Generic medicines in Australia: business dynamics and recent policy reform

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Abstract

This article describes the role of generics in the Australian prescription drug market and patterns of business activity in this dynamic market segment. The Pharmaceutical Benefits Scheme (PBS) is the central mechanism for the supply of prescription medicines. PBS prices are arrived at through cost-effectiveness analyses comparing new products against already available products and therapies. In this system, prices do not operate effectively as incentives for consumers or prescribers to choose generics, and their market share was historically marginal. In recent years, generics suppliers achieved a growing market share through discounts (trading terms) to pharmacists. It is estimated that around 30% of PBS scripts, representing around 15% of PBS sales by value, are now filled with generics. Complex changes to the PBS were introduced in 2007, to be phased in over the period to 2012, aimed at increasing the scope for cost benefits to the government, and to lesser extent consumers, from the expanding availability of generic medicines.

Keywords: Australia, generic medicines, Pharmaceutical Benefits Scheme, pharmacies

Introduction

Prescription drug sales in Australia at around US$8 billion constitute a small share of the US$800 billion global market. Yet Australia is a high income economy with strict regulatory requirements closely monitored by drug policy analysts and the pharmaceutical industry. Prescription medicines are subsidized by the Commonwealth (federal) government through the Pharmaceutical Benefits Scheme (PBS). The PBS is designed to ensure ‘timely access to the medicines that Australians need, at a cost individuals and the community can afford’ and forms a central component of the National Medicines Policy. Through the PBS the government exercises strong market power which has delivered, for decades, relatively low prescription drug prices. The design of the scheme precludes effective price competition and generics prices historically approximated those of originator brands. Consequently the Australian market was until recently the almost exclusive preserve of the big brand companies. The generics sector remains small, in both value and volume terms, by comparison with economies such as the US and the UK, though policy changes and the increasing availability in international markets of cheap generics ensure an expanding role for generics also in Australia. Recent assessments suggest that around 30% of PBS prescriptions are dispensed with a generic, representing around 15% of the value of sales. In response to escalating health costs, and patents expiring on many big products, the Department of Health and Ageing (DoHA) has been searching for ways for tax payers and consumers to benefit, to a greater extent than hitherto, from low cost generics. The result is a major policy reorientation in 2007 aimed at driving down generics prices. This article briefly explains these changes, against the background of a sketch of regulatory arrangements and the business of generics in Australia. The focus is on the PBS market, which represents the bulk of prescription drug sales (public hospital tendering arrangements have long ensured a dominant role of generics in that sector).

Prescription drug regulation and the role of generics

Australia’s system of drug regulation encompasses two major steps. Medicines must first be entered on the Australian Register of Therapeutic Goods (ARTG) following approval by the Therapeutic Goods Administration (TGA) for acceptable quality, safety and efficacy. Generic products are assessed by the TGA for bioequivalence with the originator brand through a process of rigorous scientific evaluation normally completed within 45 working days. Each submission is assessed on a case-by-case basis. Omnitrope (supplied by Sandoz/Novartis) was the first biosimilar introduced (in November 2005) to the Australian market. Notwithstanding the efficiency and high reputation of TGA procedures, regulatory requirements are considered relatively inhospitable to the
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generics sector. Patent rights extend beyond those mandated by the Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPS) to include a five-year data exclusivity period, precluding data submitted to the TGA relating to a pharmaceutical product from being used by another company in applying for marketing approval until five years after approval of the original product. Moreover, patent extensions of up to five years are available for pharmaceutical standard patents, under certain circumstances, to compensate for delays in the marketing approval process. Such extensions are not available in countries such as New Zealand, Canada, South Africa, China or India. Mylan, the parent company of market-leading Alphapharm, considers consequent delays in patent expiries to be ‘somewhat responsible for under-penetration of generic products’ in Australia. Generics can also not be produced for exports whilst patents still apply in Australia. This latter constraint “places Australian generic manufacturers at such a disadvantage, even relative to generic manufacturers located in the US, Canada or Western Europe, that global companies are actively choosing their non-Australian facilities to manufacture new products.”

Following marketing approval, companies in most cases apply for PBS listing. This is normally required for sales to be commercially viable, making the prescription medicines market to all intents and purposes synonymous with the PBS. This is an uncapped scheme introduced in the early 1950s to provide all residents, irrespective of financial circumstances, with timely access to necessary medicines. More than 70% of all dispensed prescriptions are subsidized under the PBS, at a cost to tax payers of about AUS$7 billion in 2007-08. In July 2008, 641 medicines, in the form of 2,995 branded products, were available through community pharmacies under normal PBS arrangements.

The government is responsible for approximately 85% of the total cost of the PBS, with the remainder paid through patient co-payments (complemented by safety net provisions). Co-payments in 2009 were AUS$32.90 for general patients and $5.30 for pensioners and other concessional categories. Many products, particularly generics, are priced (for general patients) below the co-payment, a trend reinforced by the 2007 changes described below. In these circumstances no subsidy takes effect, which gives pharmacists discretion to determine the price to the customer. There are close to 5,000 community pharmacies, operated as small business enterprises, which draw for most of their revenue on fees and charges, negotiated with the government, for dispensing PBS products. The pharmacy owners are represented by a politically influential lobby group, the Pharmacy Guild of Australia (PGA).

New PBS listings require a recommendation by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent statutory body, to the Minister of Health and Ageing. Before the listing of a new drug, a price acceptable to the government is negotiated with the supplier through the Pharmaceutical Benefits Pricing Authority (PBPA). The principle of reference pricing is central to the PBS, that is, products that (in the judgment of the PBAC) produce similar health benefits are subsidized at the same level. In other words, the government subsidizes ‘each of the available brands to the level of the lowest priced brand. The PBS listing and pricing process has delivered relatively favorable prices for patented drugs whilst ‘in general, the prices Australian taxpayers pay for generic medicines are high compared to some other OECD countries.’

In therapeutic group (groups of non-identical drugs with similar safety and health outcomes) and multi-brand markets, companies are at liberty to charge a price higher than the lowest priced brand, with patients then paying, in addition to the co-payment, a brand or therapeutic group premium. In 2008, “the average brand premium was $3.03, and premiums ranged from $0.08 to $76.86. The majority of brand premiums were in the range of $1.00 to $4.00. The brand premiums, often poorly understood by consumers, in conjunction with other changes explained below, provide a window of opportunity for generics suppliers. A space for the generics sector was first opened up with the introduction of brand substitution by pharmacists in 1994, and subsequent policy changes have progressively widened the commercial potential of consumers avoiding brand premiums by choosing a brand priced at the base rate. Where a prescription has been issued for a product with a price premium, the pharmacist can at the patient’s request dispense another brand of the same medicine, unless the prescribing doctor has specifically indicated otherwise. About 55% of all PBS prescriptions are substitutable, yet only 33% are substituted – the difference points to the potential for further generics growth through substitution (even in the absence of additional medicines coming off patents).

A conundrum for the government which was only marginally mitigated by the brand premium policy (introduced in 1990) and the therapeutic group premium policy (in 1998) is the absence of incentives for PBS suppliers to compete on price, with reference pricing ensuring that any price cuts offered to the PBS flow through to all other suppliers of the same or similar products. Rather than competing on price, generics suppliers in the past decade gained access to the PBS market through discounts or trading terms to pharmacists, typically around 30% and often 50% or more. In other words, pharmacists have been reimbursed by the government at prices well above the prices actually paid. From a pharmacy perspective, such trading terms came to be considered standard business deals rewarding efficiencies and scale. With weak incentives for prescribers and consumers to choose generics, the discounts served as an incentive for pharmacists to drive generic substitution. That the cost benefits of cheaper generics were flowing to pharmacists, while PBS prices continued to approximate those of the originator brands, became increasingly palatable to the government. This formed the context for recent changes to the PBS, which radically extend an earlier policy measure (introduced in 2005) which mandates that the first new generic brand of a medicine
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The generics business in Australia

It is estimated, as noted, that around 30% of PBS prescriptions are dispensed with a generic, representing between 10% and 15% of the value of PBS sales. But reliable market information is not readily available. The detailed data on the community pharmacy market collected by the PGA is not publicly released, but used selectively for lobbying purposes. For their part, generics suppliers share with the PGA an interest in withholding information about market shares and pharmacy trading terms. The lack of transparency is reinforced by increasingly blurred lines globally and in Australia between the originator and generics sectors.

Several leading brand companies are also major generics suppliers, most significantly Novartis through its Sandoz division. The use of authorized or pseudo-generics is common practice, that is, products cross-licensed by a brand company to a specialized generics supplier, or marketed by an originator company by a subsidiary under a different name. Around 20% of all generics available in Australian community pharmacies are estimated to be in this category, which includes re-packaged versions of major products such as Ventolin, Losec, Valium, Normison, Augmentin and Prozac. Repackaged is the key term – pseudo-generics are not bioequivalent, alternative brands but by definition identical to the originator product, typically from the same production line. The extent of this practice can be gauged from the estimate that ‘of the 300-plus products sold by Alphapharm, the nation’s biggest generic drug company … a quarter is made by other companies’. Pseudo-generics are the subject of legal and political controversy in the USA but in Australia it is a phenomenon yet to be systematically investigated.

There are around ten companies supplying generics to the PBS, with two firms dominating. The Generic Medicines industry Association (GMiA) claims its six member companies supply 98% of generic prescriptions. Alphapharm has a market share of around 60% and Sigma about 20%. Only three firms – Alphapharm, Sigma and Hospira – undertake manufacturing or R&D associated with manufacturing in Australia, the others are engaged solely in the marketing of imported final drugs.

The member firms of the GMiA can be briefly characterized as follows. Alphapharm is a subsidiary of US-based Mylan Pharmaceuticals, ranked 29 on PharmExec’s list of global pharma companies. Alphapharm has made ‘branded generics’ the dominant business model, that is, its products are marketed through the advertising of the company name. Sigma Pharmaceuticals forms part of an Australian-owned health care company, headquartered in Melbourne, which is also a leading full-line wholesaler and the operator of a number of pharmacy retail brands (including Amcal, Guardian, and Amcal Max). It claims to be the Australian generics company with the largest manufacturing capability, and expanded its market position through acquisition of Herron in 2003 and a merger with Arrow Pharmaceuticals in 2005. Ascent Pharmahealth is a subsidiary of GenePharm Australasia in 2003. It is a distribution-only firm which claims the number three position.

Following a merger in 2008 with the Indian firm Strides Arcolab it now operates also in Asian markets including Singapore, Hong Kong, Malaysia, Thailand and Vietnam. Apotex, a subsidiary of the global Canadian Apotex group, is a specialized generics company, with about 6,800 employees globally. Hospira Australia was established in Australia through the acquisition in 2007 by the US-based global ‘speciality pharmaceutical and medication delivery company’ of the same name (with more than 14,000 employees) of the Australian firm Mayne Pharma, the leading Australian supplier of injectable generic pharmaceuticals. Sandoz, as noted, is a division of Novartis, one of the world’s largest pharma companies. Non-GMiA members supplying generics in the PBS market include Ranbaxy and Pharmacor. Ranbaxy, India’s largest drug company, which established Australian operations in 2004, was acquired in 2008 by the Japanese multinational Daiichi Sankyo. Pharmacor is an Australian firm established in 2006 which markets ‘small niche products where it’s not worthwhile for the larger companies to focus’.

Generics suppliers in Australia operate in a growing and dynamic market but one characterized by lack of transparency and distortions such as dominance by a few major players and shadowy cross-licensing arrangements. Consolidation is happening in the international generics sector at a rapid pace and most firms in Australia are now linked into global corporations drawing on manufacturing in locations such as India. The government is presently seeking to address some of the problems of the generics market through major changes to the PBS.

PBS reform

The key premise of the complex reform legislation introduced in 2007 is that generics prices have been too high and the aim of is to ensure better value for taxpayers. The importance of this policy shift is highlighted by the looming expiry of patents on more than 100 PBS drugs in the next decade. In 2006 the government foresaw PBS savings from these changes of AUS$3 billion over ten years, but a recent estimate suggests that savings may exceed AUS$7 billion over that period. Prices of generic drugs will be cut, pharmacy trading terms will be scaled back, and real prices paid by pharmacies made transparent through the phasing in of price disclosure requirements. The legislation was preceded by negotiations with the different sections of the industry behind closed doors. The gain for Medicines Australia, representing originator companies, is a weakening of the reference pricing system, a concession made by the government in exchange for the brand industry’s acceptance of measures ensuring lower generics prices and incentives for greater uptake of generics by pharmacists.
is achieved through the de-linking, for PBS pricing purposes, of patented products from generics, even where delivering similar therapeutic benefits, unless deemed ‘interchangeable at the patient level’33,34.

This delinking is brought about through the break-up of the PBS into two formularies (from August 2007): F1 encompassing single brand drugs, in most cases under patent, and F2 comprising drugs with multiple brands (and single brand drugs in a Therapeutic Group with a drug that has multiple brands). Until December 2010, F2 is divided into F2A (products discounted by less than 25% as at 1 October 2006) and F2T (products then discounted by more than 25%) with different pricing arrangements and different implementation dates for price disclosure. Mandatory price cuts were imposed on all F2 drugs on 1 August 2008: F2A prices were cut by 2% cut (to be followed by additional 2% cuts in 2009 and 2010) while a 25% price cut was imposed on 99 F2T drugs. The 12.5% price reduction imposed at the time of listing of the first generic brand of a drug will continue to apply. While the market impact of price disclosure arrangements, to be phased in over several years, is difficult to assess, they have commenced taking effect: in August 2009, price reductions were applied to four PBS drugs following the first round of the price disclosure system35. In the meantime, newspaper reports suggest that high trading terms continue for some products, with the government ‘paying between 50 per cent and 80 per cent more for generic drugs [under the PBS] than the pharmacists are paying for the medicines themselves’36.

Prescribers figure only peripherally in the present drive for greater uptake of cheaper generics, while the government has allocated some additional resources to a campaign by the National Prescribing Service to inform consumers about generics37. But the reform emphasis is squarely on the mandatory price cuts and associated measures to achieve greater generics pricing transparency and on changes in incentives for pharmacists. The community pharmacy sector is very sensitive to its dependence on regulatory protection and the volume and value of PBS products dispensed. The PGA viewed with apprehension the prospect of lower generics prices and the scaling back of trading terms and is concerned about the possibility of more far-reaching regulatory changes38. But community pharmacy reform has been deferred by the government, possibly to be revisited in context of negotiations with the PGA about arrangements to follow the Fourth Community Pharmacy Agreement, which expires in June 201039. The 2007 reform included a favorable compensation package for community pharmacy

• An incentive payment from 1 July 2007 of 40 cents for each prescription processed with PBS Online.
• A payment of AU$1.50 from 1 August 2008 for the dispensation of substitutable, premium free PBS-subsidized drugs.
• A 15% increase in dispensing fees and adjustments to pharmacy mark-ups from 1 August 2008.25

It was reported in March 2009 that generic substitution had increased by around 20% following PBS changes coming into effect in August 2008 with 29% of pharmacists increasing their substitution to some degree36. Recent changes also includes the establishment of an industry-government Access to Medicines Working Group, to provide an avenue for direct communications between Medicines Australia and DoHA, to consider issues related to the PBS, including matters such as the future of pharmacy compensation arrangements and consumer education programs to promote generics39.

It is too early to assess the implications of the F1-F2 reform and related PBS changes for different industry segments. The PGA remains uneasy about the future of community pharmacy while Medicines Australia appears broadly satisfied with recent developments. For its part, the generics sector reports declines in revenues and profitability as a result of price cuts. Yet medium and long term prospects for generics suppliers remain positive as PBS reforms and patent expiries accelerate the growth of the market share of generics37. According to Ascent Pharmaceuticals “The one-off effect of the PBS reforms will allow the industry to grow profitably going forward from these new price levels. This along with increased generic substitution and the introduction of new generic medicines is expected to bring strong margin value growth to the sector. The market outlook for generic pharmaceuticals remains strong with generic substitution in Australia expected to grow strongly over the next few years”40.

Concluding remarks

The generics sector is an established and growing segment of the Australian drug market and the PBS changes initiated in 2007 will accelerate this process. Following the introduction in 1994 of brand substitution, the major impediment to the growth of the generics sector, due to small price differentials, was the absence of incentives for doctors, pharmacists and consumers to choose generics. Recent changes do not significantly address the role of prescriber and consumer incentives, but will make dispensing pharmacists more inclined to support generic substitution. However the direct cost benefits to government are arrived at through mandatory price cuts and price disclosure requirements. These steps in conjunction with coming patent expiries will significantly increase, over the next decade, the market share of generics from the present level of around 30% of dispensed PBS drugs. But the brand industry remains strongly entrenched, as reflected in intellectual property rights legislation unfavorable to the generics sector and the design of the F1/F2 reform. Moreover, the generics market is distorted by the dominance of a small group of suppliers and cross-licensing (pseudo-generic) arrangements with the major brand companies.

References

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