictive, that the limit of 10% on the amount of overseas expenditure that can be claimed and that most R&D undertaken by generics companies does not qualify.

The underlying conceptual basis of the R&D concession is that its purpose is to support the creation and development within Australia of Australian owned products and processes. The pharmaceutical industry brings to sharp focus some of the issues posed for this approach by the globalisation of knowledge intensive industries. Few if any Australian companies can expect to develop a drug to market with full ownership, and in the vast majority of cases equity in the product will be progressively sold off, or the product entirely sold off, as the drug proceeds through the pipeline. At the same time, research undertaken within Australia on drugs that are not Australian owned may have great spillover benefits for the country.

In my view, Australia's advantage lies more in developing the country as a major centre for industry R&D rather than in supporting only the development of Australian owned products. This would imply that international companies should be encouraged to access the concession without giving up beneficial ownership, but that the concession should not be significantly extended to work done overseas. Consideration should also be given, for this industry, to allowing firms the option of a 200% concession on incremental expenditure, provided that they give up the base 125% concession.

A new industry development program

The principles for, and some elements of the possible content of, a new industry development program to succeed PIIP has been discussed in the Action Agenda document, which also contains an outline of an industry proposal. Further discussion of these issues will be contained in the full paper.

(Further discussion of the evaluation of the Factor (f) program, and of the objective and principles for, and the constraints on, such a program)

Development paths for Australian firms

Since the Factor (f) program was introduced in 1987, the structure of the Australian industry has changed markedly, particularly in terms of the number of small Australian firms seeking to gain a foothold in biomedical markets. Thus, more than ever, a central policy challenge concerns ways in which governments can facilitate and support the emergence of these firms.

Our approach to this issue has so far been empirically based. That is, we have tried in separate papers to document changes in structure, technology and linkages in the global industry, to examine their implications for the Australian industry and to analyse the actual development paths pursued by Australian owned firms in recent years. It is hoped that reflection on this analytical work will help to identify the points at which public policy can useful intervene to promote the growth of these firms, and their integration into the rapidly expanding global marketplace.

References

Harvey, K. 2002, 'Securing the future of the PBS', *The Drawing Board: An Australian Reveiw of Public Affairs*, June, http://www.econ.usyd.edu.au/drawingboard/

IMS Health 2001, *LifeCycle Database* (CD ROM), London.

Kleinke, J.D. 2001, 'Price of Progress: Drugs and the Health Care Market', *Health Affairs*, vol. 20, no. 5, pp. 43-60.

Newhouse, J. 2002, 'Why is there a quality chasm?', *Health Affairs*, vol. 21, no. 4, pp.13-25.

PAREXEL 2001, *PAREXEL's Pharmaceutical R&D Statistical Sourcebook 2001*, Boston.

PhRMA (Pharmaceutical Research and Manufacturers of America) 2002, *Pharmaceutical Industry Profile*, Washington DC.