# Australia's 'free-ride' in pharmaceuticals: Can it last?

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## ABSTRACT

*The pharmaceutical subsidy scheme in Australia works in the public interest by keeping prices low while assuring access to drugs across most of the drug classes. By separating the approval to market drugs from the decision to subsidise them, the Commonwealth is able to take advantage of its position – to 'free-ride' on research and development expenditure in other countries. The first part of this paper examines the factors which allow Australia to free-ride. The second part explores some international and domestic factors which may influence the sustainability of the free-riding strategy.*

Pharmaceuticals make up only 10.5 per cent of the total health care budget of Australia, a country where 8 per cent of gross domestic product is spent on health care. On a per capita basis, Australian expenditure on drugs is about 45 per cent that of the United States and much less than that of the European Community (Spivey, Wertheimer & Rucker 1992). As a small market, sales in Australia do not significantly affect the pharmaceutical research and development taken on by the multinational drug firms. The current policy allows Australia to 'free-ride' on research paid by others, and on the profitable sales under patent protection in other countries. Australian health care policies, in particular the Pharmaceutical Benefits Scheme, work to keep prices on pharmaceuticals low by international standards.

It is the goal of this paper to explain the factors which allow the Australian free-ride and to identify possible causes of the erosion of this privilege. The distribution, prescription and use of pharmaceuticals at prices below world average result from a combination of (a) other countries' policies for the development of new therapies; (b) the market structure and

underlying cost characteristics of the international industry; (c) Australian government policy; and (d) the prescribing behaviour of Australian clinicians. Australia has chosen a set of national policies which gives it a privileged place as the recipient of a cross-subsidy from the industry in other countries. The most important component of Australia's regulatory policy is the separation of the decision on approval of a drug on the clinical grounds of safety and efficacy from the price-subsidy decision.

This paper is in two parts. The first part, the political economy of the Australian pharmaceutical industry, deals with (A) some basic economic principles which help to explain the policy environment; (B) technological assessment of research and development; (C) public policy and public finance; (D) elements of market structure of the industry which affect the strategic choices of the international firms; and (E) a brief economic explanation of Australia's price-contingent subsidy scheme. Points (B) and (C) above are determined by social and political forces so therefore can best be explained by a description of the function of the institutions concerned with regulatory policies. Points (D) and (E), the firm specific issues, are amenable to the micro-economic methods commonly used in economics for industrial organisation studies. The second part of the paper explores some international and domestic factors which may influence the sustainability of the free-riding strategy.

## The political economy of the Australian pharmaceutical industry

### Basic economics

The Pharmaceutical Benefits Scheme ingeniously uses two basic economic concepts. The first is the public good nature of research and development for drugs. Research and development will be conducted for the large North American and European markets where there are well over 600 million potential consumers. This research and development will be conducted with little or no concern for the Australian market. It is not necessary to recoup research and development expenditure from the sales of drugs in Australia. They will be developed anyway. We cannot be excluded from the research and development which is done elsewhere – the Pharmaceutical Benefits Scheme exploits Australia's relationship to the international market in terms of the small size of its own market and its geographic distance from the sources of research and development. Australian people benefit from this clever policy.

The second basic concept utilised is the notion that governments should consider subsidies to monopolists, or to foreign producers who operate as monopolists or cartels. The use of subsidies for monopolists, particularly those in decreasing costs industries, has been suggested for many years by economists – it has long ago found its way into the basic economics texts. A monopolist prices their product above the marginal cost of the product to be sold, thus restricting the amount sold. By giving a per-unit subsidy on drugs at a set price, the Pharmaceutical Benefits Scheme can allow greater access to drugs and still enable the companies to recover what they would otherwise receive in monopoly profits.

## Technological process

Most drug research programs which begin in medical research laboratories, both public and privately funded, do not result in a product being accepted and sold to the public. Research is risky. A drug can 'fail' by not meeting government regulatory standards. Successful drugs must pay for the entire research and development budget of the firm, including research and development for unsuccessful products. Control of the technological process of research and development crucial to the return on the companies' investment is affected by government policy, as well as the attitude, beliefs and knowledge base of the medical community. Regulatory control of the technological process is by means of the evaluation of the therapeutic usefulness of the new drug in the medical community. The evaluation process goes according to the rules set out to guide the clinical trials in the United States and in the European Community and, to a lesser extent, by the actions of the Australian regulators. In the past the rationale for regulation has not been driven by pecuniary factors, but by questions of clinical efficacy. Yet the institutionalised process influences the behaviour of the medical community and therefore the pecuniary consequences to all concerned.[1] In the case of drugs, it is the regulatory and medical community which has traditionally controlled their use; it is driven by consumer preferences to a much lesser extent.

The methods of regulatory authority brought to bear by the Department of Human Services and Health in Australia are the review of the efficacy and safety of a drug for marketing approval, and then a review of submissions to the Pharmaceutical Benefits Advisory Committee for the purposes of setting a price at which the drug is to be subsidised. Drug utilisation review and periodic hearing on price changes follow.

The submission for subsidy now requires statements on the 'cost-effectiveness' of the drug as compared to existing therapies. An estimation of the impact of a new drug on the Pharmaceutical Benefits Scheme budget, as well as the budget of the Department of Human Services and Health, also has to be made. Drugs of similar therapeutic type are compared to one another, under the rationale that the scheme will give therapeutically equivalent therapies similar prices. This results in the choice of a set of therapies which are seen to be essential, or that are demanded by the medical community, which is bounded by economic constraints.

The inclusion of an economic evaluation to the regulatory policy has changed the information requirements for submission to the Pharmaceutical Benefits Advisory Committee. Likewise, even in the United States, where health maintenance organisations and the publicly funded medical care programs have imposed maximum prices for the set of drugs on their formulary lists. This increasing emphasis on accountability in the use of medicines has changed the ethical assessment process, a process which was dominated by a technical imperative handed down from the medical profession. Australia has taken an aggressive path to tying public finance criteria to the technical evaluation process.

## Public policy and public finance

Public policy towards pharmaceutical use is based on the goal of encouragement of the widespread access and availability of drugs to the consumers. The government has been able to maintain a relatively low percentage of recurrent health expenditure on drugs of 10.5 per cent (up from 8.5 per cent in 1986), given that the world average is approximately 16 per cent (Spivey, Wertheimer & Rucker 1992). Given that the hospital system is funded by the States, and medical care within and without hospitals is financed by the Commonwealth, new drugs which cause a change in the accompanying medical costs can shift costs between levels of government.

To some extent Australia has the ability to free-ride, not only on the research and development from multinational firms, but on the public investment in medical research as carried out in other countries. Note that a firm cannot appropriate the entire gain from the trials process as there is information which becomes a public good (Comanor 1986, p 1212). Although industry expenditure internationally for research and

**Table 1: Percentage of recurrent health expenditure on drugs**

| Year | Pharmaceuticals* |
|---|---|
| 1982–83 | 8.5 |
| 1983–84 | 8.7 |
| 1984–85 | 8.6 |
| 1985–86 | 8.7 |
| 1986–87 | 8.7 |
| 1987–88 | 8.6 |
| 1988–89 | 8.9 |
| 1989–90 | 9.3 |
| 1990–91 | 9.5 |
| 1991–92 | 9.9 |
| 1992–93 | 10.5 |

Source: Australian Institute of Health and Welfare Bulletins

*Includes benefit paid items (64%) and other items (36%).

**Table 2: Pharmaceutical expenditure by country, 1990**

| Country | Health expenditure as percentage of GDP (market prices) | | Pharmaceutical expenditure as percentage of total health expenditure* (latest year) |
|---|---|---|---|
| | Public | Private | |
| Australia | 5.2 | 2.3 | 8.7 (88) |
| Canada | 6.7 | 2.3 | 11.6 (87) |
| France | 6.6 | 2.3 | 16.7 (90) |
| Germany | 5.9 | 2.2 | 20.7 (88) |
| Greece | 4.0 | 1.3 | 23.9 (89) |
| Italy | 5.9 | 1.7 | 18.4 (89) |
| Japan | 4.9 | 1.7 | 18.4 (88) |
| The Netherlands | 5.9 | 2.2 | 15.3 (87) |
| United States | 5.2 | 7.1 | 8.2 (90) |
| United Kingdom | 5.2 | 0.9 | 10.5 (90) |

Source: 1.Office of Health Economics 1992

2. Scrip Yearbook 1992

*Includes OTC and prescription drugs dispensed in an ambulatory (non-hospital) setting.

development has been large in comparison to other industries, there is evidence that in France, the United States and Germany industry research activities are closely related to other forms of medical research (Comanor 1986, p 1200). Australia also free-rides on the patent policy in the United States and the European Community which provides the opportunity of monopoly profits to successful drugs, allowing the drug companies to recoup their research and development investment in those countries. Since little research and development is conducted in Australia, the government need not be concerned about the welfare of those in other countries who are involved in research and development.[2] 'The subsidy scheme works particularly well if the producers are foreign, so that the government's welfare concerns are purely strategic' (Johnston & Zeckhauser 1991, p 28).

Australia has one of the most tightly regulated drug industries in the world. Drugs are sold in retail pharmacies and private hospitals. They are provided in public hospitals and clinics. Public hospitals have formulary budgets out of which quantities and prices are negotiated, either by the hospital or the area health service directly with the private drug firms. The public hospitals have a certain degree of monopsony power and are part of the global budgeting scheme which has controlled hospital costs in Australia. (Hospital formularies often use the Pharmaceutical Benefits Scheme prices as price guidelines.)

Retail pharmacies have the same mark-up on each and every drug and compete for volume of drugs in defined geographical areas. The most important policy is the price-contingent subsidy program (Pharmaceutical Benefits Scheme). A per-unit subsidy is paid to the drug producers at an agreed price. For retail sales to general users there is a maximum charge per prescription of $16, and a lesser amount for concessional consumers. Drugs for which an agreement on price between the company and the Pharmaceutical Benefits Advisory Committee is not reached are allowed to be sold at whatever price the drug companies and retail pharmacies set, but go unsubsidised.

The net effect of the government policy is the ability to set a target amount of expenditure for pharmaceuticals each year in the hospitals and to set the prices for prescriptions. Based on epidemiological evidence, it is possible to get a good estimate of the yearly prescription expenditure (85 per cent of prescription drugs sold in Australia are covered by the Pharmaceutical Benefits Scheme). In addition, by requiring an economic evaluation to accompany a submission for listing on the Pharmaceutical

Benefits Scheme, the Commonwealth can make an estimate of what it will have to invest to allow new drugs to be subsidised and sold in Australia. The combined effect is a degree of fiscal control which is not possible in other countries.

## Industry strategic decisions

For any given drug, the sales by Australian affiliates fit into the global strategy for the foreign-based multinational firms. Research and development and patent monopoly are based in other countries, most development and production taking place in the United States, Germany, Switzerland, the United Kingdom and France. (The first three countries have historically had the most free-market approaches to the pricing of drugs after the granting of patent status.)

The most strategic point in time for the company in Australia is the Pharmaceutical Benefits Scheme listing decision; the firm will be adding a drug at the Australian dosage to the portfolio of drugs that it holds. (The portfolio decisions can be viewed as more or less a pure investment decision. Each drug is like a bond in the portfolio with a return on investment and a time to maturity in respect to the patent life of the drug.) The Australian drug is evaluated as to how it will contribute to the risk/return profile of the international firm as a whole (the firm's position in diversifying its portfolio).

A firm will only accept a price and a listing if the profit it would receive under the subsidy scheme exceeds the amount that it would have received without the subsidy. We can also assume that a firm makes a greater return the sooner it begins to market a drug, so there is an incentive to have a longer period of profit before it goes to generic form. (Note that Australia has been slower than most other countries to move to generics in many important therapeutic classes. From 1994 Australian Commonwealth and State legislation permits limited generic substitution. The price differential between the patented medicines and the generics in research and development countries is significant. The Pharmaceutical Benefits Scheme price for brand name products is not significantly above the worldwide production price.)

In the major international markets, drug firms produce and distribute a large number of products, and the margins realised for individual products may not be typical of the firm as a whole. They rely on the revenues generated by a small number of products. So what is relevant to the firm

is an average price-cost ratio for the firm as a whole. However, the Australian addition to the firm's portfolio is expected to be at or below the average price. In 1987 the world average price for the 80 largest selling drugs was 82 per cent higher than the average price in Australia, and about 90 per cent of the world average prices were greater than the Australian prices. 'New products are introduced into therapeutic markets where they compete actively with existing products, and those that cannot maintain their market position are often withdrawn. High rates of product introduction and obsolescence are found regardless of the magnitude of price-cost margins' (Comanor 1986, pp 1186).

Assuming that (a) decreasing costs due to the fact that research and development can be as much as 20 per cent of sales (Comanor 1986), (b) the Australian market is only a small percentage of the total world market, and (c) both failed and successful drugs are taken into account, the Australian sales of the drug are subsidised by the abnormal profits of a few drugs sold in the major markets. So the presence of this source of subsidy is important to Australia's free-riding.

In the research and development countries where prices are substantially uncontrolled, products which have provided important therapeutic gains upon introduction are most likely to be priced substantially above their competitors, while those with little or no therapeutic advantage are most frequently priced below rival products. However, many drugs with a clear therapeutic advantage may make a higher per-unit profit, but may be in a rather narrow market due to the epidemiology of the disease which is treated. 'New drugs are a major determinant of industry profits. The picture that emerges is that major pharmaceutical firms earn normal profits on their older products but quite high returns on newer ones' (Comanor 1986, pp 1193).

As the end of patent life approaches in the research and development countries, competition usually increases in therapeutic groups. In the United States, Temin has been able to demonstrate that 'restrictions on the rate of introduction of new drugs thus far have the effect of lowering drug prices on average' (1979, pp 151–61). By being willing to wait on the regulatory authorities elsewhere, as well as being willing to restrict the type of drugs in each therapeutic group to the lower priced ones (at a time when the time to maturity of the drugs sold in other countries is lower), Australia is able to have more bargaining power.

To the international company, the Australian sales of a drug listed on the Pharmaceutical Benefits Scheme will never be a source of recoupment

of research and development, whether or not the drug would fall into this category in the research and development country. There is the possibility that the company will choose not to accept the Pharmaceutical Benefits Scheme price, or not to market a drug in Australia, since it will not make a positive contribution to the return of the portfolio even though it can be sold at a profit overseas.

Although a free-rider on international research and development, Australians should be concerned about the profitability of the industry. The rate of new product introduction is tied to the amount spent on research and development, which in turn has a constant relationship to industry profit levels. It has been estimated that factors which reduce pharmaceutical industry profits lead to lower research spending by approximately 25 cents in the dollar (Grabowski, Vernon & Thomas 1978). Clearly, there is the prospect of reduced research outlays in Australia with any decline in industry profits.

## The Australian subsidy scheme

Johnston and Zeckhauser have modelled the Australian pharmaceutical subsidy scheme for a monopolist who has a clear therapeutic advantage in their drug and as a two-player oligopoly considering price competition. (They use a theoretical model of a two-player oligopoly considering 'Bertrand' price competition.) Although such abstract theorising requires the blurring of some institutional details, their models capture some important characteristics of the scheme.

For the monopoly situation, the one producer is offered a per-unit subsidy if it sets price equal to marginal cost. The quantity sold increases to the point where the monopolist earns slightly more than they would at a monopoly price. (The dead weight loss of monopoly is turned into consumer surplus.) For the situation in which 'two or more firms possess market power for a particular therapeutic use, the subsidy creates a game…to determine who joins first and reaps most of the benefits. Properly constructed, the game transfers significant oligopoly profits to the consumer' (Johnston & Zeckhauser 1991, p 5). The government can play off one oligopolist against the other. By choosing an appropriate strategy in the domestic market, it improves the outcome for Australians. The subsidised firms have been enticed to lower their prices and increase the quantity sold.

The importance of adequately assessing the degree of product competition within therapeutic groups before the subsidy decision can

improve the viability of the scheme and is crucial to the public finance decision. ('The extent to which a price-contingent subsidy can increase net consumer surplus depends on own and cross price elasticities of demand. Low own elasticities imply that profits were high, but deadweight loss was low. High cross elasticities imply that profits were high, but dead weight loss was low. High cross elasticities boost the potential for playing firm against firm' (Johnston & Zeckhauser 1991, p 21)). Since most manufacturers have only a few big sellers, there is an increased advantage to listing potential big sellers first on the scheme. This enhances the viability of the scheme and decreases the pay-offs from collusion. The subsidy scheme creates a 'first mover' advantage which rewards the first company that gets its drug listed with a subsidy. This ensures that the companies are enthusiastic players, who have little to gain from collusion.

## Potential threats to the scheme – can it last?

Any factors which (a) increase the amount of return necessary in the Australian market, (b) decrease the incentive to be a first mover for a subsidy, (c) increase the costs in the Australian market or (d) decrease the percentage of drugs marketed under a subsidy have the potential to affect the subsequent ability to free-ride.

### International factors

1. **Profit rates are falling** in the research and development markets. The causes are increased cost of research and development and the price caps put on by the German Government, and Medicaid and the health maintenance organisations in the United States. Some of the sources of high return on research and development investment have been lost. This may induce the companies to require a higher return in Australia. They may not be willing to market drugs in Australia or may be forced into a tougher bargaining position for a subsidised price.
2. **Mergers of multinational drug companies** have resulted from lower profits. The number of producers has decreased, making it more unlikely in the future that the oligopoly game will be played because of product competition. Although the Pharmaceutical Benefits Scheme works to the benefit of the Australian people, the government can extract more benefits when an oligopoly situation exits.

3. **Decreased research and development expenditure** has already begun to follow the lower profits. In the future there will be fewer drugs to consider for Australian marketing. This may affect the bargaining power of the Pharmaceutical Benefits Pricing Authority, but it is difficult to predict the direction of the impact.
4. **Sales of the drugs in the transitional economies of Asia** are growing rapidly. The Chinese and Indonesian Governments buy drugs in each therapeutic class in volume, so as to receive low prices. The importance of increased sales in the Australian market may be reduced since the companies may be able to receive greater profits in the Pacific Rim. Even though the countries (like Canada) which have tied marketing to price have not fared as well as Australia in negotiations with the drug companies, these countries have been small enough to be incidental to the total return on investment of research and development. The huge potential of the Asian markets may make the Australian markets less attractive to the companies.

## Internal factors

1. **Regulatory requirements** are fixed costs imposed on the manufacturer marketing the new drug. The increased amount of information needed under the new submission guidelines could increase the amount of funding required to obtain a Pharmaceutical Benefits Scheme listing. It could lead to more drugs being marketed without a subsidy, thus reducing the welfare benefit transferred to the people of Australia under the scheme. These guidelines, by requiring the demonstration of cost-effectiveness, may lead to an increased number of unsubsidised drugs.

   Australia's success is due to the small size of its market and its geographical location, causing little notice and having a negligible effect on drug development. An aggressive position in the regulatory arena may be counterproductive.
2. **Fiscal constraint** on the size of the growth in the Pharmaceutical Benefits Scheme budget could result in the decrease in the percentage of drugs listed on the scheme. As has been suggested above, it may be necessary to increase the profit margins for drugs sold in Australia because the source of industry profitability in the research and development countries has decreased, thus increasing the percentage of the medical care budget spent on drugs.

## Conclusion

The pharmaceutical subsidy scheme in Australia works in the public interest by keeping prices low while assuring access to drugs across most of the drug classes. By separating the approval to market drugs from the decision to subsidise them, the Commonwealth is able to take advantage of its position – to free-ride on research and development expenditure in other countries. The multinational companies sell their products in Australia with the perception that research and development costs are sunk (having been met by revenues in other countries). The subsidy scheme gives the certainty of a constant return above the marginal cost of their efforts in Australia.

Public expenditure on drugs can be controlled in Australia; the percentage of recurrent expenditure on drugs has grown slowly but steadily in recent years. During the eighties, drug prices were allowed to rise more or less across the whole range of drugs, with newer types of compounds being given a premium over the old. Since January 1993 the new regulatory procedure required mandatory economic evaluation. New drugs are compared to drugs already listed with similar therapeutic effect – they are evaluated on the basis of 'cost-effectiveness' analysis, and prices chosen accordingly.

As first envisaged in 1957, the Pharmaceutical Benefits Scheme was designed for the subsidisation of a core of drug classes but grew to encompass 85 per cent of prescription drugs. In order to control the growth of the Pharmaceutical Benefits Scheme budget, the number of drugs offered a subsidy may have to decrease. If the percentage of drug sales covered by the scheme gradually decreases due to regulatory decisions, then at what level of subsidy does the conduct of the international firms in Australia change? If the scheme is restricted to only certain defined drug classes, will the price subsidy game change? The relative attractiveness of the Australian market as a part of an international market should be of concern to those who want to preserve the viability of the scheme, especially since the international market is becoming more concentrated in terms of the number of suppliers, and the international market is expanding due to growth in the emerging economies. These topics of research need to be explored further by economic researchers and policy analysts.

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## Endnotes

1. This technological process can be explained by reference to the institutionalist theory of instrumental valuation and institutional (ceremonial) dominance. Instrumental valuation is the human activity of exploration and experimentation that develops new knowledge, skills and tools. It is the problem-solving activities associated, in our case, with the use of a new drug. 'Technology is thus defined as the package containing not just the up-to-date tools, but the necessary skills to use them' (Swaney 1989, p 570). However, instrumental valuation has direct bearing on the usefulness of the goods and services delivered, and is normally dominated by institutionally warranted processes – the vested interests involved or the social or legal right to income and political power. Only in times of institutional change do new forms of instrumental valuation become the guiding force (Bush 1989, p 456).

2. The 'Factor F' scheme was devised for firms who researched and manufactured drugs in Australia. The scheme allows an improved price to the company for their value adding activities in Australia. There is no doubt that the Factor F scheme has allowed companies to retain their manufacturing plants in Australia, and has led to Australian-based suppliers exporting to Asian and regional markets. The amount of subsidies paid through this scheme was about $80 million in 1993–94, mostly for manufacturing of drugs. 13.6 per cent of increased activity is due to research and development, whereas increases in production contribute 86.4 per cent (Australian Pharmaceutical Manufacturers Association Inc. 1993, p 10). The amount of research and development done under this scheme will not change the free-riding scenario. In terms of production costs, in his review of the political economy of the worldwide pharmaceutical industry, Comanor noted that 'a striking feature of the literature…is the absence of any attention paid to process innovation. Because production costs represent so small a share of the manufacturer's price, little research has been directed towards that objective' (Comanor 1986, p 1189).