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# Generic drug prices and policy in Australia: room for improvement? A comparative analysis with England

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## Abstract

**Objective.** To assess the degree to which reimbursement prices in Australia and England differ for a range of generic drugs, and to analyse the supply- and demand-side factors that may contribute to these differences.

**Methods.** Australian and English reimbursement prices were compared for a range of generic drugs using pricing information obtained from government websites. Next, a literature review was conducted to identify supply- and demand-side factors that could affect generic prices in Australia and England. Various search topics were identified addressing potential supply-side (e.g. market approval, intellectual property protection of patented drugs, generic pricing policy, market size, generic supply chain and discounting practices) and demand-side (consumers, prescribers and pharmacists) factors. Related terms were searched in academic databases, official government websites, national statistical databases and internet search engines.

**Results.** Analysis of drug reimbursement prices for 15 generic molecules (representing 45 different drug presentations) demonstrated that Australian prices were on average over 7-fold higher than in England. Significant supply-side differences included aspects of pricing policy, the relative size of the generics markets and the use of clawback policies. Major differences in demand-side policies related to generic prescribing, pharmacist substitution and consumer incentives.

**Conclusions.** Despite recent reforms, the Australian Government continues to pay higher prices than its English counterpart for many generic medications. The results suggest that particular policy areas may benefit from review in Australia, including the length of the price-setting process, the frequency of subsequent price adjustments, the extent of price competition between originators and generics, medical professionals' knowledge about generic medicines and incentives for generic prescribing.

**What is known about the topic?** Prices of generic drugs have been the subject of much scrutiny over recent years. From 2005 to 2010 the Australian Government responded to observations that Pharmaceutical Benefits Scheme prices for many generics were higher than in numerous comparable countries by instituting several reforms aimed at reducing the prices of generics. Despite this, several studies have demonstrated that prices for generic statins (one class of cholesterol-lowering drug) are higher in Australia compared with England and many other developed countries, and prices of numerous other generics remain higher than in the USA and New Zealand. Recently there has been increasing interest in why these differences exist.

**What does this paper add?** By including a much larger range of commonly used and costly generic drugs, this paper builds significantly on the limited previous investigations of generic drug prices in Australia and England. Additionally, this is the first comprehensive investigation of multiple supply- and, in particular, demand-side factors that may explain any price differences between these countries.

**What are the implications for practitioners?** Practitioners may contribute to the higher prices of generic medications in Australia compared with England through relatively low rates of generic prescribing. There are also significant implications for health policy makers, as this paper demonstrates that if Australia achieved the same prices as England for many generic drugs there could be substantial savings for the Pharmaceutical Benefits Scheme.

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## Introduction

A 'generic' drug is bioequivalent to the originator: the same active molecule, with the same bioavailability, efficacy and safety when given in an identical dose, form and route of administration.[1] Generics can be produced when originator drugs' patents expire, and do not incur the same development or approval process expenses as originators, thus providing the same therapeutic benefit at lower cost. As such, generics are often the target of government policy as they offer potential savings for drug budgets.[2]

From 2005 to 2010 the Australian Government responded to observations that Pharmaceutical Benefits Scheme (PBS) generics prices were higher than in numerous comparable countries by instituting several reforms.[3] Despite this, several studies have demonstrated that prices for generic statins (one class of cholesterol-lowering drug) are higher in Australia than in England and many other developed countries,[4,5] and prices of numerous other generics remain higher than in the USA[6] and New Zealand.[7]

Recently, there has been increasing focus on trying to identify the reasons for price differences. Duckett *et al*. have questioned the transparency and independence of the Pharmaceutical Benefits Pricing Authority (responsible for recommending prices for the PBS) and the potential influence of vested interests on pricing policy.[8] Clarke and Fitzgerald and Duckett *et al*. have cited long delays in generic price adjustments following originator expiry compared with other countries, during which PBS prices do not reflect true market prices.[5,8,9] Some authors have suggested that the pricing methods of some countries are superior to the price-disclosure method used by Australia.[7,8] However, all analyses have all been limited to a small range of pricing policy factors that may influence prices.

Several studies that have systematically examined European generic drug reimbursement prices and usage suggest that multiple supply- and demand-side factors, and not just pricing methods, must be considered in order to understand differing drug prices.[10–18]

The present study seeks to identify whether price differences between Australia and England persist for drugs other than statins, and identify supply- and demand-side factors that might explain these differences. Based on World Health Organization guidance, England is a suitable comparator for Australia with respect to generics prices and policy.[19] The countries exhibit similarities in population health profiles, health system financing and broad principles underpinning medicines funding.[20–23] However, substantial differences in pharmaceutical expenditure exist. In the financial year ending June 2011, total Australian Government expenditure on the PBS was approximately AUD $8.9 billion (excluding public hospitals), a 5.7% increase from the previous year.[24] This corresponded with growth in prescription volumes of 2.3%. By comparison, for a population more than twice the size (51.5 million *v.* 22.6 million), the National Health Service (NHS) in England spent approximately AUD $13.3 billion (£8.81 billion, using average annual exchange rate to December 2011 ($0.6641 : £1)) on prescription medications in 2011 (excluding public hospitals), a 0.1% fall from 2010 despite an increase in volumes of 3.8%.[25–27] Differences in the prices and use of generics potentially contribute to this disparity.[24,28]

Note that this is an abridged version of a more detailed Masters dissertation (available on request), and many aspects of the background and results have been simplified.

### *Objectives*

The aims of this study were:

(1) To determine the difference between government reimbursement prices in Australia and England for a range of popular generics dispensed by community pharmacies.

(2) To identify differences in supply- and demand-side factors that may influence relative reimbursement prices and market share of generics in Australia and England.

## Methods

### *Part 1: generic drug price comparison between Australia and England*

The methods used in this section drew on World Health Organization guidance for international comparisons of drug prices.[19] Drugs were selected based on the following criteria: they appeared on the 50 highest government-cost PBS drugs in 2011, were off-patent, belonged to 'F2' of the PBS schedule (and had an equivalent listing in Category M of the NHS Drug Tariff (DT)). Prices were compared for individual drug 'presentations' (different strengths, formulations and routes of administration of a particular molecule) meeting the above criteria.

PBS reimbursement prices for pharmacies (exclusive of mark-ups and fees) were obtained from the 'ex-manufacturer prices' column of the PBS 'agreed prices spreadsheet 31/05/2012'[29]. English prices were obtained from the July 2012 edition of the Electronic Drug Tariff.[30] However, pharmacy reimbursement by the NHS for a drug is less than the DT list price due to 'clawback'. In England, 'clawback' is applied to pharmacy reimbursement for most drugs, whereby the Department of Health estimates the likely discount received by pharmacies based on sales data from independent pharmacies (not chains) and deducts a percentage from the DT list price.[30,31] The size of the clawback depends on the value of drug sales by the pharmacy, with higher values attracting larger deductions.[30] Pharmacies retain any profit from discounts exceeding the clawback.[32] Therefore true reimbursement prices lie between the current minimum (5.76%) and maximum (11.5%) clawback from the DT list price.[30,32] In the present study a 5.76% clawback is applied to all drugs (giving the highest possible reimbursement prices). Prices for each presentation were converted to Australian dollars using the average annual exchange rate to June 2012 (AUD$0.6753 = GBP£1).[33] Pack sizes were adjusted to ensure comparability by dividing the DT price in AUD by the DT pack size and multiplying by the PBS pack size.

### *Part 2: factors that influence generic prices and market share*

A literature review was conducted to identify key factors influencing generic prices and market share in Australia and England. First, searches of academic databases were undertaken (Google Scholar, Cochrane Library, Pubmed, EMBASE and EconLit) to identify papers exploring differences in generic drug prices between two or more countries. Results were restricted to English-language sources published after 2000. The major factors that these papers cited as influencing generic drug prices were collated and grouped into either supply-side or demand-side factors.[13,16,31,32,34–37] This approach was used to ensure that a comprehensive range of potential influences on generic prices were considered. Supply-side topics identified included market approval, intellectual property protection of patented drugs, generic pricing policy, market size, generic suppliers, the role of community pharmacies and discounting practices, whereas

demand-side topics related to consumers, prescribers and pharmacists.

In order to identify information about each of these topics with respect to England and Australia, iterative searches were undertaken of the same academic databases, as well as official government websites, national statistical databases and Google.

Search terms used included 'generic medicines', 'off-patent medicine', 'generic medicine markets', 'pharmaceutical supply chain', 'demand for generics drugs', 'intellectual property law', 'evergreening', 'pharmaceutical policy', 'generic pricing', 'price disclosure', 'Category M', 'pharmacy reimbursement', 'pharmacy discounts', 'clawback', 'generic prescribing', 'consumer perceptions of generics', 'generic substitution', 'branded generics', 'medication co-payments', 'prescribing software', 'Pharmaceutical Benefits Scheme', 'Drug Tariff', 'Pharmaceutical Price Regulation Scheme', 'New Pharmacy Contract', 'Fifth Community Pharmacy Agreement', 'community pharmacy', 'manufacturers' and 'wholesalers'. These were searched alone, in combination, and with the suffix 'Australia' or 'England' or 'UK'. Reference lists of identified sources were searched to identify additional resources. Priority was given to information from official government sources, international health and economic institutions, statistical databases, legal documents and peer-reviewed journals. When other resources were used (including publicly available pharmaceutical industry information, news articles and other websites), attempts were made to triangulate across multiple sources to reduce possible factual error or bias. Where possible, information relating to England only was used due to some policy differences between UK countries.

## Results

### *Part 1*: generic drug price comparison between Australia and England

Fifteen drug molecules, comprising 45 individual presentations, met the selection criteria. Table 1 contains complete results of price comparisons. Across all drug presentations, PBS prices were on average 7.32 times higher than DT prices. Anastrozole 1 mg tablets, around 40 times more expensive on the PBS than the DT, demonstrated the largest difference. Only paracetamol 500 mg tablets were cheaper on the PBS (61% cheaper). Fig. 1 illustrates the average price differences between DT prices (denominator) and PBS prices for the 15 drug molecules.

Some of the largest differences in this group were for the four drugs still in their initial 18-month data-collection cycle in Australia, and therefore awaiting potential price adjustments through price disclosure. However, 9 of the remaining 13 drugs were still at least twice as expensive in Australia.

### *Part 2: factors that influence generic prices and market share*

A summary of the results of comparisons of supply- and demand-side factors affecting generic prices and market share are shown in Table 2. Those factors where a clear difference was evident are discussed below. For other factors, there was no major difference, or uncertainty often due to limited available information. A more comprehensive discussion including all results of the literature review is available on request.

#### *Supply-side factors*

##### *Pricing policy*

In both Australia and England, community pharmacies are reimbursed by government for drugs purchased based on agreed price schedules (less any patient co-payments), paid extra fees and mark-ups as part of government service agreements, and may retain at least some of the profits from margins between the reimbursement price and actual purchase price. Reducing this profit margin for pharmacies has been the target of pricing policy in both countries.

All PBS-subsidised generics (branded and unbranded) are listed on 'F2' of the PBS Schedule, which comprises off-patent originator drugs and their generic versions, and a small number of patented drugs (remaining patented originator drugs appear on F1).[38] 'Price disclosure' is used to set the price for all F2 drugs (with a small number of exceptions). All NHS-subsidised generics are listed on the DT. There are several different groups within the DT – namely Categories M, A and C – each associated with different pricing mechanisms. Category M is the largest group and contains popular and readily available unbranded generics, and reimbursement prices are set using 'price disclosure'.[39]

Both countries therefore use price disclosure to set reimbursement prices for most generic drugs. This method uses data obtained from all manufacturers of a particular drug molecule to determine the sale price to pharmacies (net of incentives) weighted by volume across all doses and forms.[40,41] The aim is to achieve reimbursement prices that reflect actual market prices, reducing the profit margins for pharmacies on sale of government-subsidised drugs.[42] However there are some key differences in how price disclosure is applied in each country.

In Australia, the price disclosure formula includes all generics (branded and unbranded) and the originator for a specific drug molecule, and the reimbursement price is therefore the same for all versions of a drug. In contrast, in England price disclosure is only used for unbranded generics, with different methods used to set prices for branded generics and originators. In Australia, all drugs undergo a mandatory 16% price reduction when first listed on F2, and are not subject to further price reductions until the first price disclosure cycle to obtain price data is complete, which takes at least 18 months (there is a mandated 12-month period of data collection and 6 months of calculations).[43] In England there are no mandatory price cuts on listing of a generic in Category M; however, adjustments to reimbursement prices based on price disclosure calculations occur immediately, often resulting in rapid price reductions.[44] Subsequent price adjustments are made three times a year in Australia, while they are made quarterly in England.

In England, clawback (see Methods) is also applied as a means of containing any additional profit margin made by pharmacies on the sale of NHS reimbursed drug.[32]

##### *Market size and share*

There is limited publicly available information about the Australian and English generics industry, making it difficult to fully appreciate the market dynamics or terms of trade in the supply chain.[34] Although the potential consumer market for generics is obviously much larger in England compared with Australia due to differences in population size, generics' share of

**Table 1. Comparison of reimbursement prices for 15 drug molecules (45 presentations) between Australia and England**

Drug, molecule name; Q, quantity; PBS, Australian Pharmaceutical Benefits Scheme; Q, quantity; PBS ex-manufacturer price AUD, PBS reimbursement price for drugs (in Australian dollars); DT, United Kingdom drug tariff; DT price (GBP), DT list price; 5.63% CB, minimum clawback rate applied to DT drugs; DT price (5.63%CB) in AUD@PBS Q, DT prices (with 5.65% clawback deducted) converted to Australian dollars (using annual average exchange rate to June 2012 AUD0.6753 to GBP1) and adjusted for quantity ((DT price in AUD/DT quantity) × PBS quantity); % price difference (PBS-DT/DT), percentage difference between DT price (in AUD, adjusted for quantity) and PBS price (DT price the denominator)

| Drug | Dose formulation | PBS Q | PBS ex-manufacturer price (AUD) | DT Q | DT price (GBP) | DT price (5.63% CB) in AUD@PBS Q | % price difference (PBS-DT/DT), 5.63% CB |
|---|---|---|---|---|---|---|---|
| Anastrozole | Tablet 1 mg | 30 | 123.41 | 28 | 2.03 | 3.05 | 3950.04 |
| Atorvastatin | Tablet 10 mg | 30 | 24.83 | 28 | 3.25 | 4.88 | 408.98 |
| Atorvastatin | Tablet 20 mg | 30 | 36.64 | 28 | 6.16 | 9.25 | 296.26 |
| Atorvastatin | Tablet 40 mg | 30 | 51.59 | 28 | 6.16 | 9.25 | 457.94 |
| Atorvastatin | Tablet 80 mg | 30 | 73.74 | 28 | 10.00 | 15.01 | 391.26 |
| Clopidogrel | Tablet 75 mg (as besilate) | 28 | 36.39 | 28 | 2.32 | 3.25 | 1019.60 |
| Metformin | Tablet 500 mg | 100 | 4.24 | 28 | 0.85 | 4.25 | -0.31 |
| Metformin | Tablet 850 mg | 60 | 4.24 | 56 | 1.28 | 1.92 | 120.68 |
| Olanzapine | Wafer 10 mg | 28 | 133.23 | 28 | 80.06 | 112.16 | 18.78 |
| Olanzapine | Wafer 5 mg | 28 | 65.94 | 28 | 16.75 | 23.47 | 181.00 |
| Olanzapine | Tablet 15 mg (orally disintegrating) | 28 | 199.84 | 28 | 45.37 | 63.56 | 214.40 |
| Olanzapine | Tablet 20 mg (orally disintegrating) | 28 | 266.44 | 28 | 60.34 | 84.54 | 215.18 |
| Olanzapine | Tablet 10 mg | 28 | 133.23 | 28 | 4.57 | 6.40 | 1980.91 |
| Olanzapine | Tablet 2.5 mg | 28 | 33.31 | 28 | 1.63 | 2.28 | 1358.66 |
| Olanzapine | Tablet 5 mg | 28 | 65.94 | 28 | 2.80 | 3.92 | 1580.97 |
| Olanzapine | Tablet 7.5 mg | 28 | 99.93 | 28 | 3.19 | 4.47 | 2136.01 |
| Omeprazole | Capsule 20 mg | 30 | 11.01 | 28 | 1.57 | 2.36 | 367.19 |
| Pantoprazole | Tablet (enteric coated) 20 mg | 30 | 5.94 | 28 | 1.32 | 1.98 | 199.79 |
| Pantoprazole | Tablet (enteric coated) 40 mg | 30 | 12.18 | 28 | 2.04 | 3.06 | 297.76 |
| Paracetamol | Tablet 500 mg | 100 | 1.53 | 100 | 2.81 | 3.94 | -61.14 |
| Perindopril | Tablet 2 mg | 30 | 4.01 | 30 | 1.82 | 2.55 | 57.27 |
| Perindopril | Tablet 4 mg | 30 | 7.50 | 30 | 1.95 | 2.73 | 174.53 |
| Perindopril | Tablet 8 mg | 30 | 11.49 | 30 | 2.16 | 3.03 | 279.69 |
| Pioglitazone | Tablet 15 mg | 28 | 39.14 | 28 | 10.92 | 15.30 | 155.84 |
| Pioglitazone | Tablet 30 mg | 28 | 60.20 | 28 | 15.76 | 22.08 | 172.65 |
| Pioglitazone | Tablet 45 mg | 28 | 78.28 | 28 | 17.80 | 24.94 | 213.91 |
| Quetiapine | Tablet 100 mg | 90 | 94.49 | 60 | 10.84 | 22.78 | 314.79 |
| Quetiapine | Tablet 200 mg | 60 | 128.75 | 60 | 10.86 | 15.21 | 746.22 |
| Quetiapine | Tablet 25 mg | 60 | 33.39 | 60 | 4.13 | 5.79 | 477.08 |
| Quetiapine | Tablet 300 mg | 60 | 188.91 | 60 | 15.32 | 21.46 | 780.17 |
| Ramipril | Capsule 1.25 mg | 30 | 2.49 | 28 | 1.09 | 1.64 | 52.19 |
| Ramipril | Capsule 10 mg | 30 | 8.07 | 28 | 1.43 | 2.15 | 275.96 |
| Ramipril | Capsule 2.5 mg | 30 | 3.64 | 28 | 1.17 | 1.76 | 107.26 |
| Ramipril | Capsule 5 mg | 30 | 4.57 | 28 | 1.29 | 1.94 | 136.01 |
| Risperidone | Tablet 0.5 mg | 60 | 16.31 | 20 | 0.86 | 3.61 | 351.23 |
| Risperidone | Tablet 1 mg | 60 | 31.48 | 20 | 0.97 | 4.08 | 672.16 |
| Risperidone | Tablet 2 mg | 60 | 72.00 | 60 | 1.88 | 2.63 | 2633.65 |
| Risperidone | Tablet 3 mg | 60 | 111.03 | 60 | 2.26 | 3.17 | 3406.71 |
| Risperidone | Tablet 4 mg | 60 | 149.88 | 60 | 2.41 | 3.38 | 4339.10 |
| Sertraline | Tablet 50 mg | 30 | 7.67 | 28 | 1.59 | 2.39 | 221.37 |
| Sertraline | Tablet 100 mg | 30 | 7.67 | 28 | 1.90 | 2.85 | 168.93 |
| Simvastatin | Tablet 10 mg | 30 | 6.35 | 28 | 0.87 | 1.31 | 386.25 |
| Simvastatin | Tablet 20 mg | 30 | 9.14 | 28 | 0.96 | 1.44 | 534.28 |
| Simvastatin | Tablet 40 mg | 30 | 13.15 | 28 | 1.20 | 1.80 | 630.04 |
| Simvastatin | Tablet 80 mg | 30 | 18.90 | 28 | 2.05 | 3.08 | 514.20 |
| Mean % price difference | | | | | | | 731.90 |
| Median % price difference | | | | | | | 314.79 |

the local pharmaceutical markets in the UK is also much larger than Australia by value and volume (10.2% *v.* 18.5% value, 30% *v.* 67.4% volume).[45–48] Unlike Australia, the UK is considered to be a highly competitive market and attractive for generic suppliers.[48] The number of suppliers is much greater in the UK (at least 22 manufacturers and around 34 wholesalers) compared with Australia (10 and at least 5). Analysis is complicated by the relationship between originator and generics manufacturers, with many engaging in the production of 'pseudo-generics' – repackaged versions of the originator sold under a generic name by a

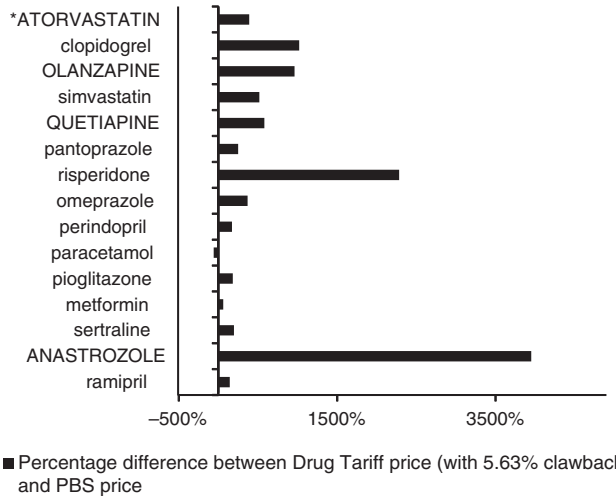


**Fig. 1.** Percentage difference between Drug Tariff prices (denominator) and Pharmaceutical Benefits Scheme prices for 15 generics (aggregated at molecule level). *Capitalised drugs had not undergone price disclosure adjustments in Australia at 31 May 2012.

subsidiary of the originator company or cross-licenced to a generics supplier.[34,49,50] Approximately 18% of Australian generics fall into this category,[51] and it is uncertain how many do so in the UK.

### *Demand-side factors*

#### *Prescribers*

In Australia between 2009 and 2010, only 19.5% of primary care prescriptions were written using the International Non-proprietary Name (INN),[52] compared with 82.7% in England.[53]

There are no requirements for generic or INN prescribing in Australia, and the Australian Medical Association opposes compelling medical practitioners to prescribe by generic name.[54] Additionally, in 2010 the government signed a Memorandum of Understanding with Medicines Australia (an originator medicines lobby group) agreeing not to introduce any measures to increase generic prescribing.[55] Primary care prescribing software was previously sponsored by pharmaceutical companies and promoted branded medications; however, since 2011 legislation prevents this.[56,57] Surveys of medical practitioners have found a reluctance to prescribe generics due to concerns about patient safety (such as confusion from different packaging) and the quality of generics.[58–60] Additionally, a survey of medical students indicated poor knowledge about generics, particularly with respect to bioequivalence, quality and safety.[61]

By comparison, INN prescribing is strongly encouraged in England through various measures, including teaching medical students to use INN,[62] clinical guidelines recommending generics, prescribing software indicating generic availability,[32,63] and prescribing incentive schemes and local formularies established by Primary Care Trusts (PCTs) (recently abolished bodies that previously administered general practice services in the UK).[64] PCTs also published prescribing data for each of their commissioned primary care practices, creating peer pressure to reduce expensive or unnecessary prescribing. Unlike its Australian counterpart, the British Medical Association encourages generic prescribing and has advocated for incentives to increase rates.[65]

#### *Consumers*

There are consumer co-payments for all drugs in both countries. In Australia, there is a two-tiered co-payment, with a higher payment for 'general patients' and lower payment for the ~85% who are concession and pension card holders.[66] In the UK there is single flat fee per script item from which ~85% are completely exempt.[41]

Unlike in England, in Australia there are also small financial incentives for consumers to choose generics. Where multiple generic versions of a drug exist, manufacturers are able to set their own prices above the level of the PBS subsidy (subject to Ministerial approval); however, the consumer must pay the excess. This additional charge is known as the 'Brand Price Premium'. At the time of the analysis, Brand Price Premium applied to 276 PBS items, averaging $3.64 per item, and ranging from $0.34 to $308.30 (80% of items were in the range of $0.87–$3.93).[67] At least one brand of each drug must not have a premium.[40] Additionally, for drugs that fall below the general copayment, pharmacies have more discretion over price and in most instances price the generic below the originator.[68]

Australia and England have both used advertising campaigns and pamphlets to raise awareness about generic medicines.[40,69,70]

#### *Pharmacists*

In contrast to England, in Australia pharmacists are permitted to substitute generics for prescriptions written for branded drugs (provided that the prescriber has not prohibited it, the patient agrees, and the brands are interchangeable according to the PBS schedule[67]). Although 55% of PBS prescriptions are potentially substitutable, actual substitution rates are only ~33%, as it is not always offered and patients do not always agree.[33,71]

Since 2008, pharmacies have also received an incentive payment ($1.56 at August 2010) for each Brand Price Premium-free drug they dispense.[72] Prior to the introduction of price disclosure, there was also an incentive to dispense generic medications based on generous discounts received from suppliers. The reduction of these discounts due to price disclosure may have diminished the incentive for brand substitution.[40,73]

## Discussion

The results show that reimbursement prices are, on average, significantly higher in Australia than in England for a range of generics among the 50 highest Australian Government-cost PBS drugs in 2011. If the PBS prices for these drugs were the same as the DT prices, there could be significant savings for the PBS. The results of Part 2 identify several differences between the two countries that may contribute to the observed price disparities; key differences are discussed below.

### *Supply-side factors*

#### *Pricing of generics*

Although F2 and Category M both use price disclosure methods, specific features of the overall pricing systems differ substantially. A key difference is the delay from first listing of a

**Table 2. Supply-side and demand-side factors affecting drug reimbursement prices and market share for Australia and England**

Clear difference, there is an obvious difference between the two countries for a given factor that may contribute to differences in price or market share; uncertain difference, there may be differences but it is not apparent based on the available information or the effect is of differences is difficult to determine; no/minor difference, there is little substantial difference between countries or the differences are unlikely to affect prices or market share

| | Australia | England | Clear difference | Uncertain difference | No/minor difference |
|---|---|---|---|---|---|
| Supply-side factors | | | | | |
| Market approval and bioequivalence testing | | | | | √ |
| Intellectual property protection of patented drugs | | | | | √ |
| Generic pricing policy | | | | | |
| Method | Price disclosure | Price disclosure | | | √ |
| Transparency of methods/data | Limited | Limited | | | √ |
| Time from listing to first price adjustments from price disclosure | Min. 18 months[43] | Immediate | √ | | |
| Frequency of new generic drug listings | 3 times per year[43] | Quarterly | √ | | |
| Frequency of price adjustments after first round of price disclosure | 3 times per year[43] | Quarterly | √ | | |
| Statutory price cuts | 16% off initial PBS price of brand and any generics on first listing of a generic[55] | No | √ | | |
| Originator v. generic price once generic available | Originator, branded and unbranded generics same price | Originator and branded generic prices different to unbranded generics | √ | | |
| Clawback of supply chain discount | No | Yes | √ | | |
| Reimbursement price includes margin for pharmacists | No | Yes | √ | | |
| Size of generic market (as % of total local pharmaceutical market) | | | | | |
| Value | 10.20%[47] | 18.50%[45] | √ | | |
| Volume | 30%[47] | 67.4%[79] | √ | | |
| Suppliers | | | | | |
| Number of manufacturers | Approx. 10[47] | >22[79] | √ | | |
| Number of wholesalers | >5[80] | Approx. 34[81,82] | √ | | |
| Community pharmacy | | | | | |
| Payment for services | | | | | √ |
| Regulation of profits on sales of government subsidised drugs | No | Yes (via clawback and an agreed margin on generic drug sales) | √ | | |
| Source of profits | | | | | √ |
| Pharmacy representative group influence over policy | Believed to have strong influence[83] | Uncertain influence | | √ | |
| Discounts in the supply chain | | | | | |
| Size | Previously large but reducing since introduction of price disclosure[84] | Should be minimal due to price disclosure and clawback but evidence they may exceed clawback[31] | | √ | |
| Demand-side factors | | | | | |
| Consumers | | | | | |
| Awareness programs | | | | | √ |
| Financial incentives to choose generics | May be an additional co-payment for certain brands[40] | No | √ | | |
| Prescribers | | | | | |
| Rate International Non-Proprietary Name prescribing in primary care | 19.50%[52] | 82.70%[53] | √ | | |

(*Continued next page*)

**Table 2.** (*continued*)

| | Australia | England | Clear difference | Uncertain difference | No/minor difference |
|---|---|---|---|---|---|
| Incentives for generic prescribing | None | Many | √ | | |
| Prescribing software that facilitates generic choices | No | Yes | √ | | |
| Pharmacists | | | | | |
| Generic substitution | Allowed (60% eligible scripts substituted)[33] | No | √ | | |
| Substitution incentive payments | Yes | N/A | √ | | |
| Ability to compete for consumers on price | When price falls below general patient co-payment | No | √ | | |

drug on either F2 or Category M to first price adjustment based on price disclosure (18 months for F2 compared with immediate Category M adjustments). If F2 drugs that had not yet faced price disclosure adjustments are removed from the price comparisons in Part 1, the average price difference falls, supporting the argument made by other authors that this delay before initial price disclosure adjustment contributes higher generic prices in Australia compared with other countries.[5,8,9,41] International evidence indicates that potential savings for governments from generic entry are greatest immediately following patent expiry of the originator, as over time price erosion diminishes, fewer generic suppliers enter the market (and some exit), and new therapies may displace old ones;[16] thus this 18-month period is potentially a lost savings opportunity for the Australian Government.

Even when F2 drugs that had not faced price disclosure adjustments were removed from the results, the PBS prices were still much higher than the DT prices. This suggests that the actual market prices might also differ (as theoretically reimbursement based on price disclosure should reflect pharmacy acquisition prices). One possibility is that the inclusion of originator, branded generic and unbranded generic versions of a drug in the F2 price disclosure formula pushes prices higher than if only unbranded generics were included. In England originator and unbranded generic reimbursement prices are separate – originators remain on a separate list (the Pharmaceutical Price Regulation Scheme) at a price the manufacturer determines (often much higher than the generic price). In addition to changing the outcome of price disclosure calculations, separating the prices of the originator and generics allows generic entrants to compete with the originator on price as well as discounts to pharmacies to gain market share.[11,12] In contrast, originators and generics suppliers in Australia can only compete with one another using discounts, as reimbursement prices are the same.

Another contributor to price differences could be the frequency of revisions and new listings, which occur more often for Category M than for F2 – European evidence indicates that more frequent price adjustment leads to lower prices and greater market penetration of generics.[14]

The impact of regulating pharmacy profits through clawback is difficult to determine; however, it has been suggested that clawback acts as a strong incentive for pharmacies to bargain with multiple suppliers, enhancing competition and driving prices lower.[74]

### *Market and suppliers*

The UK generics market is much larger than in Australia in terms of consumer base and number of suppliers. This may result in more competition and greater economies of scale of production in England. However, smaller consumer and supplier markets than Australia (such as New Zealand) have also been able to achieve lower generic prices and more competition, so market size is not necessarily a limiting factor.[7,8] Market share may be just as important as size. Differences in local pharmaceutical market share both in terms of value and volume not only suggest that overall market conditions in England are more supportive of generics than in Australia, but also have implications for generics prices. There is evidence that in countries where generics occupy a larger share of the pharmaceutical market (such as the UK), generics prices tend to be lower.[11] This in turn suggests that efforts to address demand-side factors in order to grow the generics market in Australia may be important.

## *Demand-side factors*

### *Prescribers*

The large disparity between Australia and England with respect to generic prescribing rates is potentially an important factor underlying the differences in market volume and value, and in turn prices. The high rate of INN prescribing in England suggests that the incentives to prescribe generics are effective. Many of these incentives are intimately linked to the structure and funding of primary care, and therefore would not be possible in the Australian context where primary care is organised very differently. However, other measures used in England that do not rely on primary care structure (including fostering INN prescribing habits among medical students, software that promotes generics, and advising generics in clinical guidelines) are not instituted in Australia either. This may in part stem from historical resistance by key stakeholders (e.g. the Australian Medical Association who cite patient safety concerns,[54,58] and Medicines Australia[55]), as well as poor prescriber knowledge about generics.[61,75]

### *Pharmacists*

Pharmacist-initiated brand substitution in Australia increases the volume of generics dispensed. However, given that the relative volume of generics dispensed in England is more than

double that in Australia, generic prescribing may be more effective at increasing generic use than pharmacy substitution (although evidence shows this is only the case if regulations and incentives for pharmacists align with those of prescribers[62]).

### *Consumers*

In contrast to England, there are direct (but small) financial incentives for consumers to agree to generic substitution in Australia. Surveys have found Australian consumers understand what generics are and do respond to financial incentives, but are also strongly influenced by their medical practitioner's advice and perceived attitudes.[68,75] Given the nature of the relationship and information asymmetry between prescriber and consumer, it has been argued that there is limited scope for consumers to drive demand for generics.[76] There is also no data available about consumers' degree of price sensitivity in Australia. Moreover, the fact that England has higher generic consumption yet no consumer price signals suggests that they are not necessary to increase demand. The impact of co-payments on equity of access to medicines and transaction costs involved in administering them also needs to be considered.[18,68,77,78]

### *Limitations and assumptions*

The dissertation this paper is based on contained more extensive generic drug price comparisons and discussion regarding supply-side and demand-side factors in both countries; only a small amount of that information is presented here to highlight key findings. Factors that were not discussed here (where differences between the two countries were small or indeterminate) may also have important influences on generic prices.

In the methods for Part 1, prices for drugs were compared initially at the presentation level then aggregated at the molecule level. The aggregated differences need to be interpreted with caution, as it is possible that some presentations for which significant price difference existed did not meet the selection criteria, and aggregate results for some molecules are therefore incomplete. Additionally, the method used to equalise pack sizes assumes that drug prices are proportional to the pack size, which may not always be the case. Using the average annual exchange rate to convert DT prices to Australian dollars assumes that this reflects the relative prices of drugs at the time points assessed.

For Part 2, the method used to identify supply-side and demand-side factors to explore further may have meant that some important factors influencing price were neglected (for example, prescribing patterns for particular medical conditions in each country). Additionally, reliance on only publicly available information prevented more detailed analysis of generics pricing and markets in both countries. Obtaining data from pharmacies and manufacturers (which is heavily protected), as well as pharmaceutical market data that is available for purchase, would have potentially enabled more detailed and accurate assessment. Based on the available data and the methods used, the relative impact of differences in each factor on generic prices could not be determined.

## Conclusions and policy implications

This comparison with England indicates the potential for the Australian Government to achieve PBS savings through lower generic drug reimbursement prices and greater usage. Although it is difficult to attribute price differences to specific factors, this analysis suggests that there are at least some supply-side and demand-side policies that could benefit from review in Australia. With respect to the supply side, the PBS could achieve short-term savings if price disclosure adjustments occurred sooner after first listing. Further, more frequent price adjustments and opportunities for generic listing may improve competitiveness. Greater price competition and growth in generic markets might be achieved by separating pricing for originators and their generic counterparts by allowing manufacturers to compete on price as well as discounts.

However, given the relatively low demand for generics in Australia, such supply-side measures are unlikely to have the same outcomes that they do in England. Therefore, review of demand-side policies is also essential. In particular, this analysis suggests that increasing generic prescribing may be more effective at increasing generic market share than the combined effect of pharmacist substitution and financial incentives for consumers. Future policy development in this area could include mechanisms to improve medical students' and doctors' knowledge about generics, promoting generics through prescribing software and clinical guidelines, and creating incentives (financial or non-financial) for generic prescribing.

Although lower generic prices and greater usage may be desirable for the Australian Government from an economic perspective, the political feasibility of achieving this given historical resistance from key stakeholders is uncertain. Nonetheless, this political challenge needs to be balanced against pressure to improve health system efficiency and sustainability, and the obvious potential for generics to play a role in achieving these goals.

## Competing interests

The authors declare there are no competing interests.

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