

High prices for generics in Australia — more competition might help

Liliana Bulfone

Abstract

It is commonly believed that dispensed prices of medicines in Australia are substantially lower than those in other developed countries, particularly the US. This article reports the results of an analysis comparing dispensed prices for the most commonly prescribed and the highest cost items in Australia with dispensed prices in the US. Although a large majority of items are less expensive in Australia than in the US, Australian prices are higher for a substantial number of products, particularly generic drugs. This article examines various policies affecting the pricing of generics in Australia. It is postulated that the main cause for higher prices for a substantial number of generic products is the lack of price competition. This results from government policy which ensures that a price reduction by one company is communicated immediately to all competitors in that market along with an invitation to match the reduced price. The dominant strategy for all suppliers is to only reduce their price in response to a reduction in price by a competitor. The result is a lack of differentiation in pricing across brands of a medicine on the Schedule of Pharmaceutical Benefits. The government could improve the structure of the generics market and encourage greater competition by ceasing to disclose competitor firms' offers to other competitors. The government could conduct pricing reviews of each generic product relatively infrequently (eg, only once annually or every 18 months). At the time of the pricing review, the government would request confidential offers on price for a generic from all players in the market. Brands should then all be listed under the Pharmaceutical Benefits Scheme (PBS) at the offered price. Prices offered by the individual supplier would apply until the next pricing review. The PBS would continue to subsidise up to the price of the lowest priced brand, with brand premiums applying to all brands priced higher than the benchmark price. Such an approach would provide opportunity for players in the market to capture market share by being the lowest priced brand.

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MOST PRESCRIPTION-ONLY medications dispensed to Australians by community pharmacies are included in the Schedule of Pharmaceutical Benefits, a list of medicines subsidised by the government. The Schedule is part of the wider Pharmaceutical Benefits Scheme (PBS) administered by the Department of Health and Ageing and Medicare Australia.

For each product subsidised under the PBS, the price that the manufacturer can charge is agreed between the manufacturer and the government. Based on this ex-manufacturer price, a dispensed price, which allows for a specific wholesaler mark-up, a specific pharmacy mark-up and a specific dispensing fee is calculated and the final dispensed price is included in the Schedule of Pharmaceutical Benefits.

Pharmacies purchase PBS-listed drugs from the wholesaler or supplier, and claim the difference between the dispensed price and the patient copayment contribution from Medicare Australia. There are essentially two levels of patient copayment — one level for general patients and one for concessional patients. About 85% of prescriptions subsidised under the PBS are dispensed to concessional patients.

The major purchaser of pharmaceuticals in Australia is therefore, indirectly, the government. However, to the extent that they are required to pay copayments and brand premiums, patients are also purchasers of pharmaceuticals. In rela-

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tion to products available under the PBS that are available with more than one brand (eg, products for which generics are available), under the “brand premium” arrangements, the Commonwealth reimburses the price of a medicine only to the level of the lowest priced brand. Patients pay the difference (a brand price premium) for higher priced brands of medicines if they choose to take these instead of the benchmark (lowest-priced) product.

According to two commonly cited Productivity Commission reports, “International Pharmaceutical Price Differences”¹ and “Evaluation of the Pharmaceutical Industry Investment Program”,² prices for pharmaceuticals listed on Australia’s Pharmaceutical Benefits Scheme are substantially lower than in other similar countries, particularly the US. It is also commonly believed that drug prices in the USA are the highest in the developed world. It is often claimed that one of the principal reasons for the lower prices observed in Australia is the bargaining power of the government relative to that of the suppliers. The bargaining power arises from the fact that most medicines, as discussed above, are paid for, at least to some extent, by the government, which is in effect, close to being a monopsony buyer.

For each financial year, the government publishes a report of expenditure on pharmaceuticals and prescription volumes in that year.³ This report includes a list of the items that were of the highest cost to government and a list of items that were dispensed in the highest volumes. This paper reports the results of an analysis comparing Australian and US prices of drugs that are included in either the list of 100 highest government cost items or in the list of 100 highest volume items in the financial year ending 30 June 2007.

Results of price comparison

Australian prices for the 144 unique items included in either the list of 100 highest government cost items or in the list of 100 highest volume items (some items are included in both lists) were sourced from the May 2008 Schedule of Pharmaceutical Benefits. The base price, which

represents the dispensed price for the lowest priced brand, for the item was used. Dispensed prices for the same items when supplied in the US were sought from drugstore.com, an online US pharmacy, in May 2008. US prices were available at drugstore.com for 102 of the 144 unique items. A number of products (eg, insulins, chemotherapeutic agents, hypnotics) are not available through the online pharmacy. As with the Australian prices, prices for the lowest-priced brand available were included in the analysis. To facilitate a price comparison, US prices were converted to Australian dollars using the exchange rate that applied in May 2008 (1A\$ = 0.94US\$).

Box 1 summarises the comparison of prices in Australia and US per dosing unit (ie, tablet, capsule, vial, etc) for each of the 102 items for which both Australian and US prices could be identified. The table is divided into items for which generics are available in Australia and those for which generics are not available. Of the 102 items, 50 (49%) of the items were for products for which no generic was available. Australian prices were similar or lower than US prices for 44 (88%) of these items. The remaining 52 (51%) items were products for which a generic brand is available in Australia. Australian prices were similar or lower for 33 (63%) of these items.

Although prices for originator branded products (including products still under patent) in Australia are, generally, lower than in the USA, there are a substantial number of instances where dispensed prices for generic products in Australia are higher than in the USA.

There are a number of issues in relation to the approach used to compare drug prices in Australia with those in the US that should be kept in mind in considering the results of the analysis. First, the conversion of US prices to Australian dollars was conducted at a time when the US dollar was at its weakest level in many years (1A\$ = 0.94US\$) and therefore the prices, expressed in Australian dollars, for drugs in the US could normally be higher than reported in this analysis. A sensitivity analysis was conducted assuming an exchange rate of 1A\$ = 0.60US\$. The number of generic products priced higher in

I Comparison of dispensed prices for items of high cost to government or dispensed in high volumes

Item	Originator brand	Australian price/unit	US price/unit in A\$
PRODUCTS WHERE GENERIC IS NOT AVAILABLE IN AUSTRALIA			
Australian price is more than 10% higher than US price			
ETANERCEPT 50mg injections (pack of 4)	Enbrel	\$1,745.39	\$1,565.63
ETANERCEPT 25mg injections (pack of 4)	Enbrel	\$899.01	\$796.72
LEFLUNOMIDE 20mg tablets ^{1*}	Arava	\$4.79	\$1.42
FAMCICLOVIR 250mg tablets ^{1*}	Famvir	\$6.36	\$3.26
EZETIMIBE 10mg + SIMVASTATIN 80mg tablets	Vytorin	\$4.69	\$3.58
EZETIMIBE 10mg + SIMVASTATIN 40mg tablets	Vytorin	\$3.97	\$3.58
Australian price is within 10% of US price or lower than US price			
ADALIMUMAB 40mg injections	Humira	\$872.69	\$829.39
DONEPEZIL 10mg tablets	Aricept	\$5.52	\$6.03
WARFARIN SODIUM 5mg tablets	Coumadin/Marevan	\$0.23	\$0.50
WARFARIN 1mg tablets	Coumadin	\$0.20	\$0.50
WARFARIN 2mg tablets	Marevan	\$0.21	\$0.53
ATORVASTATIN 80mg tablets	Lipitor	\$3.64	\$4.25
EZETIMIBE 10mg tablets	Ezetrol	\$2.33	\$3.55
CANDESARTAN 16mg tablets	Atacand	\$0.96	\$2.20
CANDESARTAN CILEXETIL 8mg tablets	Atacand	\$0.77	\$2.13
TELMISARTAN 80mg tablets	Micardis	\$0.96	\$2.34
RALOXIFENE 60mg tablets	Evista	\$2.07	\$3.61
IRBESARTAN 300mg tablets	Avapro	\$0.94	\$2.48
TELMISARTAN 40mg tablets	Micardis	\$0.72	\$2.27
ATORVASTATIN 40mg tablets	Lipitor	\$2.60	\$4.25
VALACICLOVIR 500mg tablets	Valtrex	\$5.15	\$6.80
ATORVASTATIN 10mg tablets	Lipitor	\$1.35	\$3.05
CANDESARTAN 16mg + HYDROCHLOROTHIAZIDE 12.5mg tablets	Atacand Plus	\$1.03	\$2.84
CLOPIDOGREL 75mg tablets	Isocover/Plavix	\$2.94	\$4.82
ROSIGLITAZONE 4mg tablets	Avandia	\$2.16	\$4.08
IRBESARTAN 150mg tablets	Avapro	\$0.78	\$2.69
CELECOXIB 200mg capsules	Celebrex	\$1.01	\$2.94
VENLAFAXINE 75mg capsules (modified release)	Efexor-XR	\$1.53	\$3.82
ATORVASTATIN 20mg tablets	Lipitor	\$1.90	\$4.25
PANTOPRAZOLE 40mg tablets	Somac	\$1.27	\$3.84
VENLAFAXINE 150mg capsules (modified release)	Efexor-XR	\$1.83	\$4.47
TIOTROPIUM 18mcg capsules for inhalation	Spiriva	\$2.53	\$5.25
FLUTICASONE 250mcg + SALMETEROL 25mcg oral pressurised inhaler (120 doses) ²	Seretide	\$0.65	\$3.48

I continued

ESOMEPRAZOLE 40mg tablets	Nexium	\$2.00	\$5.32
FLUTICASONE 500mcg + SALMETEROL 50mcg oral pressurised inhaler (60 doses) ²	Seretide	\$0.65	\$4.50
LANSOPRAZOLE 30mg capsules	Zoton	\$1.24	\$5.47
ROSIGLITAZONE 8mg tablets	Avandia	\$3.22	\$7.59
QUETIAPINE 200mg tablets	Seroquel	\$3.19	\$7.60
RABEPRAZOLE 20mg tablets	Pariet	\$1.24	\$5.67
ESOMEPRAZOLE 20mg tablets	Nexium	\$1.25	\$5.83
ANASTROZOLE 1mg tablets	Arimidex	\$6.11	\$10.79
OLANZAPINE 5mg tablets	Zyprexa	\$3.61	\$8.80
OLANZAPINE 7.5mg tablets	Zyprexa	\$5.36	\$10.66
OLANZAPINE 10mg tablets	Zyprexa	\$7.09	\$13.08
QUETIAPINE 300mg tablets	Seroquel	\$4.52	\$10.53
RISEDRONATE 35mg tablets	Actonel	\$13.03	\$24.19
CAPECITABINE 500mg tablets	Xeloda	\$5.78	\$19.86
GLATIRAMER ACETATE 20mg injections	Copaxone	\$38.92	\$75.27
LATANOPROST 0.005% (50mcg/mL) eye drops 2.5mL	Xalatan	\$36.65	\$74.43
FLUTICASONE 250mcg + SALMETEROL 50mcg powder for inhalation in breath actuated device (60 doses)	Seretide	\$58.33	\$208.51

PRODUCTS WHERE GENERIC IS AVAILABLE IN AUSTRALIA**Australian price is more than 10% higher than US price**

SIMVASTATIN 80mg tablets*	Zocor	\$2.54	\$1.17
CARVEDILOL 25mg tablets*	Dilatrend	\$1.57	\$0.53
PRAVASTATIN 40mg tablets*	Pravachol	\$1.78	\$0.92
SIMVASTATIN 40mg tablets*	Zocor	\$1.82	\$0.99
MELOXICAM 15mg tablets*	Mobic	\$0.93	\$0.22
PRAVASTATIN 20mg tablets*	Pravachol	\$1.21	\$0.64
OMEPRAZOLE 20mg tablets ^{3*}	Losec	\$1.16	\$0.61
PAROXETINE 20mg tablets*	Aropax	\$0.99	\$0.46
TRIMETHOPRIM 300mg tablets*	Triprim	\$1.15	\$0.71
SERTRALINE 50mg tablets*	Zoloft	\$0.96	\$0.53
SERTRALINE 100mg tablets*	Zoloft	\$0.96	\$0.57
SIMVASTATIN 20mg tablets	Zocor	\$1.32	\$0.99
FLUOXETINE 20mg tablets*	Prozac	\$0.85	\$0.53
SIMVASTATIN 10mg tablets	Zocor	\$0.97	\$0.71
RANITIDINE 150mg tablets*	Zantac	\$0.33	\$0.18
ATENOLOL 50mg tablets*	Tenormin	\$0.35	\$0.21
METOCLOPRAMIDE HYDROCHLORIDE 10mg tablets*	Maxolon	\$0.28	\$0.18
AMOXYCILLIN 500mg capsules	Amoxil	\$0.54	\$0.46
PARACETAMOL 500mg tablets ⁴	Panadol/Tylenol	\$0.08	\$0.06

I continued**Australian price is within 10% of US price or lower than US price**

ALENDRONATE 70mg tablets	Fosamax	\$11.57	\$10.64
CEPHALEXIN 500mg capsules	Keflex	\$0.55	\$0.53
PARACETAMOL 500mg tablets	Panadol/Tylenol	\$0.04	\$0.06
FRUSEMIDE 40mg tablets ⁴	Lasix	\$0.08	\$0.15
ALLOPURINOL 300mg tablets	Zyloprim	\$0.18	\$0.24
VERAPAMIL HYDROCHLORIDE 240mg tablets (sustained release)	Isoptin SR	\$0.60	\$0.67
METOPROLOL 50mg tablets	Betaloc	\$0.11	\$0.23
PROCHLORPERAZINE 5mg tablets	Stemetil	\$0.32	\$0.46
TRAMADOL 50mg capsules	Tramal	\$0.45	\$0.60
DICLOFENAC SODIUM 50mg tablets (enteric coated)	Voltaren	\$0.23	\$0.41
ISOSORBIDE MONONITRATE 60mg tablets (sustained release)	Imdur	\$0.46	\$0.71
DIAZEPAM 5mg tablets	Valium	\$0.15	\$0.43
METFORMIN 500mg tablets	Diabex	\$0.14	\$0.44
METFORMIN 1g tablets	Diabex	\$0.23	\$0.53
DILTIAZEM HYDROCHLORIDE 180mg capsules (controlled delivery)	Cardizem CD	\$0.72	\$1.06
CITALOPRAM 20mg tablets	Cipramil	\$0.95	\$1.42
MIRTAZAPINE 30mg tablets	Avanza	\$1.07	\$1.63
DILTIAZEM HYDROCHLORIDE 240mg capsules (controlled delivery)	Cardizem CD	\$0.81	\$1.38
AMLODIPINE 5mg tablets	Norvasc	\$0.63	\$1.35
FELODIPINE 5mg tablets (extended release)	Plendil ER	\$0.59	\$1.38
AMLODIPINE 10mg tablets	Norvasc	\$0.96	\$1.84
OXAZEPAM 30mg tablets	Serepax	\$0.28	\$1.28
RAMIPRIL 10mg capsules	Tritace	\$0.93	\$2.20
FELODIPINE 10mg tablets (extended release)	Plendil ER	\$0.92	\$2.20
PERINDOPRIL ARGININE 2.5mg tablets	Coversyl	\$0.48	\$1.77
PERINDOPRIL ARGININE 5mg tablets	Coversyl	\$0.72	\$2.01
PERINDOPRIL ERBUMINE 4mg tablets	Coversyl	\$0.72	\$2.01
RAMIPRIL 5mg tablets	Tritace	\$0.61	\$1.99
PERINDOPRIL ARGININE 10mg tablets	Coversyl	\$1.00	\$2.43
AMOXYCILLIN 875mg + CLAVULANIC ACID 125mg tablets	Augmentin Duo Forte	\$1.59	\$5.10
HYPROMELLOSE 0.3% + DEXTRAN 0.1% eye drops 15ml	Tears Naturale/Poly-Tears	\$9.43	\$17.01
LEVONORGESTREL 150mcg + ETHINYLLOESTRADIOL 30mcg tablets 21 (+ 7 inert tablets)	Microgynon 30ED	\$4.10	\$35.10
SALBUTAMOL 100mcg oral pressurised inhaler (200 doses) ⁴	Ventolin	\$8.34	\$40.41

* Price in Australia remains higher even if exchange rate of 1A\$ = 0.60US\$ (rather than 1A\$ = 0.94US\$) is applied.

¹ Generic available in US but no generic available in Australia.

² Inhaler not available in the US. US price corresponds to Advair Diskus 60 dose pack.

³ US price is for OTC supply.

⁴ Paracetamol is known as acetaminophen in the US; frusemide is known as furosemide in the US; salbutamol is known as albuterol in the US.

Australia is reduced from 19 items to 15 items (marked with an asterisk in Box 1). Thus, the finding of higher prices for a substantial number of generics remains an issue even if changes in the exchange rate apply.

Second, prices paid by individuals at drug-store.com may not reflect the average price paid in the US. It is possible that lower prices are paid by government agencies (eg, the Department of Veterans' Affairs [VA], Medicaid, Medicare) and other agencies with substantial buying power (eg, private health insurance companies, health maintenance organisations [HMOs]).

Third, patients in the US are able to access lower priced drugs by subscribing to various prescription programs and plans (eg, Walmart offers customers a \$4 Prescription Program;⁴ under this program, up to 30 days supply of eligible generic drugs at commonly prescribed dosages are provided for \$4; eg, the US price listed in Box 1 per metoprolol 50mg tablet is \$0.23 A\$ (compared with the Australian price of \$0.11) however this drug is available under the Walmart program [60 tablets for \$4], such that the price per metoprolol 50mg tablet under this program is \$0.07 A\$, which is lower than the price in Australia).

That prices paid for generic medicines in Australia are high in comparison with those paid in other countries was acknowledged by the previous Minister for Health, Tony Abbott,⁵ in a media release announcing a new policy measure in relation to generic medicines. The Department of Health, in 2005, published a comparison of prices for generic medications in Australia, the United Kingdom and New Zealand.⁶ A table from this document is reproduced at Box 2.

One factor identified as contributing to high Australian prices for generics is the practice of discounts (through trading terms) offered by generic manufacturers to pharmacists, which are generally not reflected in the price paid by the consumer (the exceptions are discounting pharmacies such as Chemist Warehouse which pass on some of the discounts in an effort to win price-conscious consumers). This incentive for pharmacists to switch patients to the manufacturer's

particular generic brand has been one of the few means available to generics suppliers to influence market share. This has been a successful strategy because, although prescribers determine the medication a patient will take by writing a prescription, pharmacists have an influence on the actual brand dispensed (unless the doctor specifically endorses the prescription with a direction stating that brand substitution is not permitted).

Government policy responses to high generics prices

The government has introduced a number of measures to address the issue of high prices for generic medicines and the discounting of generics to pharmacies.

In 2005, the government introduced a requirement for the first generic version listed of an existing PBS medicine to be automatically subjected to a reduction of at least 12.5 per cent in the government benchmark price.

Further price reductions for generic products will apply as a result of other changes introduced in August 2007. These changes are described in detail by de Boer and Searles in this issue (*pages 176 and 186*), and in other sources.^{7,8} In summary, these changes involve a classification of medications on the PBS into two different formularies: one classification (F1) essentially applies to single brand medicines excluding single brand medicines which are interchangeable at the patient level with multiple brand medicines, and the other (F2) to medicines where generics or interchangeable alternatives are available. Medicines in the following groups have been recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) and determined by the Minister to be interchangeable at the patient level: ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, H2 receptor antagonists, proton pump inhibitors and the HMG coenzyme A reductase inhibitors (pravastatin & simvastatin only).

For medicines included in the F2 classification, further discounts are mandated. The extent of discount to be applied is related to whether the

2 Price comparisons reported by the Department of Health and Ageing

QUESTIONS AND ANSWERS continued

Attachment 1

Medicine Price Comparisons – Australia – United Kingdom – New Zealand (compiled 24 November 2004)

All prices in AUD pro rata to 30 tabs/caps		UK ¹	NZ ²	AUST	No of PBS brands	% price decrease since new brands*	Date first new brand	PBS govt cost by medicine 2003-04#
Aciclovir 200mg	viral infections	\$11.83	\$2.75	\$62.45	4	8%	Feb 1995	\$8.5 M
Ciprofloxacin 750mg	antibiotic	\$128.68	\$29.33	\$199.29	6	6%	Aug 1995	\$11.3 M
Norfloxacin 400mg	antibiotic	\$26.07	\$25.29	\$41.98	9	10.4%	May 2002	\$2.3 M
Enalapril 10mg	hypertension and heart failure	\$12.17	\$0.84	\$21.30	9	24%	Dec 1998	\$21.1 M
Lisinopril 10mg	hypertension and heart failure	\$10.64	\$6.54	\$22.12	10	30%	Feb 1998	\$20.3 M
Citalopram 20mg	depression	no generic	\$3.93	\$33.43	6	11%	Aug 2001	\$44.7 M
Fluoxetine 20mg	depression	\$4.97	\$1.45	\$33.03	9	42.5%**	Feb 1996	\$27.6 M
Famotidine 40mg	gastric ulcers and reflux	\$60.92	\$1.10	\$21.27	9	42%**	Aug 1989	\$4.3 M
Omeprazole 20mg	gastric ulcers and reflux	\$33.58	\$22.73	\$42.17	4	55%**	Feb 1999	\$183 M

* cumulative reductions in PBS price since listing of first additional brand.

** price reductions include the impact of changes other than entry of new brands such as the effect of changes in the level of restriction – for example the removal of the Authority requirements for the Selective Serotonin Re-uptake Inhibitors (eg fluoxetine) and Proton Pump Inhibitors (eg omeprazole).

includes all forms and strengths of that medicine.

1

http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/GenericMedicines/MaximumPriceScheme/ListOfMaximumPriceGenericMedicines/fs/en?CONTENT_ID=4026674&chk=Vw8wqY

2 <http://www.pharmac.govt.nz/interactive/index.asp>

The above figure is Attachment 1 from: "Australian Government Department of Health and Ageing. Update (March 2005) questions and answers on new pricing and listing arrangements for generic medicines on the Pharmaceutical Benefits Scheme."⁶ Copyright Commonwealth of Australia; reproduced by permission.

medicine was heavily ($\geq 25\%$) discounted to pharmacy as at 1 October 2006. For drugs that were not heavily discounted, staged price reductions of 2% per year for 3 years were to apply commencing on 1 August 2008. For drugs that were heavily discounted, a price reduction of 25% was to be applied. In addition, suppliers listing new brands of a medicine will be required to disclose the actual market price as a condition of listing. Pricing based on disclosure will then continue on an annual cycle.

Compensation is provided for pharmacists and wholesalers for loss of income from statutory F2 price reductions.

This takes the form of:

- An incentive of \$1.50 for pharmacists to dispense a substitutable, premium-free medicine. This applies only to PBS subsidised medicines. Under-copayment medicines and private scripts are not eligible for this payment.

- An incentive of 40c for each prescription processed using PBS Online; and
- Increases in pharmacy mark ups and dispensing fees.

Additional funding of \$69 million over three years will be added to the Community Services Obligation (CSO) Funding Pool to compensate wholesalers for the impact on the wholesale margin resulting from the new pricing arrangements.

Issues in relation to these policy measures include:

- The mandatory price reductions go some way in addressing the issue of high priced generics, but are unlikely to generate the maximum savings possible, which would be those that would occur if there was a move to a more competitive environment.
- As noted by de Boer and Searles in this issue and elsewhere by Faunce and Löfgren⁸ and

Searles et al,⁹ the creation of the F1 classification will insulate high priced single brand (patented) F1 drugs from the reference pricing that applied under previous PBS processes. Once a new drug is listed as an F1 drug, its price will not be linked to the price of any similar drug in the F2 classification. F1 drugs are considered not interchangeable at the individual patient level with drugs that have multiple brands, so the manufacturers may be able to retain their original PBS price until the listing of a bioequivalent brand satisfies the new standards for a shift to the F2 classification. Reductions in F2 drug prices will not affect F1 prices, even where the therapeutic effect of an F2 medicine is similar though not necessarily “interchangeable at the individual patient level”. Thus, the creation of the F1 category is likely to, over time, result in higher prices for

some patented drugs than would have been the case under previous PBS arrangements.

- To apply blanket cuts across the board is to take a blunt axe to prices where a surgeon’s scalpel may be more appropriate. As shown in Box 1, not all generics are priced at inappropriately high levels and the policy may be inappropriately harsh on these products and inappropriately soft on other products. Some companies may be forced to charge prices that might ultimately put their viability at risk.

Economic theory and the generics market in Australia

In this section, policies influencing the pricing of generic drugs are discussed and causes of higher prices, compared with those in the US, are identified.

3 Calculation of potential savings

Item	Price differential per unit	Number of units per prescription	Number of prescriptions in 2006/07	Potential savings
SIMVASTATIN 40mg tablets	0.8291	30	2,448,471	\$60,901,809
OMEPRAZOLE 20mg tablets	0.548	30	3,198,775	\$52,589,514
SIMVASTATIN 80mg tablets	1.3691	30	646,323	\$26,547,236
PRAVASTATIN 40mg tablets	0.8624	30	1,012,764	\$26,201,282
MELOXICAM 15mg tablets	0.7023	30	1,040,527	\$21,921,690
SIMVASTATIN 20mg tablets	0.3288	30	2,027,661	\$19,999,640
PAROXETINE 20mg tablets	0.5307	30	904,811	\$14,405,361
CARVEDILOL 25mg tablets	1.0361	60	231,485	\$14,389,912
SERTRALINE 50mg tablets	0.4248	30	982,847	\$12,524,608
ATENOLOL 50mg tablets	0.1324	30	2,964,234	\$11,769,691
SERTRALINE 100mg tablets	0.3893	30	952,978	\$11,130,175
PRAVASTATIN 20mg tablets	0.5724	30	508,046	\$8,724,015
RANITIDINE 150mg tablets	0.157	60	704,868	\$6,639,007
SIMVASTATIN 10mg tablets	0.2655	30	665,309	\$5,298,549
FLUOXETINE 20mg tablets	0.3181	28	544,997	\$4,853,913
PARACETAMOL 500mg tablets	0.0206	100	1,623,756	\$3,352,192
AMOXYCILLIN 500mg capsules	0.0814	20	1,146,189	\$1,865,118
TRIMETHOPRIM 300mg tablets	0.444	7	423,384	\$1,315,853
METOCLOPRAMIDE HYDROCHLORIDE 10mg tablets	0.1024	25	422,256	\$1,081,115
Total				\$305,510,680

New drugs are initially available with patent protection. This protects the manufacturer's investment in research, development, marketing and promotion. The originator firm has the sole right to sell the medicine while the patent is in effect. Once the patent for that medicine has expired, other firms are all free to market their own brand of that medicine.

Firms producing generic medicines do not have to match the investment of companies developing new drugs and should therefore be able to pass on their lower costs in the form of lower consumer prices. The presence of more companies and products in the market would be expected to increase competition and lower prices for generics compared with originator brands. However, in Australia there is typically little difference between the price of the originator brands and the generic brands. Furthermore, there is typically little or no difference between the prices of different brands of generics.

As an example, consider the market for simvastatin 40mg tablets, a cholesterol-lowering agent, which is included in the top 5 items in both the list of highest government cost items and the list of

highest volume items. As shown in Box 3, potential savings of at least \$60 million could be generated for the government if the price for this item were reduced to the price in the US. Merck Sharp & Dohme was the original producer of simvastatin in Australia and Zocor® is the originator brand of this product. Another brand of simvastatin, Lipex®, was also originally available. This brand was marketed by Amrad Pharmaceuticals through a partnership arrangement with Merck Sharp & Dohme. The Australian patent for simvastatin expired in mid 2005 and, as at 1 May 2008, there were 15 bioequivalent brands available on the PBS. Box 4 summarises the availability of simvastatin 40mg on the PBS as of 1 May 2008.¹⁰ All but two brands (the originator product and the licensed pseudo-generic – see further below) of simvastatin 40mg were priced at \$54.65. The price for the originator brands, Zocor® and Lipex®, was \$55.99. This lack of price differentiation across the market for a single item and the small difference between the price of the originator brand and the generic brand is typical for the majority of medicines where patents have expired and generic alternatives are available.

4 Availability of simvastatin 40mg on the Pharmaceutical Benefits Schedule at 1 May 2008

Proprietary name	Manufacturer	PBS dispensed price for 30 tablets
Chem mart Simvastatin	Chem mart Pty Ltd	\$54.65
GenRx Simvastatin	Apotex Pty Lt	\$54.65
Ransim	Rambaxy Australia Pty Ltd	\$54.65
Simvabell	Bellwether Pharma Ltd	\$54.65
Simvahexal	Sandoz Pty Ltd	\$54.65
Simvar 40	Arrow Pharmaceuticals Pty Ltd	\$54.65
Simvastatin-DP	Genepharm Pty Ltd	\$54.65
Simvastatin generichealth	Generic Health Pty Ltd	\$54.65
Simvastatin-RL	Real-RL (Division of GlaxoSmithKline Australia Pty Ltd)	\$54.65
Simvastatin Winthrop	Winthrop Pharmaceuticals (Division of Sanofi-Aventis Australia Pty Ltd)	\$54.65
Simvasyn	Pharmacor Ltd	\$54.65
Terry White Chemists Simvastatin	Terry White Chemists	\$54.65
Zimstat	Alphapharm Pty Ltd	\$54.65
Lipex 40	Alphapharm Pty Ltd	\$55.99
Zocor	Merck Sharp & Dohme (Australia) Pty Ltd	\$55.99

Box 5 shows the change in the PBS dispensed price for simvastatin 40mg over time. The price shown is the benchmark price, the price of the lowest priced brand available. From this figure, it can be seen that the first substantial price drop occurred in August 2005, when the patent on simvastatin expired and generic brands of simvastatin became available on the PBS. The price reduction occurred primarily as a result of the mandatory 12.5% price cut, as explained above.

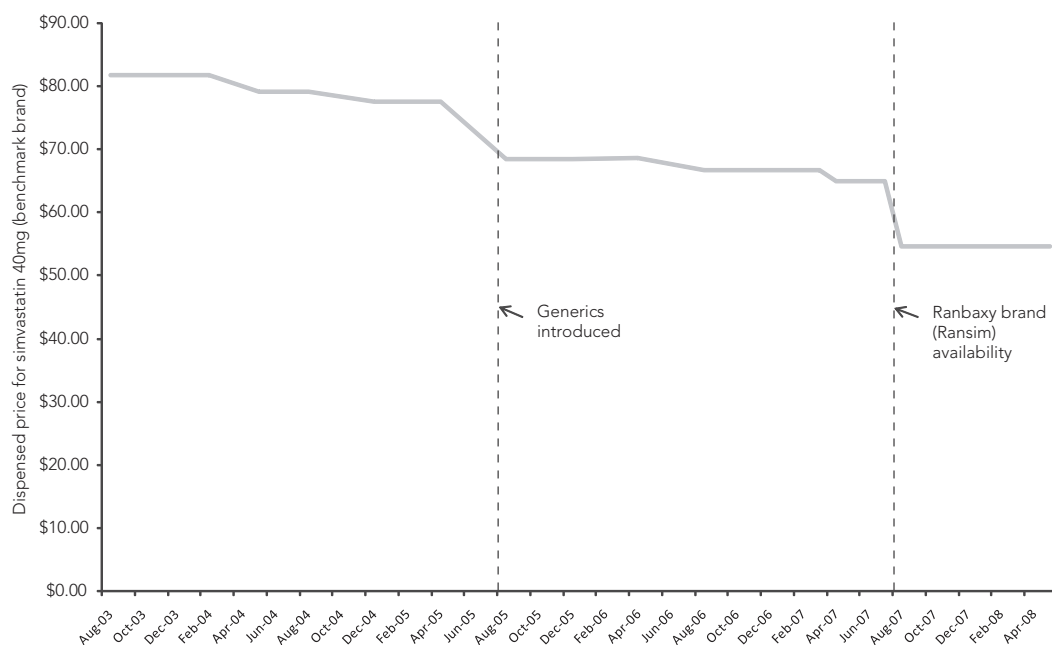
The second significant price reduction resulted from the entry of the Indian-based firm Ranbaxy to the Australian generics market. It is likely that Ranbaxy's aggressive pricing strategy was designed to result in the capture of significant market share. However, for reasons discussed below, it is unlikely that this result will have been achieved.

The different brands of a medicine could be considered perfect substitutes. If the market for a medicine was a typical competitive market, the price of a particular brand of a generic medicine would have direct consequences for the volume

of that product demanded and supplied. As the price for a particular brand of the medicine decreases, one would expect the market share for that particular brand to increase.

As discussed above, the major purchaser of pharmaceuticals in the Australian market is the government. However, to the extent that they are required to pay copayments and brand premiums, patients are also purchasers of pharmaceuticals. Also, as discussed already, under the brand premium arrangements, the Commonwealth reimburses the price of a medicine only to the level of the lowest priced brand. Patients pay the difference (a brand price premium) for higher priced brands of medicines if they choose these instead of the benchmark product. The fact that patients themselves are faced with an economic incentive to choose the lowest priced brand should ensure competition among the suppliers. However, as illustrated by Box 5, with the exception of the lowering of the price of simvastatin that accompanied the introduction of the Ranbaxy brand, there is very limited price competition.

5 Change in Australian price for simvastatin 40mg over time



Ranbaxy’s aggressive pricing strategy could signal a lack of understanding of the Australian generics market and could be ill-advised from a business perspective as the strategy was unlikely to result in significant capture of market share. Game theory is used to explain why this is the case. Firms marketing generic medicines in Australia can be considered to be presented with circumstances akin to what, in game theory, is called an “iterative prisoner’s dilemma”.

The prisoner’s dilemma was illustrated by Poundstone (1993)¹¹ using the following hypothetical situation: two members of a criminal gang are arrested under the suspicion of having committed a crime together. However, the police do not have sufficient evidence to obtain a conviction on the principal charge. The two prisoners are isolated from each other, and the police visit each of them and offer the following deal: if evidence is offered against the other prisoner and the other prisoner remains silent, he is freed and the other prisoner will be given three years in prison on the main charge. If both stay silent, both will get only a year in prison on a lesser charge because of lack of proof on the main charge. If both confess, each get charged and receive a two-year sentence. The game is summarised in Box 6. The prisoners are given some time to think this over but in no case may either prisoner learn what the other has decided until they have both made irrevocable decisions. Each prisoner is informed that the other suspect is being offered the very same deal.

Overall and on balance, both prisoners would be better off cooperating with each other and

remaining silent. However, if each prisoner is concerned only with his own welfare and minimising his own prison sentence, each of the prisoners has an individual incentive to offer evidence against the other suspect. Each prisoner can reason as follows: “Suppose I testify and the other prisoner doesn’t. Then I get off scot-free (rather than spending a year in jail). Suppose I testify and the other prisoner does too. Then I get two years (rather than three). Either way I’m better off giving evidence.” Offering evidence against the other suspect is a dominant strategy for both players in this game. No matter what the other player’s choice is, each prisoner can reduce his sentence by confessing. Unfortunately for the prisoners, this leads to a poor outcome where both offer evidence against each other and both are given severe sentences. The conflict between the collective interest and self-interest is the core of the prisoner’s dilemma.

When the prisoner’s dilemma game is played repeatedly, or iteratively, players have an opportunity to “punish” each other for previous non-cooperation. Cooperation is therefore more likely to arise as an equilibrium outcome. The incentive to offer evidence may then be overcome by the threat of punishment, leading to the possibility of a superior, cooperative outcome.

In the case of the firms marketing generic medicines in Australia, the game could be considered to be structured as shown in Box 7. The game here is repeated as firms continuously compete in the market for a specific generic product over an infinite horizon. Also, the same firms tend to compete each time a patent on

6 Classic prisoner’s dilemma

		Prisoner A’s choices	
		Offer evidence against other suspect	Remain silent
Prisoner B’s choices	Offer evidence against other suspect	2-year sentence / 2-year sentence	3-year sentence / Free
	Remain silent	Free / 3-year sentence	1-year sentence / 1-year sentence

7 Generic medicine manufacturers' dilemma

		Manufacturer A	
		Offer lower price	Don't offer lower price
Manufacturer B	Offer lower price	No change to market share (decreased profit) No change to market share (decreased profit)	Decreased market share (decreased profits) Increased market share (increased profits)
	Don't offer lower price	Increased market share (increased profits) Decreased market share (decreased profits)	No change to market share (no change to profits) No change to market share (no change to profits)

another product expires. This could partly explain the cooperative outcomes that can be observed in reality.

However, there is an important deviation from the classic prisoner's dilemma proposed here as the primary cause of cooperative outcomes in the Australian generic medicines market — the degree of information provided to players in the game. Where in the classic prisoner's dilemma the police do not inform suspects of each others' choice, the government openly provides information on action taken by competitors in the market: when a manufacturer offers the government a lower price for one particular brand of medicine, the government immediately affords all other manufacturers of that medicine the opportunity to match that price. The government thereby removes the risk of the worst possible outcome to players in the market. Thus, there is little real chance that one competitor will lower its price to obtain greater market share with other competitors in the market not reducing their price at the same time. The dominant strategy for all manufacturers of a generic medicine is to only reduce their price in response to a reduction in price by another competitor. There is no incentive to be the first to offer a reduced price. Indeed, there is a

strong incentive for manufacturers to cooperate with each other by not offering reduced prices at all.

Alternate approach — competitive tendering

Some commentators (eg, Searles et al⁹) have suggested that competitive tendering, where arrangements for the supply of one or more subsidised brands of a medicine are made after consideration of tenders to supply, should be adopted, and note that this approach has been successful in other countries such as New Zealand. However, the structure of the drug purchasing system, and the overall role of the pharmaceutical industry in the economy, may be substantially different in these countries.

One of the objectives of Australia's National Medicines Policy¹² is to sustain a responsible and viable medicines industry in Australia. The government considers that industry policy and health policy should be coordinated to provide a consistent and supportive industry environment, and appropriate returns on research and development, manufacturing, and supply of medicines. As competitive tendering creates barriers to mar-

ket access (and results in the “locking out” or exclusion of firms in the short term, which could have consequences for viability of the firm), such a policy may not be consistent with Australia’s National Medicines Policy. Furthermore, the reliance on one or two suppliers for a generic product increases risks of disruptions in supply due to unforeseen circumstances.

Another issue that could arise if a system of competitive tendering were adopted relates to the availability of “pseudo-generics” in the Australian market. Pseudo-generics are generic products that are made by brand-name producers copying their own brand-name drugs. The problem could also occur as a result of close relationships between a generics supplier and the company that manufactured the originator brand as a result of cross-licensing agreements and the acquisition of generics suppliers by large multinational companies. Hollis¹³ notes that pseudo-generic drugs are often treated as though they were independent generics, and this is the case in Australia. The company associated with the originator brand will always be able to release its pseudo-generic before other generics enter the market. This weakens the incentive for generic firms to invent around the brand-name firm’s patents, since the pseudo-generic can always get to market first.

A third problem also has the potential to arise. Where the company that successfully tenders to be the supplier of a generic product is owned by the company producing the originator brand, there will be an economic incentive for the manufacturer to under-supply the generic product to the extent that is possible as it forces consumers to switch to the higher priced originator brand.

Alternative — alter structure of the market to encourage competition

An alternative approach to remedying the problem of pricing cooperation is to change the structure of the generics market to discourage such cooperation. Besanko et al¹⁴ explain how price cooperation is harder to achieve under some market structures than others. Four market struc-

ture conditions that can affect the attainment of cooperative pricing are:

- **Market concentration** — as the number of firms increases, the likelihood of cooperative pricing decreases. This is because firms that undercut other firms have more to gain (in terms of increase in relative market share) compared with when there are fewer firms in the market.
- **Structural conditions that affect reaction speeds and detection lags** — the speed with which firms can react to their rivals’ pricing moves affects the sustainability of cooperative pricing. The greater the time period before a firm can react to competitors’ price cuts, the lower the likelihood of cooperative pricing. Long lags between price cuts and competitor response also reduce the effectiveness of retaliatory price cuts aimed at punishing price cutting firms.
- **Firm asymmetries** — where firms are not identical in terms of cost structures or capacity, cooperative pricing becomes less likely. Smaller firms benefit less from cooperative pricing and have greater incentives to price competitively. Firms with lower marginal costs are also more likely to price competitively.
- **Multimarket contact** — firms that compete with each other in more than one market are more likely to price cooperatively.

The government is limited in its ability to influence three of these four conditions to manipulate the structure of the generics market. However, it is able to influence reaction speeds and detection lag conditions. As discussed above, firms marketing generics in Australia are able to respond instantly to competitors’ price cuts as the government informs them directly of the price cut to be applied by competitors. The structure of the market could be improved (to encourage greater competition) by cessation of the government practice of disclosing of competitor firms’ offers to other competitors. The government could conduct pricing reviews relatively infrequently (eg, only once annually or every 18 months). At the time of the pricing review for a generic product, the government would request confidential offers on price for that product from each player in the

market. Brands should then all be listed on the PBS at the price offered. Prices offered would apply until the next pricing review. The PBS would continue to subsidise up to the price of the lowest priced brand, with brand premiums applying to all brands priced higher than the benchmark price.

Such an approach would provide opportunity for players in the market to capture market share by being the lowest priced brand in a market. This would encourage competition in the market and result in lower prices for generics. In addition, this approach removes incentives for generic manufacturers to attempt to gain market share by offering discounts to pharmacies rather than directly to patients.

A potential issue that might be raised in response to this proposal is that patients may need to switch brands every 12–18 months if they wish to always use the base-priced brand. However, this problem is not unique to this model. The approach where generics manufacturers offer sizeable discounts through pharmacy trading terms to switch patients to particular generic brands could also result in relatively frequent changes in the generic brand given to patients.

The industry may claim that there is limited scope under this option for fine tuning of decisions if the manufacturer sets the price incorrectly. The potential impact on the business could be large and the ongoing viability of the manufacturer could be threatened. However, walking the tight-rope of offering a product at the “right” price that ensures market share without putting manufacturers’ viability at risk is a fact of life in other competitive markets. Unlike the government, manufacturers have information about the cost of producing a product and should therefore be able to calculate the best price it can offer without putting the company’s viability at risk. Most generics manufacturers produce more than one product and therefore an error (pricing too high) in one product market may mean a loss of market share for that item, but the manufacturer can continue to compete in other product markets. If the manufacturer finds that their prices are always higher than competitors’ prices then that manufacturer would

have the incentive to examine their processes for opportunities to improve efficiency.

Box 3 provides estimates of potential savings to the government if dispensed prices for generic items in Box 1 that cost more in Australia than the US were reduced to US levels. This table demonstrates that savings of up to \$305 million could be achieved. Sensitivity analysis that included an exchange rate of 1A\$ = 0.60US\$ (instead of 1A\$ = 0.94US\$) demonstrates that savings up to \$112 million could be achieved.

Conclusion

The prices of several generic products, including high-volume drugs, are substantially higher in Australia than in the USA. The response by the Australian government to the problem of high generics prices paid through the PBS has been to indiscriminately mandate price reductions. This policy is inappropriately harsh on products that are already competitively priced and is inappropriately gentle on some other products such as those that are priced at more than double the price in the US. That higher prices are paid for a substantial number of generic products is partially explained by the government policy of immediately communicating price changes proposed by one competitor to all other competitors, along with an invitation to match the offered price. Using game theory, it is postulated that this policy contributes to the suppression of competition. Instead of mandating indiscriminate price reductions, the government could improve the structure of the generics market and encourage greater competition by ceasing to disclose competitor firms’ offers to other competitors and concurrently introducing periodic price reviews for each product to reduce the speed with which players in the market can react to changes in price by a competitor. The fostering of a more competitive generics market is likely to yield substantial savings to the PBS.

Competing interests

The author declares that she has no competing interests.

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