Pharmaceuticals in Australia: developments in regulation and governance

Hans Lofgren\textsuperscript{a,}\* , Rebecca de Boer\textsuperscript{b}

\textsuperscript{a}School of Social and International Studies, Deakin University, Geelong VIC 3217, Australia
\textsuperscript{b}43/201 Goyder St, Narrabundah ACT 2604, Australia

Abstract

The pharmaceutical domain represents a type of internationalised policy network theorised in recent writings on neoliberalism, neo-corporatism and governance. This article presents an analysis of developments in prescription drug regulation in Australia. A relatively stable, state-managed pattern of interaction has been superseded by less closed exchange, and the government itself has fragmented into agencies pursuing different objectives. Developments in the three core regulatory areas are described: safety and efficacy controls, social policy (access and equity), and state support for industry (economic) development. Consensus-building occurs within the context of the National Medicines Policy. The pharmaceutical industry, represented by Medicines Australia, has a stake in all aspects of pharmaceutical policy and regulation, and draws upon unique resources (expertise and lobbying capacity). The context for the developments described is Australia's abandonment of a protectionist version of the Keynesian welfare national state in favour of the model of the competition state, which is oriented towards support for the growth of high technology industries such as pharmaceuticals, premised on partnerships with business.

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Introduction

Pharmaceutical policy in OECD countries encompasses the interplay of regulation for the purposes of product safety and efficacy, health and social policy (access and equity), and support for industry (economic) development (Jacobzone, 2000). In Australia, our contention is that the trend is for product safety and efficacy controls, and social policy, to be increasingly influenced and shaped by economic objectives and the imperative of industry competitiveness. This is consistent with broader shifts in the role of government in the past 20 years; the predominant perspective in Australia today is that 'first preference [should be given] to the private sector, and outsourcing or privatizing ... are tablets of faith' (Halligan, 2002, p. 59). The aim in this paper is to provide a descriptively detailed and theoretically cogent interpretation of recent developments in the Australian pharmaceutical sector.

Methods and sources

Seventeen semi-structured interviews, each lasting between 1 and 1\frac{1}{2} h, were undertaken between July and September 2001 with individuals selected because of their central participation in the regulatory system, and/or role as a representative of an industry or other stakeholder group. To facilitate discussion interviews were not taped, but an interview report was written immediately following each interview. In a number of cases, interviews were followed up by later requests for clarification or supplementary information. Interviewees were based within the Department of Health and Ageing, the Therapeutic Goods Administration, the...
The context for our analysis is Australia’s abandonment, since the 1980s of a protectionist version of the Keynesian welfare state, in favour of the neo-liberal model of free-trade oriented shareholder capitalism (Frankel, 2001; Jessop, 2002a). Labour governments in Canberra between 1983 and 1996 promoted a re-orientation of business towards international markets, and presided over the privatisation of government business enterprises and the deregulation of the financial system. Under these governments, the public sector was transformed through cutbacks and out-sourcing, and the general embracing of the market paradigm. Since 1996, the conservative coalition of the Liberal and National parties has continued broadly similar economic policies, viewing the public sector ‘as an adjunct to the private sector’ (Halligan, 2002, p. 47). The focus of government interaction with business is on the provision of favourable regulatory conditions, and social policy is increasingly subordinated to economic policy considerations (see essays on the governance of Australia’s economy in Bell, 2002). By contrast, in the postwar ‘mixed’ economy, the welfare state was conceived as a means of compensating for some of the negative effects of the market economy. When regulation of the pharmaceutical sector was extended in Australia in the 1950s and 1960s to enhance product safety and equitable access to appropriate drugs, this was understood by policy makers and industry alike as the imposition of constraints on business (Industries Assistance Commission, 1986; Johnston, 1986; Sloan, 1995).

Conceptualising pharmaceutical sector governance

The term governance is employed in a recent public policy literature to designate coordination and social order achieved by way of horizontal and internationalised networks, with state agencies operating as coordinators and catalysts (Coleman & Perl, 1999; Pierre, 2000). Governance can be understood, following Jessop, as an interactive process of ‘self-organised steering of multiple agencies, institutions, and systems which are operationally autonomous from one another yet structurally coupled due to their mutual interdependence’ (Jessop, 1998, p. 29). Ideally, governance would signify a genuinely pluralist configuration of dialogue and shared objectives. However, the reconciling of public and private interests may or may not be achieved, and the precise attributes of relations between public and private actors within any particular sector must be examined empirically, as is the purpose of this paper. The notion of ‘partnership’, used frequently to describe public–private interaction, including health and pharmaceutical policy at national and global levels, implies shared, or at least overlapping, objectives, but is also often employed as a rhetorical device (Buse & Walt, 2000a, b).

Goverance, in Jessop’s sense, is particularly conspicuous in high-technology industry sectors such as pharmaceuticals where joint ventures, alliances, licensing and marketing agreements, research and development (R&D) networks, and similar phenomena, have proliferated (Cooke, 2002). In the regulatory domain, a plethora of consultative arrangements allow for the exchange of technical and political resources between firms and state agencies. Webs of interdependence should not be confused with de-regulation: scientific and technological developments, including the emergence of biotechnology, and the globalisation of innovation, production and markets, have spurred evermore complex regulation and new forms of state
activity, but the capacity of government agencies to impose regulatory controls autonomously has diminished (Achilladelis & Antonakis, 2001).

How should pharmaceutical sector governance be conceptualised? This is not a central question in the literature on the pharmaceutical industry, which is generated mostly by economists and/or expert ‘insiders’ associated with particular vested interest (exceptions include Braithwaite & Drahos, 2000; Davis, 1992, 1997; Hancher, 1990; Lexchin, 1990; Vogel, 1998; Wiktór-owicz, 2000). Abraham and Lewis however have presented an insightful analysis on the basis of a study of safety and efficacy regulation in the European Union and several of its member states (Abraham & Lewis, 1999, 2000, 2002; Abraham & Reed, 2001; Lewis & Abraham, 2001). They demonstrate that regulatory reform, such as reduced processing times driven by competition between national regulatory agencies, has been framed by a neo-liberal agenda, and pose the question: How should the ‘regulatory state’ in the pharmaceutical sector, at EU and national levels, be characterised:


The answer, according to Lewis and Abraham (2001, p. 72), is that ‘there is little evidence of pluralist regulatory politics’ at the national level, and ‘corporate bias remains intact’ in UK, Germany and Sweden. Similarly, at the EU level, the industry has managed to reproduce ... its privileged access to national regulators, while supranational regulatory institutions have offered very limited access and encouragement to other organised interests. Thus, not only are pluralist politics rare, there is little evidence even of tripartite neo-corporatism in which the state encourages empowerment of consumer interests in order to advance regulatory norms of the “public interest”... The consequence is a European regulatory state whose predominant feature is neo-liberal corporate bias, (Lewis & Abraham, 2001, p. 75, emphasis in original)

This characterisation could, in large parts, be applied to Australia’s pharmaceutical sector, as described in subsequent sections. Abraham and Lewis focus however mainly on safety and efficacy regulation. The weighing up of evidence becomes more complex and, perhaps, more subjective, where the analysis, as in this paper, encompasses the full range of government–industry relations—safety and efficacy controls, pricing and reimbursement issues, and economic development policy. This broader perspective brings forth, in Australia, a pattern with somewhat stronger ‘pluralist’ elements than discerned by Abraham and Lewis in their study of the EU. The politics of the Pharmaceutical Benefits Scheme, in particular, is not characterised by ‘social closure’ to the same extent as either safety and efficacy regulation or the economic development programs of the Department of Industry. It must also be recognised that there is an institutional legacy of state predominance in the Australian pharmaceutical sector, which to this day has some bearing on regulation and policy. Traditional arm’s length and authoritative pharmaceutical regulation, administered by the Department of Health, is in contrast to the mainstream Australian approach to business regulation which builds on cooperative and trust-based relations, and avoids litigation and strict law enforcement (Grabosky & Braithwaite, 1986). The difference is explained by the historical weakness of the pharmaceutical industry in Australia—certainly by comparison to the UK, Germany or Sweden, studied by Abraham and Lewis. Manufacturing operations established by international companies in Australia in the 1950s and 1960s were confined largely to formulation and packaging from imported active ingredients, exports were insignificant, and almost no R&D was undertaken. Until the late 1980s, the government was concerned primarily with ensuring access to pharmaceuticals at low prices, with little regard to the interests of suppliers (Johnston, 1986; Parry & Thwaites, 1988). The historical emphasis on health and social policy objectives provided the basis for corporatist ‘strong state’ relations with the industry, and indeed other sectoral interests such as wholesalers and retail pharmacy. The pronounced ‘corporate bias’ of present-day government–business relations is a relatively recent phenomenon resulting from purposeful interventions by (Labor and Coalition) governments since the mid-1980s.

It is important to explore changes in pharmaceutical sector regulation as framed and influenced by neo-liberalism. Yet neo-liberal policy adjustments do not necessarily result in a consistent neo-liberal regime of free markets, managerial prerogatives and minimal government. In fact, a pattern of ‘reliance on partnerships, networks, consultation, negotiation, and other forms of reflexive self-organization’—an apt description of the pharmaceutical domain—is inconsistent with a neo-liberal model of governance (Jessop, 2002b, p. 460). Moreover, elements of either pluralism or corporatism within particular policy networks need to be contextually--ised by more basic economic and social developments:

One should not conflate the global neoliberal turn with the broader set of recent changes in economic, political, and social life. For, although the rise of neoliberal discourse and the pursuit of neoliberal strategies has helped to shape the form and content of these changes, the latter have more general (and
The notion of the 'competition state', which is bringing about an 'expansion of de facto state intervention and regulation in the name of competitiveness and marketisation', provides a way of capturing developments in European and Australian pharmaceutical regulation (Cerny, 1997, p. 251). This concept draws attention to the decline of social protection relative to state intervention in support of internationally competitive production, and highlights that regulation may be extended in some sectors. This type of state takes different forms, depending on 'institutional legacies, the balance of political forces and the changing economic and political conjunctures in which different strategies are pursued'; in the same way that there were different varieties of the Keynesian welfare state (Jessop, 2002a, p. 259). The neoliberal form is only one of its possible variants, and what we find in the pharmaceutical sector is more consistent with neo-corporatism, as indeed demonstrated by Abraham and Lewis. State agencies retain substantial authority and, notwithstanding 'corporate bias', there is ultimately 'not ... industrial self-regulation' (Lewis & Abraham, 2001, p. 73).

State fragmentation and the national medicines policy

Public authority in Australia with respect to prescription drugs is shared among the Therapeutic Goods Administration (TGA) which administers product safety controls, the Pharmaceutical Benefits Branch of the Department of Health and Ageing, with responsibility for access and equity arrangements, and the Pharmaceutical Section of the Department of Industry, Tourism and Resources, which sponsors programs to assist industry development. 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. A relative decline in the authority of the Health Department commenced with the launch in 1987 of the Factor (f) program (see details later in the paper), operated by the Department of Industry, to encourage investments in manufacturing, exports and R&D, which signaled that industry support would from now on be assigned higher priority. Until then, the Department of Health had been able to exercise dominance vis-à-vis the pharmaceutical industry in regard to PBS pricing arrangements and the operations of the TGA (Parry & Thwaites, 1988). The new direction in the late 1980s was triggered by the then Labour government's concern for the future of Australian high-technology manufacturing. The Department of Industry began to apply pressure for more business-friendly regulation, and criticised the entrenched position of the Department of Health, which was to protect consumer welfare 'without primary concern for the profits of multinational drug manufacturers' (Johnston, 1986, p. 44).

The fragmentation and conflict between these agencies predictably generated countervailing demands for coordination and regulatory coherence, which resulted in the adoption of the National Medicines Policy (NMP) as a framework premised on 'a partnership approach to policy development' (APAC, 2000, p. 2). The NMP concept has its genesis in resolutions of the World Health Assembly and the activities of the World Health Organization (WHO), in particular its Action Programme on Essential Drugs, established in 1981 to provide support for member countries in the development of drug policies (World Health Organization, 1992). The declared purpose of Australia's NMP was to overcome adversarial relations between key stakeholders and to ensure equitable access to safe and efficacious medicines of good quality. It has contributed to a more dense web of formal and informal exchange: state agencies, the pharmaceutical industry, health practitioners, consumers and other interests now 'work together as partners to promote the objectives of the policy' (APAC, 2000, p. 4). First formulated in 1994–1995, the NMP provides a framework within which actors pursue diverse strategies. The policy identifies four central objectives:

- timely access to the medicines that Australians need, at a cost individuals and the community can afford;
- medicines meeting appropriate standards of quality, safety and efficacy;
- quality use of medicines (QUM); and
- maintaining a responsible and viable medicines industry. (APAC, 2000, p. 3)

The formal recognition of a 'viable industry' as one of four core policy aims signaled that the views of the pharmaceutical industry were to be taken into consideration in all areas of regulation, and gave expression to the government's shift in the late 1980s to a more business-friendly position. Its first major manifestation was the Factor (f) program, but the general and ongoing implication for safety and efficacy regulation and the operation of the PBS is that the arguments of the industry have to be given a more attentive hearing than in the past. The substance and details of policy and regulation framed by the NMP emerge from bargaining within committees and working parties. The Australian Pharmaceutical Advisory Council (APAC), established in 1991, with member organisations that include
suppliers, health professionals and providers, scientists, pharmacists, consumer and patient advocacy organisations, provides a mechanism for consensus-building. Member organisations must be able to represent their organisations’ positions in policy discussions and to in turn convey back to organisations’ memberships and associated networks the deliberations of the Council. After appropriate consultation, members are able to commit the organisations to agreed positions and actions. (APAC, 2000, p. 5)

Statements such as this suggest a deliberative and inclusive model of interaction between groups and government, notwithstanding that participants bring highly dissimilar and unequal resources to this process. Most groups are concerned with a limited range of issues; the Pharmaceutical Guild of Australia, for example, have a stake mainly in the regulation of remuneration to ‘community pharmacists’. Consumers, patients and health professionals have broader interests, and government and business recognise the importance of coalition-building with consumer and professional groups. Typically funded largely by governments, many Australian consumer and patient advocacy groups are engaged in dialogue with (and are indeed sometimes sponsored by) the pharmaceutical industry. The industry—represented by Medicines Australia—has a stake in each and every aspect of pharmaceutical policy and regulation. Its near-monopoly of technical–scientific knowledge of products and production technology, and costs, bestow upon firms and Medicines Australia particular power resources. The embracing of a rhetoric of partnership, and the proliferation of consultative arrangements, since the 1990s, does not eliminate tensions within the policy network on issues such as drug pricing. The price-depressing effects of the PBS remain a major issue of contention, criticised by Medicines Australia as incompatible with expanded industry activity in Australia (Evans, 2002a). A spokesperson for the pharmaceutical industry stated to us that the industry continues to engage in ‘guerilla warfare’ with the Department of Health, which is criticised for an alleged narrow focus on cost containment. Conversely, a representative from the Health Department characterised the pharmaceutical industry as ‘ruthless’. Yet this conflict between suppliers and the Department of Health, which dates back to the 1950s, is now only one element within a more varied pattern of interdependencies and policy considerations, and the Department’s exercise of power vis-à-vis the pharmaceutical industry is now more constrained than in the past.

Product regulation—the Therapeutic Goods Administration

Stringent drug regulation was introduced across many countries in the 1960s, following the thalidomide disaster, and has since been embraced by the industry as a commercially essential seal of safety and quality. Yet tension between government and business arises inescapably from the industry’s natural proclivity to accept greater risks. In Australia, the TGA undertakes assessments, similar to those of the US Food and Drug Administration (FDA), to ensure that prescription and ‘over-the-counter’ medicines, medical devices, and related products, supplied in or exported from Australia, meet appropriate standards. The activities of the TGA must be ‘aligned with the Government’s broad health and industry policies’ which includes ensuring that therapeutic goods are made available in a ‘timely manner’ and that the pharmaceutical industry is ‘free of unnecessary regulatory burdens’ (Therapeutic Goods Administration, 1999, p. 1).

The regulation of medicinal drugs is based on complex risk-benefit assessments; for example, the risks of making drugs available too quickly are weighed against the cost of delayed access to potentially life-saving new medicines (Daemmrich & Krücken, 2000; Jacobzone, 2000). The high commercial stakes that companies have in the outcome of the regulatory process, and their technical and other resources, mean that ‘the pharmaceutical industry tends to dominate the process’ (Wiktorowicz, 2000, p. 7). In the past decade the International Conference on Harmonization (ICH) process has brought about an acceleration of the development towards global standardisation of the scientific and technical aspects of product registration requirements, a process accompanied by a convergence in the philosophy and practices of regulatory agencies (Abraham & Reed, 2001; Braithwaite & Drahos, 2000; Vogel, 1998). Global interdependencies dictate that the time taken to process marketing applications must approximate international ‘best practice’.

Similar to developments in the US, Canada, and elsewhere, the TGA has evolved from an arm’s-length regulator not overly concerned about the commercial interests of pharmaceutical firms, into a services provider operating in partnership with the industry. In the past, the TGA was criticised for its scientifically driven culture; it was said to be a ‘black hole’ operating at a distrustful distance from product sponsors. In 1991 the APMA claimed that

[m]ost senior TGA officers have a strongly negative attitude towards the industry and this philosophy has permeated relatively low levels of the agency. The role of TGA officers has been emphasised as being the protectors of the public’s safety rather than its
health and welfare. Sponsor companies are seen as adversaries rather than organisations which share many of the TGA’s goals and with considerable expertise to offer. (Australian Pharmaceutical Manufacturers Association, 1991, p. 10)

A major shift towards an industry-responsive and market-oriented approach commenced in 1991, triggered by a government review, the Baume report, which stressed the need for improved industry relations and more extensive use of international cooperative agreements (Baume, 1991). The then Labor government accepted the review’s recommendations, many of which were aimed at achieving reduced review times. The industry was skeptical of the government’s commitment to change, but it soon became clear that all recommendations would be implemented in full. An APMA official noted in 1993:

The impact of a less negative regulatory environment on multinational companies is quite amazing. In fact it took a while after the Baume report came out until companies accepted that indeed it would be implemented in the spirit in which it was delivered and that these changes would indeed happen; that the regulations instead of hindering the clinical trial and the registration of new and improved drug products in Australia would indeed be streamlined and that timely availability would be one of the government’s criteria which has indeed occurred. (Industry Commission, 1993, p. 1433)

A new national manager appointed in 1992 established an Industry/Government Consultative Committee as a mechanism for direct industry input to decision processes in regard to matters such as fees and charges, strategic planning, and the monitoring of agency performance. The TGA’s growing reliance on revenue raising, including inspection and evaluation fees and annual registration charges, required more industry responsive attitudes and practices. An initial cost-recovery target of 50 percent was achieved by 1996–1997, and full cost recovery for all activities within the scope of the Therapeutic Goods Act, including public health responsibilities and industry regulation, was introduced in 1998 (Australian National Audit Office, 2000). The TGA now meets annually with ‘representatives from the major industry groups and consumers to discuss and agree on the TGAs schedule of fees and charges for the coming year’ (Therapeutic Goods Administration, 2000, p. 19). The push to make the TGA more efficient and industry-friendly was given a further boost with reports by the Industry Commission (now the Productivity Commission, the Australian government’s major economic policy research agency) and the Auditor General in 1996, and another review instigated in the same year by the newly elected Coalition government (Australian National Audit Office, 1996; Industry Commission, 1996). Its terms of reference signaled the reduction of processing times, that business should be relieved of unduly complicated regulatory requirements, and that more extensive use should be made of evaluation reports and decisions from overseas agencies. Provisions for public access—or lack of access—to regulatory information submitted by the industry to, or generated by, the TGA has not changed in the past decade.

Unlike the situation which applies for regulatory bodies in certain overseas countries, virtually none of the information held by the TGA is currently made available publicly. ... The cost-effectiveness data considered by the Pharmaceutical Benefits Advisory Committee (PBAC), when recommending that a drug be listed on the Pharmaceutical Benefits Scheme (PBS), are also secret. (Eadie, 2002, p. 78)

Medicines Australia, with reference to the WHO Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, is seeking to maintain long-standing secrecy arrangements (Evans, 2002b).

As a result of changes throughout the 1990s there is today a ‘high level of industry confidence in TGAs evaluation processes’ (Australian National Audit Office, 2000, p. 13). The trust-based approach to drug evaluation that has transformed the TGA raises the question of risk of agency capture to the detriment of public health and safety. This is a spectre raised by the CHF:

A requirement for TGA to move to full cost recovery would in effect lead to the establishment of an industry funded agency—that is, one reliant on the fees paid by industry for conducting all its services, including ‘public good’ services. Such an agency would be less subject to governmental control and less accountable to the community as a whole. (Consumers’ Health Forum, 1996)

The Industry Commission acknowledged this possibility—a particular danger where the regulator is self-funding’ (Industry Commission, 1995, p. 355). TGA senior management, however, point to ‘enormous checks and balances ensuring that the TGA is not readily captured’, and, to its domestic and international reputation as effective regulator (interview). More definite pronouncements in regard to safety and efficacy regulation in Australia, and the risk of ‘capture’, would need to be based on detailed case studies beyond the scope of this paper.
The Pharmaceutical Benefits Scheme

The Pharmaceutical Benefits Scheme (PBS), Australia’s publicly funded program for universal access to prescription drugs, commenced in 1951 (Sloan, 1995). The past decade presents a mixed picture of sustained government–business conflict on some issues pertaining to the PBS, and closer, more consensual, relations on other matters as a result of incremental changes in response to industry demands for greater ‘transparency’. All in all, PBS administrators today take closer account of the views of the industry. Importantly, domestic drug prices for new innovative products are now approximately in line with prices in comparable overseas markets (Productivity Commission, 2001). Yet, controversy continues to be fueled by the processes whereby products are listed on the PBS and prices determined, notably the role of reference pricing. Tension is inherent in the very design of the PBS: the aims of cost-effective supply and the appropriate use of medicines conflict with the industry objective of maximising sales and profits. One of our industry informants referred to continuing ‘skirmishes with government’ and a senior public servant described interaction with the industry as a ‘hard game’ characterised by a ‘lack of consensus’. Moreover, rapidly rising PBS costs driven by a combination of growing consumer demand and the introduction of new, more expensive drugs, ensure intense public debate and have raised doubts about the scheme’s sustainability.

The PBS was originally intended as a listing device whereby drugs classified as ‘disease-preventing and life-saving’ would be provided free of charge to all Australians (Sloan, 1995, p. 5). Co-payments now apply but the purpose of the PBS remains to ‘improve the health of all Australian residents by ensuring they have access to necessary and lifesaving medicines at an affordable price’ (Department of Health and Ageing, 2003). In the past the PBS has at times given rise to open confrontation with pharmaceutical companies as well as the retail pharmacy sector, which derives most of its income from the PBS. Particularly controversial was the introduction in the early 1990s of the requirement that a cost-effectiveness analysis be undertaken as a condition for PBS listing. Australia was the first country in the world to introduce this as a mandatory condition for listing on a national drug formulary (Hill, Henry, & Stevens, 2001). This precedent can be perhaps be considered ‘Australia’s global contribution’ to pharmaceutical policy (interview). With a shift towards global pricing, the industry is apprehensive that decisions influenced by cost-effectiveness analyses could produce benchmark prices with international repercussions.

Listing of new innovative products on the PBS follows a positive recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC) which requires demonstration of clinical efficacy and, as noted, cost effectiveness. The Minister of Health, though not bound by PBAC recommendations, normally accepts its advice. The PBAC is not involved in direct price negotiations with suppliers. Rather, it provides the Pharmaceutical Benefits Pricing Authority (PBPA) with advice regarding cost-effectiveness for each medication. The PBPA is an independent, non-statutory authority consisting of representatives from industry, consumers, and the Departments of Health and Industry (Sloan, 1995).

For products with properties similar to already listed drugs, Australia’s version of reference pricing, the Brand Pricing Policy, first introduced in 1990, may come into effect: suppliers of such drugs can set their own price, but consumers pay as a ‘premium’ whatever the supplier may charge in excess of the PBS-approved price for the benchmark product. In February 1998, the Brand Pricing Policy model was extended to drugs with similar clinical effect in the form of the Therapeutic Group Premium (TGP) Policy. Pharmacists can substitute between generic products (unless vetoed by the prescriber) but are unable to substitute between different chemical entities. The TGP policy is criticised, by the originator-brand sector, as undermining ‘the benefits of patent protection by pooling out-of-patent products with patented products ... and makes product differentiation difficult’ (Australian Economic Analysis Pty Ltd., 1998, pp. 4–5).

Until 1970 the membership of the PBAC 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 insulate officials, as well as scientific and medical experts, from lobbying by industry and other interest groups. Today, however, positive recommendations made by PBAC are listed on the internet with a brief rationale, and other measures to increase transparency are expected. Medicines Australia, whilst rejecting public access to clinical trial data submitted to the TGA as part of product approval applications, lobby for ‘absolute transparency for the operations of the PBAC ... [including] all aspects of its operations and [this should] include peer review’ (Evans, 2002b). Direct industry representation on the PBAC has been particularly contentious issue. Early in 2001, the then Minister for Health reconstituted the Committee and appointed as one if its members a former chief executive officer of the APMA whose rationale for membership was his ‘broad experience in the pharmaceutical industry’ (Wooldridge, 2001). The PBAC previously had comprised experts such as pharmacologists, general practitioners, specialists and pharmacists, with a consumer representative included from the late 1990s. The recent change in PBAC composition has been described as a ‘weakening of Australia’s regulatory framework’ signaling the legitimacy of industry participation in all areas of pharmaceutical policy (Loff & Cordner, 2001).
It was expressed frequently in interviews that the PBS has created an unrealistic expectation that pharmaceuticals will continue to be provided at low costs to all consumers. Industry representatives in particular argued that the Australian public is unaware of the true cost of pharmaceuticals. In addition, questions about the sustainability of the PBS were frequently raised with many participants pointing to current high rates of PBS cost increases, suggesting that a radical new approach is required. Since its inception, expenditure has risen, on average, by 10% per annum (Goddard, 2001). However, for the year 2000/2001, expenditure increased by 22%, reaching AU$4.2 billion dollars (Senate Community Affairs Legislative Committee, 2001). In the federal Budget for 2002/2003 significant increases in consumer co-payments were proposed as a means of curbing rising government costs. This was criticised by consumer groups as an attempt to undermine equity and access (Donovan, 2002), and the Labor party and the Australian Democrats blocked the necessary legislation in the Senate. The question of PBS sustainability gives rise to two very different perspectives. One entails an increased role of government in the regulation of access to and pricing of pharmaceuticals, including stricter application of cost-effectiveness assessments and reference-pricing, and measures to encourage the use of cheaper generics. The other perspective is a shift in the direction of a US-style 'free market' for drugs, which could take the form of subsidies for only a basic range of drugs, or subsidies only for low-income earners, and greater reliance on private insurance. Ultimately, the preference among many industry executives is for the US model of weak public regulation of prices. There has been a stalemate between conflicting views on the question of PBS reform for several years, and debate continues both in technical terms among core policy actors and in the wider political arena.

The Action Agenda program

State support for R&D, manufacturing, and exports, consistent with a broader shift towards a high-technology, information-based economy, comprise a third policy focus in the pharmaceutical domain. The federal government, propounding a pragmatic mix of free market and activist industry policy, in May 2001 launched a pharmaceutical industry Action Agenda as a framework for specific programs and initiatives that enable industry and government to work together to strengthen the capacity of Australian industries to compete globally ... the aim ... is to identify impediments to growth for specific industry sectors and to remove them, to find out where the opportunities lie and to take advantage of them. Action Agendas are driven by industry, with government providing a facilitation role. (Industry Science and Resources, 2001)

This Action Agenda seeks to strengthen opportunities for multinational corporations, local firms, and research bodies to expand activity on the basis of domestic strength and expertise in areas such as basic scientific research and a capacity to cost-effectively manage clinical trials. The aim is to double Australia’s share of the global pharmaceutical industry by 2010 (Hill, Kirchner, & Holmes, 2001). As explained to us by a government official, it is necessary to ‘create a climate of seeing the advantage of working together’ in order to attract to Australia as many stages as possible of the pharmaceutical value chain.

The Action Agenda builds on earlier initiatives, commencing in the mid-1980s, to bring about a greater degree of trust between pharmaceutical companies and regulatory agencies. The key industry support intervention of the past 20 years was the Factor (f) program, introduced to encourage investments in Australia by globally oriented pharmaceutical companies. The program was structured to provide compensation to selected firms for low PBS prices in exchange for an expansion of R&D, manufacturing and export activities in Australia. This design left the PBS unaffected, while channeling substantial payments to corporations (in the order of AU$1 billion between 1987 and 1999) and sending a signal to the pharmaceutical industry that the government was now putting in place a more business-friendly regulatory environment (Lofgren, 1997). This policy was continued by the conservative Coalition government in the form of a smaller scheme—the Pharmaceutical Industry Investment Program (PIIP)—at a cost of around AS$300 million for the period 1999–2004 (Pharmaceutical Benefits Pricing Authority, 2001). In its May 2003 Budget, the federal government announced the introduction of a new initiative, the Pharmaceutical Partnership Program ‘to promote high quality pharmaceuticals R&D activity’, at a cost of AS$150 m between 2004 and 2009, which replaced the PIIP (Macfarlane, 2003).

Medicines Australia claims credit for persuading the government to initiate the Agenda process, bringing together multinational research-based firms, the generics industry, the biotechnology and medical research sectors, and state agencies into a multitude of working groups and committees, enabling dialogue and the building of trust (Australian Pharmaceutical Manufacturers Association, 2001, p. 6). A Leaders Group representing the various sections of the industry, the medical research sector and the Departments of Industry and of Health have responsibility for management of the
Action Agenda, which is supported financially and in-kind by both government and industry.

Industry support and regulatory issues are notionally kept separate from questions of social policy. For participants in the Action Agenda, the PBS is to be accepted 'as a given, recognising that the PBS is the cornerstone of equitable access ... and use of an evidence-based approach to listing will continue on into the foreseeable future in its present form' (Pharmaceutical Industry Action Agenda, 2001). Yet the PBS, which affects significantly the operating environment for the pharmaceutical industry, particularly in respect of drug pricing, is in reality at the centre of government–business interaction within the context of the Action Agenda. A survey of senior company executives established that pricing and reimbursement issues ‘were ranked as the most important factors influencing decisions to invest’ (Pharmaceutical Industry Action Agenda, 2002a).

The Action Agenda process is dominated conspicuously by senior company executives; non-business actors, such as welfare and consumer groups, are effectively excluded. This has rarely been criticised publicly: close exchange, premised on shared objectives, between business and government is central to the predominant model of governance. In this perspective, if Australia is to be recognised as an attractive location for pharmaceutical industry activity, it is a matter of simple common sense that business be accorded a privileged role in the public policy process.

Conclusion

The common trend across the areas of product safety regulation, social policy, and support of industry expansion is a tendential shift towards more trust-based exchange among a wider range of actors, and a blurring of public–private boundaries. This trend is most advanced in the Action Agenda program, whereas the PBS continues to give rise to significant divergences. Even in this area, however, discussions are notionally premised on a presumption of partnership relations, as distinct from outright bargaining. Government unity and coherence has splintered, notwithstanding attempts at coordination through the National Medicinal Drug Policy. Instead of dominance by a single powerful state actor—the role of the Department of Health before around 1990—we find three major agencies each linked into a distinct configuration of interest groups. The TGA has developed greater responsiveness to its fee-paying industry clients, and its activities are shaped increasingly by international cooperative agreements and the ICH process. The PBS ‘listing process’ is now more open to industry scrutiny and influence, and consumer and patient advocacy groups exercise more influence than in the past. The Action Agenda program allows for cooperative exchange between core actors, whilst excluding groups and individuals first and foremost committed to public health and welfare rather than industry growth. The predominant view, articulated most forcefully by the Department of Industry, and Medicines Australia, is that the role of government is to provide a business-friendly regulatory environment premised on partnerships between public and non-state actors (Hill et al. (2001); Pharmaceutical Industry Action Agenda, 2002b).

Many issues continue to generate tension: the PBS listing process, whether particular new drugs should be subsidised at all, the possible legalisation of direct-to-consumer advertising, remuneration for pharmacists, the role of reference pricing and generics, and so on. But the sheer technical complexity of policy and regulation, and their political and social implications, make necessary a degree of mutual trust between suppliers, doctors, pharmacists, consumer representatives, and government agencies. Collaboration as well as conflicts is framed by a policy paradigm that takes the imperative of international competitiveness for granted, constraining the range of options considered realistic and reasonable. The distribution of power within the network is ultimately highly inequitable. Medicines Australia, representing major transnational firms, is the only actor, other than government, with a stake in all aspects of policy, and draws on unique resources in respect of policy analysis, international coordination, lobbying, and direct access to government. There is a loose ‘oppositional’ assembly of public health professionals, welfare sector organisations, researchers and some public servants, but individuals within this category operate within the constraints of pressures on the PBS budget and the perceived imperatives of globalisation. The Department of Health until the late 1980s had the capacity to keep at bay pressures from the pharmaceutical industry, and other lobbyists. Today’s widespread celebration of trust, and rhetoric of partnership, gives expression to a different form of network interaction framed by the immutable logic of business.

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