

Generic drugs: international trends and policy developments in Australia

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Abstract

Public and private third-party payers in many countries encourage or mandate the use of generic drugs. This article examines the development of generics policy in Australia, against the background of a description of international trends in this area, and related experiences of reference pricing programs. The Australian generics market remains underdeveloped due to a historical legacy of small Pharmaceutical Benefits Scheme price differentials between originator brands and generics. It is argued that policy measures open to the Australian government can be conceived as clustering around two different approaches: incremental changes within the existing regulatory framework, or a shift towards a high volumelow price role of generics which would speed up the delivery of substantial cost savings, and could provide enhanced scope for the financing of new, patented drugs.

Introduction

The escalating cost of medicinal drugs is causing increasing concern both in Australia and overseas. In the 2002-2003 budget the Australian government proposed a 30% increase in both patient co-payments and safety net thresholds to transfer more of the costs of the PBS from government to consumers. This initiative was subsequently blocked by the Senate because of concern that it would reduce equity of access to necessary medicines by poorer Australians.

More recently, the government's \$24 million 'PBS Community Awareness' advertising campaign noted that, '[t]he cost of the PBS is currently over \$4.5 billion a year. And it's increasing rapidly. In the last four years it's gone up by over 60%. If the costs keep rising at this rate the whole scheme may eventually become unsustainable' (Department of Health and Ageing 2003). A commentary on this campaign noted that by focusing solely on patient behaviour and 'waste' the government had lost an opportunity to initiate a balanced and constructive debate about the future viability of the PBS (Doran and Henry 2003). Such a discussion must consider the prices of drugs negotiated under the PBS and in particular the effectiveness of generic drug policy, reference pricing, and other strategies aimed at more cost-effective drug use. These issues are especially topical given recent controversies over the US-Australian free trade agreement. In January 2003, the Pharmaceutical Research and Manufacturers of America (PhRMA) lobbied US trade negotiators to seek Australian government commitments to 'refrain from trade distorting, abusive, or discriminatory price controls such as current PBS "reference pricing" priorities' (Burton 2003).

This paper addresses the role of generics and reference pricing programs in international markets, and the development of generics policy in Australia, and seeks to delineate present challenges.

The essential attribute of generics 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 and generic substitution. 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 strategies for drug expenditure control’ (Lopez-Casanovas and Puig-Junoy 2000: 91) – is based on the principle that a drug’s benefits should be compared systematically to alternative drug treatments. In Australia, the proportion of Pharmaceutical Benefit Scheme (PBS) scripts filled by generics makes up around 20 percent of the total market and it is expected that this share will continue to grow.

Policy in this area is fraught with contention arising inescapably from the fact that generic drugs – and indeed products with similar therapeutic effects – invite cost 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 pressures on originator-firms to develop and deliver innovative NCEs (new chemical entities). 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 autonomy of doctors. The response by R&D-based firms to generic 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, including the development of new patented products that in effect do not differ from existing drugs (Redmond 2001, Productivity Commission 2001: 54).

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). Generics 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. Obstacles to the market entry of generics in most instances are not technical, but derive from institutional arrangements, including the prescribing behaviour of doctors, brand loyalties, and regulatory and reimbursement systems, including retail pharmacy regulation and practices.

Generics have a long history, but the 1984 US Drug Price Competition and Patent Restoration (Hatch-Waxman) Act was the decisive moment in the development of the generics industry. 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). 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. By 1997, 63 percent of Health Maintenance Organizations are said to have imposed mandatory generic substitution (Mrazek and Mossialos 2000). When a generic now enters the US market, ‘the bottom almost immediately falls out of a branded product’s volume’ (Lipson 2001). It is reported, for example, that Eli Lilly lost 80 percent of its US market share for Prozac in the first week following the beginning of generic competition 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) however accept generics as interchangeable.

Generics have to meet the same standards as the innovators’ brand name products, and price is the only substantive difference. Critical commentary on the role of generics has therefore shifted from a focus on intrinsic product attributes, to arguments pertaining to, for example, the importance of information provided by brand suppliers to doctors, and the economic effects on different sections of the pharmaceutical industry, notably in terms of return on investment in innovation. Problems of non-equivalence in some instances, and the vulnerability of some patients to sudden brand changes, figure in the debate on generic substitution, highlighting that subsidy systems must 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 between different categories of payers, and the consequent commercial impact on the originator and generics sectors.

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. Conversely, brand name drugs met 55 percent of all prescriptions, accounting for approximately 91.6 percent of total consumer spending. Advocates of measures to facilitate the up-take of generics argue 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). 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 (Department of Health 2001: 3).

Generic suppliers emerged historically in separation from the research-based industry – the so-called Big Pharma sector – but there is today interdependence and overlap between the innovator and generics sectors. Brand name firms often supply drugs also under generic labels, drawing on technical and production factors to establish first-mover advantages. 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. For example, Acimax sold by Alphapharm in Australia is made by AstraZeneca, and is in every respect identical to Losec (Probyn 2002). Generics firms typically have production costs similar to those of Big Pharma, and the key difference is that generic firms expend less on marketing and R&D (Burstall, Reuben, and Reuben 1999).

The generics industry is dominated by multinational firms such as Ratiopharm International (Germany), Ranbaxy (India) and Merck KGaA (Germany), and is represented by national and international industry associations. Teva Pharmaceutical Industries (Israel) 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 with six member firms (Alphapharm, Arrow Pharmaceuticals, Biochemie Australia, Douglas Pharmaceuticals, Hexal Australia, and Mayne). Plainly the regulatory issues pursued by the GMiA and its counterparts often conflict with the position of the brand industry. Yet there is a perplexing blurring of boundaries, as exemplified by Douglas Pharmaceutical's alliances and distribution agreements with several multinationals including Pfizer, Merck Sharp & Dohme, and Eli Lilly, 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 gives rise to extensive legal and political wrangling in the US and elsewhere (Santini 2001, Wechsler 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, Australia, and elsewhere.

The generics market in the USA, the EU and Japan in 2000 was estimated at around US\$33 billion, and is said to be growing at a rate of 10-15 percent, 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.

The growth of the generics sector is a challenge to Big Pharma. Industry observers note however that R&D based firms have 'learned how to prosper even in the face of generic erosions' (Lipson 2001, Berndt 2001). Moreover, vigorous competition in the off-patent sector is a powerful stimulus for innovation: expectations of a rapid decline in sales revenue following patent expiry provide a strong incentive to engage in research and to achieve other efficiency gains (Gambardella, Orsenigo and Pammolli 2000). The originator sector benefits also, at least under certain conditions, from the lessening of pressures for stringent cost-cutting measures resulting from the availability of cheaper generics, allowing private and public purchasers to pay higher prices for innovative NCEs.

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 and Smith 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: 91). The term reference pricing is thus not strictly accurate: rather it is the reimbursement level that is controlled for a cluster of drugs. RP is a key feature of cost-containment arrangements in many jurisdictions, including Germany, Sweden, Denmark, Italy, New Zealand, the Canadian province of British Columbia, Spain and Australia. Pharmacy Benefit Managers in the USA similarly 'favour incremental therapy, using the more expensive drugs at a later stage' (Jacobzone 2000: 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: 33).

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 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, and Smith 1999, Nilsson and Melander 2000).

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. Governments or other bulk purchasers no longer need to consider each and every product price; instead the focus is on the clustering of products into groups, and the determination of a 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: 41).

The RP concept is easily grasped but technical designs can be exceedingly complex. Arrangements differ with respect, most importantly, to the basis for the clustering of drugs into reference priced groups, which can be based on bioequivalence only, and/or pharmacological and therapeutic equivalence. In Denmark and Sweden what is referred to as RP encompasses essentially the clustering of generics with chemically identical brand products. 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 has 'led to very significant savings: several billion deutsche marks every year in Germany' for the past decade (Jacobzone

2000: 42). Several aspects of RP in Germany have given rise to tension with the originator industry. RP has been controversial also, for example, 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 is the question of whether patented drugs should be included in the same groups as off-patent products. In Germany drugs that have received market approval after 1995 cannot be included in level 2 or 3 reference groups until their patents have expired (London School of Economics 2002).

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, PBS listing of new medications is on an evidence basis, and this kind of cost minimization has been applied to many 'me too' products considered for listing since 1993. Where there is no demonstrated benefit over existing drugs, prices for the new products are referenced to already listed equivalents. 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.

The generics industry does not necessarily prosper under RP schemes and there is no direct relationship between RP and the market penetration and pricing level of generics. RP operates in countries with both high generic market share, such as Germany and the USA, as well as in countries with a low market share, such as Australia. Substitution rights and appropriate incentives for pharmacists are necessary for RP arrangements to enable generics suppliers to prosper. The reference benchmark can otherwise serve as a pricing floor, forcing generic and branded product prices towards convergence, 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).

The authors of a comprehensive literature review emphasize that published 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: 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 behavior, and have 'failed to deliver in practice' (Furniss et al. 1999: 11-12). A key objection is that the levelling of prices around the reference level creates an impediment to R&D, since the value of small-step, incremental innovations tends not to be recognized. Another theme in critiques of RP is the risk of negative health effects where in order to ensure an optimal outcome a patient requires a particular, more expensive, product within a reference category. However, exceptions operate at the patient level in British Columbia, Denmark, Sweden and elsewhere. Clearly, assessments of the RP approach should not be based on generalizations but must take into account the design and operation of specific programs, including outcomes in terms of health, government cost-savings and effects on various industry sectors.

Australia introduced a form of RP in the latter half of the 1980s, with the commencement of PBS 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 has concluded that the application of RP in the 1990s 'may have been significant' in keeping Australia's prices relatively low (Productivity Commission 2001: xxx).

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 since at least the 1970s. In the late 1980s, generics accounted for less than 2 percent of dispensed PBS items. In 2000-01, this figure had reached close to 20 percent (Pharmaceutical Benefits Pricing Authority, personal communication). 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.

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 NCEs, along the lines of the post-1984 US system. But the major historical impediment to the growth of the generics industry in Australia has been a lack of consumer and prescriber cost incentives due to small price differentials.

In the 1970s and 1980s, where more than one firm could potentially supply a product, brand companies were compelled to accept prices approximating that of the cheapest generic equivalent even if the generic supplier in practice would not be able to meet a significant share of total demand. PBS pricing arrangements in this period in effect delivered low prices without the physical market presence of generics.

In May 1983 the generic pricing was made formally binding in the form of the Generic Pricing Policy. 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 (Industries Assistance Commission 1986: 35). 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, renamed Medicines Australia in 2002), implementation of the Generic Pricing Policy was deferred, and in the next budget, the differential was increased to 10 cents. Following a general inquiry into the pharmaceutical industry in 1986, the Generic Pricing Policy was reconfirmed with a decision to apply a 20 cent differential from September 1987. Brand industry 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. 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: 61-62). By this stage, tensions between the Department of Health and the brand industry had made the Generic Pricing Policy unsustainable.

This was the context, then, for the introduction in December 1990 of a reference-pricing arrangement, known first as the Minimum Pricing Policy, later as the Brand Premium Policy or the Brand Pricing Policy. Its basis is a fixed reimbursement price derived from the lowest priced brand of products considered interchangeable. 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 PBS 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 in the absence of brand substitution remained constrained. Unless a prescription was written generically or the lowest priced brand specified, the patient had to pay a brand premium on top of the co-payment (if applicable). Nor were any concerted efforts instituted to encourage doctors to prescribe generically. An explicit aim of the new policy was to support the development of an Australian generics industry, but the supply of generics could not expand without provisions for brand substitution or effective measures to foster generic prescribing. Most doctors continued to prescribe brand name products, and generic companies increased their PBS market share only marginally in the first years after 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 brand industry lobbying and public debate. 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 AUS\$1.40 to AUS\$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 brand industry has a strong aversion to this form of reference pricing, as demonstrated by the Pharmaceutical Research and Manufacturers of America's (PhRMA) appraisal of the TGP policy as 'undermining the intellectual property rights of pharmaceutical manufacturers by devaluing the value of patents and effectively denying market access to new medicines' (Pharmaceutical Research and Manufacturers of America 2002: 7). Notwithstanding this critique, price competition, reference pricing, and support for the development of a generics industry are now established elements of Australian pharmaceutical policy employed to contain rising PBS costs.

Generic drugs policy options for Australia

At first glance it would appear that a growth in the volume of scripts filled by generics would not substantially affect government PBS expenditure since generics prices typically approximate those of originator brands. From a cost-containment perspective however, the key factor is the overall impact of generic competition on the prices of both originator brands and generic equivalents over time. The suppliers of originator brands do not generally accept significant price differences, as this would risk a loss of market share. Omeprazole provides a case in point. The dispensed price in September 2002 for Losec was AUS\$47.65, only AUS\$1.50 above the price of the Alphapharm generic brand. But 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. The generics industry claims that in this way generics have saved taxpayers in the order of AUS\$1 billion since 1995, despite significant obstacles at the level of doctor and pharmacy practices (personal communication).

Viable generics firms are required for price competition to occur, and this necessitates acceptance of generics and generic substitution by consumers, pharmacists and doctors. Brand prescribing however remains routine in Australian 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, only 47 percent of prescriptions were filled at the benchmark level. In the remaining 53 percent consumers apparently accepted the need to pay a brand premium, or were perhaps not presented with the option of choosing an alternative benchmark product (Pharmaceutical Benefits Pricing Authority 2001). In other words, the use of generics in Australia remains at an artificially low level.

The Australian government can choose policy measures in respect of generic medicines that can be conceived as clustering around two different approaches. The first entails incremental changes 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 is premised on the expectation that opportunities for the supply of generics will expand by default as patents expire, and the focus is on education campaigns directed at doctors, pharmacists and consumers.

It remains unclear how Australian drug prices, say, five years after the commencement of price competition compare to 'global' generics prices. But the predominant view is that the Australian 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, and current arrangements provide little incentive for generic suppliers to compete aggressively on price. The second approach would seek to bring about a shift to a high volume/low price generics market in order to speed up the delivery of substantial cost savings. This would probably require a shift to a different overall pricing system, which raises issues not addressed in this paper.

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), by January 2001 Pharmac had advanced to the point of initiating 'the largest ever tender, involving some 153 products' (PHARMAC 2001: 17). 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 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). PHARMAC's 2003 annual review notes, in the context of reporting on the effective management of rising pharmaceutical costs, that 'tendering is used extensively, with more than a quarter of the [Pharmaceutical] Schedule (by volume) being tendered' (PHARMAC 2003: 13).

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). One of two options now considered is the introduction of centralized purchasing through competitive tendering. 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 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). However, if the Australian government wishes to provide direct support for industry development, this should arguably take the form of transparent budget allocations, not artificially high product prices. In New Zealand the political fall-out from reference pricing and generics tendering was manageable because there was very little primary pharmaceutical research undertaken and the pharmaceutical industry had only a weak presence. By contrast, in Australia the government is seeking to provide a supportive regulatory environment to facilitate the growth of an important high-tech industry. 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.

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