Generic Drugs: International Trends and Policy Developments in Australia

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Introduction

The use of relatively inexpensive generic drugs is a topical theme in pharmaceutical policy and regulation internationally.[1] This paper addresses, first, the role of generics in international markets, and the experience of reference pricing programs. Second, the paper examines the development of generics policy in Australia, and seeks to delineate, in broad terms, present policy challenges.

The essential attribute of generic drugs is that they cost less than their original brand equivalents. Public and private third-party payers therefore increasingly encourage or mandate the use of generics through measures such as generic prescribing[2] and generic substitution[3] (Jacobzone 2000, p. 42). Reference pricing schemes, taking advantage of the price competition made possible by the market entry of generics, have been introduced, or are under consideration, in many countries. The encouragement of generics through reference-based pricing – now 'one of the preferred models for drug expenditure control' internationally (Lopez-Casanovas and Puig-Junoy 2000) – is based on the principle that a drug's benefits should be compared systematically to alternative drug treatments. In the US, where around half of all scripts are filled by generics, a coalition of employers, state governors, consumer groups, and unions is lobbying for legislative changes to speed-up the commencement of generic competition,[4] and the debate on the introduction of pharmaceutical benefits under Medicare revolves around the use of generics (Gleckman 2002; Toner 2002; Wechsler 2002). In Australia, the proportion of Pharmaceutical Benefit Scheme (PBS) scripts filled by generics makes up around 20 percent of the total market (in volume terms). It is expected that this share will continue to grow, and the role of generics in the PBS market is the focus of considerable interest. A commentator in the *Australian Journal of Pharmacy* suggests that 'the future for the PBS is to encourage generic introductions' as a means of achieving cost-savings on out-of-patent products, thereby freeing up money to pay for new patented products (*Australian Journal of Pharmacy* 2001).

Policy in this area is fraught with contention that arises inescapably from the fact that generic drugs – and indeed products with similar therapeutic effects – invite cost-effectiveness comparisons and make substitution possible. On the one hand, generic competition is seen as a means of containing costs, and also as a way of adding to innovative pressures on originator-firms. To this should be added, of course, that the generics industry makes up a distinct sector with its own commercial imperatives. The opposing perspective is to consider the growth of generics as damaging to the research-based industry, and generic substitution and related measures as an intrusion on the professional authority of doctors. The response by R&D-based firms to generic

[1] Several acknowledgements will be included in the final version of this paper.

[2] Generic prescribing can be the prescribing of a generic brand by its own brand name, but more commonly refers to the prescribing of a compound by its generic name.

[3] Generic or brand substitution, legal in Australia since 1 December 1994, is the practice of substitution, without prior consultation with the prescriber, by a pharmacist of a therapeutically equivalent brand of a prescribed PBS item, for the brand specified by the prescriber, where the 'no substitution' box has not been ticked on the prescription form.

[4] See Business for Affordable Medicine, http://www.bamcoalition.org/. Two other coalitions, Rx Health Value and the Coalition for a Competitive Pharmaceutical Market, also lobby on behalf of purchasers for facilitated market entry for generics.

competition is to seek recognition for the purportedly unique properties of their branded drugs by way of various brand management strategies aimed at reinforcing 'perceptions of higher quality' and to protect and extend patents (Productivity Commission 2001, p. 54; Redmond 2001).

Generic drugs in international markets

The term generic drug in this paper refers to 'a copy of an original product whose patent has expired' (Lewis 2001). Alternatively, generics are sometimes defined as medicines 'for which the patent of the active substance has expired', thus encompassing all out-of-patent products including originator brands (Nilsson and Melander 2000, p. 1195).[5] Generics (irrespective of definition) can be marketed as branded products – that is, with a trade name belonging to the producer – or under the generic name of the active compound. Suppliers of generic drugs can also seek to establish brand reputation on the basis of the marketing of the name of the company.[6] Obstacles to the market entry of generics in most instances are not technical, but derive from institutional arrangements, including the prescription practices of doctors, brand loyalties, and regulatory and reimbursement systems, including retail pharmacy regulation and practices.

Generics have existed throughout the history of the pharmaceutical industry, but modern generics firms emerged only in the mid 1960s in the context of the shakeup of regulatory arrangements in the USA following the thalidomide tragedy. The 1984 US Drug Price Competition and Patent Restoration (Hatch-Waxman) Act was the decisive moment in the development of the generics industry in the world's major pharmaceutical market. The Hatch-Waxman Act provided for facilitated market entry for generic versions of all post-1962 approved products, in exchange for an extension of the patent period (Congressional Budget Office 1998). This opened 'the floodgates for generic competition of pharmaceutical products, creating the modern generic pharmaceutical industry' (Barr Laboratories 2002). In the first year after the introduction of the Hatch-Waxman Act the FDA received more than 1,000 applications for approval of new generic drugs (Harnden 1998). However, it took until the 1990s for generic competition to alter significantly the dynamics of the US pharmaceutical market. A key driver was the spearheading by Health Maintenance Organizations and Pharmaceutical Benefit Management companies of cost-containment measures such as generic prescribing, brand substitution by pharmacists, and reimbursement on the basis of cheapest brand (Santini 2001). By 1997, 63 percent of Health Maintenance Organizations are said to have imposed mandatory generic substitution (Mrazek and Mossialos 2000). The Waxman-Hatch Act is estimated by the Congressional Budget Office to have saved consumers US$8-10 billion in 1994, and presumably at least as much in subsequent years (Congressional Budget Office 1998, p. ix).

The reputation of generics was generally poor until relatively recently, and the major companies could plausibly advise doctors to prescribe 'only known and respected

[5] This definition was recently used by the Productivity Commission Productivity Commission (2001). *International Pharmaceutical Price Differences: Research Report*. Canberra, AusInfo.

[6] As exemplified by *Alphapharm*, the largest of the generics suppliers in Australia; see http://www.alphapharm.com.au/.

brands' (Evers 2001, p. 30). Generics however have to meet the same standards as the innovators' brand name products, and in terms of product attributives price is the only substantive difference.[7] Problems of non-equivalence in some instances, and the vulnerability of some patients to sudden changes in medication, figure in the debate on generic substitution, highlighting that subsidy systems need to be designed to accommodate exceptional individual needs. But from a policy perspective, key issues pertain rather to the effect of regulatory arrangements on total pharmaceutical expenditure, the distribution of expenditure on different categories of payers, and the consequent commercial impact on the originator and generics sectors. When a generic enters the market in the USA, 'the bottom almost immediately falls out of a branded product's volume' (Lipson 2001). For example, the US patent for Zantac expired in mid-1997; two years later generics accounted for 90 percent of sales of this product, and its 'pharmacy cost' was about 10 percent of the pre-expiry level (Berndt 2001, p. 107). It is reported that Eli Lilly lost 80 percent of its US market share for Prozac in the first week after the entry of generics in 2001 (Griffith 2001). But brand products normally retain substantial sales, sometimes even at prices exceeding those before the commencement of price competition. Well-informed purchasers (including Health Maintenance Organizations in the US and hospitals in Australia) accept generics as perfect substitutes, whereas non-insured consumers in the US often pay higher prices for originator products as a result of perceptions of product differentiation.

The highest market share for generics is found in countries where the industry historically had the greatest pricing freedom, including Germany, the Netherlands, the UK and the US. Where systems of price control have been in place, such as Australia, generics have a smaller market share. In 2001 in the US, generics made up around 45 percent of all prescriptions filled, compared to less than 20 percent in 1984, but represented only 8.4 percent of total consumer spending on prescription drugs.[8] Conversely, brand name drugs met 55 percent of all prescriptions, accounting for approximately 91.6 percent of total consumer spending (Generic Access http://www.gphaonline.org/). Advocates of measures to facilitate the up-take of generics argue, however, that the market share for generics has been stagnant since around 1993, in spite of many products coming off patent (U.S. Senate Health 2002). This is the context for recent efforts to eliminate alleged loopholes allowed by the 1984 Hatch-Waxman Act (Hess 2002). For example, a lawsuit has recently been filed against Bristol-Myers Squibb by more than 30 US States charging fraudulent patent applications and frivolous lawsuits aimed at delaying generic versions of Taxol (McCarthy 2002). In July 2002, a US Senate Committee approved a bill to limit the ability of brand companies to get an automatic 30-month patent extension, and also to make it more difficult for market entry of generics to be delayed by way of payments to the first generic firm to win approval not to start selling its product.[9]

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[7] Critical commentary on the role of generics has shifted from a focus on the attributes of the products, to arguments pertaining to, for example, the support to doctors provided by different types of suppliers, and the economic effects on different sections of the pharmaceutical industry, notably in terms of return to innovation.

[8] According to a spokesperson for Pharmaceutical Research and Manufacturers of America, generics now represent 49 percent of all prescriptions Appleby, J. and J. O'Donnell (2002) "Consumers Pay as Drug Firms Fight over Generics". *USA Today*. 6 June, pp. 01A.

[9] As of August 2002, the bill has been passed in the Senate (on a 78-21 vote) but faces an uncertain future in the House of Representatives. See newspaper reports available on the website of Business for Affordable Medicine, http://www.bamcoalition.org/index.htm.

In the UK, more than 70 percent of scripts are written generically, thus making the issue of generic substitution less pressing. Pharmacists have an economic incentive, through supplier discounts, to dispense generics, which now account for around 50 percent of all dispensed drugs in the UK (Department of Health 2001, p. 3). In the Netherlands, the share of generics is said to be between 30 and 35 percent in volume terms (OXERA 2001, Appendix A8), and in Germany more than 50 percent (Mrazek and Mossialos 2000).

Generic suppliers emerged historically in separation from the research-based industry – the so-called Big Pharma sector – but there is today complex interdependence and overlap between the innovator and generics sectors. Brand name firms often supply drugs also under generic labels, drawing on technical and production advantages to establish first-mover advantages (Ferrandiz 1999; International Federation of Pharmaceutical Manufacturers Associations 1997). Conversely, some generic companies produce patented drugs under license from, or on contract for, brand name companies, and engage in patenting of dosage forms, release mechanisms etc. based on their own R&D capacities. At times, identical drugs from the same production line appear in the same market at different prices as branded products and generics. Principally generic firms compete on price, and according to a study of the European market operate 'on a knife edge' of narrow margins of profitability.[10] Production costs are typically not lower than for those of Big Pharma, but generally in the pharmaceutical industry the cost of production forms a small proportion of total revenue, and the key difference is that generic firms expend less on marketing and R&D (Burstall, Reuben et al. 1999).

The generics industry is today dominated by multinational firms such as *ratiopharm International* (Germany), *Teva Pharmaceutical Industries* (Israel), *Ranbaxy* (India) and Merck KGaA (Germany) (Alphapharm's parent company). The sector is represented by national and international industry associations seeking to establish an influence in regulatory developments (Evers 2001).[11] *Teva Pharmaceutical Industries* was reported in 2001 to be the world's largest generic company with 8,600 employees and a US market share of 12 percent (Berger 2001). In Australia, the Generic Medicines industry Association (GMiA) was established in early 2001. Its six member firms (Alphapharm, Arrow Pharmaceuticals, Biochemie Australia, Douglas Pharmaceuticals, Hexal Australia, and Mayne) employ in total around 1,500 people. Sigma is the only other generic supplier to the PBS, but its products are now marketed and distributed through Arrow Pharmaceuticals. Alphapharm is the largest of the generics suppliers, with more than 550 employees and a product range of over 200 items said to be 'the most comprehensive … of any pharmaceutical company in Australia' (see http://www.alphapharm.com.au/index.html). Plainly the GMiA pursues an agenda that differs from that of the brand industry on a range of matters of commercial import (such as generic substitution). Yet there is a perplexing blurring of boundaries, as exemplified by Douglas Pharmaceutical's listing of alliances and distribution agreements with several multinationals including Pfizer, Merck Sharp &

[10] An assessment of profitability in the Australian generics sector could not be undertaken for this paper, but it was claimed in personal communications that two suppliers operate with very small returns.

[11] These include the European Generic medicines Association (EGA) (http://www.egagenerics.com/index.htm) and the Generic Pharmaceutical Association (GphA) in the USA (http://www.gphaonline.org/).

Dohme, and Eli Lilly (see http://www.douglas.co.nz/company.cfm) and Biochemie Australia's status as an entity within a global generics business owned by the Swiss Big Pharma company Novartis.

The regulation of generics continues to give rise to extensive legal and political wrangling in the US and elsewhere (Santini 2001; Wechsler 2001b; Wechsler 2001c; Wechsler 2001a). Examples of recent patent conflicts include disputes between Eli Lilly and Barr Laboratories over Prozac, and Bristol-Myers Squibb and Ivax Corp. over the cancer drug Taxol (Santini 2001). Most attention is paid to legal action taken by Big Pharma against generic challenges, but the Canadian generic-drug company *Apotex* (with 4,200 employees) is reported to be 'embroiled in almost 100 lawsuits' and to be 'famous for suing anybody who tries to stop it selling a generic version of a bestselling drug' (*The Economist* 2002) . In Europe, the debate revolves around the generic industry's lobbying for the 'Bolar concept', that is, the right to undertake the development work required for the production of a generic during the period of market exclusivity, as allowed in the US and elsewhere.

The generics market in the USA, the EU and Japan in 2000 was estimated at around US$33 billion, and is expected to grow at rate of 10-15 percent in the next few years, compared to a growth rate of around 7-9 percent for the pharmaceutical sector overall (Lewis 2001). It is accepted by industry analysts that the continued rapid expansion of the global generics sector is inexorable. As a result of regulatory developments in the USA aimed at 'drug company tactics for delaying generics, the generic onslaught will be unstoppable' (Barrett 2002). The patents of many big-selling products will expire in the next five years; '(o)f the leading 35 molecules world-wide in US$ terms, 13 will lose their patent protection by 2005' (Lewis 2001). The first biotechnology products are also reaching the end of their patent-protection, providing a strong incentive for generics suppliers to upgrade their technological capacity. It is understandable then that generic firms in the US are said to be 'grabbing the attention of institutional investors' and to be 'morphing into what Wall Street has dubbed specialty pharmaceuticals' (Santini 2001).

The growth of the generics sector is a challenge to Big Pharma. According to Pharmaceutical Research and Manufacturers of America (PhRMA), proposed changes to the Hatch-Waxman Act 'would impede the ability of the research-based industry to realize in a timely way the promises that accelerating biomedical advances hold for patients in all parts of the world' (Glover 2002). Industry observers note howver that R&D based firms have 'learned how to prosper even in the face of generic erosions' (Berndt 2001; Lipson 2001). Moreover, some analysts consider the post-1984 expansion of the generics sector in the USA to be a key driver of the enhanced international competitiveness of US-based pharmaceutical firms. Vigorous competition in the off-patent sector has been a powerful stimulus for innovation: expectations of a rapid decline in sales revenue following patent expiry provides a strong incentive to engage in research and to achieve other efficiency gains (Gambardella, Orsenigo et al. 2000). At the same time, in the US market, brand suppliers have been able to achieve high returns on patented products.[12] The originator sector benefits also from the lessening of pressures for stringent cost-

[12] It is often noted in the US debate that the drug industry has been the most profitable of all industries, as measured by median return on revenue, for each of the last tend years.

cutting measures resulting from the availability of cheaper generics, allowing private and public purchasers (such as the PBS) to pay higher prices for patented, innovative drugs (Gambardella, Orsenigo et al. 2000; Morris 2001). Arguments along these lines cannot however be translated directly into support for any particular policy position in Australia. The small size of the Australian market means that no Australian generics policy could have any effect on the innovation efforts of globally oriented firms. The research-based industry argues however that 'the increased substitution of generics for branded products … could jeopardize the levels of future R&D investment in Australia, with subsequent effect on the Australian economy and erosion of employment and export achievements' (APMA 2002). The plausibility of this contention hinges on the precise rationale for pharmaceutical industry R&D spending in Australia, estimated to be in the order of A$300m annually. Factors other than return on sales said to be stimulating pharmaceutical industry R&D activity in Australia include a high quality basic medical research and health sectors, a capacity to support clinical trials, and generally low costs compared to alternative locations (Pharmaceutical Industry Action Agenda 2002).

Reference-based pricing

Reference pricing (RP) refers to 'any system that establishes a common reimbursement level for a group of comparable or interchangeable drugs' (Narine, Senathirajah et al. 1999). The public or private purchasing agent 'decides on a reimbursement price and then the user/patient or insurer pays the difference if the chosen medicine is more expensive' (Lopez-Casanovas and Puig-Junoy 2000, p. 91). The term reference *pricing* is thus not strictly accurate: it is the *reimbursement* level, not pricing as such, that is controlled for a cluster of drugs. RP is a key feature of cost-containment arrangements in at least twelve countries or jurisdictions, including Germany, Sweden, Denmark, Italy, New Zealand, the Canadian province of British Columbia, Spain and Australia. There is increasingly international policy diffusion with respect to the design of RP programs; British Columbia, for example, drew directly on the New Zealand RP model (Maclure, Nakagawa et al. 2001, p. 46).

Australia introduced a form of RP in the later half of the 1980s, with the commencement of price reviews by therapeutic groups. Price increases were not granted where alternative products (brands or similar products in the therapeutic group) were available at a lower price. At this stage there was no move to reduce prices to that of the lowest product within a therapeutic group, but a product could not be granted a price increase unless clinical benefits were demonstrated. The Productivity Commission, assessing developments throughout the 1990s, noted that the application of RP 'may have been significant' in keeping prices relatively low in Australia (Productivity Commission 2001, p. xxx).

RP builds on long-established principles of evidence-based formulary management integral to public and private drug benefit plans and hospital formularies, including Australia's PBS. Medical conditions can be treated, in most instances, with different brands of the same drug (where the patent has expired) or by one of several similar (patented and/or generic) drugs, at varying prices, which achieve the same or similar therapeutic effects. If a newer, more expensive drug is not deemed to provide additional benefits over a cheaper treatment, then a subsidy is provided only to the

level of the least expensive alternative (Cassels 2002; Lopez-Casanovas and Puig-Junoy 2000; Nakagawa and Hudson 2000; Narine, Senathirajah et al. 1999; Nilsson and Melander 2000). Pharmacy Benefit Managers in the USA 'favour incremental therapy, using the more expensive drugs at a later stage' (Jacobzone 2000, p. 24). A spokesperson for the Wellpoint Health Network affirms that '(e)veryone is working feverishly to embrace reference-based drug pricing', described as 'the technique of establishing one reimbursement value for an entire class of drugs, based on the most efficient drug in that class' (Otrompke 2001, p. 33).

As noted, RP affects directly the reimbursement/subsidy level only, leaving suppliers free to price their products above that level. Prescribers and consumers also retain freedom of choice, though the intention behind the RP approach is to reinforce their price sensitivity. The result is a step towards free pricing in only a limited sense. The form of management of the market by governments or other bulk purchasers changes: rather than having to consider each and every product price, regulation now revolves around the clustering of products into groups, and the determination of the reference price. As a consequence, suppliers of referenced products are subjected to pressure to lower prices to a level approximating that of the reference product. In practice then RP 'might be seen as more "intelligent" price fixing, where prices are fixed according to the implicit characteristics of products' (Jacobzone 2000, p. 41).

The RP concept is easily grasped but technical designs can be exceedingly complex.[13] Arrangements differ with respect, most importantly, to the basis for the clustering of drugs into reference priced groups, which can be based on chemical equivalence only, and/or on the basis of pharmacological and therapeutic equivalence. In Denmark and Sweden what is referred to as RP essentially encompasses only the clustering of generics with chemically identical brand products. But RP can also represent an extension of the logic of generic substitution to chemically distinct entities that have been accepted by regulatory authorities as therapeutically equivalent. In Germany, the first country where RP was introduced (in 1989), reference prices are determined for three different types of drug groups. The first level entails a reference price for different versions of off-patent products with identical active ingredients. The effectiveness of this form of RP was extended in February 2002 when the 'or the same' box on scripts became the default option for doctors. Pharmacists in Germany are now obliged to recommend a version of the drug prescribed from among the cheapest third of those available (Orellana 2002). The second level pertains to 'drugs with pharmacologically and therapeutically comparable active ingredients', and the third to 'drugs with therapeutically comparable effects'. RP in Germany is said to have 'led to very significant savings: several billion deutsche marks every year in Germany' for the past decade (Jacobzone 2000, p. 42). In June 1998, as part of the introduction of a new health care bill, the German reference pricing market was extended by a further 15 drug groups. This measure, and other aspects of RP in Germany, has given rise to considerable tension with the originator industry (SCRIP 2001b; SCRIP 2001a). Similar issues have been controversial elsewhere, including in New Zealand, British Columbia, and Australia. In New Zealand, the RP approach 'caused a great deal of bitterness among companies' in the mid-1990s (St John 1996). Particularly sensitive, and seen by the originator industry as 'contrary to the spirit of

[13] See, for example, descriptions of the process of reference price setting in Germany London School of Economics (2002). Germany: Overview of the Health System. http://pharmacos.eudra.org/F3/g10/docs/tse/Germany.pdf.

intellectual property legislation', is the question of whether patented drugs should be included in the same groups as off-patent products (Lopez-Casanovas and Puig-Junoy 2000, p. 94). In Germany drugs that have received market approval after the end of 1995 cannot be included in a level 2 or 3 reference groups until their patents have expired (London School of Economics 2002).

British Columbia's Reference Drug Program (RDP) was introduced in 1995 and has given rise to a sizeable literature (Anis 2002; Cassels 2002; Kent 2000; Lindsay and West 1999; Maclure, Nakagawa et al. 2001; Menon 2001; Nakagawa and Hudson 2000; Narine, Senathirajah et al. 1999). RDP applies to drugs that are not identical, but belong within the same drug category and are used to treat the same conditions. Phamacare, the province's publicly funded drug insurance program, pays for the least expensive drug in a particular therapeutic class, unless a medical reason can be given for a more expensive alternative. Full public funding is provided if a patient needs a more expensive drug for medical reasons, following a doctor's application for special authorization. In 2000, a GP typically applied for 16 to 20 such applications per month (Kent 2000). If a non-reference drug is prescribed the province's computer system alerts the dispensing pharmacist, who provides the patient and/or doctor with the following options: to request a Special Authority; if there is no reason for a non-reference drug, for the doctor to change the prescription; or the patient may decide to pay the difference between the prescribed and the reference drug (Maclure, Nakagawa et al. 2001, p. 39). The primary focus of RDP is said to be on 'the baseline prescribing habits of physicians', seeking to ensure 'that the most cost-effective agent within a drug class is used initially' (Nakagawa and Hudson 2000).

RP can operate in the absence of generics, where a group of patented ('me-too') products with similar therapeutic effects are assigned a common reference price. In Australia, for example, listing of new medications is on an evidence basis, and many 'me too' products considered since 1993 have been listed on the basis of cost minimisation. As there is no demonstrated benefit over existing drugs, prices for the new products are referenced to the existing products. But in practice, in most systems, the reference price is derived directly from the cheapest generic, or, where arrived at through more complex calculations, is influenced substantially by the prices of generics.

Substitution rights and appropriate incentives for pharmacists are necessary for RP arrangements to enable generics suppliers to achieve a substantial market share. Even so, the generics industry does not necessarily prosper under RP schemes; there is no direct relationship between RP and the market penetration and pricing level of generics. RP operates in countries with high generic market share, such as Germany and the USA, as well as in countries with a low market for generics, such as Australia. The reference benchmark serves as a pricing floor, and generic as well as branded product prices will tend to converge at or close to that level, with consequent weak incentives for doctors to prescribe generics (or generically), or for consumers to request generic substitution. This is reported to be the pattern in Germany and Sweden where in the 1990s both branded and generic products eventually became uniformly priced at the reference level. In Sweden, the immediate effect of the introduction of a reference price system in 1993 'was that most original pharmaceuticals out of patent and high priced branded generics reduced their prices to the reference level' (Nilsson and Melander 2000). In New Zealand, it was the introduction of tendering for generics

from 1996 – rather than RP, practiced since the 1980s – which transformed the generics market from 'one that could be characterised as high-price, low-volume to one that can be characterised as low-price, high volume' (OXERA 2001, app. A9). Similarly in Australia, the introduction of the Therapeutic Group Premium (TGP) arrangements (an extension of RP) in 1998 (as further described in the next section) has not significantly facilitated an expansion of the generics industry.

The authors of a comprehensive review of the RP literature emphasise that published empirical studies do 'not allow for a clear-cut identification of the effects of RP in isolation from other regulatory policies or influential factors' (Lopez-Casanovas and Puig-Junoy 2000, p. 90). Most of the literature is descriptive, often with a polemical edge. For example, Furniss et al assert that 'most reference price systems are essentially arbitrary', that they undermine innovation, destroy market-based behaviour, and the RP approach has 'failed to deliver in practice' (Furniss, Edwards et al. 1999, pp. 11-12). A key objection is that the leveling of prices around the reference level creates an impediment to R&D, since the value of small-step, incremental innovation tend not to be recognised. Another theme in the critical commentary on RP relates to negative health effects where patients for an optimal outcome require a particular, more expensive, product within a reference category, but exceptions operate at the patient level in British Columbia, Denmark, Sweden, and elsewhere. Clearly, assessments of the RP approach need to be based on the study of the design and operation of specific programs, including outcomes in terms of health, government cost-savings and effects on various industry sectors.

Developments in Australian generic drugs policy

A challenge to the originator brand-sector, in terms of supply of generics in the PBS market, only began in the 1990s, but generic drugs have had an impact on the pricing of pharmaceuticals in Australia at least since the 1970s. Key policy junctures include the Generic Pricing arrangements of the 1980s, the Brand (or Minimum) Pricing Policy introduced in December 1990, the legalisation of brand substitution in 1994, and the Therapeutic Group Premiums (TGP) policy from February 1998.

The marketing approval requirements for generics until 1989 were virtually as demanding as for new chemical entities, and importation of generics in finished form was prohibitively complex. In that year, marketing approval was made speedier for generic than new drugs, along the lines of the post-1984 US system. Having been accepted by the TGA as bioequivalent, a generic has since been identified as such in the *Schedule of Pharmaceutical Benefits*. But the major historical impediment to the growth of the generics industry in Australia is that the PBS has provided no cost or other incentives for consumers, doctors, or pharmacists to choose generic products. In contrast, generics have been widely used in hospitals since the 1950s, where brand substitution has long been widely practiced.

In the late 1980s, generics accounted for less than 2 percent of dispensed PBS items. In June 1990, 88 percent of prescriptions are said to have been written for 'premium priced brands'. Two years later, this had declined to 77 percent, while prescribing for 'benchmark priced brands increased from 8 to 13% and generic or unbranded prescribing increased from four to 9%' (Australian Parliament 1993). The supply of

generics has since increased incrementally, but the generics market is considered still to be 'in its infancy' (Smeaton 2000). Precise data on its size are not readily available; the Productivity Commission (2001, p. 33) states that whilst Australia 'is considered to have a fairly significant generic market … the exact share is not known'. Yet it is reported authoritatively that:

> In cost terms, generics increased from 4.5 per cent in 1990/91 to 10.2 per cent in 1998/99, whilst prescription volumes rose from 5.0 per cent in to 15.5 per cent'. (Stevens 2001)

In 2000-01, generics made up close to 20 percent of all dispensed prescription drugs (PBPA personal communication), and the generics firm Alphapharm was the number one PBS supplier in volume terms (Pharmaceutical Benefits Pricing Authority 2000, p. 31).

The Commonwealth government made attempts in the 1980s to implement measures in support of the generics sector. In 1983, Health Minister Neil Blewett considered legislation permitting generic substitution. Glaxo in response considered entry into the generics market via one of its UK divisions then marketing a wide range of generics (Sparks 1984). In 1987 a proposal on generic substitution was presented to the health ministers' council, but ultimately failed due to opposition from doctors and the pharmacy sector (Australian Parliament 1993).

Until recently, as noted, generic drugs made up only a small proportion of drugs supplied in the PBS market, but price negotiations have long been affected by their existence. In the 1970s and 1980s, where more than one firm could potentially supply a product, brand companies were compelled by the Department of Health to accept prices approximating that of cheapest generic equivalent (even if the generic supplier in practice would not be able to meet a significant share of total demand). By 1983, around 80 percent of drug sales were accounted for by medicines for which generic versions were available, or which were potentially subject to generic competition (Industries Assistance Commission 1986, p. 38). PBS pricing arrangements in this period in effect delivered low prices without the physical market presence of generics. The near-monopoly supply of originator brands was further cemented by a perception within the medical and pharmacy professions of generics as second-rate products.

In May 1983 the new Labor Government made generic pricing formally binding in the form of the Generic Pricing Policy (sometimes referred to as the Generic Differential Policy). Previously other factors such as comparable UK prices were taken into account in determining Australian prices for out-of-patent products, but this approach was now expressly abandoned. The immediate aim was to achieve budgetary savings through a maximum price premium of 5 cents for a PBS out-of-patent originator brand drug over a generic version of the same product. The brand industry alleged a lack of consultation on this policy, and reacted strongly to its expected impact on profitability (Industries Assistance Commission 1986, p. 35). The introduction of formal generic prices was seen as a sharpening of the long-standing policy objective of paying lowest possible prices consistent with reliable supply. Nor was this approach welcomed by the generics industry, since it provided little prospect of increased demand for generics.

The Department of Health requested almost immediately that more than twenty manufacturers reduce a number of product prices in compliance with the mandated generic pricing differential. Following lobbying by affected companies and the Australian Pharmaceutical Manufacturers Association (APMA)[14], implementation of the Generic Pricing Policy was deferred until October 1983. In the next budget, the differential was increased to 10 cents for prices negotiated from 29 February 1984, but implementation was postponed until after an IAC inquiry into the industry. In the meantime, the 5 cents differential was expected to deliver savings in the 1984-85 year corresponding to 1.3 percent of Government outlays on the PBS (APMA 1985). Following the release of the 1986 IAC report, the Generic Pricing Policy was reconfirmed with a decision to apply a 20 cents differential from September 1987. Again, lobbying resulted in delay of implementation until December 1988 when the price of all out-of-patent products were to be reduced to within 20 cents of the lowest priced generic, or be delisted from the PBS. Eight companies initially refused to accede to these price decreases, which resulted in the delisting in April 1989 of twelve products. Within a few months, however, these drugs were again listed on the PBS at the lower price (Sloan 1995, pp. 61-62). By this stage, tensions between the Department of Health and the brand industry had made the Generic Pricing Policy unsustainable. The capacity of the Department of Health to unilaterally determine pricing arrangements was weakened with the government's shift towards a more industry-friendly position, as evidenced by the 1987 launch of the Factor (f) program and the 1991 Baume-review of the TGA (Lofgren 1997).

This was the context, then, for the introduction in December 1990 of a reference-pricing arrangement with greater pricing flexibility for suppliers, known first as the Minimum Pricing Policy, later as the Brand Premium Policy or the Brand Pricing Policy (Pharmaceutical Benefits Pricing Authority 2000, p. 8). Its basis is a fixed reimbursement price derived from the lowest priced brand of products considered interchangeable, the so-called benchmark brand. Direct price controls were thereby made redundant, and a measure of price competition made possible by allowing suppliers to set their own price for multi-branded products. For products other than the benchmark product, consumers pay the basic patient contribution plus the price differential over the lowest priced brand, with the price premium not counting towards the safety net. This introduced a financial incentive for consumers to accept or request the lowest priced brand in a class of drugs approved for a particular indication. But while the role of the patient in the decision-making process was given explicit recognition, this choice remained constrained in the absence of brand substitution. In reality manufacturers rather than consumers were given more choice. Suppliers could set their own price on multi-brand products, while consumers remained obliged to accept the particular brand specified by the prescribing doctor. Unless a prescription was written generically or the lowest priced brand specified, the patient had to pay a brand premium on top of the copayment (if applicable). Nor were any concerted efforts instituted to encourage doctors to prescribe generically. For its part, the APMA accompanied an endorsement of the Minimum Pricing Policy with the cautioning of doctors and consumers against choice of the cheapest brand. An explicit aim of the new policy was to support the development of an Australian generics industry. Without provisions for brand substitution or effective measures to foster generic prescribing, it could not be expected however that the Minimum Pricing Policy would

[14] In 2002 renamed Medicines Australia.

have a significant impact on dispensing patterns. Most doctors continued to prescribe brand name products, and generic companies increased their PBS market share only marginally in the first years after December 1990.

Generic or brand substitution, allowing pharmacists to substitute a generic for an original product (if not disallowed by the prescribing doctor) was introduced in December 1994, accompanied by intense public debate and concerns expressed by the originator industry and sections of the medical and pharmacist professions. 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, though pharmacists are unable to substitute between different chemical entities. This arrangement applies to four groups of products, where the lowest priced brand sets the benchmark price.

At 30 June 2001 the TGP policy comprised 190 brands at the benchmark level, 33 brands with a brand premium, and 22 with a therapeutic premium, ranging from $1.40 to $7.01 (Pharmaceutical Benefits Pricing Authority 2001). The effect then would seem to be for prices to converge at or close to the benchmark level. The TGP policy is criticized, 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, p. 4-5). The APMA/Medicines Australia claims that it sacrifices 'optimal patient care for cheapest patient care, putting patients' health at risk' (APMA 1997). The brand industry's aversion towards Australia's form of reference pricing is further demonstrated by the Pharmaceutical Research and Manufacturers of America (PhRMA) referring the TGP policy as an intervention undermining 'the protections afforded by, inter alia, the TRIPS Agreement, the Agreement on Government Procurement, the TRIMS Agreement and GATT Article III (see http://www.phrma.org/intnatl/multilat/agservices.phtml). Brand industry criticism of the operation of the TGP policy resulted in a review (that commenced in September 2000) of the methodology employed to calculate monthly treatment costs used in product comparisons used in these groups and other products that have been listed under the cost minimisation approach.

PBS listing, where proposals entail new, patented drugs, entails complex assessments, and often difficult price negotiations. There are few formal hurdles however to the PBS listing of new brands of already listed products. Listing of a new brand is relatively easy in that all that needs to be established is bio-equivalence. Sponsors of the new brand are able to list at a price of their choosing – it can be below, equal to, or above the benchmark price. Suppliers are free to charge a brand premium to be paid by the consumer. However, if below the benchmark price, suppliers of alternatives are advised that the benchmark has been reduced. Applications to list a new brand at a price lower than the current benchmark price are similarly facilitated, though assurance must be given of capacity to supply at least 20 percent of the market where a new brands becomes the benchmark product. Where a benchmark priced drug is considered clinically inappropriate the prescriber can apply to the Health Insurance Commission for an exemption to supply a more expensive alternative drug at not extra cost to the patient.

Price competition, and the notion of support for the development of a generics industry, is by now an integral feature of PBS policy to contain cost increases. With around 14 percent average annual PBS expenditure growth over the 1990s, the question is how price competition is to be managed most effectively.

Policy models with respect to generic drugs in the PBS market

A high percentage of all dispensed prescriptions could conceivably be filled generically.[15] Even more importantly, generic competition has the effect, over time, of substantially lowering the prices of all brands of a particular product (see project paper by Sweeny). At issue is the precise mechanisms whereby price competition and generic substitution can be appropriately encouraged, the magnitude of the savings that can be generated for various categories of payers, and the impact of generic competition on different stakeholders.

The generics industry has an interest in expanding volume (market share), but not necessarily in the lowering of prices beyond the level that will deliver volume growth. Consumers have an immediate interest in substitution as a means of minimising costs. The originator industry is driven by the commercial imperatives of retaining market share and of minimising price declines. From the point of view of PBS cost-containment, the situation looks quite different depending on whether the analysis is grounded in a short-term or dynamic perspective. At first glance it would appear that a growth in the volume of scripts filled by generics will not substantially affect the PBS cost to taxpayers since generics prices typically approximate those of originator brands, as further discussed below. However, the analysis presented by Sweeny (project paper) of price developments in particular markets following the commencement of generic competition demonstrates a substantial reduction of prices over time. But the question remains how Australian prices arrived at, say, five years after the commencement of price competition compares to 'global' generics prices or to prices in particular overseas markets. Suffice to note here that conflicting claims are made with respect to the question of generics prices in Australia. The predominant view appears to be that the market is shaped by the historical legacy of small differentials between the prices of branded and generic drugs, resulting in a high-cost/low volume generics market. Nonetheless, the GMiA claims that generics have saved taxpayers in the order of $850 million since 1995 even with significant obstacles at the level of doctor and pharmacy practices (personal communication).

Viable generic firms are required for price competition to occur, and this necessitates acceptance of generics and generic substitution by consumers, pharmacists and doctors. The savings that consumers could achieve if benchmark drugs were dispensed consistently are in the order of $56 million annually ($1.68 x 33.4m - weighted average brand premium times prescriptions dispensed with a brand premium) (Pharmaceutical Benefits Pricing Authority 2001, p. 13). This in terms of the overall PBS market is a small amount. Therapeutic substitution – that is, the replacement of a pharmaceutical substance with a drug with a different chemical composition, usually but not always in the same therapeutic class – which is currently

[15] The British Generic Medicines Association claims: 'If all prescriptions for medicinal products which are not covered by patent were filled generically, the proportion met by generics would rise from 52% to around 80%' [in the UK] (http://www.britishgenerics.co.uk/bgma.htm).

not legal, would also in the short term have little effect on aggregate expenditure. It should be noted however that this assessment does not take into account savings made by general patients when purchasing drugs that are priced below the general co-payment level of $22.40 (this could be considerable as most generic products are low priced).

It would seem then that greater acceptance of generics can have only marginal, if any, immediate effects on government PBS expenditure. But this conclusion applies only if dynamic developments are disregarded. From a government cost-containment perspective, as noted, the key factor is the overall impact of generic competition on the prices of both originator brands and generic equivalents. The level of savings from the brand premium policy can thus be significant whilst the price differentials between brands are small. The reason for this is that the suppliers of originator brands do not like to have too much of a price difference, as this would result in the loss of market share. Omeprazole provides a case in point. The current dispensed price (September 2002) for Losec is $47.65, only $1.50 above the price of the Alphapharm brand. However, when the generic was first listed, the benchmark price was reduced by 25 percent and there was a subsequent 22 percent reduction – which means in effect that the current benchmark price is about half that prior to the entry of the generic.

Notwithstanding some initiatives in the past decade to encourage the use of generics, the Australian generics market remains underdeveloped by comparison with many other countries (Smeaton 2000). Generic (brand) substitution, possible since 1994, is yet to be generally accepted by prescribers, dispensers and consumers. Generic prescribing is encouraged in medical schools, and is the established norm in hospitals, but brand prescribing remains routine in private medical practice and 'no substitution' is the default setting in commonly used prescribing software. Similarly, pharmacists often retain a preference for original brand products and intense marketing efforts are required to make pharmacists stock generics and support substitution. It is believed that in the order of 20 percent of pharmacists generate around 80 percent of all substitutions (personal communication). In the year to May 2001, where brand substitution is possible, 47 percent of prescriptions were filled at the benchmark level. Consumers accepted to pay a brand premium, or were perhaps not presented with the option of choosing an alternative benchmark product, in the case of 53 percent of prescriptions (Pharmaceutical Benefits Pricing Authority 2001).

Policy measures in respect of generic medicines in Australia can be conceived as clustering around two different approaches. The first entails incremental measures within the existing regulatory framework, such as the announcement in the May 2002 budget that the government 'will regulate to ensure that prescribing software used by doctors enables the use of generic drugs, unless the doctor consciously chooses a brand name alternative' (Department of Health And Ageing 2002). This would be premised on the expectation that opportunities for generics suppliers will expand by default as patents expire, and the focus is on information and education programs to encourage generic prescribing by doctors, generic substitution by pharmacists, and general consumer acceptance of generics. The use of information technology can enhance the effectiveness of this approach: online systems can generate information automatically for doctors about generically and therapeutically equivalent drugs, as

well as benchmarking data prescribing patterns.[16] Presently, the Australian market sustains six companies supplying generics to the PBS. Five of these are estimated to have a share of the generics market of between 3 and 8 percent (Arrow Pharmaceuticals, Biochemie Australia, Douglas Pharmaceuticals, Hexal Australia, and Mayne); Alphapharm alone supplies more than 70 percent of all generics. Their prices are by definition below those of the originator brands but, as already discussed, are not necessarily substantially lower.

The second approach would seek purposefully to bring about a shift to a high volume/low price role of generics in order to speed-up the delivery of substantial cost savings. This could probably occur only within the context of a shift to a different overall pricing system, which raises complex issues not addressed in this paper. However, current arrangements arguably provide little incentive for generic suppliers to compete aggressively on price, since 'true prices' in the global generics market are unlikely to be reflected in PBS pricing. The introduction of competitive tendering for generic drugs would be a radical way of taking advantage of the existence of a distinct global generics market. The impetus for a consideration of the competitive tendering model comes from developments in New Zealand and the UK. PHARMAC, the agency managing New Zealand's pharmaceutical schedule, first implemented competitive tendering for generics in 1996. Two firms then dominated the New Zealand generic market, and prices were 'close to the prices of branded equivalents' (OXERA 2001, appendix A9). From initial tendering for one product (paracetamol), PHARMAC by January 2001 had advanced to the point of initiating 'the largest ever tender, involving some 153 products' (PHARMAC 2001, p. 17). Tenderers bid for sole-subsidised supplier status, which entails an obligation to meet total market demand for three years, and allows for bulk purchase of chemicals and economies of scale to be achieved in the production process. The agency also enters into price-reduction agreements with suppliers in exchange for the exclusion of products from sole supply tender invitations.

Centralised tendering in New Zealand has resulted in a significant decrease in off-patent pharmaceutical prices, and is said to have provided scope for the listing of 'uniquely new chemical entities and new formulations of previously-funded pharmaceuticals that are associated with significant patient benefits' (PHARMAC 2001, 18). Savings from tendering are said to be in the order of 15-20 percent. Before tendering:

> …the two generics suppliers [Douglas and Pacific, a subsidiary of E-Merck] shared the market with multi-nationals which controlled approximately 60% of the market with branded drugs. After tendering began, the generics firms were willing to undercut the branded prices (i.e., choosing high-volume, low-cost).

It is reported that '(o)verall, the New Zealand move to centralised purchasing of pharmaceuticals has gone quite smoothly' (OXERA 2001, Appendix A9).

[16] In the UK doctors are assisted by computer databases listing generics; more than 70 percent of prescriptions are written generically and 52 percent are dispensed generically Department of Health (2001). *Options for the Future Supply and Reimbursement of Generic Medicines for the NHS: A Discussion Paper*. London. http://www.doh.gov.uk/generics/options_paper.pdf.

The UK Department of Health has paid tendering arrangements in New Zealand close attention in the context of a review of the market for generic medicines, initiated in 1999 following unanticipated supply problems and price increases for generic drugs (Department of Health 2001). The Department commissioned a consultancy study, presented in September 2000 (OXERA 2001). One of two options now considered is the introduction of centralised purchasing through competitive tendering, and eport suggests several ways in which this might be done. Its favoured model would entail the Department letting contracts by competitive tender for the exclusive right and obligation to supply a specified volume of a specific preparation at a specified price to community pharmacists and dispensing GPs.

A competitive tendering model for Australia could add to tensions between the R&D based industry, the generics sector, and government, and would need to be considered within the context of the National Medicines Policy which has a viable pharmaceutical industry as one of its aims (Department of Health and Aged Care 2000). Arguably, however, the Commonwealth should accept to pay prices for off-patent drugs reflecting real conditions in the global generic medicines market.[17] If the Commonwealth wishes to provide direct support for industry development, this should arguably take the form of transparent budget allocations, not artificially high product prices, consistent with the design of the Pharmaceutical Industry Investment Program (PIIP) and its predecessor, the Factor (f) scheme. In New Zealand the political fall-out from reference pricing and generics tendering was manageable because there was no primary pharmaceutical research undertaken (except with respect to a very narrow range of cancer drugs) and 'there was no substantial pharmaceutical industry presence' (OXERA 2001, appendix A9). By contrast, in Australia the government is seeking to provide a supportive regulatory environment to facilitate the growth of an important high-tech industry (Hill, Kirchner et al. 2001; Pharmaceutical Industry Action Agenda 2002). It is critical then that policy affecting the generics market be structured in way that does not put at risk the overall development of pharmaceutical industry activities. The focus would need to be on facilitating the use of lower-priced generics as a means of providing scope for the financing of innovative, patented drugs within a sustainable PBS.

[17] The precise nature of conditions in this rapidly changing and globalising market may be difficult to establish. The UK Department of Health noted that there is a 'lack of transparency over the nature of the market and prices', and that its '(I)nvestigation of the market over the last two years has underlined how little information the Department has about the true level of competition in the generics market' Ibid.

References

Anis, A. (2002). "Why is Calling an ACE an ACE so Controversial?: Evaluating Reference-Based Pricing in British Columbia." *Canadian Medical Association Journal* 166(6): 763-764.

APMA (1985). *Comments on the Bureau of Industry Economics Submission to the Industries Assistance Commission Inquiry into the Pharamceutical Industry*. Sydney, Australian Pharmaceutical Manufacturers Association.

APMA (2002). Briefing Papers: Generic Medicines. <www.apma.com.au>

Appleby, J. and J. O'Donnell (2002) "Consumers Pay as Drug Firms Fight over Generics". *USA Today*. 6 June, pp. 01A.

Australian Economic Analysis Pty Ltd (1998). *Pharmaceuticals and Australia's Knowledge Economy.* Sydney, APMA.

Australian Journal of Pharmacy (2001). "Capital Hill: Balancing Standards and Costs." *Australian Journal of Pharmacy* 82(September): 812.

Australian Parliament (1993). *Department of Health, Housing, Local Government and Community. Senate Estimates Committee C*. Canberra.

Barr Laboratories (2002). History of Generic Industry. <http://www.barrlabs.com/pages/induhist.html>

Barrett, A. (2002). "No Quick Cure for Big Pharma." *Business Week Online* (May 6). <http://www.businessweek.com/>

Berger, S. (2001) "Teva Becomes World Largest Generic Drug Maker". *Jerusalem Post*. 26 July, pp. 14.

Berndt, E. R. (2001). "The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" *Health Affairs* 20(2): 100-114.

Burstall, M. L., B. G. Reuben, et al. (1999). "Pricing and Reimbursement Regulation in Europe: An Update on the Industry Perspective." *Drug Information Journal* 33(3): 669-.

Cassels, A. (2002). *Paying for What Works: BC's Experience with the Reference Drug Program as a Model for Rational Policy Making*. Vancouver, Canadian Centre for Policy Alternatives. <http://www.policyalternatives.ca/>

Congressional Budget Office (1998). *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*. Washington, Congress of the United States. <http://www.cbo.gov/>

Department of Health (2001). *Options for the Future Supply and Reimbursement of Generic Medicines for the NHS: A Discussion Paper*. London. <http://www.doh.gov.uk/generics/options_paper.pdf>

Department of Health and Aged Care (2000). National Medicines Policy. <http://www.health.gov.au/pbs/natmedpol/nmp2000.pdf>

Department of Health And Ageing (2002). Portfolio Budget Statements. <http://www.health.gov.au/budget2002/index1.htm>

Evers, P. (2001). "Generics Past, Present and Future." *Pharmaceutical Times* (October): 30-32.

Ferrandiz, J. M. (1999). "The Impact of Generic Goods in the Pharmaceutical Industry." *Health Economics* 8: 599-612.

Furniss, J., J. Edwards, et al. (1999). "Reference Pricing: Why Hope cannot Triumph over Reality." *Scrip Magazine* (October): 11-15.

Gambardella, A., L. Orsenigo, et al. (2000). *Global Competitiveness in Pharmaceuticals: A European Perspective*, Prepared for the Directorate General Enterprise of the European Commission. <http://www.unisi.it/epris/3.htm>
Gleckman, H. (2002). "The Backlash Against Big Pharma." *Business Week Online* (May 27). <http://www.businessweek.com/>
Glover, G. J. (2002). Hearing on Generic Pharmaceuticals: Marketplace Access and Consumer Issues April 23, Commerce, Science and Transportation Committee of the United States Senate. <http://commerce.senate.gov/hearings/042302glover.pdf>
Griffith, V. (2001) "Eli Lilly hit as Prozac Users Switch to Generics". *Financial Times*. August 21.
Harnden, D. (1998). "Can Generics Survive under Hatch-Waxman?" *Scrip Magazine* (December): 32-34.
Hess, G. (2002). "Pharmaceutical Industry to Fight All Efforts by Generics Makers to Weaken Patent Protection." *Chemical Market Reporter* 261(9).
Hill, J., A. Kirchner, et al. (2001). Pharmaceutical Industry Action Agenda: Discussion Paper, Pharmaceuticals Section, Department of Industry, Science and Resources.
Industries Assistance Commission (1986). *Pharmaceutical Products*. Canberra, Industries Assistance Commission.
International Federation of Pharmaceutical Manufacturers Associations (1997). The role of Generics. <http://www.ifpma.org/>
Jacobzone, S. (2000). *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals*. Paris, OECD.
Kent, H. (2000). "BC's Reference-Based Pricing Stirs Controversy." *Canadian Medical Association Journal* 162(8): 1190.
Lewis, G. (2001). The Generics Market: Current and Future Status, European Generics Association. <http://www.imshealth.com/>
Lindsay, R. and D. S. West (1999). "National Pharmacare, Reference-Based Pricing, and Drug R&D: A Critique of the National Forum on Health's Recommendations for Pharmaceutical Policy." *Canadian Public Policy* 25(1): 1-25. <http://www.econ.queensu.ca/pub/cpp/mar1999/LINDSEYchap.pdf>
Lipson, D. (2001). "A Five-Year Forecast: Clear Seas Ahead?" *Pharmaceutical Executive* 21(October).
Lofgren, H. (1997). "Industry Policy to Set the Market Free: Drug Pricing and the Factor (f) Program." *Labour & Industry* 8(2): 67-84.
London School of Economics (2002). Germany: Overview of the Health System. <http://pharmacos.eudra.org/F3/g10/docs/tse/Germany.pdf>
Lopez-Casanovas, G. and J. Puig-Junoy (2000). "Review of the Literature on Reference Pricing." *Health Policy* 54: 87-123.
Maclure, M., R. S. Nakagawa, et al. (2001). 'Applying Research to the Policy Cycle: Implementing and Evaluating Evidence-Based Drug Policies in British Columbia'. *Informing Judgment: Case Studies of Health Policy and Research in Six Countries*, ed. D. M. Fox and A. D. Oxman. New York, Milbank Memorial Fund: 36-70.
McCarthy, M. (2002). "US States File Lawsuit against Bristol-Myers Squibb." *Lancet* 359(9323): 2092.
Menon, D. (2001). "Pharmaceutical Cost Control in Canada: Does it Work?" *Health Affairs* 20(3): 92-103.
Morris, J. (2001). "Following the Smart Money." *Scrip Magazine* (June): 6-7.

Mrazek, M. F. and E. Mossialos (2000). "Increasing Demand while Decreasing Costs of Generic Medicines." *Lancet* 356(9244): 1784-1785.
Nakagawa, B. and R. Hudson (2000). "Reference-Based Pricing." *Canadian Medical Association Journal* 162(1): 12-14.
Narine, L., M. Senathirajah, et al. (1999). "Evaluating Reference-Based Pricing: Initial Findings and Prospects." *Canadian Medical Association Journal* 161: 286-288.
Nilsson, J. L. G. and A. Melander (2000). "Use of Generic Drugs and Effects of the Reference Price System in Sweden." *Drug Information Journal* 34(4): 1195-1200.
Orellana, C. (2002). "Germany Brings in Generic-Drug Plan in a Bid to Cut Costs." *The Lancet* 359(9309): 862. <http://www.thelancet.com/journal/vol359/iss9309>
Otrompke, J. (2001). "Changing the Formulary Format Puts the Focus Back on Value." *Managed Healthcare Executive* November: 33-34. <http://www.managedhealthcareexecutive.com/mhe/data/articlestandard/mhe/022002/6351/article.pdf>
OXERA (2001). *Fundamental Review of the Generic Drugs Market*. London, Department of Health. <http://www.doh.gov.uk/generics/oxera_report_no_frames.htm>
PHARMAC (2001). Annual Review. <http://www.pharmac.govt.nz/download/AnnRvw-2001.pdf>
Pharmaceutical Benefits Pricing Authority (2000). *Annual Report For the Year Ended 30 June 2000*. Canberra, AusInfo.
Pharmaceutical Benefits Pricing Authority (2001). *Annual Report for the Year Ended 30 June 2001*. Canberra, AGPS.
Pharmaceutical Industry Action Agenda (2002). *Local Priority: Global Partner*. Canberra, Department of Industry Science and Resources. <http://www.industry.gov.au/library/content_library/Pharmaceuticals_Industry_Action_Agenda.pdf>
Productivity Commission (2001). *International Pharmaceutical Price Differences: Research Report*. Canberra, AusInfo.
Redmond, C. (2001). "Branding: Change & Challenge." *Pharmaceutical Executive* 21(9): 58-66.
Santini, L. (2001). "Strong Medicine." *Investment Dealers Digest*.
SCRIP (2001a). "Germany HM Promises Ref Price Review." *SCRIP* (2616): 6.
SCRIP (2001b). "Challenge to German Reference Prices." *SCRIP* (2605/06): 5.
Sloan, C. (1995). *A History of the Pharmaceutical Benefits Scheme 1947-1992*. Canberra, AGPS.
Smeaton, J. (2000). "The Generics Market." *Australian Journal of Pharmacy* 81(963): 540-542.
Sparks, N. (1984). *Strategic Analysis of Establishing a Generic Pharmaceutical Operation as a Division of Glaxo Australia Pty. Ltd.* Melbourne, University of Melbourne.
St John, P. (1996). "Confronting the Issue of Drug Pricing." *Scrip Magazine* (October): 57-60.
Stevens, A. (2001). Country Profile: Pharmaceutical Pricing and Reimbursement Policies in Australia, LSE Health. <http://pharmacos.eudra.org/F3/g10/docs/tse/Australia.pdf>
The Economist (2002). "Generic Gadfly." *The Economist* 363(8268): 65.
Toner, R. (2002) "Rising Drug Costs a Powerful Issue for National and State Politicians". *New York Times*. 1 April.

U.S. Senate Health, E., Labor and Pensions Committee, (2002). *Chairman U.S. Senator Edward Kennedy (D-MA) Holds Hearing on Generic Pharmaceuticals, 8 May*, Washington Transcript Service.
Wechsler, J. (2001a). "Pressure Mounts to Revise Generic Drug Policies." *Pharmaceutical Technology* (February): 16-25.
Wechsler, J. (2001b). "Generics Debate Escalates." *Pharmaceutical Executive* (February): 22-24.
Wechsler, J. (2001c). "Industry Under Investigation." *Pharmaceutical Executive* (June): 24-28.
Wechsler, J. (2002). "Debate and Estimates Rise Over Medicare Drug Benefit." *Pharmaceutical Executive* (April): 21.