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Economic Evaluation and the Reimbursement of Pharmaceuticals in Australia

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ABSTRACT

A concern to contain the costs of providing equality of access to prescription medicines while preserving health benefits has led most countries to regulate the availability and price of pharmaceuticals. Australia has successfully reduced the price of pharmaceuticals to about 50 to 60 per cent of the world price. However, in the 1980s utilisation and cost increases led to 6 per cent annual growth in real expenditure. In 1993, Australia became the first country to require economic evaluation in support of applications for listing of new pharmaceuticals for reimbursement. Some questions have been raised as to whether economic evaluation techniques are capable of ensuring a more rational diffusion of drugs, given the lack of standard methodology for economic appraisal and the ability of economics to make what are essentially political decisions on rationing. The inclusion of cost effectiveness criteria for reimbursement and pricing may slow down the adoption of new, more expensive drugs. Whether this is efficient depends not only on its impact on costs, but also on health outcomes.

Economic Evaluation and the Reimbursement of Pharmaceuticals in Australia

1 Regulation of Pharmaceuticals Worldwide

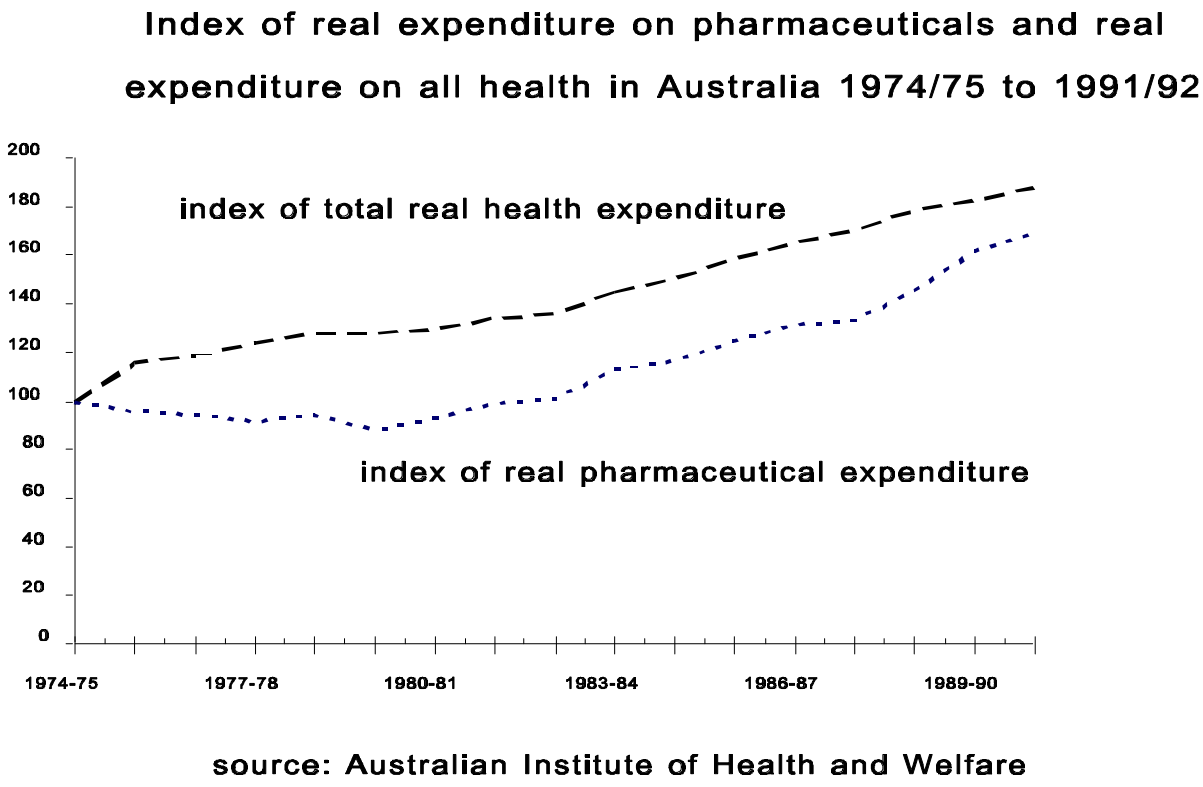
All countries regulate pharmaceuticals. There is widespread agreement that an unregulated free market would not produce socially desirable outcomes, either in terms of safety or access to life-enhancing medicines. The market for drugs is not like other markets, and the pharmaceutical industry is not like other industries. Most high potency drugs are available only by prescription, because it is judged that individuals (and, indeed, the doctor) cannot assess the suitability of each and every drug which may be appropriate for a medical condition. The range of drugs is so vast and complex that information failures abound. Most governments recognise that information failures require regulation on at least safety and therapeutic efficacy. Many go further by reimbursing consumers for at least part of the cost of prescription drugs, on the grounds that access to life enhancing medicines should not be related to ability to pay. The combination of imperfect information, doctor decision-making and third party reimbursement means that the demand elasticity is low, conferring considerable monopoly power upon the seller of listed drugs. This has led many governments to attempt to control the price, the degree of product differentiation and other forms of non-price competition, the development of new more costly preparations, and any perceived over-prescription or inappropriate use of pharmaceuticals. In summary, a concern to contain the costs of providing equality of access to prescription medicines, while preserving health benefits, has led most countries to regulate the availability and price of prescription pharmaceuticals.

2 Expenditure on Pharmaceuticals

In Australia, total expenditure on pharmaceuticals in 1990-91 was $2803 million, representing some 9.6 per cent of recurrent health care costs (Australian Institute of Health and Welfare 1994). Real expenditure on pharmaceuticals grew at an average annual rate of 6 per cent in the 1980s compared to 4.2 per cent for all recurrent health expenditure.

Thus, the share of pharmaceuticals in health expenditure rose from 8.6 per cent in 1980-81 to 9.0 per cent in 1990-91. As shown in Figure 1, a period of falling real expenditure on pharmaceuticals in the 1970s, was followed by a period of rapid real expenditure growth in the 1980s. The Commonwealth Treasury forecasts a rapid rate of growth in real

Figure 1



Commonwealth expenditure on pharmaceuticals in the coming years, and a growth in their share of total expenditure on health (Table 1).

Table 1 Forecasts of Average Annual Real Public Expenditure Growth in Health (per cent)

	1994/5	1994/5 to 1997/8
All government health expenditure	3.7	2.5
All government pharmaceutical expenditure	8.4	9.3

Source: 1994 Budget estimates

The rapid rise in expenditure on pharmaceuticals comes in spite of the success of regulation in reducing the price of prescribed pharmaceuticals to about 50 to 60 per cent of the world price (Bureau of Industry Economics 1991). Since 1963, the government has controlled the prices of prescribed drugs by restraining prices paid to suppliers of drugs eligible for the Pharmaceutical Benefit Scheme subsidy. Australian consumers have benefited from these low prices at the expense of producers, most of whom are foreign. Foreign consumers have not been protected by the exercise of countervailing power from their government or any other monopsonistic buyer and have born a much higher share of the research and development costs than Australian consumers.

Table 2 shows the relative price of pharmaceuticals in a number of comparable countries. The comparisons show Australian prices to be amongst the lowest of the developed countries surveyed. For 20 of the largest selling products in Australia, of the developed countries surveyed only Italy had lower prices.

In the United States, the world's largest producer of pharmaceuticals, the producer price index for prescription drugs rose at an annual average rate of 8.4 per cent between 1982 and 1992 , while the index for all commodities wholesale prices increased by 1.6 per cent, that is, a real price increase of 6.8 per cent (Scherer 1993). Over the period 1980-81 to 1989-90 the real cost of a prescription in Australia rose by 27 per cent, that is, an average annual rate of 2.7 per cent. Thus, while prices have been lower, Australia has not escaped the world increase in the price of drugs, albeit at a lower growth rate.

Table 2 Comparison of Average Ex-Factory Drug Prices, By Country, 1990[a]

	53 of the 80 largest selling products in Australia		20 of the 24 largest selling products in Australia	
Country	World average = 100	EC average = 100	World average = 100	EC average = 100
USA	155	177	211	242
Canada	155	177	137	157
UK	135	154	99	114
Ireland	125	143	107	123
Netherlands	123	140	120	138
Germany	122	139	155	179
New Zealand	112	128	48	56
Japan	109	124	123	141
Finland	107	122	120	139
World average	100	114	100	115
Europe average[b]	89	101	90	104
EC average[c]	88	100	87	100
Belgium	84	96	75	86
Austria	83	95	91	105
France	72	82	71	82
Australia	60	69	48	55
Portugal	60	68	73	84
Greece	54	61	79	91
Italy	52	59	41	47
Spain	51	59	48	56

Notes
[a] The indexes show the unweighted average price for two baskets of products. The total 80 products are not used in the analysis because not all products were sold in each of the countries.
[b] The Europe average is represented by the UK, Ireland, Netherlands, Germany, Finland, Belgium, Austria, France, Portugal, Greece, Italy and Spain.
[c] The EC average is represented by Belgium, Germany, Greece, Spain, France, Ireland, Italy, Netherlands, Portugal and UK (data for Denmark and Luxembourg are not available through IMS).

Source
Bureau of Industry Economics 1991, *The Pharmaceutical Industry: Impediments and Options*, Australian Government Publishing Service, Canberra, p. 37.

Nor has Australia escaped an increase in utilisation of new, more expensive, drugs. In spite of increased co-payments for prescriptions in the late 1980s, which increased the proportion of expenditure on prescriptions met by the consumer from 35.6 per cent in 1980/81 to 43.3 per cent in 1990/91, the number of prescriptions per capita rose by 23 per cent in that period.

The increase in real expenditure per capita in the 1980s was therefore both due to an increase in the cost of new drugs, and an increase in utilisation per head, particularly of those new expensive pharmaceuticals. For example, there is a worldwide trend towards the increased prescribing of the more expensive angiotension converting enzyme inhibitors and calcium antagonists for the treatment of hypertension, and a corresponding reduction in the use of diuretics and beta blockers. This, combined with a progressive lowering of the levels of blood pressure at which treatment is recommended, has resulted in more people being treated, and a substantial increase in the drug costs associated with hypertension (Hurley, Williams & McNeil 1990), the condition with the single largest drug expenditure (Carter 1994). There does not, however, appear to be strong evidence of the cost effectiveness of these new drugs relative to that of more conventional diuretics or beta blockers (Edelson, Wenstein, Tosteson et al 1990).

An increase in the use of new drugs is not inherently a problem. New drugs may lead to improvements at an acceptable cost in the length and quality of life of individuals. They may reduce the use of expensive surgical procedures. Some new drugs do both of these. However the very rapid acceleration in the number of new drugs, and the potential that new methods of drug development and discovery have for a continuing acceleration in utilisation and cost in the next decade, make it imperative that we assess their costs and outcomes.

3 The Regulation of Pharmaceuticals in Australia

Australia has a two tier system of drug regulation. The first tier is the approval of a prescription drug for marketing by the Therapeutic Goods Administration (TGA) and the Australian Drug Evaluation Committee. Before any drug can be reimbursed, the TGA must grant marketing approval on the basis that it is safe, efficacious and of acceptable quality. Eligible drugs are then subject to a second tier of regulation which is a consideration for reimbursement under the Pharmaceutical Benefit Scheme (PBS). The PBS provides a list of marketed drugs that are subsidised by the Commonwealth government. Although some approved drugs are marketed without subsidy, the PBS represents the major market for prescription drugs outside of hospitals, accounting for over 90 per cent of prescriptions. Drugs are placed on the list on the advice of the Pharmaceutical Benefit Advisory Committee (PBAC). Until 1990 advice from the PBAC was based solely on the criteria of effectiveness and safety relative to existing drugs and clinically defined need. From 1993, following a change to the National Health Act the PBAC now must also compare the cost effectiveness of new drugs relative to alternative therapies.

4 The Administration of the PBS

The Commonwealth government reimburses pharmacists the drug wholesale price plus a fixed dispensing fee and pharmacist's margin less any patient contribution. Patient contributions are the first $16 of each prescription up to a safety net limit of $400 per family in one year, after which patients pay $2.60 per script. For concessional beneficiaries and pensioners (who accounted for 80 per cent of total payments in 1992) the $2.60 contribution per item is removed once total expenditure exceeds $135.20 in a year. For pensioners and concessional beneficiaries, pensions and benefits have been supplemented since 1990 by the amount of the safety net. The administrative arrangements are thus complex. This means that interpretation of the impact of policy on trends in expenditure over time (and equity) are difficult to interpret as there have been a number of shifts in the population eligibility and rates of subsidy over time.

There is a danger, at least in principle, of a lack of coordination, particularly between the evaluation function of the PBAC and the price negotiation function of the Pharmaceutical Benefit Pricing Authority (PBPA). To date there is no formal coordination of the evaluation and pricing arms of the regulatory process, although the recommendations to the PBAC, including information on relative cost effectiveness, are made available to the PBPA. It is difficult to see how the PBAC can evaluate cost effectiveness without knowing the final agreed price. In practice this might mean that the cost effectiveness of drugs proposed for listing would be modelled with a degree of sensitivity analysis on price. However the guidelines discussed below do not make provision for this. The PBPA does come to the negotiation process with a recommendation from the PBAC on value for money at a given price and suggestions for price acceptability (or reduction).[1] The basis of price negotiation may shift over time from a cost only basis (subject to minimum effectiveness) to consideration of both costs and outcomes. Since pharmaceutical companies themselves must prepare and submit an economic evaluation to the PBAC at a stated wholesale price this could simplify the process of price negotiation in the future.

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[1] The PBPA does consider a number of factors when setting prices. In addition to costs and outcomes, the PBPA has an additional pricing guideline (Factor f) which explicitly accommodates a goal of encouraging an internationally competitive pharmaceutical industry in Australia. For a discussion of the Factor f Scheme see Bureau of Industry Economics (1991).

5 The Use of Economic Appraisal in the Regulation of Pharmaceuticals in Australia

In 1993 Australia became the first country to require economic evaluation in support of applications for listing of new pharmaceuticals for reimbursement. The commonly stated reason for this was the potential to encourage a more rational diffusion of new technologies in health. Perhaps most importantly its aim is to minimise arbitrary decisions by government about the listing for reimbursement of new and expensive drugs. In some respects the introduction of cost effectiveness guidelines for the reimbursement of pharmaceuticals is a more explicit formalisation of a process which has been going on for a number of years. That is to say drugs of a similar therapeutic effect have tended to be listed at a similar price. If a drug has a superior therapeutic effect, however, the question is how much of a price premium is warranted. As Drummond (1992) argues, while economic evaluation can provide an opportunity to address this issue more explicitly, there are two main points of contention:

1 Whether the analytic methods of cost effectiveness analysis are sufficiently well developed that a standard approach can be taken to the evaluation of each new product.

2 It has to be possible in practice to carry out economic evaluations in such a way that they are reliable, meaningful and sufficiently timely to be a useful input into the listing and pricing decision.

In an attempt to standardise the economic methodology, the Commonwealth has issued guidelines for the submission of new pharmaceutical products for reimbursement (Commonwealth Department of Health and Human Services 1992). There is also an accompanying background document arguing the case for the particular choices made in the guidelines (Evans, Freund, Dittus et al 1990). These guidelines are clear and well written, and probably represent a consensus view among economists on the application of cost effectiveness analysis in the field of health program evaluation. This is almost certainly true for the estimation of the costs of alternative treatments for a given condition where outcomes are similar in nature. That is to say, there is little, if any, disagreement on issues relating to the classic application of cost effectiveness analysis.

More contentious have been the debates on the appropriate methodology of economic evaluation where the outcomes of treatment alternatives vary. The issue of the measurement of health outcomes has been a preoccupation of many health economists since debates in the 1970s on the relative merits of the human capital or willingness to pay approach to the value of life (Steadman & Bryan 1988; Viscusi 1993). More recently, debate has focused on the notion of directly measuring the utility of health gains, and weighting morbidity differences between treatment alternatives by a quality adjustment to estimate so called incremental Quality Adjusted Life Years for a new treatment (Williams 1985; Drummond 1989; Richardson 1991). At present there is no general agreement on the appropriate economic measure of outcome in the absence of a reliable estimate of the willingness to pay for health benefits. As a consequence, the guidelines do not require companies to submit more than an analysis of the net costs of introducing a drug over current treatment, while quantifying any reduction in mortality or morbidity. They encourage the use of

quality of life improvement indices as an outcome measure, but discourage the use of human capital to measure either lives saved or productivity gains. The arguments over the inclusion of productivity gains is not trivial since many drugs and other treatments can determine whether someone can resume their usual activities, including work. The decision whether to include productivity gains depends on the perspective of the analysis and therefore the meaning of benefits (to whom) in economic appraisal (Richardson 1991).

In addition to the theoretical controversies, there is also a more practical set of issues such as how to link economic analysis with clinical trials (Drummond & Davies 1991); whether there is an inherent bias in requiring companies to prepare their own economic assessment for consideration by a committee (Hillman, Eisenberg, Pauly et al 1991); and problems in extrapolating data from international trials to the Australian context (Drummond, Bloom, Carrin et al 1992). Some concerns have also been raised as to what constitutes acceptable evidence on the efficacy and effectiveness of a new product.

The guidelines suggest that the best evidence is a direct comparison in a randomised controlled trial of the new product and the treatment which it is most likely to replace. In practice, the evidence on effectiveness is likely to fall short of this ideal, creating some inevitable uncertainty as to what constitutes acceptable evidence, and providing considerable discretion to the regulators. It has been noted, with some irony, that many of the drugs currently subject to reimbursement (and most medical interventions) would fail the effectiveness and efficiency data requirements of the guidelines, since few have been subject to randomised controlled trials under Australian conditions, and fewer still have undergone any economic evaluation.

This raises the general issue of the appropriate comparator in an evaluation of the incremental costs and benefits of introducing a new drug. Clearly the cost effectiveness of any alternative is dependent on the choice of comparator treatment and the disease for which it is to be used. Strategic behaviour on the part of the producers can be expected in the choice of comparator and the indication for which the drug is to be listed.

Problems also arise in the case of treatment for new diseases (AIDS for example) or for diseases for which there is currently no treatment. In this case there is no ready comparator in that therapeutic class, and a judgment must be made on the acceptable cost per unit of health outcome. That is to say, a new treatment may cost $100,000 per additional year of life saved (adjusted for the quality of that life). Is this too much? Some drugs currently listed on the PBS and some surgical procedures currently performed may have a cost per life year saved in excess of $100000. The answer to `which if any of these treatments should be funded?' is a political one, as economics has little to say about whether a life year is worth that amount. We can compare across other types of intervention (Street & Richardson 1992; Drummond, Torrance & Mason 1993), suggesting how many lives (or years of life) could be improved with that $100000.

This can be illuminating but does not resolve the issue of whether the community values a life year the same across areas of health care, in different contexts, or between different individuals. Indeed, our preference for such things as expensive neonatal intensive care, new drug treatments for those with AIDS, and breast cancer treatments is in contrast to our comparative neglect of aged care and mental illness. This suggests that we do not value every year of life the same no

matter to whom it accrues (Nord 1994). Thus while economic evaluation may improve the transparency of decision making in drug reimbursement, it can not as yet provide an agreed methodology, or a set of value judgments, for some of the more difficult decisions which will face the PBAC in the next few years.

6 The Predicted Impact of Economic Evaluation on Expenditure

The effect of the inclusion of cost effectiveness as a criterion for reimbursement and pricing, on prescription drug prices and expenditure is hard to predict. On the one hand, we might expect that increased regulation would slow down the approval of subsidy process, and thereby delay price and utilisation increases over time. Indeed many industry observers perceive the process as one which deliberately slows down the introduction of new drugs. We might observe, in the next decade, a reduction in the rate of cost increases in Australia compared to other countries, if not an absolute fall in relative prices. However, economic evaluation is not designed to control costs, and the aim of policy is not just to contain public expenditure. It may be that many new, expensive, but more effective drugs will be accepted as eligible for reimbursement. An analysis of the effect of the new strategy on the efficiency and equity of the PBS would require a study, not only of the impact on relative drug prices and changes in the composition and growth of expenditures, but also on the impact on health outcomes.

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