Balancing health and industrial policy objectives in the pharmaceutical sector: Lessons from Australia

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Abstract

Introduction: Policy-makers worldwide struggle to balance health with industrial policy objectives in the pharmaceutical sector. Tensions arise over pricing and reimbursement in particular. What health plans view as necessary to maintain equitable access to medicines, industry views as inimical to R&D and innovation. Australia has grappled with this issue for years, even incorporating the goal of “maintaining a responsible and viable medicines industry” into its National Medicines Policy.

Methods: This case study was conducted via a narrative review that examined Australia’s experiences balancing health and industrial policy objectives in the pharmaceutical sector. The review included electronic databases, grey literature and government publications for reports on relevant Australian policy published over the period 1985–2007.

Results: While pharmaceutical companies claim that Australia’s pricing and reimbursement policies suppress drug prices and reduce profits, national policy audits indicate these claims are misguided. Australia appears to have secured relatively low prices for generics and “me-too drugs” while paying internationally competitive prices for “breakthrough” medicines. Simultaneously, Australia has focused efforts on local pharmaceutical investment through a variety of industry-targeted R&D incentive policies.

Discussion: Despite the fact that policy reviews suggest that Australia has achieved balance between health and industrial policy objectives, the country continues to face criticism from industry that its health goals harm innovation and R&D. Recent reforms raise the question whether Australia can sustain the apparent balance.

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1. Introduction

The affordability, quality and accessibility of medicines is a priority for healthcare systems around the world, as is investing in and supporting research and development (R&D) in the pharmaceutical sector. Governments are active in the pharmaceutical sector because scientific and economic benefits from R&D are not strictly limited to private returns for investors, and because medicines themselves are “life and death” products [1,2]. The unique characteristics of pharmaceuticals and the pharmaceutical market necessitate the delineation and protection of intellectual property, the regulation of product safety and efficacy, the maintenance of programs to ensure access to necessary medicines, and the monitoring of prices to ensure they are not excessive—to name just a few forms of government intervention [3]. But, in many countries, the pharmaceutical sector is a substantial contributor to the local economy and manufacturers often argue that policy interventions interfere with a free market, reduce firms’ ability to recover R&D investment and, therefore, threaten local pharmaceutical activity. Indeed, policy-makers around the world struggle to balance health policy objectives (access to affordable and essential medicines) with industrial policy objectives (promoting innovation and local R&D activity) in the pharmaceutical sector. Tensions arise over pricing and reimbursement in particular. Limited health care budgets and competing demands for scarce resources force governments to set limits on which medicines to cover, for whom, and at what price [4]. However, what health plans view as necessary to maintain equitable access to medicines, industry views as inimical to R&D and innovation.

Australia has grappled with the health–industry balance in pharmaceutical policy for many years, even incorporating the goal of “maintaining a responsible and viable medicines industry” as one of four primary themes of its National Medicines Policy (NMP). In this paper, we review Australia’s approach to health and industry objectives as a case study in pharmaceutical policy. We present findings of this case study in three parts. First, we summarize Australia’s efforts to meet health-related goals of pharmaceutical policy – providing affordable access to necessary medicines – through the pricing and reimbursement policies of the Pharmaceutical Benefits Scheme (PBS). Second, we review Australia’s efforts to meet industry-related goals – fostering domestic investment by pharmaceutical companies – through policies and programs managed by the Department of Industry, Tourism and Resources. Third, we review both the pharmaceutical industry’s criticisms of the Australian PBS and evidence from national policy audits to explore the impact of health policy on local economic development.

The findings of this case study may provide important lessons for other countries, particularly because
the health/industry struggle is not unique to Australia [5]. Most importantly, it appears that policies designed to promote public health objectives have not adversely harmed the pharmaceutical industry in Australia. Because the PBS promotes what is often referred to as value-based pricing [6], Australia has managed to secure relatively low prices for “me-too drugs” while paying internationally competitive prices for “breakthrough” medicines. Simultaneously, Australia has encouraged local pharmaceutical investment through a variety of general and industry-specific incentive programs. Whether this apparent balance will last – particularly in light of reforms that may strengthen industry authority in pharmaceutical policy, such as the Australia–US Free Trade Agreement, which came into effect on 1 January 2005 – is an empirical question: time will tell. At present, Australia’s pursuit of seemingly conflicting policy objectives offers key lessons for other countries seeking to pursue industrial development while simultaneously providing equitable and affordable access to medicines.

2. Methods

Our objective was to explore Australia’s pursuit of both health and industrial policy objectives in the pharmaceutical sector. To do so, we developed a case study using an extensive search strategy and relatively inclusive criteria for inclusion in a narrative review of the literature. We searched electronic databases [EconLit (Ebsco), MEDLINE and EMBASE (Ovid)] for publications published during the period of 1985–2007. Grey literature (letters, editorials, news and opinion pieces, reports) and government publications found on Australian government websites published during the same period were also searched via the Internet. Searches combined subject headings and keywords for “Australia/Australian and pharmaceutical(s)/medicine(s)” with “government regulation(s) or health policy/policies or industrial policy/policies”. Other search terms and their affiliated truncations, used singularly and in conjunction, included words like “innovation,” “R&D,” “expenditures,” “Pharmaceutical Benefits Scheme,” “National Medicines Policy,” and “industry.” Notwithstanding government publications that described the NMP, PBS or economic development policies in Australia, our inclusion criteria for this review was that studies/reports either: (1) evaluated the interplay between health and industrial policy objectives in the pharmaceutical sector; or (2) contained qualitative or quantitative data of the balance (or trade-off) between health and industrial policy objectives. Results were screened to remove disease-specific studies, such as cost-effectiveness analyses of particular therapies and drug utilisation studies, and those that were not focused specifically on Australia’s pharmaceutical sector (e.g., articles that focused specifically on the biotechnology industry were excluded). Citation tracing from relevant articles and authors’ personal files provided additional relevant articles. Remaining articles centred on industrial, economic, health and/or pharmaceutical policy. The literature search was carried out by two independent researchers (MM and DG). The primary authors (SM and MM) read all included articles and structured the narrative based on the data, content, and conflicting stakeholder perspectives found in the literature.

3. Results

3.1. Australia’s National Medicines Policy (NMP)

Policy tensions arise from the disparate objectives of different government portfolios. In Australian pharmaceutical policy, particular tensions arise between the goals of the Department of Health – which promotes a public health agenda (access to affordable medicines) – and the Department of Industry, Tourism and Resources—which promotes an economic development agenda (promoting and attracting local R&D activity). Lofgren and de Boer note that “for at least the past 15 years, Australian pharmaceutical policy and regulation has been framed by a divide between the Departments of Health and of Industry” [7]. In recognition of the importance of, but potential conflict between, health and industrial policy goals, Australian pharmaceutical policy since the late 1990s has been framed by the NMP as a “framework based on partnerships” with “elements of social and economic policy” to guide and unify pharmaceutical policy development [8].

The overall aim of the NMP is to meet Australian’s health needs while maximizing health outcomes and economic objectives [8]. The NMP contains four cen-
tral pillars: (1) timely access to the medicines that Australians need at a cost individuals and the community can afford; (2) medicines meeting appropriate quality, safety and efficacy standards; (3) quality use of medicines; (4) maintenance of a responsible and viable medicines industry. An oversight committee called the Australian Pharmaceutical Advisory Council – which is comprised of representatives of key health professions, the pharmaceutical industry, and members of government – meets twice yearly to discuss important issues and needs in relation to the NMP and to advise the Minister on priority issues [9]. The explicit linkage of health and industrial policy objectives in the NMP means that, regardless of the inherent tensions, pharmaceutical policy in Australia is supposed to be developed with consideration of both. Lofgren and de Boer reflect that the formal recognition of a viable industry as a central policy aim signals the increasing importance and influence of industry in Australia’s pharmaceutical policies [7]. This provokes the question of whether the NMP successfully unifies health and industry objectives, or whether it instead represents a collision of inherently conflicting goals.

3.2. Health-related policy goals: timely and affordable access to medicines

Australians’ access to health care is supported through a universal, tax-financed health insurance system, Medicare, that provides subsidized access to private physicians’ services and hospitals and free access to state run public hospitals. The PBS is the primary policy instrument for achieving the NMP goal of “timely access to the medicines that Australians need, at a cost individuals and the community can afford.” Formally established in 1950 and enshrined in the 1953 National Health Act, the PBS aims to provide universal access to essential and lifesaving medicines. Since its inception, the PBS has evolved from a subsidy for 139 medicines to a program providing coverage for over 2800 products representing 80% of all dispensed medicines in Australia [10]. In 2005/2006, the total government cost of the PBS exceeded AUD$6 billion [10], which was 300% more than a decade earlier and comprised approximately 16.5% of Australia’s total federal health budget [11]. Similar to experiences elsewhere, pharmaceuticals are the fastest growing cost component of Australia’s health care sector and expenditure growth has outpaced growth in the overall economy [12]. In the decade to 2004/2005, total health care expenditures grew at a real average annual rate of 5.1%, while real growth of pharmaceutical expenditures averaged 8.9% over the same period [12]. Since 1997/1998, however, real growth of pharmaceutical expenditures has averaged 11.6%, up from 8.5% for the period from 1994/1995 to 1997/1998 [12]. Growth of Government spending on pharmaceuticals (11.0% in the decade to 2004/2005) has also outpaced growth of total health expenditures (5.6%) [12]. Consistent with experiences elsewhere, Australian pharmaceutical cost growth is attributed, in part, to the use of newer and more expensive medicines over time [13].

The PBS Schedule (i.e., Australia’s national formulary) lists all subsidized medicines available in Australia, along with information about co-payments and prices accepted by government. The government pays the difference (if any) between a patient’s co-payment and the accepted PBS price. As of 2007, co-payments are AUD$4.90 for concession card holders (the financially disadvantaged, veterans, and beneficiaries of the Department of Family and Community Services), and AUD$30.70 for general beneficiaries (all others). Annual out-of-pocket expenditures are limited to AUD$274.40 per family for concession card holders (after which the remainder of their medicines that year are 100% subsidized by the Australian government) and AUD$1059 per family for general beneficiaries (after which they face the concessional co-payment of AUD$4.90 for the remainder of the year) [14].

In general, pharmaceutical products are listed on the Schedule if they are deemed safe and of high quality, and both clinically and cost-effective in comparison to relevant alternatives. The PBS has long pursued value-based formulary management by requiring that drugs of comparable clinical effectiveness be priced at comparable levels. Since 1993, Australia has formalized this by requiring any manufacturer wishing to have its medicine listed on the Schedule to submit evidence of the product’s cost-effectiveness relative to the most commonly prescribed comparator [15]. Australia was one of the first, but is certainly not the only, jurisdiction to require such health economic evidence for its formulary listing process [16,17]. The cost-effectiveness requirement aims to ensure value for money in government pharmaceutical expenditures and affordability of
medicines for the Australian community. It also enables the government to reward innovative, new medicines by allowing higher prices to be paid for medicines that deliver better health outcomes relative to comparators [15].

Responsibility for reviewing data regarding the clinical- and cost-effectiveness of medicines that manufacturers seek to have listed on the Schedule falls with the Pharmaceutical Benefits Advisory Committee (PBAC). Established under the National Health Act 1953 as a statutory independent advisory body to the PBS, the PBAC is comprised of health professionals (general practitioners, specialists and practicing pharmacists), other experts (e.g., pharmacologists and health economists), and consumers. Other members may be added if deemed by the Minister as having qualifications or experience that enables them to contribute meaningfully to PBAC deliberations. Under this clause, a pharmaceutical industry representative was appointed to the PBAC in 2001. The PBAC meets three times per year and the review process is on a fixed, 17-week cycle. Following a review, the PBAC advises the Minister on whether a medicine should be listed on the Schedule and under what conditions. The Minister cannot list a medicine without a positive PBAC recommendation; evidence suggests it is rare for the Minister to reject positive recommendations [18].

When the PBAC recommends listing a product at the price proposed by the manufacturer, price negotiations are not required. In other cases where the PBAC issues a positive listing recommendation, a price must be negotiated before the medicine is listed on the Schedule. Price recommendations fall under the responsibility of the Pharmaceutical Benefits Pricing Authority (PBPA), which is a non-statutory body established in 1988 to secure a stable and affordable supply of pharmaceuticals in a way that is “consistent with maintaining a sustainable, viable and responsible pharmaceutical industry in Australia” [19]. When negotiating a listing price with the manufacturer, the PBPA may consider a range of factors such as domestic and international price comparisons and activity being undertaken by the supplying company in Australia, including new investment, production, and R&D [19]. In effect, this latter consideration – item f in the alphabetical list of PBPA considerations – rewards domestic industrial activity with PBS prices above that which would be determined on the basis of international comparisons or strict cost-effectiveness in the domestic setting (more on this below). Upon successful price negotiation, both the listing and price recommendations are forwarded to the Minister for final decision.

If the PBAC issues a negative listing recommendation based on cost-effectiveness criteria, the manufacturer may re-submit an amended application at a subsequent committee meeting with a lower price, better safety and efficacy data, or a more narrowly targeted treatment indication. Under the new provisions of the Australia–US Free Trade Agreement (AUSFTA), which were sought by the pharmaceutical industry, manufacturers may now alternatively seek an independent review of a negative PBAC determination [20]. The independent review is not designed to serve as a forum for manufacturers to challenge PBAC decisions: no new information or evidence beyond that which was previously considered by the PBAC may be considered in the review and the PBAC remains the “gatekeeper” to the PBS. Only one request for independent review has been made to date and the PBAC reaffirmed its original recommendation to reject the medicine for listing on the Schedule [21]. Australia’s Health Minister, Tony Abbott, believes that, “throughout the negotiation of [Australia–US Free Trade Agreement] the Australian Government protected the fundamental architecture of the [PBS] and the integrity of the [PBAC] as the pre-eminent advisory body to government on the listing of medicines on the PBS” [22]. There is a body of critics, however, that strongly disagrees with Abbott’s view, arguing that the AUSFTA threatens the price of medicines in Australia and undermines the value-based approach to pricing and reimbursement undertaken by the PBS [23–25]. Because AUSFTA was only recently implemented, there is no evidence to conclude either way. Empirical data are needed to address critical issues such as these; in time, the full impact of AUSFTA on the PBS will be revealed.

While a national formulary in and of itself is a powerful bargaining tool insofar as it consolidates bargaining clout within one central body, the PBS also employs numerous pricing, reimbursement and cost-sharing policies to obtain value for money in government spending. Policies employed by the PBS include (but are not limited to) generic substitution, therapeutic reference based pricing, and price–volume agreements [26].
3.3. Industry-related policy goals: responsible and viable pharmaceuticals industry

The pharmaceutical industry features prominently in most government’s industrial development frameworks because in addition to developing medicines which may improve health, pharmaceutical sector activity can be a significant contributor to both global and local economies. Consistently ranked as one of the most profitable industries in the world, the most recent Fortune 500 survey identified the pharmaceutical industry as the second most profitable with a return on revenue of 19.6% [27]. The pharmaceutical sector is also one of the most research-intensive industries and, according to the OECD, countries that invest in R&D activities are more likely to secure a strong economic future [28].

Accounting for slightly over 1% of global sales, the pharmaceutical industry in Australia is relatively small when placed in a global context [29]. It has, however, experienced rapid and steady growth with expenditures under the PBS expanding at an average annual rate of 12.4% from fiscal year 1993/1994 to 2003/2004. Indeed, the pharmaceutical industry is a significant contributor to the Australian economy with a high R&D and knowledge intensity, a skilled workforce and high wages. In 2004/2005, approximately 34,000 people were employed by the pharmaceutical industry and, next to automobiles, pharmaceuticals are Australia’s second largest manufactured export [30].

The Department of Industry, Tourism and Resources (DITR) holds primary responsibility for the fourth arm of Australia’s NMP: the maintenance of a responsible and viable medicines industry. Industry-related objectives are achieved through a combination of general economic development strategies and sector-specific incentives.

3.3.1. Generic economic development policies

As in most other industrialized countries, Australia has implemented a range of generic programs and policies to promote, attract, and support domestic investment in R&D. Key components of the industry development agenda include direct government support for basic science, research infrastructure, and higher education through a combination of grants, tax concessions, venture capital, and import/export programs [30]. Generic R&D incentive programs are also offered, including the R&D Tax Concession and the Commercial Ready Programs. The former is an entitlement-based program that provides a 125% tax concession for eligible R&D activity. This indirect tax support comprises roughly 60% (or AUD$600 million) of the government’s total business R&D support [31]. The Commercial Ready Program is a competitive merit-based grant program designed to support innovation and its commercialisation in small and medium-sized enterprises. Launched in 2004 as part of the “Backing Australia’s Ability—Building our Future through Science and Innovation,” AUD$5.3 billion is available over 5 years in the form of competitive grants for R&D and early stage commercialisation activities [31].

3.3.2. Pharmaceutical sector-specific economic development policies

The DITR also offers a number of sector-specific programs to support and encourage local R&D investment in the pharmaceutical industry. The overall objective of the DITR with regards to the pharmaceutical industry is to “improve the long-term sustainability and international competitiveness of the Australian pharmaceuticals industry, stimulate investment in the industry, and develop Australia as a regional centre for R&D, manufacturing and export” [30]. Pharmaceutical sector-specific economic development programs include the Factor f scheme, the Pharmaceutical Industry Investment Program (PIIP), and the Pharmaceutical Industry Action Agenda.

3.3.2.1. Factor f scheme. The Factor f scheme (1988–1999) was a key component of the Pharmaceutical Industry Development Program adopted by the government in 1987 and represents Australia’s first major initiative to encourage the growth of the pharmaceutical industry in the country. Factor f – so called because industry activity was sixth in the list of pricing factors (item f, alphabetically) considered by the PBPA under the PBS – would allow firms undertaking new R&D or value-added production to receive premium prices under the PBS. Premiums were to be valued at a maximum of 25% of the additional research or production activity. Factor f was the mechanism used to support the objective of maintaining a viable pharmaceuticals industry [33]. While Factor f was viewed by some as a PBS price correction scheme rather than an
industry development program [33], others have credited the AUD$958 million paid to companies under the scheme as potentially important in “...turning around the substantial disinvestment in the pharmaceutical industry that occurred in the 1980s” [34].

3.3.2.2. **The pharmaceuticals industry investment program (PIIP).** The successor to the Factor f scheme, the PIIP (1999–2004), was designed to stimulate new, additional investment in pharmaceutical production and R&D activity in Australia. Like Factor f, the PIIP aimed to compensate manufacturers with products listed on the PBS for what the industry viewed as “price suppression”. Specifically, the PIIP was “intended to induce domestic activity lost as a result of such price suppression”: in exchange for higher prices for medicines listed on the PBS, firms were required to undertake additional manufacturing and R&D activity in Australia [35]. The program was administered by the PBPA. The AUD$300 million in available PIIP funding over 5 years was less than that which was available through the Factor f scheme.

3.3.2.3. **Pharmaceuticals Industry Action Agenda.** The Australian Government launched the Action Agenda in 2001 as an integrated policy framework for 16 specific programs and initiatives designed to increase Australia’s position and sustainability in the global pharmaceuticals industry and to facilitate collaboration between the pharmaceutical industry and government in working towards a common goal of “promoting sustainable economic development of Australian firms” [34]. The overall objective is to double Australia’s share of the global pharmaceutical manufacturing, research and development activities by 2012 through collaborative efforts between industry, government and research [36]. A key item on the Action Agenda was the introduction of the Pharmaceuticals Partnership Program (P3), which is the successor to the PIIP and will operate until June 2009. A 5-year AUD$150 million program, the P3 is a competitive entry program that requires applicants to meet a set of eligibility criteria and then compete for available funds against a set of merit criteria. In contrast to both the PIIP and the Factor f scheme, nowhere in the stated objectives of the P3 is there mention of compensating firms for price suppression faced under the PBS, and eligibility is not affected by whether or not a company has a product listed on the PBS. Successful applications receive AUD$0.50 for each additional dollar spent on eligible R&D in Australia, up to a maximum of AUD$10 million over the 5-year life of the program. Overall, the program is expected to support an additional AUD$500 million of investment in new pharmaceuticals R&D in the country [32].

3.4. **Industry criticisms and evidence of policy impacts**

Australia is regarded as a leader in efforts to sustain health policy objectives in the pharmaceutical sector. Duckett has noted that “Australia’s arrangements for the supply of pharmaceuticals are the envy of many other developed countries... in terms of equity, the structure of the PBS minimizes the financial barriers to access to pharmaceuticals” [37]. Despite (or perhaps because of) this, the pharmaceutical industry has persistently claimed that the PBS stifles incentive for innovation and local investment activity, and threatens global pharmaceutical prices. According to the Productivity Commission, pharmaceutical companies perceive that they receive low prices under the PBS resulting from the government exercising its monopoly purchasing power and claim that this acts as a deterrent to R&D activity in Australia [35]. Companies also claim that the PBS makes Australia a hostile environment for new investment in pharmaceutical production or R&D [35]. Moreover, although Australian tax subsidies for R&D activities are among the most attractive among OECD countries [38], multinational entities are only eligible for concessions if the intellectual property is Australian-owned. This restriction makes it difficult for foreign-owned multinationals to access the concession; the pharmaceutical industry has therefore argued that the concession should be provided regardless of where intellectual property is located [36].

It would appear that both health and industrial policies are criticized by the pharmaceutical industry in Australia. If it is true that Australia’s policies limit incentive for innovation and local R&D activity, it would be reasonable to expect that evidence would support criticisms of price suppression, price suppression would result in lower domestic activity than would otherwise occur, and the country would rank poorly relative to others on locational indicators.
3.4.1. Pharmaceutical prices in Australia

In 2001, the Productivity Commission compared Australian prices for the 150 top-selling pharmaceuticals (accounting for 80% of PBS expenditures) with prices in the US, Sweden, France, New Zealand, Spain, Canada, and the UK [39]. Comparisons of prices in Australia versus each comparator country were made for (1) new innovative drugs, (2) new “me-too” drugs, and (3) generics (specifically, brand and generic copies of off-patent drugs). While international price comparisons are notoriously difficult and subject to uncertainty given that they do not account for unmeasured price discounting in many countries (especially the US), the primary findings of the analysis were that:

- the prices of new innovative drugs in Australia are broadly similar to those in the comparator countries, with the exception of the US and to a lesser extent the UK;
- the prices of ‘me-too’ drugs in Australia are the lowest among the comparison countries, except for New Zealand;
- the prices of generic drugs in Australia are among the lowest of the comparator countries, except for New Zealand and Spain.

Table 1 illustrates the Productivity Commission’s estimates of the ratio of Australian prices to foreign prices in 2000.

A 2007 study also found that Australia’s prices for innovative drugs were on par with those in the US.

Roughead et al. compared government drug prices in Australia and the US for new drugs that had been deemed to be ‘breakthroughs’ or ‘potentially innovative’ by either Canadian or US drug regulators, respectively [40]. They found that the Australian government prices were higher than US government prices for 64% (n = 14) of the 22 ‘breakthrough’ products sold in both the US and Australia. When the prices of all 22 ‘breakthrough’ products were taken into consideration it was found that Australian prices were higher, on average, by 4.2% [40].

The fact that Australia has secured relatively low prices for generics and ‘me-too’ drugs while paying internationally competitive prices for innovative medicines may simply reflect “value-based pricing,” where government spending is focused on products that generate substantial health benefit over existing alternatives. Rather than stifling innovation in the pharmaceutical sector (as claimed by the pharmaceutical industry), such pricing may be a means of fostering innovation of great value to society by concentrating rewards on therapies that address unmet health needs [6].

3.4.2. Profits to firms

While evidence indicates that the PBS has been an effective bargaining tool for securing lower drug prices for the Australian community (or rather, for securing prices that reflect the added therapeutic benefit of the product), the impact on profits is not as direct as might

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<td>Ratio of Australian price to foreign price, 2000 (weighted results$^a$)</td>
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$^a$ The estimates are based on the lowest and highest list price of manufacturers supplying the matched molecules. The results use an Australian basket of the most popular molecules and are weighted by Australian sales volumes. As the bilateral comparisons are based on Australian consumption patterns and different bundles of pharmaceuticals for each country, the results do not provide a good guide to relative price levels across other countries. The Australian to US price ratio may be higher than reported here because of the practice of discounting, which is thought to be more widespread in the US than in Australia.

$^b$ Includes both generic (copies) and originator brands that are off-patent.
be concluded. The Productivity Commission notes that “for price suppression to have any adverse effects on the local pharmaceutical industry, it must also reduce profits below what they would have been otherwise” [35]. If “otherwise” is interpreted as a world without PBS benefits, the net change in profits to firm may be minimal. While firms may indeed agree to price reductions for some products, they accept these prices in exchange for coverage under a universal public benefit program. As such, significant volume gains accrue to firms that secure listing status on the PBS Schedule [10]. Whether in Australia or elsewhere, price reductions are often agreed upon by the manufacturer in exchange for greater sales volume under a drug plan [5]. In fact, the Productivity Commission argues that “if marginal costs are sufficiently low and gross revenues increase, then profits may increase for those firms whose products are listed” [35].

Total pharmaceutical sales revenues have certainly increased under Australian policies, despite the Australian approach to pricing. Indicative of the possibility that industrial policy objectives have a consideration of, if not influence on PBS policy-makers, data from the Australia Institute for Health and Welfare suggest that total expenditures on medicines (government plus non-government expenditures) in Australia grew at a faster average annual rate from 1997/1998 to 2002/2003 than they did from 1994/1995 to 1997/1998: 11.6% versus 8.5%, respectively [12]. Though causality cannot be established, it is noteworthy that this increase corresponds to the introduction of the NMP in 1999.

3.4.3. A hostile investment environment?

In addition to price and profit suppression, one of the main criticisms of the PBS is that it makes Australia a “hostile location for new investment in pharmaceutical production or R&D” and consequently reduces local pharmaceutical activity [35]. In Australia and elsewhere, pharmaceutical executives report that pricing and reimbursement policies play a critical role in investment decisions. Empirical research suggests otherwise, however. Empirical analyses led the Australian Productivity Commission to conclude that evidence of a connection between pricing and industrial activity was not strong [35]. While the views and perceptions of industry executives may correlate with investment decisions in some cases, the Commission concluded that “in general it is likely that the fundamental qualities of the micro and macroeconomic environment – such as input costs, skilled labour availability, quality, access to regional markets and innovative capabilities – are more important determinants of location choices” [35]. Evidence from other studies substantiates this statement.

A 2005 benchmarking study commissioned by the DITR to examine the overall attractiveness of Australia with respect to pharmaceutical investment decisions relative to the six comparator countries (Germany, India, Japan, Singapore, the UK and the US) using close to 200 individual indicators ranked Australia as second overall, behind only Singapore, for the overall attractiveness of the investment environment [29]. Australia also ranked very highly on incentives and government support schemes available to pharmaceutical firms, on the size of the educated and skilled workforce, and on intellectual property rights legislation [29]. These findings suggest that despite industry criticism of the PBS, Australia ranks favourably relative to comparator countries for indicators known to impact locational investment decisions.

4. Discussion

Australia’s experiences with its health and industrial policy objectives demonstrate the inherent difficulties in balancing the two, but also provide important evidence on the possibility of achieving such a balance. Most importantly, it appears that policies designed to promote public health objectives have not adversely harmed the pharmaceutical industry in Australia. Evidence suggests that, through the pricing and reimbursement policies of the PBS, Australia pays internationally competitive prices for ‘breakthrough’ drugs, thereby rewarding innovation, while securing relatively low prices for ‘me-too’ drugs offering little added health value relative to existing medicines. While prices arrived upon for PBS listing may generate negative perceptions among pharmaceutical firms, findings from comprehensive studies suggest that firms generally make investment decisions based on broader business fundamentals [35]. Accordingly, upon initial glance the NMP appears to be a viable tool for unifying health and industrial policy objectives. However, the use of health policy levers to attract industry, and flowing subsidies designed to encourage local R&D activity to industry through the pricing and reimbursement sys-
tem, appears to have increased industry influence in the health policy arena and created upward pressure on drug expenditures.

Nevertheless, until recently it could be argued that Australia had found an enviable balance between health and industry policy. There have, however, been a number of changes in recent years that appear to put industry considerations in a more privileged position in the policy process. In 2001, a former drug industry executive was appointed to the PBAC; this act was criticized for catering to industry considerations in an ostensibly health-specific process [41]. In January 2005, Australia entered into the Australia–United States Free Trade Agreement; some experts believe that provisions of the agreement may further increase industry influence over PBS processes [25], though it is still too early to tell. In May 2005, the Australian government announced plans for the PBAC to become funded through cost recovery charges; this too has been criticized for creating potential conflicts of interest [42] though again, only with time will the full implications be realized. In November 2006, reforms to the PBS were announced that, according to some, signal the demise of Australia’s reference pricing system [43] (postscript for further details). Of great concern is that amidst these developments, the Australian Pharmaceutical Advisory Council – which oversees the NMP and advises the Australian Government on a broad range of medicines issues, including the interdependence of the four NMP pillars – has not met in over a year (where until May 2006 they met twice yearly). This raises the question of who is monitoring the balance between the four NMP pillars.

The lines between health and industrial policy objectives in Australia are becoming increasingly blurred and recent developments carry with them the potential to shift the balance between the two policy objectives (postscript for further details). Indeed, it appears already that industry is gaining increasing prominence in Australian health policy. While earlier industry-supporting policies were developed in recognition of some of the tensions created by health-related pharmaceutical policies, they remained independent of the health policy processes. The recent changes appear, in contrast, to place industry influence directly within the structures and processes of health-related decision-making. Such may be the factor that tips the scales in favour of industry over health policy.

4.1. Postscript

The Australian case study does not end here. In addition to the gradual changes noted above that appear to have put industry-related goals in a more privileged position, a number of policy developments that have recently occurred raise concerns that pricing and reimbursement policies under the PBS will no longer represent therapeutic value-for-money and therefore potentially undermine the health-related goals in Australia’s health–industry balancing act. While we are unable to provide a full analysis of these very recent policy changes (because they are only just occurring at the time of writing this manuscript), we offer a brief, initial overview here.

The Australian government is amidst PBS reforms designed to achieve two broad, potentially conflicting goals: (1) to generate approximately AUD$3 billion in savings to the PBS over 10 years [44]; (2) to improve recognition of “the importance of innovative patented drugs” [45,46]. In order to achieve the former without detracting from the latter by way of potential price suppression, the savings objectives of the current PBS reforms will be met through reduced prices of generic drugs paid by government and by transferring to government some of the manufacturer discounts that have historically flowed to pharmacists. Recognition of innovation is to be achieved by decreasing brand premiums faced by patients who need innovative drugs while increasing the number of ‘innovative’ medicines on the PBS. According to the Minister, the reforms are designed to “ensure that taxpayers get better value for their PBS spending” [45].

The first major pricing reform was implemented in August 2005 and entailed a mandatory 12.5% price reduction for the first new brand of a medicine already listed on the PBS Schedule. Because of the reference price system that was in effect, the generic price reduction would effectively lower the price offered under the PBS for all brands in the same reference pricing group [19]. A health–industry tension was therefore created even through the intent of the policy was to lower prices of generic medicines.

While the absolute price of generic drugs has been found to be lower in Australia than other OECD countries [39], Australian generic prices are relatively high when compared in terms of discounts vis-à-vis pioneering brands [45,46]. Furthermore, non-generic
brands achieve relatively high market share following patent expiry in Australia [15]. These problems may stem from both the lack of incentive faced by generic manufacturers to compete on price once the PBS sets a benchmark price for a given therapeutic class. Under a reference pricing system, manufacturers may have incentive to match the posted benchmark price and then compete by way of discounting to retailers (pharmacists) rather than to government (the PBS). Indeed, in Australia, Canada [47] and elsewhere with similar generic reference pricing policies, substantial discounts are offered by sellers of multi-source drugs to ensure their brand is the dispensed brand drug of choice. Other manufacturers may choose to post a price higher than the benchmark, leaving patients to pay a premium for their brand. Under the reform of 2005, benchmark prices for generic medicines effectively fell by 12.5%, lowering profits to manufacturers that reduced their prices and increasing patient charges when manufacturers chose not to compete on price.

With neither patients, pharmacists, nor manufacturers happy with the 2005 policy, the Government announced in November 2006 further changes to the PBS that would, as of 1 August 2007, effectively de-link prices of single brand versus multiple brand products through the creation of two distinct formularies. Under the old policy the patent status of a medicine did not affect the price paid for listing on the PBS (i.e., the prices of patented medicines were linked to those of generics through the reference pricing scheme). Under the new (and extraordinarily complicated) policy, the two formularies will be divided such that price reductions on off-patent medicines do not affect the reference price allowed for patented medicines. While the stated objective of the reform is "to give Australians continued access to new and expensive medicines while ensuring the PBS remains affordable into the future" [47], the reform represents a significant change of fundamental principles for the Australian system insofar as it undermines the PBS’ guiding principle of “purchasing outcomes” (i.e., value-based pricing or achieving the desired outcome at the best possible price regardless of the patent status).

Given the PBS reforms were so recently announced, peer-reviewed articles and research reports have yet to appear in the published literature. However, the media (i.e., newspapers and other print media) was quite critical of the reforms following their announcement. Articles appearing in Australian newspapers criticize the government for what appears to represent succumbing to industry pressure, and for implementing a system under which Australia will be forced to pay high prices for medicines that offer little to no added value in terms of health outcomes (i.e., the abolition of the historic “value-based pricing” system). One Australian newspaper quotes Professor David Henry as cautioning that separating medicines into two categories risks directing the efforts of drug companies to demonstrating the non-substitutability of their products rather than towards introducing new medicines [49]. Critics have also accused the government for caving to the “powerful pharmacy lobby by agreeing to pay compensation of AUD$1.1 billion to pharmacists for giving up the ‘discounts’ they get by purchasing medicines for less than the Government allowance and keeping the change” [49].

From the government perspective, the PBS reforms are regarded as timely in light of the significant number of drugs that will come off-patent over the next 10 years (estimated at about 100), and important to ensuring the affordability of the PBS by allowing government to pay less for certain medicines (i.e., generics) without increasing the cost to patients [48]. The government expects the reforms to generate savings of more than AUD$3 billion over the next 10 years [44]. Ultimately, it is hoped that the PBS reforms will enable an increase in the number of new medicines listed on the Schedule [48]. However, in the creation of two distinct formularies, these new reforms will significantly alter the paradigm of purchasing health outcomes that has historically guided drug purchasing policy in Australia. It is therefore hypothesized that the reforms will further shake what balance has been achieved between health and industry objectives, with the scales tilting in favour of industry-related policy goals.

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1 With the new policy, the government has created two separate formularies – Formulary 1 (F1) and Formulary 2 (F2) – based on whether a drug is a single- or multi-sourced product. F1 will contain all patented medicines for which there is a single brand, except for those single brand medicines that are interchangeable at the patient level with a multiple brand medicine [48]. Reference pricing can occur between drugs that are linked with reference pricing groups on F1. The second formulary – F2 – will comprise multiple and single brand medicines that are interchangeable with multiple brand medicines at the patient level. Reference pricing will occur across different brands of the same medicine listed on F2 [48].
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