Competition and Drug Pricing in the PBS: An Economic Interpretation

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Competition and Drug Pricing in the Pharmaceutical Benefit Scheme – An Economic Interpretation

Introduction

There is now a significant descriptive literature on pricing processes in the Pharmaceutical Benefits Scheme (PBS), such as Salkeld, Mitchell and Hill (1999), Henry and Lopert (1999), the Productivity Commission (2001) and Birkett, Mitchell and McManus (2001). Yet there seems to be little recent empirical work on pricing outcomes – examples of such studies are George, Harris and Mitchell (1998), Hill et al. (2000) and the Productivity Commission (2001) – and there has been little work which attempts to provide an economic interpretation of the operations of the PBS. The objective of the present paper is to begin to provide such an economic interpretation, drawing on both the limited published empirical work and on the further studies being undertaken in this project.

As Goddard, Henry and Birkett (2001) and others have pointed out, the agencies of the PBS are constrained by the secrecy provisions of the *National Health Act 1953*, and 'a serious lack of transparency surrounds the PBAC processes' (p. 81). This is one of the factors that complicate the interpretation of the PBS. Another is the nature of the global pharmaceutical industry itself. As is often pointed out, this is an industry in which the costs of innovation and drug development are very high relative to production costs, and in which the final consumers know little about the product purchased. As a result, strategic interaction between large firms and powerful purchasing groups, whether public or private, pervades the industry. The precise nature and impact of these processes of strategic interaction is often difficult to delineate. It is also clear that the nature of competition in less regulated markets such as the USA has been changing rapidly in recent years.

The paper will describe and attempt to assess some of the evidence in relation to six hypotheses. It is very preliminary. In its subsequent development it will attempt to pull together evidence from international sources and other Australian studies, from our case studies and from our analyses of various data sources, to assess these hypotheses. The six hypotheses are as follows.

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.

The paper will be organized in terms of these six hypotheses.

1. Increasing Role of Benefit Paid Pharmaceuticals

In 1990-91, benefit paid pharmaceuticals (that is, those transactions of drugs within the PBS and the Repatriation PBS on which the Commonwealth paid a benefit) accounted for 52.8% of the total Australian pharmaceutical market, excluding hospitals. Other pharmaceuticals, which include transactions on which the individual pays the full cost and over-the-counter medicines, thus accounted for 47.2% of this market. Of the total cost of drugs the Commonwealth met 44.8% so that, with only 1.6% being met by other sources, individuals bore 53.6% of total costs (Table 1).

By 2000-01 the situation had changed significantly, with both the benefit paid share and the Commonwealth share increasing substantially, to 68.1% and 57.8% respectively. Over the decade the share of total costs borne by individuals fell by 12 percentage points, to 41.6%. Payments by individuals under the PBS rose in line with Commonwealth payments, so this trend reflects the coverage of the PBS rather than trends within it. The increased coverage of the PBS may have been due to the increasing importance of new drugs, which are largely introduced through the PBS. In the past twelve months, a number

of measures have been taken which are likely to increase the share of total costs borne by individuals. These include the increase in co-payments, the decision not to list a number of high profile drugs on the PBS and increased enforcement of restrictions on the indications for which subsidised products can be used. But the underlying trends in new drug development, and the complexity of endogenous responses within the PBS, may mean that, under current arrangements, this trend continues for some time.

Table 1. Components of the total pharmaceutical market (excluding hospitals), Australia, 1990-91 to 2000-01 (constant prices, referenced to 1999-00)

Year	Benefit Paid Pharmaceuticals			Other Pharmaceuticals	Total Market	Shares of Total Market	
	Commonwealth	Individuals	Total			Benefit Paid Share	Commonwealth Share
			($million)			(%)	
1991-92	1526	356	1882	1704	3586	52.5	42.6
1992-93	1812	406	2218	1664	3882	57.1	46.7
1993-94	2122	444	2566	1700	4266	60.2	49.7
1994-95	2325	514	2839	1895	4734	60.0	49.1
1995-96	2741	541	3281	1818	5099	64.3	53.8
1996-97	2781	561	3342	1910	5252	63.6	53.0
1997-98	2803	598	3400	2219	5619	60.5	49.9
1998-99	3092	603	3695	2314	6009	61.5	51.5
1999-00	3523	652	4175	2273	6448	64.7	54.6
2000-01	4186	743	4929	2313	7242	68.1	57.8
Annual Percentage Change, 1990-91 to 2000-01 (%)							
	10.7	10.6	10.7	3.8	7.9	2.6	2.6

Source: AIHW (2002).

2. Fully 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 PBS makes use of competitive forces in negotiating and setting prices, and hence to some degree mimics the operation of the marketplace. It is difficult to understand at all clearly how the balance between regulation and competition, between market power and economic principles, operates within the PBS.

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. Both of these ideas raise a number of questions about their practical application. In terms of an application of the first idea, how is the value of the innovative cost effectiveness of a given drug, the margin of improved performance, to be valued? How are the prices of other drugs, which provide the benchmark for pricing the new drug, to be set? For how long will the price of the new drug be set, and when will it be reviewed against other drugs? What costs and benefits are to be included in the economic evaluation process? In terms of applications of the second idea, how accurately can the comparability of drugs be determined across the reference group? How is the price of the lowest priced drug determined? Is any premium to be paid for improved performance over the lowest priced drug?

It is possible to conceive of a 'pure' application of each of these ideas, although neither would be practical. In a pure cost effectiveness regime, the base drug would be valued in terms of its contribution to human welfare, at an explicit and agreed value of the outcomes, for example of the value of a quality adjusted life year saved. All drugs with similar effect would be benchmarked relative to the base drug, with any price differential reflecting improved outcomes at the same valuation. The effectiveness and price of all drugs would be reviewed regularly, to reflect the impact of new products. But the foundation of the pricing regime would be the economic value to society of the base drug.

In terms of a pure market power regime, the key consideration is the price of the lowest priced drug in any reference group, and the main constraint is the price at which firms will continue to deliver drugs into the Australian market. Measures would be adopted to drive down the price of the lowest price drug (such as by tendering for generics), to reach the minimum price at which in-patent drugs would still be supplied.

The Australian system seems to be a mixture of these ideas, and it is difficult to be clear about their relative importance or interaction. The price for a new patented drug is set having regard to an economic evaluation of that drug against a single comparator, chosen by the proponent firm but against criteria set by the PBAC. If the evaluation is positive at the submitted price, a PBS price is likely to be approved, either at that level or at a lower negotiated level. Once installed in the PBS, the price of the drug is likely to be reviewed periodically against other products in the therapeutic reference group. These products are likely to include both other in-patent drugs and generics. The initial price of generics will

be determined in terms of the lowest price that can be negotiated, for adequate volumes, with a preferred supplier.

Thus the initial price for a new in-patent drug appears to be set in terms of incremental cost effectiveness, but there are a number of potential limitations on this process. Only one comparator is used, only direct health benefits are included, the value per unit ascribed to incremental benefits is not disclosed and the setting of the final price, both in terms of the price submitted by the firm and the price determined within the PBS, is not transparent. Most importantly, perhaps, the price against which this whole process is benchmarked (the price of the comparator drug) is that which has emerged from the overall operations of the PBS, and does not necessarily have any cost effectiveness basis.

Once the drug enters the reference pricing reviews, however, different dynamics come into play. Broad equivalence in effect of all drugs within a given therapeutic group is assumed, and no further detailed cost effectiveness studies are undertaken. The benchmark price, which will often be the price for a generic drug within the group, is determined in most cases by negotiations with a preferred supplier. So at this stage the overall level of prices for the group is determined by strategic interaction between the purchasing agency and the preferred supplier, rather than by considerations of cost effectiveness.

3. Extensive Non-Price Competition between Suppliers

The fact that there is little or no competition by price does not mean that there is no competition within the PBS. Indeed, the case studies and other information suggest that there is in fact quite vigorous non-price competition in many parts of the benefit paid pharmaceuticals market. This involves marketing, support to customers and related activities, as well variations in terms of formulation, delivery systems and so on. Such competition in part reflects the increasing rivalry between in-patent drugs in the global industry, as the average period of therapeutic exclusivity under a patent declines sharply.

4. Low and Short-Lived Returns to Innovation

The role of cost effectiveness studies in the PBS has been widely highlighted in the health economics literature, most recently for example in Birkett et al. (2001), with Australia being the first country to introduce a formal requirement for cost effectiveness analysis in relation to drug pricing. In principle a cost effectiveness regime would imply that drugs are rewarded in terms of higher prices for genuine innovation in terms of effectiveness. Some of the limitations on the operation of a full cost effectiveness regime in the PBS have been noted above. Indeed, our hypothesis, derived from other studies and for the case study work summarised in other papers, is that by international standards the Australian system provides low and short-term returns to innovation.

Apart from international comparisons for prices of prices for innovative drugs (by which I mean drugs with a demonstrated therapeutic advantage relative to alternatives, and not just any new drug) there are a number of other relevant features of the Australian system, noted below.

(i) *Valuing Benefits.* In a cost effectiveness regime in which benefits are measured in terms of life years gained or quality adjusted life years gained (QALYs), an indicator of the initial return to innovation provided is the incremental cost per life year or per QALY gained implicit in the price. In an important study, George et al. (1998) reviewed 34 cases over the period 1993-96 for which this measure is available. Of these cases, the PBAC recommended the listing of the drug at the requested price in 16 cases with an implied value of a life year gained between $5,050 and $36,450 (unweighted average of $15,075) and in three cases with an implied average price between $53,000 and $68,913 (unweighted average of $62,479), recommended listing at a lower price in four cases (a values of $16,049, $16,423, $78,157 and $209,674 respectively) and rejected or deferred the application (not necessarily because of price) in 11 cases.

These average implied values are low by the standards of international studies, suggesting that the initial returns to genuine innovation embodied in PBS prices is low. On the basis of the available evidence from the USA, for example, several studies (such as Murphy and Topel 1999; Cutler and McClellan 2001) use US$100,000 as the value of an additional year of life. By this standard the figures disclosed in the Australian study are certainly low.

(ii) *Coverage of Benefits.* In principle cost effectiveness analysis should involve social cost effectiveness not just health system cost effectiveness. That is, the net cost to society of providing a drug (costs incurred less benefits gained) should be measured against the value of the quality-adjusted life years gained. This might imply that economic benefits (such as increased working time and resulting income flows) should also be taken into account, but these might also be incorporated in the value ascribed to an additional life year. But it does seem inconsistent to use only health system cost effectiveness together with a low value for a life year gained. Nevertheless, there are many issues to be considered in determining the coverage of benefits to be included in these evaluations (see, for example, Olsen and Richardson 1999).

(iii) *Changes Over Time.* These considerations relate to the returns to innovation implicit in the initial price approved by the PBAC. But, as discussed above, there seems to be a substantial conflict between the use of a cost effectiveness approach to initial pricing and a reference pricing approach to changes in price over time. The reference pricing system often leads to a reduction in price, on the grounds of a comparison of costs with other drugs or therapies, without any reference to the original cost effectiveness studies. These changes erode the return to innovation implicit in the original price. In its 2001 study, the Productivity Commission examined three cases of relative prices over the period 1993 to

2000 – ranitidine, paroxetine and Salmetrol, comparing Australian prices to those of a number of other countries. In each case, other than paroxetine in the UK, there were substantial reductions in the Australian price relative to that in other countries over the period. In the case of the USA, for example, the reduction in relative prices was of the order of two thirds. Similar effects are evident in the case studies undertaken by Kim Sweeny for this project.

These considerations raise the question as to how the return to innovation should be measured across a whole pricing system. The most well known study is that of Lu and Commoner (1998), which uses FDA classifications of the therapeutic effectiveness of new drugs to study the returns to innovation in the USA. They find that for drugs involving an important therapeutic gain prices are much higher than for existing substitutes (nearly three times for such drugs for acute conditions and about double for such drugs for chronic conditions) and that these relativities are largely maintained in real terms over time. For drugs with little or no therapeutic gain, the initial price was not significantly different from that of existing substitutes, but did tend to rise over time. We are still exploring different ways of approaching this issue empirically for Australia.

5. Relatively High Price, Low Volume Approach to Generics

There are many complications and mysteries in the markets in various countries for generic drugs, some of which have been explored by my colleague Hans Lofgren, and little hard information is available for Australia. For this analysis a generic is copy of (the same molecule as) the original patented drug, so that the original drug is not counted as a generic. Available data for other countries often include the original drug, or are not clear on this point, so that care must be taken in using these data.

There are several ways to obtain data to provide a clearer view of the generics situation in Australia. One approach, which will give an initial approximate view, proceeds by identifying the suppliers of generics by company. The accuracy of this approach will depend on how completely companies supplying generics are identified and on the extent to which some companies supply both innovative drugs and generics. This approach has been pursued on the assumption that the latter effect is small in Australia. The second approach, which should give a more definitive result, is to identify the originally patented drug for each molecule listed on the PBS (or at least a sufficient coverage of molecules to include the vast bulk of PBS expenditure), and then divide PBS activity by innovative drugs and generics.

Some initial results of the first approach are provided in Table 2. On these figures, generic accounted for about 19% of scripts and just under 10% of PBS cost in 2000-01, with both of these figures increasing strongly in recent years, and especially since 1994-95. Between 1994-95 and 2000-01 the total number of scripts filled under the PBS increased

by 3.7%, but the number filled by generic suppliers rose by 21.5% per year and that by non-generic suppliers by only 1.8% per annum. For the same period the PBS cost increased by 11.8% per annum overall, with generic suppliers growing at 30.5% and non-generic suppliers at 10.9% per year. These estimates are consistent with some official figures which have been provided to Hans Lofgren, although the method of calculation of those official figures has not yet been ascertained.

Table 2. The use of generics in the Australian prescription market, initial estimates based on company analysis

Year	Share of generics in prescription drug market, 2001 (%)		Ratio of script share to value share
	By value	By number of scripts	
1991-92	3.5	5.9	1.7
1992-93	3.7	6.6	1.8
1993-94	3.8	7.1	1.9
1994-95	3.8	7.4	1.9
1995-96	4.3	8.6	2.0
1996-97	6.2	10.4	1.7
1997-98	7.2	12.8	1.8
1998-99	8.4	15.3	1.8
1999-2000	9.4	17.5	1.9
2000-01	9.6	18.9	2.0

Source: CSES analysis of HIC data.

Thus the use of generics in Australia appears to be growing strongly, but from a low base. In spite of this rapid growth, it still seems correct to classify the situation in 2001 as one of a low volume and high price use of generics. There are, however, many different models for the use of generics around the world, so that any judgment about the Australian situation needs to be interpreted in the light of this diversity. The information collected in Table 3 suggests that four different models can be distinguished.

The market situation in the USA is quite distinctive for generics, as it is for innovative drugs. Generics now account for about 45-50% of scripts issued in the USA, this share having increased very strongly in the decade to 1994 but rising only slowly since then. But the price of generic drugs in the USA is low, relative to prices for other drugs, and generics only account for 8.4% of the cost of prescription drugs. (The ratio of the script share to the value share for generics, at 5.4 for the USA in 2001, is a very rough indication of relative drug prices within the country.) This then is a model in which intense

market competition combined with high returns to innovative drugs generates a high volume of generic use at low relative prices.

Table 3. Some international experience with generics

Country	Share of generics in prescription drug market, 2001 (%)		Ratio of script share to value share
	By number of scripts	By value	
USA	45	8.4	5.4
Canada	40	14.3	2.8
UK	47	18	2.6
Germany	40	28	1.4
Sweden			
Netherlands	40	13	3.1
Denmark	60	35	1.7
Some others in EU	3-6	2-3	
Australia	18.9	9.6	2.0

Notes and sources: Generics here are defined as any chemically equivalent copy of a formerly patented drug, but exclude the originator drug. The 'some others in EU' category includes Spain, Belgium, France and Italy. Data are assembled from a variety of sources (including Table 1 for Australia) and refer to 2001 or nearest available year.

Secondly, there are a number of countries, mostly in Europe but including Canada, with volume shares for generics in the 40-60% range, but with implied relative prices a good deal higher than in the USA. Many of these countries have some form of reference pricing, and actively encourage the use of generics, although there remain many differences between them. In general they involve a share of expenditure in terms of scripts comparable with that in the USA, with a considerably higher share of generics by value, implying that in these countries the prices of generics relative to innovative drugs is higher than in the US. This is not necessarily to say, of course, that the absolute level of generic prices is higher in these countries than in the USA.

A third group consists of a number of EU countries, including Spain, Belgium, France and Italy, in which the use of generic drugs is very low, of the order of 2-3% of prescription drugs by value. In many of these countries generic use is growing very rapidly, but from an extremely low base.

In this comparison Australia occupies a middle position, with a generics share in terms of scripts below 20% and with an implied relative price below that in Canada, the UK and Germany, and well below that in the USA. Again, this is not necessarily to say anything about the absolute level of generics prices in Australia, by comparison with the level of those prices in other countries. But it does suggest that, relative to many but not all countries, Australia has a low generics share and a high price of generics relative to in-patent drugs. On the absolute level of generics prices, the Sweeny studies suggest that, after excluding exchange rate effects, the average price for generics tends to be higher than in countries such as USA and New Zealand, but is generally lower than in the main European countries.

This tentative conclusion to which this evidence leads – that Australia is a low volume, relatively high priced user of generic drugs – is inconsistent with the findings of the Productivity Commission 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.

Our view is that this Productivity Commission analysis is seriously misleading (see Box 1). The basic problem is that, in relation to markets whose structure is very different from that in Australia, the combination of the inclusion of the innovative drug with generic copies and the use of Australian weights as the basis of comparison can give very misleading results. This argument is spelled out in Box 1.

6. Duopoly Situation for Many Post-Patent Drugs

An important fact, which also seems to emerge in the case studies, is that in many post-patent situations, a duopoly situation exists and that non-price competition takes place only between the original supplier and a single generic competitor. This seems to be in contrast to the generics market in a number of other countries. Alphapharm, and to a lesser extent Sigma, exerts a dominant position in the generics market in Australia. In 2000-01, Alphapharm had 70.2% of the identified generics market and Sigma held 15.3%, so that between them they accounted for over 85% of the market. In many of the molecules studied in the case studies, the post-patent market had only two significant players, the originating firm and Alphapharm. This matter, and its implications, is still being explored.

Box 1. The Productivity Commission (PC) analysis of generics

In undertaking their analysis, the PC include the original patented brand as a generic, make the comparison between Australia and (say) the USA on the basis of an Australian basket of drugs, and use prices obtained from IMS (primarily list prices). They find, in broad terms, that in 1999 generic prices in the USA were between 2.5 and 4.5 times those for Australia, and that Australia also provided low prices for generics in relation to Canada, the UK and Sweden.

This note concentrates on the USA/Australia comparison, and our interest is in relative prices for generics and originator drugs in the post-patent period, with generics defined as excluding the originator brand. The literature suggests that the market arrangements and outcomes for generics in the two countries are quite different. Broadly speaking, in the USA the price for the original patented brand remains relatively high after the introduction of generics, in some cases even increasing. As a result there is a wide price gap between the originator drug and the generics, with the latter capturing the dominant market share. In Australia, the PBS reduces the price of the originator drug to, or close to, the generic price, and the competition between originator and generics takes place on factors other than price. The result is the branded drug often retains 50% or more of the market for a long time.

Let us illustrate these different outcomes in some stylized facts.

	USA			Australia		
	Price	Volume	Total cost	Price	Volume	Total cost
Branded drug	85	20	1700	40	50	2000
Generic	15	80	1200	40	50	2000
Tota;		100	3900		100	4000
Average price						
Total						
Own country weights		39			40	
Aust weights		50			40	
USA weights		39			40	
Generic		15			40	
PC definition		50			40	

Using these stylized facts for 100 units of product, the total cost for these 100 units is almost the same in the two countries. Reflecting this, the average price for the total (measured as total cost divided by number of units, and hence implicitly using own country weights) is also much the same (39 as against 40). When the PC methodology is used, that is including branded drugs with generics and using Australian weights are the basis of the comparison, the 'generic' price is higher in the USA (50) than in Australia (40). For these stylized facts, the PC methodology estimates the US 'generic' price at 50, when it is in reality only 30% of that, at 15, if a definition which excludes the originator drug is used.

Thus, at least for the case of the USA, the PC methodology is likely to overstate substantially the price of generics in the USA relative to Australia. The problem arises from the combined effects of using Australian weights and including the originator drug as a generic, when both relative prices and weights are quite different in the other country. The information in Table 2 suggests that this is likely to be a problem for some other countries as well.

7. Conclusion

Around the world, the pricing of pharmaceuticals is a matter of uncertainty, debate and some confusion. The Pharmaceuticals Benefit Scheme is an important Australian institution, one that has contributed significantly to the quality, equity and cost effectiveness of the Australian health system. Not for the first time, it faces major challenges in helping Australia to deal with the revolution in drug technologies that is under way. In my view, an important step in guiding its evolution is to have a better theoretical and empirical understanding of how the PBS in fact operates, and what options are available to it. This paper is intended as a tentative and preliminary contribution to that task.

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