

AUSTRALIAN PHARMACEUTICAL POLICY AND THE IDEA OF INNOVATION

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Policy regimes are founded on the currency of ideas of how the world is and how it should be (Campbell 1998). In Australia, regulation of the pharmaceutical sector is falling in thrall of the idea of innovation - an idea holding the promise of both technological advance and economic growth. Australian pharmaceutical policy, historically concerned with securing public access to quality drugs while containing costs, is gradually but perceptibly shifting emphasis towards promoting private sector profitability and expansion. Innovation, conceived and presented as a rational and necessary predicate for improving the nation's health and international competitiveness, is central to this change in policy direction.

This paper interprets changes to Australian pharmaceutical policy from the view that ideas as well as interests shape public policy. We argue that a sequence of material changes in regulation shows the rise in prominence of the idea of innovation - an idea resonant with contemporary economic wisdom and general public sympathy towards new technologies. Linked to health and economic growth (contemporary social preoccupations), innovation has considerable cognitive and normative appeal. This appeal, coupled with generous latitude in defining when a drug is 'innovative', has seen innovation become the primary conceptual and rhetorical device used by the pharmaceutical industry in its push for regulatory reform. Although widely regarded as equitable and efficient, Australia's pharmaceutical regulation, particularly its pricing regime, has been consistently characterised by pharmaceutical manufacturers as an impediment to innovation and in need of reform.

With all Australian governments now committed to competition and being competitive, industry's arguments for reform have found an increasingly sympathetic ear. The regulatory response, exemplified in Australia's obligations under the Australia-United States Free Trade Agreement, has been to adopt innovation as a central objective and modify regulatory processes to give it greater recognition. We argue that these changes risk constraining the capacity for Australian pharmaceutical policy to meet the historical objectives of equity and efficiency.

Ideas and Interests

Like all policy, pharmaceutical policy involves a political contest over who gets what (Sell and Prakash 2004). National pharmaceutical policies typically reflect the tension between public and private interests (Grund 1996) – a contest resulting in varying articulations of ideas regarding state intervention *per se* and more specific concerns such as licensing requirements and public and private financing. There is now an immense literature and body of opinion on whose interests are best served by the prevailing national and supra-national pharmaceutical regulatory regimes (*c/f* Angell 2004; Abraham 2002). The centrality of competing interests – most importantly the state and manufacturers – in the development of pharmaceutical policy has obscured the importance of ideas. Certainly, in Australia most observers have focussed on competing interests (*c/f* Lofgren and de Boer 2004; Ranald 2007) and less on the conceptual terms on which policy is premised.

Policy emerges as material interests interact with and through ideas, broadly defined as cognitive and normative precepts, that both define policy problems and provide legitimate programs for policy action aimed at solving those problems (Campbell 1998). The properties of ideas range from more abstract ontological and normative principles to more specific theoretical propositions (Surel 2000) that may operate at a background level of taken-for-granted general assumptions (paradigms) or as explicit imperatives and justifications for policy action (Yee 1996; Campbell 2002). The normative idea of equity underpinning pharmaceutical subsidy programs or the use of cost sharing to minimise 'moral hazard'

are examples. The influence of an idea within policy at a given time will of course depend on the power of individuals and groups that champion the idea (and the effectiveness of the strategies used to promulgate it). However, influence will also depend on an idea's normative and cognitive appeal for policy makers – an appeal intimately connected to prevailing intellectual and public sentiments (Hall 1993; Sell and Prakash 2004; Campbell 2002).

No matter who is pushing what interest, not just any idea will do at any time. The negotiation of policy presupposes a shared view of how the world is – a common knowledge where certain features of the policy domain are taken for granted – the economy, its processes and problems for example (Culpepper 2008). Transcending partisanship, common knowledge paradigms consist of interrelated sets of assumptions that define and delimit what is possible, appropriate and rational (Hall 1993; Hay 2004). Policy is open to persuasion, but persuasiveness depends on the intellectual and normative clout of an idea as a feature of common knowledge as much as the interests that push it. Influential ideas are those that offer explanations and solutions to current social and economic problems and that are appealing to all parties (Culpepper 2008). In the present case of pharmaceutical policy, the shift in prevailing economic wisdom from the importance of welfare to the importance of competitiveness has considerably boosted the appeal of innovation.

Australian Pharmaceutical Policy

Universally acknowledged as central to public health, pharmaceuticals remain among the most closely regulated of consumer products (Vogel 1998). Governments are inextricably active participants in pharmaceutical markets, as licensing authorities and as customers. Close regulation of pharmaceuticals is judged necessary because of the unique nature of drug products and the distinctive demand and supply features of drug markets (Lacetera and Orsenigo 2001). In addition to the need to ensure product safety and efficacy, features such as information asymmetries, the doctor-patient agency relationship, low price elasticity, innovation-based competition and monopoly power through generous patents, all motivate regulatory intervention (Lacetera and Orsenigo

2001; Abraham 2004). Typically, the main objective of intervention is to ensure wide public access to good quality important drugs (with equity usually an important associated consideration), while containing cost and supporting industry performance. The particular character of a national pharmaceutical regulatory regime, and the priorities it attaches to given objectives, varies with different historical paths of policy development shaped by each nation's unique economic and social conditions (Lacetera and Orsenigo 2001; Wiktoriwcz 2003).

Historically, Australia's pharmaceutical regulation has been dominated by the ideas of equity, cost-containment and efficiency – explicitly via price control exercised in the public interest. The central regulatory institution is the Pharmaceutical Benefits Scheme (PBS), a universally accessible national formulary that covers approximately 75% of pharmaceuticals used in Australia (Sansom 2004). With universal insurance effectively making the PBS the sole purchaser in the market, successive Australian governments have been able to combine monopsony power with regulatory authority to achieve equitable access, while controlling expenditure and promoting efficiency. The monopsony buying power of the PBS and the application of cost-effectiveness evaluation to drugs submitted for PBS listing, together with associated initiatives such as price-volume trade-offs, are regarded as having delivered value for money from Australia's drug expenditure. These approaches have secured prices for new drugs that have been lower than in most other OECD countries (Dalton 2001; Productivity Commission 2001).

The PBS, a classic welfare state apparatus, was created in 1948 on the cusp of what is sometimes referred to as 'the golden age of pharmaceuticals', the era of spectacular growth in the pharmaceutical industry underwritten by rapid and successive introduction of 'blockbuster' drugs – single drugs applicable to large population diseases (*c/f* Lacetera and Orsenigo 2001). Through the 1950s and 1960s Australian governments implemented pharmaceutical policy as social policy with little regard for industry development (Lofgren 1997). From the earliest, price negotiation has been a particular source of tension. Drug manufacturers have argued that what they perceive to be aggressive price control has created a hostile regulatory environment in

Australia (Lofgren 1998). Despite vigorous objection to the price-suppressing impact of the PBS, the industry in Australia – for much of its history a secondary formulation and packaging subsidiary of international firms – had limited capacity to influence pharmaceutical policy (Lofgren and de Boer 2004). The PBS now operates in a different political economic environment to that of its inception and interacts with a much larger and politically more influential industry.

A Changed Political Economy

‘Neo-liberal’ premises of marketisation, competitiveness and private-over-public now inform a globally ascendant policy logic embraced in Australia as enthusiastically as it has been among other industrialised nations (Broomhill 2001; Quiggin 2001). In the contemporary ‘new economy’ the focus of policy is on the supply side where growth is achieved through innovation and other forms of entrepreneurial activity (Jessop 2002). With the enhanced global integration of markets and national economies, via trade and capital flows, capital has ‘become increasingly mobile, with circulating capital more important than fixed’ (Lloyd 2002). The threat of capital to territorial ‘flight’ from the old industrialised core states to those regions and states with more favourable regulatory regimes has placed enormous pressure on national governments to create and maintain favourable regulatory conditions to attract and retain investment (Harris and McDonald 2000). It is thus claimed that, where necessary, state intervention should be focussed on promoting international competitiveness rather than providing welfare (Jessop 2002; Brenner and Theodore 2002). In the ‘new economy’ being competitive means being innovative.

Innovation is a protean term – referring variously to product or process innovation, technological or organisational innovation and incremental or radical innovation. It may be held distinct from invention and imitation but not by necessity – innovation having elements of both (Fagerberg 2003). Despite its definitional slipperiness, innovation is a powerful, if not pre-eminent, techno-scientific and social idea. For Joseph Schumpeter, regarded by some as the emblematic economist of our times (Jessop 2002), innovation with its ‘gales of creative destruction’

constitutes our *zeitgeist* (Shionoya 2004). There is the broad contemporary acceptance that innovation – the coupling of scientific and technological possibility with market opportunity (Pavitt 1991) – is the predicate of competition and economic growth (Landes 1969; Nelson and Winter 1982; Porter 1990; Dosi, Orsenigo and Labini 2002). As the evolutionary pulse of the capital dynamic, economies expand on the imperative of innovation and the ‘always fleeting’ opportunity it brings for monopoly. Innovations, where they involve techno-scientific change, present opportunities for the entrepreneur to create ‘new combinations’ and generate new demands (Schroeder and Swedberg 2001). Nations, industries and firms that innovate prosper – a robust theoretical and empirical assertion supported by the correlation between innovation activity (typically measured by research and development spending, the issuing of patents and innovation counts) and *per capita* GDP (Fagerberg 2003; Morck and Yeung 2001).

The idea of innovation has currency at a cognitive level as a theory of dynamic competition and growth and also at a normative level as a value in tune with prevailing public sympathy to technological, scientific and material advance. Firmly established theoretically and empirically as the vehicle for growth (albeit without consensus on exactly how best to induce it), national economic policies have increasingly been framed in the terms of establishing favourable conditions for innovation (Fagerberg 2003). In Australia, major national policy reforms such as the National Competition Policy (the objectives of the related National Competition Council are to improve the ‘growth, innovation and productivity’) and support programs such as Backing Australia’s Ability have been promoted as necessary for successful innovation.

Despite these initiatives, Australia’s record in successfully producing and commercialising technological innovations has been patchy at best (Australian Parliament, House of Representatives Standing Committee on Science and Innovation 2006) with Australia placed in the bottom half of OECD nations for innovation performance (Department of Industry, Tourism and Resources 2004). Government rhetoric of innovation has not yet been matched by initiatives that deliver results. Acknowledging the nation’s poor record with innovation, within its first 100 days in office the new Rudd Labor government established a Department for

Innovation, Industry, Science and Research and has initiated a review of Australia's 'national innovation system' (Carr 2008). If Australia has yet to materially realise its potential to produce commercialisable innovations, the idea of innovation as desirable and necessary has firmly taken root.

A Changed Industry

The pharmaceutical industry presents itself as the embodiment of innovation. Showing double-digit growth rates for over thirty years, the pharmaceutical market has been one of the fastest growing global product markets (Gassmann and Reepermeyer 2005). Through successive waves of technological innovation, particularly the mass selling 'blockbuster' drugs, pharmaceutical enterprise has evolved to a globally organised, super profitable multinational industry dominated by a few firms. With its enterprise primarily based on new products, meeting the growth expectations of investors has placed considerable pressure on the industry to keep introducing new drugs (Gassmann and Reepermeyer 2005; Walsh 2004). Although the innovativeness of many new drugs is dubious, often presenting little health benefit beyond what is currently available ('me-too' drugs) manufacturers will typically – and by business necessity must – claim innovation. In the standard industry account, the considerable sunk costs (even if partly publicly subsidised) that are necessary to research and develop a new drug and the risks involved in such investment will only be undertaken where profitability can be assured via patent protection (Eisenberg 2001).

Drug innovation, in this account, is dependent on profit that is dependent on regulation conferring market advantage to first movers via intellectual property rights. Extending the length and breadth of intellectual property rights has become fundamental to the industry's business strategy. The strategy pivots on the rhetorical logic of innovation (McDonald 2004) – no patent, no (super) profit, no investment, no innovation. As the pharmaceutical enterprise has flourished, manufacturers – individually and organised in transnational business networks – have gained considerable political influence within the national and supra-national organisations (Sell and Prakash 2004). The sheer weight of influence is

clearly demonstrated in the industry's success in establishing the Agreement on Trade-Related Intellectual Property Rights (TRIPS) under the auspices of the World Trade Organisation (WTO) (Sell and Prakash 2004). This influence is not untrammelled, as the success of Doha declaration shows (Mecurio 2004). However, if once neglected by Australian regulators, the interests of the multinational globally integrated pharmaceutical industry have become impossible to ignore.

Changed Governance

As the political economic context has changed, governance of the Australian pharmaceutical sector has evolved to a distinctive neo-corporatist mode of negotiation and accommodation. Regulatory hostility has been replaced by a more sympathetic environment with pharmaceutical policy increasingly formulated within a state-capital 'partnership' (Lofgren and De Boer 2004). The pharmaceutical industry partner has steadily gained greater access to the government agencies that shape pharmaceutical policy, increasing its opportunities to interact with decision-makers and pressing forward its ideas and claims. The partnership approach has resulted in a number of significant government initiatives explicitly aimed at meeting the interests and concerns of industry. In the mid-1980s for example, the then Labor government established the Pharmaceutical Industry Development Program (PIDP) and 'Factor F' programs. Ostensibly government support for increased competitive activity via direct transfer of money to participating companies, the programs effectively constituted compensation for the price-lowering effect of the PBS (Lofgren 1997). The partnership was further consolidated in the early 1990s with the inclusion in the National Medicinal Drug Policy of the objective of maintaining a viable pharmaceutical industry. This was explicit government recognition of the need to provide a supportive environment for 'one of the largest business activities in Australia' (Lofgren and De Boer 2004, Sansom 1999).

Through the 1980s and 1990s the partnership approach and initiatives such as the factor F scheme (and later extensions such as the Pharmaceutical Industry Investment Program) advanced industry's interests – but only so far. To industry's obvious frustration, Australia's

pharmaceutical policy has throughout appeared to remain demonstrably committed to cost-containment.

Cost-containment

The rapid expansion of the pharmaceutical industry was in part induced by the creation of national health schemes among the majority of industrialised nations (Lacetera and Orsenigo 2001; Walsh 2004). However, with the decline of Keynesianism and the rise of neo-liberalism the macroeconomic cost of running national healthcare systems became defined as a problem among the governments of developed nations (Giarelli 2004). For governments responsible for providing citizens with pharmaceutical insurance (albeit at varying levels of generosity), the rising cost of funding the 'golden age' of pharmaceuticals induced a reactive 'age of cost-containment' (Lacetera and Orsenigo 2001). Pharmaceutical expenditure is a particularly visible source of health care costs. As in other countries, as Australia's drug expenditure has grown as a result of population growth, increased *per capita* consumption and the regular introduction of newer more expensive therapies. So successive governments have been eager to reduce the drug bill (Salkeld, Mitchell and Hill 1998). In Australia cost-containment has taken two major routes – the increased use of patient cost-sharing and the introduction of pharmacoeconomic analyses into the PBS listing process.

How the policy of making patients share the costs of pharmaceuticals affects equity of access will not be discussed here beyond noting that there is increasing evidence of hardship with prescription costs among low income working families (Blendon *et al* 2003; Doran *et al* 2004; Schoen *et al* 2005). The focus is on the second major route to cost-containment following the introduction in 1993 of an economic evaluation regime based on cost-effectiveness and the use of reference pricing (Salkeld *et al* 1998). New drugs submitted by manufacturers for inclusion on the PBS must undergo a pharmacoeconomic comparison of the cost effectiveness of a drug proposed for listing against an alternative from the relevant therapeutic class. Australia's version of reference pricing involves categorising medicines into therapeutic groups of

medicines that treat the same condition or have similar actions. If the proposed product is 'substantially more costly' than the selected comparator in its class it will not be PBS listed unless it provides a significant improvement in efficacy or safety over currently available therapies. Referencing the price of the proposed drug to the lowest cost therapeutic alternative (including existing generic products in a therapeutic class) restricts the listed price of a new drug that performs no better than currently available products.

For Australian governments the use of pharmacoeconomic evaluation, combined with the PBS's countervailing power as the single buyer (monopsony) in the market, has helped achieve value for money from Australia's drug spending. The Australian system is highly regarded internationally and has become a model for governments seeking to limit their pharmaceutical expenditure (Sweeney 2004; Outterson 2004a).

However, Australia's attempts to control costs have come at the cost of continuing to antagonise its 'partner' – the increasingly powerful pharmaceutical industry (Outterson 2004a; Henry, Hill and Harris 2005). Although willing to get closer to industry, successive Australian governments have also been keen to retain autonomy and authority, employ monopsony power and constrain drug expenditure. The partnership era has not dulled government desire for PBS efficiency and thrift.

Changes in the political economy have not dissolved all the tensions in Australia's pharmaceutical regulation. However, government initiatives, such as (i) industry development support programs and (ii) the adoption of industry viability as a core objective, suggest a convergence of assumptions about what is economically rational and desirable. With competition being a central concern of government activity, pharmaceutical policy too has become subject to evaluation of its capacity to contribute to the nation's competitiveness. If not quite *simpatico*, manufacturers now have a secure policy footing on which to argue that the PBS cost saving policies are in direct conflict with the objective of innovation.

The Rise of the Idea of Innovation

Industry's dissatisfaction has been mobilised into a narrative suggesting PBS cost-containment suppresses prices and fails to adequately reward innovation. The industry argues that it is difficult for innovative drugs to enter the Australian market, that the country free-rides on the innovation of other nations and is opposed to intellectual property, anti-competitive and anti-trade (Kemp 1996; Pharmaceutical Research and Manufacturers Association 2003; Mecurio 2005). In short, industry's narrative has it that Australia's regulation is anti-innovation and hostile to investment; consequently, Australia misses opportunities for industry growth, particularly that represented by the industry's continuing transformation in structure and strategies towards biotechnology (Sheehan 2002; 2003; Rasmussen 2004a; 2004b; 2005). It is claimed that this environment may eventually force international manufacturers to withdraw from Australia to more favourable regulatory environments (Sweeny 2004; Schneerman 2003). From an industry perspective, the PBS may save money on drugs but it undermines the national aspiration of economic growth.

This industry narrative is not implausible. Identifying the effects of controlling the price of pharmaceuticals is a complex and contentious task. Industry arguments draw on a considerable body of economic theory, evidence and opinion about the relationship between price regulation and innovation (*c/f* Calfee 2000; Danzon 1997). Industry's narrative has intellectual clout and there is no simple rejection of the propositions it represents. However, the impact of price control is an empirical question – no necessary relation between price regulation and innovative performance exists (Otterson 2005).

The available evidence indicates considerable uncertainty as to whether Australia's pharmaceutical regulation results in excessively low price, profit and investment for innovative medicines (Light and Lexchin 2005). Indeed, there is good evidence indicating that Australia 'pays for value' in drug innovation (Otterson 2005). Although Australian prices are considerably lower for 'me-too' drugs, prices for new innovative pharmaceuticals are closer to those in the other OECD countries (Productivity Commission 2001) and higher in some cases where the drug represents a significant advance (Roughead, Lopert and Sansom

2007). But however much Australia's pricing regime lowers unit prices it also ensures profitability through sales volumes subsidised by the universally accessible PBS (Wright 2003; 2004).

The impact of PBS pricing on investment and research and development activity is also far from clear. Australia's research and development performance clearly lags behind that of the non-price regulated US. However, causally linking this difference to the PBS pricing regime ignores other salient factors - the size of the US market, for example, and its extensive public investment in biomedical research and the legal conditions for technology transfer to the private sector (Lacetera and Orsenigo 2001; Wagner and McCarthy 2004; Acemoglu and Linn 2004). It is doubtful that pricing reform on its own would create the conditions necessary to expand Australia's research productivity.

Despite the partnership approach and its compensatory industry development programs, the industry considers that PBS policies (particularly reference pricing) contribute to a 'deteriorating environment that has direct and negative impact on local activity' (Medicines Australia 2003). From the industry's perspective, having rightly enshrined industry viability as a core objective, the government's continuing aggressive cost containment focus undermines any chance of achieving it. In short, according to this reasoning, PBS pricing inhibits innovation. Despite equivocal evidence on the impact of the PBS on profitability and investment, in the context of heightened government concern for competitiveness this argument has gained traction. The industry's 'innovation is threatened' narrative is incrementally reshaping Australia's pharmaceutical policy agenda. This assertion is supported by two recent regulatory developments – the implementation of the AUSFTA in 2005 and the 'major' PBS reforms implemented in 2007.

The Australian United States Free Trade Agreement

The Australian United States Free Trade Agreement (AUSFTA) was the first bilateral trade agreement specifically seeking change to a nation's pharmaceutical regulation (Mecurio 2005). Unsurprisingly, the negotiation and implementation of the AUSFTA was subject to

considerable debate. Advocates of the AUSFTA - chiefly industry and US and Australian government staff - presented the agreement as a remedy for Australia's chronic undervaluing of drug innovation and an unprecedented boost for industry development (Schneerman 2003; Haynes 2004). Critics argued that the AUSFTA is an increment in the process of regulatory globalisation with the potential to erode Australia's sovereignty by leaving governments vulnerable to economic coercion and subordinating Australian to US objectives. Critics consider that the AUSFTA may ultimately weaken the PBS, increase drug expenditure and diminish equity of access to essential medicines (Lokuge and Faunce 2004; Harvey *et al* 2004). The former Australian government was adamant that the AUSFTA would not change the PBS, and categorically denied that it will have any impact on drug prices or on policies that guide the selection of drugs for the PBS (Howard 2004; Davies 2004).

The pharmaceutical provisions of the AUSFTA centre on the 'importance of innovation'. The agreement established a new set of overarching 'common' principles that both nations undertook to recognise (Department of Health and Ageing 2007). Reflecting the 'spirit' of the agreement, these common 'interpretive' principles oblige Australia to give greater recognition to the importance of innovation for healthcare, the importance of government support for research and development and the need to support processes that give due recognition for innovation and the health benefits of innovative products (Department of Health and Ageing 2007). Ostensibly the agreement is not intended to modify the 'fundamental architecture' of the PBS, seeking only (but importantly) to increase the prominence of innovation in the PBS deliberative process. The provisions allow manufacturers more opportunities for representation during the drug listing process and provide a mechanism for 'review' of negative pricing decisions. The provisions also establish a Medicines Working Group, consisting of government officials from both nations, to foster mutual understanding on pharmaceutical issues (Department of Health and Ageing 2007).

Given the importance that the US government placed on their inclusion, Australian government assurances that the pharmaceutical provisions of the AUSFTA are merely 'process' related with no significant impact on the PBS, have appeared incongruent to some observers (Outterson

2004b). The professed lack of material impact on the PBS and drug prices also makes the pharmaceutical industry's enthusiastic support for the AUSFTA puzzling. This is especially so in the light of the fact that US based industry members, publicly committed to dismantling elements of the PBS (Fickling 2004), were instrumental in drafting the agreement (Faunce 2007).

Worryingly for many observers, despite being central to the AUSFTA, 'innovation' is not clearly defined, which combined with the vague and ambiguous 'interpretive principles' allows considerable scope in interpreting what obligations are established by the agreement (Lokuge and Faunce 2004; Drahos *et al* 2004). Given Australia's commitment to, and US hostility towards, reference pricing there is clearly a potential for ambiguity to result in divergent interpretations. Where differences in interpretations arise, disputes about expectations and obligations are likely to follow (Faunce *et al* 2005) With innovation poorly defined but clearly central, decisions not to list 'innovative' new US drugs (on poor cost-effectiveness grounds, for example) may be interpreted as a breach of that spirit and potentially provide the basis for a trade dispute. Few would expect a trade dispute with the USA to end in Australia's favour (Lokuge and Faunce 2004).

The difficult path of the AUSFTA through its negotiation to final implementation made clear that the US government and its close collaborators, the pharmaceutical industry, expected some change to the Australian pharmaceutical market. If the agreement does not institute overt changes to the structure of the PBS perhaps changes to process will be sufficient to satisfy those expectations. The changes to process – additional consultations with officials, a review mechanism, a high level Medicines Working Group – substantially increase the degree of access that industry has to Australia's regulatory officials. The AUSFTA brings Australian officials closer to an industry with a remarkable track record in 'dynamic competition' – innovativeness, economic, financial and (although not uncontroversially) welfare performance. Increased proximity creates greater opportunities for a well-resourced industry to push the idea that the PBS is inhibiting innovation, the technically efficient and instrumentally rational path to growth.

Regardless of the ambivalent empirical evidence of its impact on innovation, industry can present the publicly funded, universally accessible PBS as the antithesis to prevailing economic wisdom. The risk for the PBS here is not so much 'regulatory capture', but that the emphatic logic of innovation may come to not only inflect policy discourse but eventually constitute its core commonsense propositions.

Recent Reforms

Despite Australian government protestations that the AUSFTA would not result in changes to the PBS pricing regime, there is evidence that it has done just that (Faunce 2007). Under the terms of the agreement, Australia is now required to consider valuing innovation via 'competitive markets' (as in the USA) in addition to the traditional criterion of objectively demonstrated therapeutic significance. Recently implemented amendments to the National Health Act, which governs the operation of the PBS, represent a clear attempt to modify the system of reference pricing to reward 'innovation' defined by competitive markets. Broadly described, the changes divide the PBS into two formularies, thereby creating a new category for 'innovative' drugs where reference pricing against traditional comparators, on the basis of clinical equivalence, will not be used. In other words, drugs in this new category will maintain higher prices even though they offer no greater clinical benefit compared with the established alternative treatments. In drafting this reform, the then Howard Coalition government consulted closely with Medicines Australia, the peak body representing Australia's patent drug manufacturers (van Gool 2007). The reforms have been publicly endorsed by Medicines Australia and are reportedly similar to their own proposals for changes to PBS pricing (Buckmaster and Spooner 2007).

The creation of two formularies represents a significant weakening of the evidentiary process used to list drugs on the PBS. The first formulary (F1) will list drugs that are only available as a single brand and are not considered 'interchangeable' at the patient level. The drugs listed in F1 will not be price-linked to the drugs in the second formulary (F2), which will mainly be older drugs available in multiple brands. By requesting that drugs be proven 'interchangeable' before they are priced down to the

level of older equally effective products, the industry has made it harder for listing decisions to be based on the results of clinical trials. While accepting that a drug, on average, is no better than an older product, a doctor can often find a reason why a new product is not strictly interchangeable for every individual patient. As a consequence, companies will likely argue for higher prices for drugs that do not offer better measurable performance, on the grounds that someone, somewhere, has a unique need for their products (Searles *et al* 2007).

The likely impact of the formulary changes is underscored by the announcement that around 450 single-brand products will be placed in F1, and will thus be protected from price competition from around 230 multiple-brand medications in F2. This means that drugs like the cholesterol-lowering agent atorvastatin – sold under the brand name Lipitor, and the biggest single cost to the PBS, costing taxpayers nearly \$500 million in 2005-06 – will probably escape price competition from generic forms of the closely related drugs simvastatin and pravastatin. Likewise, the antidepressant escitalopram (Lexapro) and the peptic ulcer treatment esomeprazole (Nexium) are likely to be protected from price competition from the older and near-identical drugs citalopram and omeprazole. This prospect will break the link between clinical performance and price (Henry 2007).

The recent reforms are a major departure from the evidence-based approach to medicine and breach the spirit of the legislation under which the PBS currently operates. By contrast, in seeking to de-link innovation from reference pricing, as historically applied in Australia, the changes reflect the spirit if not the letter of the AUSFTA.

Conclusion

Recent developments in Australia's pharmaceutical policy can be interpreted as reflecting the ascent of the idea of innovation. Once an isolated and mostly insignificant market, Australian pharmaceutical policy has had to respond to a more powerful, globally integrated industry in the context of wider ascendancy of neo-liberal thought. In a political economic climate dominated by supply-side logic of

competition and innovation, the welfare function of the PBS has perhaps come to have the whiff of anachronism about it. Developments such as the AUSFTA and the 2007 reforms suggest that government enthusiasm for the PBS pricing regime – crucial to providing equitable and affordable access – is wilting relative to its eagerness for promoting a ‘viable’ pharmaceutical industry.

Successive industry-favourable changes to Australia’s pharmaceutical policy are partly attributable to the effectiveness of pharmaceutical industry lobbying. However, change to regulatory arrangements is as much about the causal efficacy of ideas as it is about ‘regulatory capture’. Innovation is associated with rationality, scientific/technological progress and material growth: as such it presents a compelling idea underpinning industry’s appeals for reform. The risk lies in Australia’s policy makers uncritically accepting this persuasive narrative and further shaping regulation to its logic. The net effect of the transformation of Australia’s pharmaceutical sector to a more innovation oriented and globally responsive system is contingent and uncertain. An invigorated local industry may result but so also might a loss of government authority and capacity to determine sector outcomes – efficiency and quality use of medicines, for example. Should innovation become Australia’s supreme regulatory objective, the future of the PBS may look quite different from its past and equity of access to affordable medicines may be consigned to history.

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