Healthy Policy Analysis

The Impact of Generic Entry of Pharmaceuticals in Australia

Arun M. Jones, MSc, Victoria Serra-Sastre, PhD, Hansoo Kim, PhD

A B S T R A C T

Objectives: In this article, we estimate the initial and temporal impacts of generic entry on benchmark drug prices as reimbursed through the Pharmaceutical Benefits Scheme of Australia and the degree to which further generic competition affects these prices under the current regulatory framework.

Methods: We construct a panel data set consisting of 781 Pharmaceutical Benefits Scheme listed drugs over a 95-month time period and use fixed-effect regressions. The dynamic price effects of generic competition are investigated by implementing panel methods.

Results: Our results suggest that generic entry into the Australian pharmaceutical market causes significant initial price reductions of approximately 31% and that successive generic entrants also act to further reduce drug prices. Through subgroup analyses, we identify that the effect of generic competition varies significantly according to the drug's therapeutic group and mode of drug administration and the dynamic analysis indicates that generic entry results in continuous price reductions even after large initial drops.

Conclusions: Generic competition reduces reimbursed drug prices in Australia to a greater extent than previous research has identified, although the average price effects can vary significantly depending on a drug's therapeutic group or mode of drug administration. Prices generally continue to fall significantly over time under the price disclosure mechanism.

Keywords: Australia, competition, generic, reimbursement.

VALUE HEALTH REG ISSUES. 2024; 43:101008

Introduction

In Australia, 16.3% of health expenditure is allocated to the Pharmaceutical Benefits Scheme (PBS),[1] the government scheme that reimburses prescribed medicines. Spending on the PBS has continually increased since its inception, and by the 2020-2021 financial year, its annual cost had reached $13.8 billion.[2] Before 2007, drug pricing in Australia was decided using reference pricing where efficacy was shown to be similar to other drugs in the same therapeutic group and using value pricing where no such comparable drugs existed.[3] Drug prices then were generally considered to be competitive with comparable countries, but by the mid-2000s the Australian system was not making the most of the potential savings that could be generated through competition from the growing number of generic medicines available worldwide.[3-6] As such, a major reform package was applied to the PBS in 2007 aimed at stimulating price reductions through increased generic competition.

The PBS is the major buyer of pharmaceuticals in Australia, with domestic and foreign manufacturers competing to produce both patented and generic drugs that it lists. Once patents expire, generic producers can generally enter at low cost given that they do not have the same high research and development costs that

originator brands do, and they are increasingly being produced in countries with relatively low labor costs.[7]

One reason for the lack of price competition among generics over this period is that large proportions of the discounts that were generated through generic competition were not passed over to consumers but were instead retained by pharmacists.[5,8] This is because pharmacists in Australia can substitute prescribed drugs for generic alternatives, so manufacturers would provide rebates to pharmacists in the form of extra stock or other incentives to encourage the dispensation of their brand, effectively meaning manufacturers would sell to pharmacists at discounted net prices, gaining market share, while the government still subsidized pharmacies to dispense at the higher approved benchmark price.[5] Pharmacists have argued that the value extracted via these rebates were necessary for the cross-subsidization of dispensing less profitable items.[9]

Another problem in Australia was its relatively low rate of generic uptake. Although generic competitors may enter the market at a lower price, uptake can still be low for a variety of reasons such as mistrust in the quality of generics,[10] which can result in unnecessary and costly spending on branded drugs over generic alternatives.[11,12] The Australian government has attempted to combat this through informational campaigns via consumer

and physician facing government-funded nonprofits such as Healthdirect Australia or National Prescribing Service Medicine-Wise (formerly the National Prescribing Service).

In light of the growing evidence that the Australian government was overpaying for generic drugs, Parliament passed the National Health Amendment (Pharmaceutical Benefits Scheme) Act of 2007.[13] This introduced measures relating to the mandated price reduction of drugs listed on the PBS once prespecified conditions were met, such as the splitting of the schedule into 2 separate formularies. Formulary 1 (F1) lists drugs that are still under patent or for whom no alternative brand has been evaluated as "interchangeable at the patient level" by the Therapeutic Goods Administration, whereas formulary 2 (F2) lists drugs whose patents have expired or for which bioequivalent or biosimilar alternatives are available. Drugs generally switch from F1 to F2 as soon as their first generic alternative becomes listed on the PBS.[14] However, this does not necessarily mean that drugs switch to F2 immediately upon patent expiration.

Drugs in F2 then became subject to the newly introduced price disclosure mechanism, whose aim was to bring dispensed drug prices in line with the price at which they are supplied to the market. This was done by forcing manufacturers to disclose sales and rebate information to the government, who then calculate the brand's "disclosed price." This price should better reflect the net price that a manufacturer supplies its brand of drug to market. The price disclosure mechanism dictates that a weighted average of all the disclosed prices (WADP) of a medicine across brands is calculated. If this WADP is sufficiently less than the currently approved ex-manufacturer price such that it meets the prescribed threshold outlined in the price disclosure guidelines (10% as of December 2022), then the WADP calculated becomes the new benchmark price.[15] Therefore, this mechanism targets the problem of pharmacists retaining discounts generated through generic competition by forcing reimbursement levels to be set according to the approximate price at which drugs are supplied to market.

Statutory percentage price reductions were also introduced, including the first new brand reduction that is applied once the first competitor to an F1 drug becomes listed on the PBS or anniversary reductions that apply on specific anniversaries of the drug's first listing on the PBS. A summary of how the price disclosure and statutory price reductions have evolved over time is listed in Appendix Table 1 and Appendix Table 2, respectively, in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2024.101008.

This combination of statutory price reductions and price disclosure introduced in the reforms is a hybrid of administered and market-based approaches intended to encourage competition. However, administered pricing has previously been shown to limit the penetration of generic producers into drug markets that can limit savings generated despite enforced lower prices.[16] A literature review on the effects of reimbursement regulation in European countries also echoed this sentiment,[17] suggesting that such policies could cause large reductions in drug prices once patents expire but limit the degree of price competition afterwards, which motivates us to investigate the temporal and initial effects of generic competition in Australia. (See more discussion on the reforms in Appendix Table 3, respectively, in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2024.101008).

Although there exists discussion in the literature comparing Australian generic and patented drug prices with those of other countries,[6,18,19] there is very limited literature on the actual price effects of generic competition within Australia. To the best of our knowledge, only one publication has estimated this effect and concluded a very small but statistically significant effect of generic competition reducing pharmaceutical prices.[20] Our analysis provides an update on this area since the publication of the last study over 10 years ago.

Methods

Data

Monthly data on the price of all drugs on the PBS[21] from the date of introduction of simplified price disclosure in October 2014 to September 2022 were compiled. Variables of interest here include drug name, formulary status, item code, date, dispensed price per maximum quantity (DPMQ), and competing brands. The DPMQ is the dispensed price for the maximum quantity of a specific drug and formulation that is allowed to be dispensed by a pharmacist without requiring special authorization. This is the price published in the PBS data and thus becomes the dependent variable of our analysis.

The cross-sectional unit of this analysis is the PBS item code, an identifier assigned not necessarily just to singular drugs but to drugs per their approved indication. For example, the antibiotic amoxicillin is separated into 19 item codes in the PBS; item code "12002Q" is amoxicillin indicated for use in patients with community acquired pneumonia whereas item code "8581P" is amoxicillin indicated for use in patients with acute symptoms resulting from chronic bronchitis.[22] Separate item codes, even of the same drug, can have different DPMQs. Similarly, an item code for the same indication could have a different price, which will depend on the strength or the mode of action of the drug.

Monthly government expenditure and monthly number of prescriptions per item code are obtained from the Medicare Australia statistics website.[23] Both government expenditure and number of prescriptions act as proxies for market size, which has previously been shown to influence generic competition. Large markets for "blockbuster" drugs experience greater price erosion upon patent expiration,[24] whereas market size has been shown to be a major determinant of generic entry.[25-28]

One limitation with this data set is that it does not track patient expenditure on drugs nor statistics for drugs that do not attract a PBS subsidy, such as those that fall under the copayment threshold. This could introduce bias if there are differences in the market for drugs included in our sample versus that for drugs that attract no subsidy from the PBS. We compared our data set with data published by the department of health on under copayment threshold prescriptions in 2021[29] and found that 10% of total expenditure on PBS listed drugs falls under the copayment threshold. This is a relatively small proportion of total expenditure on the PBS, and as such, excluding these drugs would have minimal impact on our estimates. Dispensed drug prices and government expenditure were then adjusted for inflation per the Australian national consumer price index to September 2022 Australian dollars.[30]

We generate a dummy variable equal to 1 if the item code in question is listed as being on the F2 and 0 when it is on F1, to estimate the price effect of switching from F1 to F2. Any observation where the formulary listed was the combination drugs list was dropped given that these items are subject to different pricing rules and only make up 2.13% of observations after October 2014.

The number of competitors to the originator for a given month is taken to be the number of brands supplying in that month minus 1 and is included as an explanatory variable, given that Bertrand competition under asymmetric information around competing firms' costs suggests that additional competitors will act to reduce prices from the monopoly case.[31]

We generate a variable for the market share held by the item code within its third level Anatomical Therapeutic Chemical (ATC)

code group by calculating the percentage of government expenditure on that item code within its third level ATC code group. Any observations with zero total government expenditure by ATC group were dropped from the analysis given that this would mean its market share would be undefined. Given that the logarithm of prescriptions and government expenditure are used in our models, we drop all observations where prescriptions or government expenditure is equal to 0; this equalizes the sample size between specifications that contain each of these regressors separately, bringing the sample size total to 300 380 observations containing 5029 separate item codes representing no more than 781 different medicines over 95 months.

Descriptive statistics of the sample and the top 5 drugs in sample by total government expenditure and total prescriptions dispensed are presented in Table 1 and Appendix Tables 4 and 5, respectively, in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2024.101008.

Model Specification

In the base case and subgroup analyses, we specify the relationship:

$$\log(DPMQ_{it}) = c + \beta F2_{it} + X'_{it}\Gamma + a_i + u_{it}$$

where β captures the estimated price effect of a drug switching to F2 and control variables are included in the X vector. The idiosyncratic error term is given by u_{it}, and an individual fixed-effect is included as a_i.

The fixed-effect accounts for differences in price caused by characteristics of the item code that do not vary over time. To decide between using the fixed- or random-effects estimator, we apply the Hausman specification test to compare the estimated coefficients of both the fixed and random-effects models together. This returns a chi-squared test statistic of 439.18 ($P < .00001$), rejecting the null hypothesis that a random-effects estimator is more suitable in favor of the fixed-effects estimator.

Given that the fixed-effects estimator controls for all time-invariant heterogeneity between cross-sectional units, it cannot be biased due to any omitted time-invariant drug characteristics, although it could be biased in the presence of time-variant heterogeneity. As such, we use the set of variables identified in the literature as having an impact on price differentials after generic entry for characteristics that vary over time. Those included in our analysis are number of prescriptions filled per item code; government spending per item code, which acts as a proxy for market size; and the market share of the item code within its own third level ATC code. We also include a first- and second-order number of competitors regressor to allow for the estimation of a quadratic relationship between number of competitors and price. A "count

of price disclosures" regressor simply counts the number of price reductions that are imposed upon an item code. Further models include semiannual time fixed-effects that coincide with price disclosure cycles to account for unobserved factors that affect prices over time.

To investigate the dynamic effects of switching to the F2 formulary, we implement the panel event study.[32] In this specification, the F2 dummy replaced with dummy variables for lags and leads relative to the time an item code switches to F2. The nth lag/lead dummies are equal to 1 if the month in question is n months after/before the switch to F2; otherwise, it is equal to 0; the first lead term is omitted to avoid multicollinearity. The equation for this specification is given below, time and item code–specific fixed effects are included as λ_t and a_i, respectively, whereas control variables are included in X_{it}.

$$\log(DPMQ) = c + \sum_{j=0}^{96} \beta_j (Lag\ j) + \sum_{k=2}^{98} \gamma_k (Lead\ k) + X'_{it}\Gamma + \lambda_t + a_i + u_{it}$$

Using this specification, we plot the estimated lag and lead coefficients graphically that gives an indication as to how the price effect of switching to F2 evolves over time. All models are estimated using Stata/SE 15.1 for Windows (64-bit) (StataCorp LLC, College Station, TX).

Results

Base Case

The results of the main specification are presented in Table 2. Coefficients in column (1) are obtained using pooled ordinary least squares on the $F2$ dummy. However, pooled ordinary least squares does not account for the unobserved heterogeneity present between cross-sectional units. Column (2) does by incorporating individual fixed effects. Models (3) to (5) account for the effects of other time-variant characteristics by including the competitors regressor and iteratively controlling for number of prescriptions filled, government expenditure, and market share. These variables are not included as controls alongside one another due to the risk of correlation between them resulting in multicollinearity.

Models (6) to (8) do the same as (3) to (5) while including a quadratic competitors term. Models (9) to (11) build on the previous models by including time fixed effects. For robustness checks, alternate time fixed effects were investigated by using annual and monthly fixed effects (results presented in Appendix Tables 6 and 7 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2024.101008). We find that changing the length of the time fixed effects has little impact on the estimates

Table 1. Descriptive statistics.

Variable	Observations	Mean	SD	Min	Max
F2 dummy	300 380	0.600949	0.489704	0	1
DPMQ	300 380	1508.874	12 635.91	0.563546	2 619 582
Prescriptions	300 380	5091.29	18 687.64	1	915 236
Expenditure	300 380	308 572.1	1 108 075	1.058533	63 521 488
Number of brands	300 380	2.369665	2.768357	1	22
Market share	300 380	4.972678	13.2269	0.00000196	100

DPMQ indicates dispensed price per maximum quantity; F2, formulary 2.

Table 2. Base case results.

	(1) log (DPMQ)	(2) log (DPMQ)	(3) log (DPMQ)	(4) log (DPMQ)	(5) log (DPMQ)	(6) log (DPMQ)	(7) log (DPMQ)	(8) log (DPMQ)	(9) log (DPMQ)	(10) log (DPMQ)	(11) log (DPMQ)	(12) log (DPMQ)	(13) log (DPMQ)	(14) log (DPMQ)
F2 dummy	−2.197*	−0.512*	−0.497*	−0.439*	−0.492*	−0.449*	−0.394*	−0.445*	−0.315*	−0.280*	−0.314*	−0.329*	−0.322*	−0.330*
	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)
Log prescriptions			0.00932*			0.00968*			0.00598*			−0.0000914		
			(.000)			(.000)			(.000)			(.852)		
Log expenditure				0.0730*			0.0723*			0.0596*			0.0134*	
				(.000)			(.000)			(.000)			(.000)	
Market share					0.00529*			0.00518*			0.00385*			0.00194*
					(.000)			(.000)			(.000)			(.000)
Number of competitors			−0.00737*	−0.0101*	−0.00741*	−0.0531*	−0.0531*	−0.0522*	−0.0511*	−0.0514*	−0.0506*	−0.0259*	−0.0270*	−0.0257*
			(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)
Number of competitors²						0.00362*	0.00340*	0.00355*	0.00241*	0.00234*	0.00238*	0.00196*	0.00213*	0.00196*
						(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)
Price disclosure counter												−0.244*	−0.241*	−0.244*
												(.000)	(.000)	(.000)
N	300 380	300 380	300 380	300 380	300 380	300 380	300 380	300 380	300 380	300 380	300 380	100 035	100 035	100 035
Semi annual time fixed effects	No	No	No	No	No	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes

Note. P values in parentheses.
DPMQ indicates dispensed price per maximum quantity; F2, formulary 2.
*P < .01.

obtained, and throughout the article, we presented results using 6-month fixed effects.

The model in column (11) is our preferred specification and it estimates that the overall effect of switching to F2 is a 31.4% price decrease. In this specification, the first competitor is estimated to result in a reduction in prices by 4.822%, as implied by summing the estimates of the first- and second-order number of competitors coefficient. The effect of the number of competitors on drug prices is diminishing as the number of competing firms increases, which is consistent with previous findings on pharmaceutical industry dynamics.[27] Limitations on the availability of formulary information from our data source before 2013 left us unable to make a direct comparison between the pre- and postreform periods, but the magnitude of this negative relationship between the number of competitors and drug prices is relatively large compared with a previous study on the effects of generic competitors on drug prices in Australia, which used data in the 4 years leading up to the reforms.[20] Our estimates were closer to but still not as large as findings from studies using American data.[24]

Our preferred model also estimates a statistically significant positive effect of market share on prices, as is consistent with previous literature on the effects of market concentration on drug prices.[33] Columns (12) to (14) investigate as a regressor the count of price disclosures, while iteratively controlling for prescriptions, expenditure, and market share. Estimates for the average price decrease resulting from each successive price disclosure lie between 24.1% and 24.4%. In the specifications containing this regressor, the effect of switching to F2 is greater, whereas the effect of the number of competitors on price is smaller. Note that the sample size for these specifications is smaller, given that data on the outcomes of price disclosure are only available after October 2014,[34] so it is not possible to count the number of price disclosures undertaken on each drug that is listed on the PBS before October 2014. Thus, this subgroup analysis is limited to drugs whose first listing on the PBS was on or after October 2014.

Subsample Analyses

Further analyses have been undertaken on subgroups of the data, separated by both therapeutic area and mode of drug administration (MoA).

We find the top 10 second level ATC groups by total government expenditure, which are listed in Appendix Table 8 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2024.101008. The preferred fixed-effects model used in the full-sample analysis (11) is then used on each subgroup, with the results tabulated in Table 3. We see a relatively wide range in estimates between separate subgroups. There is broad agreement on the negative effect of switching to F2, with all subsamples exhibiting statistically significant (P < .01) negative coefficients on the F2 dummy. The point estimates for this reduction ranged from 4.1% to 44.4%, highlighting differences between therapeutic groups in price effects after generic entry. Separate subgroups differ mostly in their estimation of the relationship between the number of competitors present and price. Five of the 10 subgroups yielded estimates suggesting a negative relationship between price and competitors that diminishes as the number of competitors increases. Among these 5 subgroups, estimates for the number of competitors coefficient ranged from −0.114 to −0.0317 (P < .001 for all 5). Subgroup L04 also estimated a negative relationship between competitors and price but this effect was increasing with the number of competitors. Four subgroups returned positive estimates for the competitors regressor, although in A10 it was not statistically significant.

For the subgroup analysis by MoA, all present in the sample are ranked by expenditure over the sample period as listed in Appendix Table 9 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2024.101008. We then use the same fixed-

Table 3. ATC code subsample analysis results.

	(1) log(DPMQ) L01 Antineo plastic agents	(2) log(DPMQ) L04 Immuno suppr essants	(3) log(DPMQ) S01 Ophthal molo gicals	(4) log(DPMQ) B01 Antit hrom botic agents	(5) log(DPMQ) J05 Antivirals for systemic use	(6) log(DPMQ) A10 Drugs used in diabetes	(7) log(DPMQ) C10 Lipid modifying agents	(8) log(DPMQ) N05 Psycho leptics	(9) log(DPMQ) L02 Endocrine therapy	(10) log(DPMQ) N06 Psychoa naleptics
F2 dummy	−0.444*	−0.283*	−0.145*	−0.411*	−0.189*	−0.272*	−0.139*	−0.0409*	−0.321*	−0.178*
	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.002)	(.000)	(.000)
Market share	0.0258*	0.0278*	0.00324*	0.00776†	0.0123*	0.00730*	0.0320*	0.0233*	0.00257*	0.0317*
	(.000)	(.000)	(.000)	(.019)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)
Number of competitors	−0.0865*	−0.0315*	−0.0333*	0.269*	−0.0713*	0.000807	0.0126*	−0.114*	0.0147*	−0.0317*
	(.000)	(.000)	(.000)	(.000)	(.000)	(.825)	(.001)	(.000)	(.003)	(.000)
Number of competitors^2	0.0110*	−0.00183*	0.00258*	−0.0196*	0.00474*	0.000828*	−0.00283*	0.00786*	0.00373*	0.00149*
	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)	(.000)
N	39 375	38 046	9233	7816	8426	5318	5329	13 769	3862	8738
Semiannual time fixed effects	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

Note. P values in parentheses.
ATC indicates Anatomical Therapeutic Chemical; DPMQ, dispensed price per maximum quantity; F2, formulary 2.
*$P < .01$.
$^\dagger P < .05$.

effects model to the top 10 subgroups according to this ranking and tabulate the results in Table 4. Note that the subgroups for MoAs implantation (fifth), application (seventh), intraintestinal (eighth), intrauterine (ninth), and sublingual (10th) are not included in our results given that one or more of the coefficients in the model cannot be estimated due to collinearity. All of those except application (seventh) are relatively small in sample size (N < 1500).

In these results, there is agreement among the different models on the negative effect of switching to F2, with the magnitudes of this reduction ranging between 7.68% and 32% (P <

.001). All models also agree on the positive effect of market share on prices, with the magnitude of this effect also varying significantly among MoAs (P < .001 for all estimates). When estimating the relationship between competitors and prices, subgroups oral (1), injection (2), and application to the eye (6) all estimate that additional competitors reduce prices, with this effect diminishing as more competitors enter. The groups inhalation by mouth (3) and transdermal (4) deviate from this relationship, with transdermal (4) estimating an increase in prices with additional competitors that rapidly declines into a negative relationship given that the second-order number of competitors coefficient is

Table 4. MoA subsample analysis results.

Independent variable	(1) log(DPMQ) Oral	(2) log(DPMQ) Injection	(3) log(DPMQ) Inhalation by mouth	(4) log(DPMQ) Transdermal	(6) log(DPMQ) Application to the eye
F2 dummy	−0.290*	−0.320*	−0.136*	−0.0810*	−0.0769*
	(.000)	(.000)	(.000)	(.000)	(.000)
Market share	0.00455*	0.00496*	0.000669*	0.00183*	0.00144*
	(.000)	(.000)	(.000)	(.000)	(.000)
Number of competitors	−0.0463*	−0.0820*	−0.00931†	0.0634*	−0.0705*
	(.000)	(.000)	(.029)	(.000)	(.000)
Number of competitors^2	0.00220*	0.00623*	−0.00296†	−0.0391*	0.0101*
	(.000)	(.000)	(.019)	(.000)	(.000)
N	166 420	96 067	4240	6549	7098
Semiannual time fixed effects	Yes	Yes	Yes	Yes	Yes

Note. P values in parentheses.
F2 indicates formulary 2; MoA, mode of drug administration.
*$P < .01$.
$^\dagger P < .05$.

negative and large in magnitude. Inhalation by mouth (3) has negative estimates for both first- and second-order coefficients of the number of competitors regressor. These may be the actual nature of the relationships between additional competitors and prices in these subgroups, but it is worth noting also it could be simply that specifying a quadratic relationship in these instances is unsuitable. Additional regressions were undertaken on these 2 subgroups with only a first order number of competitors regressor and found that the estimates for this coefficient were negative and strongly statistically significant.

Dynamic Effects

In our analysis of the dynamic effects of switching to F2, we control for competitors and market share. We find that the estimated average effect of switching to the F2 is a large initial drop in prices of 20.69%. This is the point where the first new brand statutory price reduction takes effect. In this section, we analyze whether these effects vary over time by providing a breakdown of the effects over each month.

Figure 1 plots the monthly lag and lead coefficient estimates. We see that the initial drop is followed by smaller subsequent drops that continue to trend downward generally, likely capturing the effect of successive price disclosures that compound over time. Beyond a certain point, we begin to see large jumps in the estimates and confidence intervals widening, likely a result of the sample size reducing as the months before and after F2 switch increases. Table 5 lists the estimates for the control variables included in this analysis, which largely agree with the results obtained in our base case analysis.

Appendix Table 10 in Supplemental Materials found at https://doi.org/10.1016/j.vhri.2024.101008 lists the point estimates for the lag terms starting at the month of the F2 switch (Lag 0) and at every 10th month thereafter up to month 60. We have limited the estimates shown in the table in this way for paucity, while still providing the general picture of the price evolution following the F2 switch. These results show that after the immediate drop in price following the switch to F2, prices generally continue to decline as a result of being on F2.

Discussion

The number of generic competitors for a drug in Australia is shown to be a significant driver of drug prices according to our
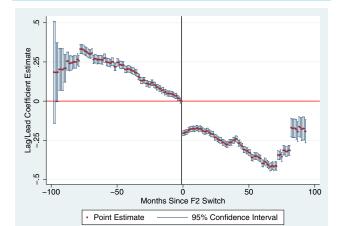
Table 5. Control variable estimates in event study.

Independent variable	log(DPMQ)
Number of competitors	−0.0461232*
	(.000)
Number of competitors^2	0.0023346*
	(.000)
Market share	0.00368*
	(.000)
Semiannual time fixed effects	Yes

Note. P values in parentheses.
DPMQ indicates dispensed price per maximum quantity.
*P < .01.

results. The extent to which this is the case in general is not as large as in other countries such as the United States.[35] However, our full-sample estimate of a 4.82% price reduction per additional competitor could indicate a significant growth in the impacts of generic competition on prices since before the 2007 reforms, where a previous study had estimated the same effect at only 0.4% to 1%.[20] The strength of our study lies in its comprehensive sample, using all PBS listed drugs rather than just a subset as previous studies have.[6,18-20]

One study over the early postreform period comparing high-income Asian and Australasian countries has shown that Australia performs comparatively well in terms of statin prices after generic entry, but New Zealand was able to achieve lower statin prices through its policy of competitive tendering.[18] Although policies such as these may be effective at targeting prices, they may also be too harsh on domestic pharmaceutical industry, potentially limiting the availability of new drugs[36] and deterring industrial presence.[37] As such the Australian policies may be striking a middle ground between the 2 extremes.

One limitation in our use of the fixed-effects estimator is that it assumes common treatment effects across cross-sectional units. This, in part, motivated our subgroup analyses where we identified variation in treatment effects across subgroups. The full-sample analysis showed that the price effects of additional competitors are diminishing as more competitors enter the market, but for certain subgroups this may not be the case. Variation in the effects of generic competition was also evident between therapeutic groups, and so although the full-sample analysis seems to indicate a relatively strong level of generic competition, between certain therapeutic groups the nature and strength of this relationship may vary. In contrast, we found market share to be a similarly significant driver of drug prices in all subgroups.

While writing this article, we found no reliable way to fully identify which brands in the data set were "true" generics as opposed to pseudogenerics, which are generic drugs identical to the brand-name drug produced by, or with license from, the originator brand. They are often produced before the drug's patent expiry and are used to improve profitability for originator brands by deterring "true" generic entry and by giving the producer market presence across different market segments.[38-40] Our models do not distinguish between their potentially differing effects on competition upon entry to the market. This could be one area for future research to consider, given that being able to control for the different types of generics allows for unbiased estimation of the effect of "true" generic competition and could

Figure 1. Lag and lead month coefficient point estimates.

serve as a starting point into research estimating the impacts of pseudogenerics on social welfare in Australia.

Conclusions

Our results show that generic entry into Australian pharmaceutical markets results in significant and continuous reductions in drug prices since the introduction of simplified price disclosure in 2014.

Author Disclosures

Author disclosure forms can be accessed below in the Supplemental Material section.

Supplemental Material

Supplementary data associated with this article can be found in the online version at https://doi.org/10.1016/j.vhri.2024.101008.

Article and Author Information

Author Affiliations: Department of Economics, City, University of London, London, England, UK (Jones, Serra-Sastre); Department Health Policy, LSE, London, England, UK (Serra-Sastre); Office of Health Economics, London, England, UK (Serra-Sastre); Centre for Applied Health Economics, Griffith University, Gold Coast, Queensland, Australia (Jones, Kim).

Correspondence: Arun M. Jones, MSc, Centre for Applied Health Economics, Griffith University, 1 Parklands Drive, Southport, Gold Coast, Queensland 4215, Australia. Email: arun.jones@griffith.edu.au

REFERENCES

1. Parliamentary Library. Budget review 2022-23. https://parlinfo.aph.gov.au/parlInfo/download/library/prspub/8564457/upload_binary/8564457.pdf. Accessed January 25, 2023.
2. Australian Government Department of Health. PBS expenditure and prescriptions report 1 July 2020 to 30 June 2021. https://www.pbs.gov.au/statistics/expenditure-prescriptions/2020-2021/PBS_Expenditure_and_Prescriptions_Report_1-July-2020_to_30-June-2021.pdf. Accessed January 25, 2023.
3. Vitry AI, Thai L, Roughead EE. Pharmaceutical pricing policies in Australia. In: Babar ZUD, ed. *Pharmaceutical Prices in the 21st Century*. Springer International Publishing; 2015:1–23.
4. Clarke PM, Fitzgerald EM. Expiry of patent protection on statins: effects on pharmaceutical expenditure in Australia. *Med J Aust*. 2010;192(11):633–636.
5. Bulfone L. High prices for generics in Australia - more competition might help. *Aust Health Rev Publ Aust Hosp Assoc*. 2009;33(2):200–214.
6. Mansfield SJ. Generic drug prices and policy in Australia: room for improvement? A comparative analysis with England. *Aust Health Rev*. 2014;38(1):6–15.
7. Horner R. The impact of patents on innovation, technology transfer and health: a pre- and post-trips analysis of India's pharmaceutical industry. *New Pol Econ*. 2014;19(3):384–406.
8. Löfgren H. Reshaping Australian drug policy: the dilemmas of generic medicines policy. *Aust N Z Health Policy*. 2007;4(1):11.
9. Beecroft G. Generic drug policy in Australia: a community pharmacy perspective. *Aust N Z Health Policy*. 2007;4(1):1–7.
10. Bulsara C, McKenzie A, Sanfilippo F, Holman CDJ, Emery JE. "Not the full Monty": a qualitative study of seniors' perceptions of generic medicines in Western Australia. *Aust J Prim Health*. 2010;16(3):240–245.
11. Rome BN, Lee CWC, Gagne JJ, Kesselheim AS. Factors associated with generic drug uptake in the United States, 2012 to 2017. *Value Health*. 2021;24(6):804–811.
12. Luo J, Kesselheim AS. Delayed generic market saturation after patent expiration—a billion-dollar problem. *JAMA Intern Med*. 2018;178(5):721–722.
13. Parliament of Australia. National health amendment (pharmaceutical benefits scheme) bill. Parliament of Australia. https://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/Bills_Search_Results/Result?bId=r2801; 2007. Accessed January 25, 2023
14. Department of Health and Aged Care, Pharmaceutical Benefits Scheme. First new brand price reductions. https://www.pbs.gov.au/info/industry/pricing/pbs-items/first-new-brand-price-reductions; Published 2023. Accessed January 25, 2023.
15. Department of Health and Aged Care. Pharmaceutical Benefits Scheme. Price disclosure guidelines. https://www.pbs.gov.au/info/industry/pricing/price-disclosure-spd/price-disclosure-guidelines. Accessed January 25, 2023.
16. Magazzini L, Pammolli F, Riccaboni M. Dynamic competition in pharmaceuticals. Patent expiry, generic penetration, and industry structure. *Eur J Health Econ*. 2004;5(2):175–182.
17. Puig-Junoy J. Impact of European pharmaceutical price regulation on generic price competition: a review. *Pharmacoeconomics*. 2010;28(8):649–663.
18. Roughead EE, Kim D-S, Ong B, Kemp-Casey A. Pricing policies for generic medicines in Australia, New Zealand, the Republic of Korea and Singapore: patent expiry and influence on atorvastatin price. *WHO S East Asia J Public Health*. 2018;7(2):99–106.
19. Muzumdar S, Wu R, Feng H. Temporal comparison of biologic medication prices between the United States and Australia. *J Dermatological Treat*. 2020;33(1):593–594.
20. Spinks J, Chen G, Donovan L. Does generic entry lower the prices paid for pharmaceuticals in Australia? A comparison before and after the introduction of the mandatory price-reduction policy. *Aust Health Rev*. 2013;37(5):675–681.
21. Department of Health and Aged Care. Pharmaceutical Benefits Scheme. Ex-manufacturer price. https://www.pbs.gov.au/info/industry/pricing/ex-manufacturer-price. Accessed January 25, 2023.
22. Department of Health and Aged Care. Pharmaceutical Benefits Scheme. Amoxicillin. https://www.pbs.gov.au/medicine/item/11947T-11998L-12002Q-13182T-13184X-1884E-1886G-1887H-1888J-1889K-3300Q-3301R-3302T-3310F-3393N-5225B-8581P-8705E-9714G. Accessed January 25, 2023.
23. Australia S. Pharmaceutical benefits schedule item statistics. http://medicarestatistics.humanservices.gov.au/statistics/pbs_item.jsp; Published 2023. Accessed January 25, 2023.
24. Saha A, Grabowski H, Birnbaum H, Greenberg P, Bizan O. Generic competition in the US pharmaceutical industry. *Int J Econ Bus*. 2007;13(1):15–38.
25. Ellison G, Ellison SF. Strategic entry deterrence and the behavior of pharmaceutical incumbents prior to patent expiration. *Am Econ J Microeconomics*. 2011;3(1):1–36.
26. Serra-Sastre V, Bianchi S, Mestre-Ferrandiz J, O'Neill P. Does NICE influence the adoption and uptake of generics in the UK? *Eur J Health Econ*. 2021;22(2):229–242.
27. Reiffen D, Ward MR. Generic drug industry dynamics. *Rev Econ Stat*. 2005;87(1):37–49.
28. Hudson J. Generic take-up in the pharmaceutical market following patent expiry: a multi-country study. *Int Rev Law Econ*. 2000;20(2):205–221.
29. Department of Health and Aged Care, Pharmaceutical Benefits Scheme. Report on under co-payment prescriptions 2022-23 (by date of supply). https://www.pbs.gov.au/info/statistics/under-co-payment/ucp-data-report. Accessed January 25, 2023.
30. Australian Bureau of Statistics. Consumer price index, Australia, December quarter. https://www.abs.gov.au/statistics/economy/price-indexes-and-inflation/consumer-price-index-australia/dec-quarter-2022; 2022. Accessed January 25, 2023.
31. Spulber DF. Bertrand competition when rivals' costs are unknown. *J Ind Econ*. 1995;43(1):1–11.
32. Clarke D, Tapia-Schythe K. Implementing the panel event study. *STATA J*. 2022;21(4):853–884.
33. Dave CV, Kesselheim AS, Fox ER, Qiu P, Hartzema A. High generic drug prices and market competition: a retrospective cohort study. *Ann Intern Med*. 2017;167(3):145–151.
34. Department of Health and Aged Care. Pharmaceutical Benefits Scheme. Historical Price Disclosure Cycles. https://www.pbs.gov.au/info/industry/pricing/historical-price-disclosure-cycles. Accessed January 25, 2023.
35. Nguyen NX, Sheingold SH, Tarazi W, Bosworth A. Effect of competition on generic drug prices. *Appl Health Econ Health Policy*. 2022;20(2):243–253.

36. Danzon PM, Ketcham JD. Reference pricing of pharmaceuticals for medicare: evidence from Germany, the Netherlands, and New Zealand. *Forum Health Econ Policy.* 2004;7:1–54.

37. Productivity Commission. Evaluation of the pharmaceutical industry investment program. https://www.pc.gov.au/inquiries/completed/pharmaceutical-investment/report/piip.pdf; Published 2003. Accessed January 21, 2023.

38. Kong Y, Seldon JR. Pseudo-generic products and barriers to entry in pharmaceutical markets. *Rev Ind Organ.* 2004;25(1):71–86.

39. Probyn AJ. Some drugs more equal than others: pseudo-generics and commercial practice. *Aust Health Rev Publ Aust Hosp Assoc.* 2004;28(2):207–217.

40. Hollis A. The importance of being first: evidence from Canadian generic pharmaceuticals. *Health Econ.* 2002;11(8):723–734.