

# The Pharmaceutical Benefits Scheme and the shifting paradigm of welfare policy

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## Abstract

*This paper describes the design and operation of the Pharmaceutical Benefits Scheme and then proceeds with an analysis of current policy deliberations which identifies an extension of the market as predominant trend. The paper demonstrates that the conditions which historically sustained the scheme are now present to a lesser extent. The Pharmaceutical Benefits Scheme has functioned as a universalist welfare program which conferred onto the Commonwealth Department of Health substantial powers vis-à-vis drug suppliers and professional groups. This position of dominance has been eroded, with challenges to established arrangements arising, in particular, from the enhanced bargaining position of business and wider pressures operating on the Keynesian welfare state.*

## Introduction

Changes to the Pharmaceutical Benefits Scheme (PBS) in the past decade can be considered a manifestation of the decline of the Keynesian welfare state in Australia and globally (Jessop 1993; Boyer 1996; Cerny 1997). Over a period of several decades, *de facto* renunciation of the price mechanism as a means of regulating the consumption of prescription drugs was made compatible with industry prosperity. This era came to an end in the 1980s with the acceleration of processes of globalisation; since then, fiscal and political pressures operating on the Commonwealth Department of Health have been reinforced by the international integration of industry research and development, production and marketing. While the long-standing trend of annual increases in aggregate PBS expenditure has not been reversed, step-by-step adjustments have made the scheme progressively less effective as a means of exercising government controls

vis-a-vis drug manufacturers. Conversely, the scope and legitimacy of market forces within this policy domain have been extended both under Labor (1983–96) and the current Coalition Government (Löfgren 1996, 1997a).

The traditional dominance of the Department of Health within the policy domain of pharmaceuticals has been based on two sets of legislative powers. First, the department is responsible for the pre-market evaluation and registration process which, until changes instigated in 1991, was organised principally along the lines of a classical bureaucracy bolstered by enlisting of external professional and scientific expertise (Baume 1991). Second, the department manages the PBS, an archetypal welfare state program which, under specified circumstances, ensures subsidised access to approved medicinal drugs and related items. These two roles are functionally and conceptually distinct, but overlap in practice. From the 1950s they became woven together into a complex system of governance within which government officials exercised a high degree of autonomous power (Johnston 1990; Hansen 1993; Sloan 1995).

Thus the PBS cannot be conceived of ‘only’ as a means of ensuring equitable access to drugs, but as the pivotal mechanism for structuring relations between the state and private and professional interests within the pharmaceutical sector. This paper argues that adjustments to the scheme since the 1980s have had the cumulative effect of reducing the capacity of the state to sustain effectively programs which conflict with the logic of the market. Paradoxically, the policy aim of achieving a ‘quality use of medicines’, requiring a high degree of centralised monitoring, guidance and control, came to the fore at the very time of the acceleration of structural changes in state–business relations which have weakened the government’s capacity to undertake such interventionist measures.

## **Design and operation**

Inclusion of medicinal drugs on the PBS is *de facto* the second step of Australia’s system of drug regulation, which follows assessment for market approval by the Therapeutic Goods Administration and the Australian Drug Evaluation Committee (Vaughan 1995). Since its inception under the Menzies Government in 1950, the PBS has evolved into an exceedingly complex institution encompassing a variety of forms of interaction between the state, drug manufacturers, wholesalers, pharmacists and the medical profession (Hunter 1963; Sloan 1995; Industry Commission 1996). Indeed, the PBS is central to the Australian pharmaceutical policy domain, which provides an exemplary case of the relatively autonomous and self-regulated sub-systems of advanced capitalism which are beyond the control of any single actor and which cannot be entirely comprehended, even by core participants (Löfgren 1997a).

The PBS is administered by the Pharmaceutical Benefits Branch of the Department of Health under the provisions of the *National Health Act 1953* for the purpose of providing ‘equity of access’ to prescription drugs. The most obvious benefit, from a patient perspective, is that the (direct and indirect) effects of the subsidy, in combination with safety net provisions, in most instances eliminate the risk of substantial financial hardship ensuing from pharmaceutical expenses in case of illness or injury. The stated aim of the scheme is:

*to provide all people in the Australian community (not attending public hospitals) [with] access to effective and necessary prescribed medications at a reasonable cost to the Government and to taxpayers consistent with a reliable supply* (Commonwealth Department of Human Services and Health 1995b, p 1).

PBS items (which are subsidised by the government if priced higher than the level of the co-payment) and drugs issued through associated programs comprise around 90% of all prescription medicines supplied through community pharmacies. In addition, the PBS substantially influences other market segments such as hospitals, private prescriptions, and various specialised Commonwealth programs (Australian Institute of Health and Welfare 1994).

PBS listing requires that the price of a product is acceptable to the government, which operates in the market place as a bulk (‘monopsony’) purchaser. As a consequence, Australian drug prices are lower than in some major OECD markets; according to a typical estimate, Australian per capita drug expenditure is around 45% of that of the United States and less than that of the European Union (Kemp 1996). A 1995 survey commissioned by the Industry Commission (1996, p 193) showed that company respondents believed, on average, that prices in a deregulated environment would be 22% higher. All consumers, as well as the government (the taxpayer) as the provider of the subsidy, derive a benefit from the general price-depressing effect of the scheme. In recent years, however, the price gap between Australia and comparable overseas markets has narrowed, reflecting the overall structural change of power in government–business relations (Industry Commission 1996, p 200).

The pricing regime sustained by the PBS is the most contentious of the mechanisms employed by the Department of Health to influence the supply of and demand for pharmaceuticals. In essence, the PBS has allowed Australia to ‘free-ride’ on research and development and other fixed costs incurred by companies in their major markets, and most analysts accept that the scheme has had, in aggregate, a depressing effect on the Australian medicinal drugs sales revenue and profitability (Johnston 1990). The industry’s laments in regard to

the pricing regime became increasingly strident from the early 1980s, and the Australian Pharmaceutical Manufacturers Association has since asserted intermittently that low prices have made firms reluctant to market particular drugs in Australia. However, it is a moot point whether it can be demonstrated that the pricing regime has had negative effects on the availability of drugs to Australian consumers. The Industry Commission (1996, p 206), which would have been inclined to jump on any such evidence, concluded only that reduced availability 'may' result 'at a certain point'.

The industry's aversion to relatively low PBS prices has been tempered by its acceptance of social and political realities. Moreover, subsidisation of consumption historically delivered a degree of protection and predictability and had a market-enhancing effect, benefiting community pharmacy in particular but also, to some extent, suppliers. Thus policy proposals from the Australian Pharmaceutical Manufacturers Association have, at least until recently, sought to ameliorate the pricing effect of the PBS rather than to bring about the outright abolition of the scheme (see, for example, Australian Pharmaceutical Manufacturers Association 1993).

The mechanism for determining the inclusion of drugs on the PBS revolves around the deliberations of the Pharmaceutical Benefits Advisory Committee, which are not readily accessible to systematic appraisal. At various points in the listing process consideration is given to medical, economic, social and other criteria, but the precise weight given to different factors cannot be disentangled due to the complexity of the judgements required. The precise rationale for decisions is not made public, and the Department of Health has traditionally sought to minimise the transparency of the process. Until 1970 even the membership of the Pharmaceutical Benefits Advisory Committee was not made public and, until 1973, reasons for its recommendations were not given (Sloan 1995, pp 7–8). The intention appears to have been to reduce the exposure of officials and scientific and medical experts to the lobbying of industry and other interest groups. In addition, a stream of new medicines, and new data on patterns of usage and effects of existing drugs, make the decision environment unstable, requiring a constant preparedness for reconsideration and intervention. Inevitably, Department of Health officials, drawing on expert advice, must have the capacity to make decisions autonomously, within certain limits. From the perspective of suppliers, lack of transparency and the autonomy of officials add up to a somewhat arbitrary wielding of bureaucratic power.

In response to perennial industry complaints, the listing process has gradually become more open, and in recent years annual meetings between the Pharmaceutical Benefits Advisory Committee and the Australian Pharmaceutical

Manufacturers Association have provided an avenue for direct exchange. It is evident from the committee's 1995 submission to the Industry Commission that it is now keen to refute accusations of being unsympathetic to the industry's concerns:

*The [PBAC's] Secretariats welcome discussion with pharmaceutical industry representatives about proposed submissions or related matters ... Over the past decade the Committee and its Secretariats have increasingly aimed to be as open as possible in its proceedings and dealings with the pharmaceutical industry (Pharmaceutical Benefits Advisory Committee 1995, p 2).*

The authority of the government within the domain of pharmaceutical policy and regulation, reinforced by the PBS, historically did not result only in comparatively low drug prices. This power also made it possible for the Department of Health to sustain a range of (relatively modest) interventionist measures for the purpose of public health, including programs to minimise waste and abuse and to foster 'appropriate' drug use. The reason for not implementing more extensive guidance of doctors' prescription decisions in order to optimise the 'Quality Use of Medicine' has to be sought in the delicately balanced pattern of relations between the Department of Health, the medical profession and drug firms. The power relations between these groups have never enabled the department to advance significantly beyond its traditional focus on access to drugs towards measures for promotion of health. However, the point emphasised in this paper is that the current trend of extending progressively the role of the market as a means of regulating drug distribution and consumption weakens the structural capacity of the government to maximise the health value of pharmaceuticals. (Conceivably, in certain circumstances, the market might itself generate monitoring and control structures similar to those of a health value oriented state authority, as evidenced by managed care in the United States, though most likely with a primary focus on costs and profitability rather than on equitable health outcomes.)

## The decline of universality

The PBS was expanded in the 1950s and 1960s into a universalist welfare program of free or low-cost prescription drug access which met most therapeutic requirements. With needs satisfied irrespective of ability to pay, prescription pharmaceuticals were *de facto* de-commodified as far as consumers and prescribers were concerned; that is, the price mechanism by and large ceased to influence their behaviour. Within the context of social policy, the PBS in this respect was atypical; in Australia, the post-war decades were the era of the 'wage earners' welfare state', characterised by full employment and a state-sanctioned arbitration and conciliation system, coupled with 'a selective and ungenerous benefits system' (Castles & Shirley 1996). Indeed, before the introduction of Medibank in 1974, the PBS was among only a small number of programs with a strong non-targeted component.

In 1978 the Department of Health defined the role of the PBS as follows:

*The Government [through the PBS] aims at having a comprehensive range of drugs and medicinal preparations available on a subsidised basis to all persons being treated by a medical practitioner in Australia ... The Department's main process for achieving the maximum value for Government expenditure under the Scheme is its price negotiation system...* (Commonwealth Department of Health 1978, p 1; emphasis added).

The wide scope of this objective is explained partly by the unique importance of pharmaceuticals to human health and welfare but, as already suggested, also by the advantages of the PBS as a mechanism which enabled the Commonwealth Government to exercise overarching dominance within the drug sector. This was highlighted in Johnston's seminal analysis of the structuring effects of PBS on the state's relations with suppliers (Johnston 1990). Johnston criticised changes introduced or contemplated in the 1980s which involved an extension of the price mechanism, demonstrating that they would have the effect of weakening the authority of the Department of Health. However, his expectation was that the government would ultimately not proceed with changes resulting in the relinquishment of the established power of the state vis-à-vis business and professional groups. Indeed, Johnston believed that the opportunities for 'free-riding' would increase rather than diminish with the unfolding of the globalisation process; the huge fixed costs of high technology industries such as pharmaceuticals would make it profitable for firms to continue to supply marginal markets with prices below those of the major countries (Johnston 1990, p 6).

However, the rapid increase of international integration of pharmaceutical research and development, production and markets in the past decade has proven Johnston's predictions mistaken. Rather than expanding the scope for Australian 'free-riding' on the overseas activities of transnational firms, globalisation processes have had the effect of weakening the effectiveness and perceived legitimacy of the PBS as a means of extracting low prices and exercising state control over the industry. Companies have become increasingly sensitive to differences in pricing between national markets; it is claimed by the industry that a low product price in a country such as Australia may be used as a reference price elsewhere, with negative effects on profitability. Consequently, the pressure for prices approaching the 'world average' is now very strong, as evidenced by submissions to the Industry Commission (1996). It is ironic that Johnston's analysis, which was presented in support of the continuance of strong government controls, contributed to the very vigour with which the industry has since argued the case for higher prices and the rolling-back of the PBS. Indeed, the Australian Pharmaceutical Manufacturers Association accepted the accuracy of Johnston's analysis but turned it on its head, arguing that transfers from international firms to Australian consumers 'amounting to over \$1 billion per annum' are illegitimate and unsustainable (Australian Pharmaceutical Manufacturers Association 1995, p ii).

Johnston's analysis was undertaken around the time of the Labor Government's reorientation of pharmaceutical policy in recognition of the new reality of industry demands for an internationally competitive regulatory environment. In 1987 the Pharmaceutical Industry Development Program was launched, with the Factor (f) program as a major component; this was followed by the transformation of the Therapeutic Goods Administration from 1991 (Löfgren 1997b). While company profitability was previously of little concern to the government, the fostering of a favourable environment for globally oriented companies has since been defined as a core policy objective, and was included as one of the four arms of the National Medicinal Drug Policy (Commonwealth Department of Human Services and Health 1995a). Indeed, the story of the National Medicinal Drug Policy is indicative of the shift from closed bargaining between the Department of Health and a small number of centralised associations towards an increasingly fluid and open pattern of exchange and coalition-building within a more politicised framework. However, the particular form which this process took under the Labor Government in the first part of the 1990s, which was premised on structured bargaining between the state and a wide range of interest groups, does not accord with the general policy approach of the Coalition Government and appears to have been silently buried.

Notwithstanding this difference of emphasis, both Labor and the Coalition share the overriding objective of fostering a favourable investment environment.

Changes to the PBS in the past decade include, most importantly, the conditioning of consumers to price signals through a co-payment and the introduction of an element of price competition through the legalisation of brand substitution in 1994. While a co-payment for general consumers was introduced in 1960, the 1986 increase of the general patient contribution from A\$5 to A\$10 for the first time excluded a significant number of products from the subsidy. This was followed by another substantial increase in November 1990 from A\$11 to A\$15. In addition, in November 1990 a co-payment was introduced for the first time for concessional cardholders, now required to pay A\$2.50 per prescription (with a corresponding increase in pension payments). General consumers now pay the full price for a large number of drugs, and this will become progressively more pronounced with each increase in the co-payment. (However, under Labor enhanced targeting was not incompatible with improvements for the most vulnerable, as evidenced by the extension in 1983 of concessional drug benefits from pensioners to several other disadvantaged groups.)

The outcome of stricter targeting and/or a more narrow listing of PBS-listed drugs is not only less pressure on the government budget and higher aggregate Australian expenditure on prescription drugs (as a result of higher prices and a weakening of controls on consumption), but a shift in sectoral power in favour of business. Inevitably, the authority of the Department of Health in respect of both pricing and prescribing practices diminishes if doctors and patients are impelled more often to look outside of the PBS listing for appropriate therapies. Significantly, a loss of PBS 'market share' will also result in a lessening in the quality of statistical data available to the government. Similarly, a widening of the scope for marketing of prescription drugs directly to the public (even if limited to non-brand advertising) will strengthen the market at the expense of the state, as will the gradual conditioning of consumers to price competition through brand substitution. The decision in the context of the 1997–98 Budget to provide a PBS subsidy within each of five therapeutic groups on the basis of a base price only further extends the same basic policy approach. The government's professed expectation is that competition will force down the price of alternative brands to a relatively insignificant amount above the base product. This policy is in line with the established practice of many Health Maintenance Organizations in the United States, and its dynamic effect (notwithstanding the possibility of short-term negative consequences for the sales and profitability of some suppliers) will further reinforce the trend towards governance through the

operation of market forces rather than the state. It is also likely in due course to produce a recurrence of the controversies generated by the legalisation of brand substitution in 1994. The impact of extending the scope of 'consumer choice' in respect of sectoral governance arrangements, as advocated by consumer and patient advocacy groups, is profoundly ambivalent and possibly unanticipated as far as the consumer movement is concerned. It is no coincidence that the industry in Australia and internationally has been seeking for some time to establish cooperative linkages with consumer groups against restrictive state controls, such as the PBS listing process. Indeed, the industry is now very attentive to the benefits it can derive from a *de facto* policy coalition with consumer groups (The international 'Patients Network' established by the multinational brand industry is a notable case in point.)

The sum total of developments in the past decade has been to make the PBS a more targeted welfare program, with direct benefits flowing mainly to concessional beneficiaries. With Labor and Liberal alike advocating welfare support only to those 'most in need', there is now no powerful voice within the political elite to defend the remaining universalist elements of the PBS. Acceptance of the proposition that private provision is preferable to public services, and that 'middle class welfare' should be minimised, is resulting in the Department of Health surrendering step-by-step to private actors much of the leverage hitherto generated by the PBS. Plainly, circumspection in respect of radical change does not flow from a fundamental acceptance of state control as legitimate and appropriate but from a pragmatic recognition of the political mobilising power of pensioners and welfare organisations, and a community pharmacy sector highly dependent on PBS dispensing.

### **Towards a new policy paradigm**

Keynesian welfare states or 'Fordism', while taking different national forms, were typically characterised by a high level of state intervention, macro-economic demand management, social partnerships involving capital and labour, quasi-full employment, and the generalisation of norms of mass consumption (Boyer 1996). The PBS can be considered Keynesian or Fordist in this general sense. As described, wielding strong market power as a bulk purchaser, the Department of Health could effectively shape the pattern of pharmaceutical supply, distribution and demand.

The possibility of fundamental overhaul of the PBS has been canvassed by the pharmaceutical industry and policy advisers over many years. Invariably their argument has been that a universal subsidy scheme, constituting a form of distortion of the 'free market', is incompatible with rational economic arrangements. Until the mid-1980s this line of reasoning was widely perceived as being invalidated by the evident benefits delivered by the PBS to Australian consumers generally and to most participants within the drug policy network. Around that time, however, the impasse between critics and supporters of the PBS changed into a process of piecemeal retreats and adjustments on the part of the Department of Health, and multinational firms have since presented their case for a transformation of the PBS and its pricing regime with increasing assurance. Their claim now is that the PBS is:

*... a product of the social welfare state of the early twentieth century. Increasingly, the Federal and State Governments are recognising that these policies send the wrong signals for efficient use of resources. In effect, these policies represent a regulatory barrier to trade and are inconsistent with the Government's initiatives to achieve improvements in resource allocation in the post-Hilmer competition environment (Australian Pharmaceutical Manufacturers Association 1995, p 27).*

The government faces a series of stark policy dilemmas in respect to the future of the PBS. The multinational companies assert that prescription drug prices approximating 'world averages' are a prerequisite for maintaining and expanding industry activities in Australia, while retention of the PBS in its traditional form will produce continued double-digit expenditure increases incompatible with fiscal restraint and an ideological commitment to the minimisation of welfare spending. However, measures such as removing the subsidy from general consumers and/or a systematic expansion of the non-PBS market (listing fewer new products on the PBS) will produce a strong political reaction. The durability and effectiveness of the scheme over several decades, in conjunction with the strengthening of welfare and consumer groups during the Hawke–Keating Governments, ensure that proposals for the transformation of the scheme or its outright abolition will inevitably generate intense conflict. Indeed, one line of industry criticism is that the PBS has created an expectation, claimed to be incompatible with the imperatives of 'international competitiveness', that medicinal drugs should be available to everyone at a low cost. Whether the outcome of political contest is radical redesign of the PBS, or the taking further of incremental measures to contain costs and widen the scope of the market, the universalist 'welfare state' function of the scheme is likely to continue to be weakened.

In summary, the socioeconomic and political conditions which sustained the PBS for almost 50 years are now present to a much lesser extent than in previous decades. Since the slow-down in economic growth and the re-emergence of high unemployment in the mid-1970s, all major welfare programs, including the PBS, have come under pressure, and bureaucratic administrative practices are now considered less appropriate than supposedly more flexible, market-like models. The virtual de-commodification of medicinal drugs from the perspective of consumers and prescribers, achieved through the PBS, is no longer seen as viable and appropriate. Today, the issue of contention between the major parties in regard to the PBS is not whether, but how best to manage the winding back of state controls and welfare benefits in favour of regulation through the market mechanism.

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