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Price and welfare effects of a pharmaceutical substitution reform

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Abstract

The price effects of the Swedish pharmaceutical substitution reform are analyzed using data for a panel of all pharmaceutical product sold in Sweden in 1997–2007. The price reduction due to the reform was estimated to average 10% and was found to be significantly larger for brand name pharmaceuticals than for generics. The results also imply that the reform amplified the effect that generic entry has on brand-name prices by a factor of ten. Results of a demand-estimation imply that the price reductions increased total pharmaceutical consumption by 8% and consumer welfare by SEK 2.7 billion annually.

Keywords: drugs; generic competition; equivalent variation; demand estimation

JEL classification: D40; I11; L65

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1 Introduction

In October 2002, the Swedish pharmaceutical market was reformed. The reform requires pharmacists to substitute the cheapest available generic (or parallel-imported product) for the prescribed pharmaceutical product in cases when neither the physician nor the consumer opposes substitution. The reform was supposed to lower pharmaceutical costs directly, as prescribed pharmaceuticals were replaced with cheaper versions, and indirectly, through increased price competition. To contain rising pharmaceutical costs, similar reforms have been introduced in many European countries and American states.

The Swedish substitution reform has increased consumers' information about available cheaper substitutes and has made it easier to substitute the prescribed pharmaceutical with a cheaper substitute. It has also increased consumers' co-payments for choosing products other than the cheapest version. All of these characteristics of the substitution reform have contributed to making consumers more price sensitive, which, in turn, may have contributed to increased price competition and thus lower pharmaceutical prices.

The main purpose of this paper is to estimate how the Swedish substitution reform has affected pharmaceutical prices, through its effect on price competition. This is done separately for generics, brand-name products that faced generic competition at the time of reform, brand-name products that did not face generic competition at that time, and a group of products belonging to none of these groups (*Others*). Based on this, one can calculate how much more current pharmaceutical consumption would have cost without the reform. Since current pharmaceutical consumption levels would not be the same without the price effects of the reform, this is not a very exact measure of the importance of the reform. I therefore quantify the importance of the reform's price effects in terms of equivalent variation, and to this end, I estimate price and income elasticities for pharmaceuticals. Equivalent variation answers the question of how much consumers would have had to receive in extra income in order to obtain the same utility level without the reform's price effects, as they now obtain with the reform's price effects, and are used as welfare measure in this paper.

Only a few studies have estimated the price effects of substitution reforms. Granlund and Rudholm (2007) estimated that the Swedish substitution reform, in its first four years, reduced the unweighted average prices by 4% for both generics and brand-name pharmaceuticals facing generic competition. These

results were obtained by using a specification that allowed prices to gradually adjust to the reform. They obtained significantly smaller effects when they estimated a specification without an adjustment process and concluded that it was important to account for the adjustment. The results of Granlund and Rudholm, though, cannot be used to estimate savings and welfare effects caused by increased price competition, since the reform effect is likely correlated with product sales values, for which they did not account. Using pharmaceutical price index data from 16 OECD countries, Buzzelli et al. (2006) estimated that substitution reforms lowered pharmaceutical prices by 3%. They did, however, not investigate whether or not prices were gradually adjusted to the reforms.¹ This paper contributes to this literature by, for example, providing the first test of whether or not a substitution reform also affects pharmaceuticals that do not face generic competition.

A few related papers estimate price and income elasticities for pharmaceuticals on an aggregated level; for example, Alexander et al. (1994), that examine how the demand for all pharmaceuticals (and not just a single product or group of products) is affected by changed income and pharmaceutical prices (and not just out-of-pocket costs) on a national level. As discussed by Getzen (2000), elasticities vary with the level of analysis, since elasticities on different levels are affected by partly different decisions. The results of the present paper are therefore not directly comparable to price and income elasticities estimated on a micro level. The present paper also relates to studies evaluating welfare effects of different reforms, for example Watal (2000) and Chaudhuri et al. (2006), which both estimated the welfare losses caused from enforcing pharmaceutical patents in India.

This paper contributes to the literature analyzing the effect of generic entry on brand-name pharmaceutical prices, by studying how a substitution reform influences this effect. To my knowledge, this has never been studied before. The empirical results in the literature analyzing the price effects of generic entry are mixed. On one hand, Caves et al. (1991) found that the initial entry of generic products led to a reduction in brand-name prices. Similarly, Wiggins and Maness (1994) and Lu and Comanor (1998) found that the number of generic products had a negative effect on brand-name prices. On the other

¹The National Corporation of Swedish Pharmacies et al. (2003, 2004) aimed to assess the savings due to increased price competition, but did not account for expiring patents or price-trends in their reports and based their estimates on a non-representative sample consisting of the substances with the largest sales values.

hand, Grabowski and Vernon (1992) and Frank and Salkever (1997) reported that brand-name prices rose in response to generic entry. One explanation of this is that generic entry reduces the own-price elasticity of brand-name products (Frank and Salkever, 1992, 1997). Frank and Salkever (1992) also demonstrated that, if consumers become more price-sensitive, under reasonable conditions this will increase the downward pressure exerted by generic entry on brand-name prices.

The next section describes the context and the substitution reform. In section three, I discuss the empirical approach, first, for estimating the reform's effects on prices, and second, regarding the welfare measure and the demand function. Section three also contains some descriptive statistics. In section four, I present the results of the various estimations and in section five I discuss other possible welfare effects. Finally, the paper's conclusions are presented in section six.

2 Swedish pharmaceutical benefits scheme

Subsidies have covered a large part of the pharmaceutical costs for Swedish consumers ever since pharmaceutical benefits scheme was introduced in 1955.² Since January 1997, a stepwise copayment structure for pharmaceuticals has been used to limit consumers' pharmaceutical costs. At first, consumers paid all costs up to SEK 400 per 12-month period, 50% of the cost from SEK 400 to 1200, 25% from SEK 1200 to 2800, and 10% from SEK 2800 to 3800; after this level, all costs in the period were covered by subsidies.³ As of 1 June 1999, all these break-points were increased by SEK 500, but have since remained unchanged.

Before the substitution reform, a reference price system, introduced in January 1993, was in effect. Reference prices were set to 110% of the cheapest available substitute products, and costs exceeding these reference prices were not included in the maximum annual copayment limit (RFFS 1992:20, 1996:31).

²The sources used in this section are SFS (1981:49) and the government bills dealing with changes in this law. These bills are listed at www.notisum.se/rnp/sls/fakta/a9810049.htm, 30 October 2008.

³All monetary values in this paper (except those regarding copayments cited in this section) are deflated by the CPI and expressed in 2007 prices. The average exchange rates in 2007 were USD/SEK = 6.76 and EUR/SEK = 9.25 (the Riksbank).

2.1 The substitution reform

The substitution reform came into effect 1 October 2002 and replaced the reference price system. This reform requires pharmacists to inform consumers whether substitute products are available, and that the cheapest available substitute product would be provided within the Swedish pharmaceutical benefits scheme.⁴ The pharmacist must also inform consumers that they can buy the prescribed pharmaceutical product instead of the cheapest substitute if they pay the price difference themselves. Finally, the substitution reform requires that pharmacists substitute the cheapest available generic (or parallel-imported product) for the prescribed pharmaceutical product in cases when neither the prescribing physician prohibits the substitution for medical reasons, nor the consumer chooses to pay the price difference between the prescribed and the generic alternative. In cases where the physician prohibits the substitution for medical reasons, the consumer is still reimbursed.

Three characteristics of the substitution reform may have contributed to making consumers more price sensitive, which in turn has resulted in more generic substitution and lower pharmaceutical prices. First, the substitution reform lowered the transaction cost of generic substitution, since before the substitution reform it was recommended that the physicians be contacted before substituting products if they had not explicitly consented to substitution on the prescriptions. Second, when substitution is presented as an option (as it always should be after the substitution reform) consumers gain information about that cheaper substitutes exist and can easily gain information also about price differences between the pharmaceutical substitutes. Finally, under the substitution reform, only costs up to 100% of the cheapest substitutable product were contained by the pharmaceutical benefit scheme, compared with 110% in the reference price system. This increased the consumer's out-of-pocket costs for choosing to buy the prescribed pharmaceutical by 0-10 percent of the price of the cheapest generic version, depending on the patient's copayment rate.

According to a theoretical model presented by Granlund and Rudholm (2007), the substitution reform likely has a greater effect on prices for brands that face generic competition than for generics. The intuition is that, while the fact that the substitution reform made consumers more cross-price sensitive

⁴The Swedish Medical Products Agency defines a product as a substitute if it has the same active substance, strength, and form (e.g. pills or oral fluid) as the prescribed product, and if its package sizes can approximately sum up to the prescribed quantity.

works for lower prices in both product groups, the substitution reform also increases the demand for generics at the expense of the demand for brand-name products, which likely reduces the incentives for generics to lower their prices but increases the likelihood of price cuts for brand-names.

Brand-name products without generic competition are likely affected less by the substitution reform than other brands, but should still be affected. At least some of these products are substitutes for pharmaceuticals subject to generic competition and hence face lower demand as the prices of these pharmaceuticals drop, which – depending on the shape of their demand functions – might cause price cuts. Patent-protected pharmaceuticals might also be directly affected by the substitution reform, since many of them face competition from cheaper parallel-imported pharmaceuticals.

The prices in the *Others* group, consisting, for example, of vitamins and/or minerals, is expected to be affected relatively little by the substitution reform, since few of these products have what the Swedish Medical Products Agency considers to be close substitutes.

2.2 Price setting and distribution

Throughout the study period, for a pharmaceutical to be included in the benefits scheme, its price had to be authorized, before October 2002 by the National Social Insurance Board and thereafter by the Pharmaceutical Benefits Board. It was easier for pharmaceutical firms to get Pharmaceutical Benefits Board approvals of price reductions than price increases, except if the new price did not exceed the price of the most expensive exchangeable product.⁵ This fact, together with pharmaceutical firms' incomplete information about the reactions of physicians, consumers and other pharmaceutical firms to the substitution reform, gave firms an incentive to adjust their prices gradually after the substitution reform of October 2002. Since the exception means that most generics could increase their prices as easy as they could reduce them, one might expect fastest price adjustments for generics; but, since their brand-competitors likely will not adjust their price immediately, neither will the generics.

⁵The Pharmaceutical Benefits Board is required to decide whether to approve price cuts as soon as possible, but is allowed 90 days (or under some circumstances 150 days) to handle applications for price increase (SFS 2002:687). Firms must justify price increases, but not price reductions. Also, the Pharmaceutical Benefits Board is restrictive in allowing price increases and only allows an increase if special reasons exist (LFNFS 2003:1).

Throughout the study period, pharmaceuticals were sold through a nationwide government owned monopoly, the National Corporation of Swedish Pharmacies, which paid and charged uniform prices nationwide for each pharmaceutical product.

3 Methods and material

3.1 Estimating the substitution reform's effects on prices

The substitution reform's effects on prices are estimated using monthly data, from January 1997 through October 2007, provided by IMS Sweden for all pharmaceuticals sold in Sweden. The reform effects were estimated separately for *Generics*,⁶ brand-name pharmaceuticals that faced generic competition at the time of reform (*BrandC*),⁷ brand-name pharmaceuticals that did not face generic competition at that time (*BrandM*), and a group of products belonging to none of these groups (*Others*), using the following specification

$$\ln Price_{it} = \beta_1 D_t + \beta_2 [D_t / (t - R)^\mu] + \beta_3 GC_{it} + \beta_4 Trend_t + \theta_i + \varepsilon_{it}. \quad (R1)$$

The dependent variable is the natural logarithm of the price per package paid by the National Corporation of Swedish Pharmacies, and thus charged by the pharmaceutical companies, for product i in month t . Product refers to the most detailed observation unit: for example, if a brand and a generic firm market two package sizes each of the same pharmaceutical, they are treated as four separate products even if the two firms' package sizes are the same.

D is an indicator variable taking the value of one after the substitution reform, that is, in October 2002 and thereafter. $D / (t - R)$, where $t - R$ is the number of months from the reform time, is included to capture the adjustment process. Here, the parameter μ measures the curvature of the adjustment process.

⁶The generics group also includes so-called branded generics. Branded generics are generic versions of the pharmaceutical product which are sold under their own product name, while other generics are sold under the substance name, usually followed by the company name.

⁷A product is defined as facing generic competition if at least one generic or branded generic has the same active substance, strength, and form (e.g. pills or oral fluid) as the product. Since, for example, a product comprising 20 pills can be replaced by two packages of 10 pills each, a brand-name product is defined as facing generic competition even if its package size differs from that of its generic competitors.

GC_{it} is a dummy that takes the value of one from the first month product i faces generic competition and is only included for the two brand-name populations. By comparing the GC_{it} coefficient between the two brand populations, I can examine how the substitution reform has affected the price effect of generic competition.⁸

A trend variable ($Trend$) is included to account for possible common price trends. Finally, product-specific fixed effects (θ_i) are included. These capture all the time-invariant differences in price levels between pharmaceutical products and thus make it possible to use the natural logarithm of the price per package as the dependent variable.

By letting the prices adjust gradually to the substitution reform, the estimation approach used here follows Granlund and Rudholm (2007). The specification assumes that the potential price adjustment was largest directly after the substitution reform and gradually decreased as time passed. This is a logical assumption, since pharmaceutical firms' knowledge of physicians', consumers' and other pharmaceutical firms' reactions to the substitution reform likely increased fastest directly after the substitution reform when the knowledge level was lowest. However, it is difficult to make any a priori assumptions about the speed of this process, so μ is allowed to be determined by the data.

This specification of the adjustment is likely to give good estimates of the substitution reform effects in the study period. It is, however, unsuitable for out-of-sample predictions (at least, for predictions into the far future), since the specification assumes that – unless the adjustment is instantaneous (i.e., $\beta_2=0$) – the adjustment will continue indefinitely. An alternate approach sometimes used in reform evaluations is to let the trend slope change with the reform. This is reasonable when evaluating reforms that might indeed change the trend slope, but when considering a reform like that examined here, which presumably will result in a new long-term price level but not a new long-term price trend, the risk of this approach is that it will ascribe price-changes unrelated to the substitution reform, to the reform effect.⁹

⁸Generic competition directly followed expiring patent on many products which suggests that much of the variation in GC_{it} is exogenous in the sense that it is explained by expiring patents rather than price changes of the brand-name products. In the absence of strong, truly exogenous instruments, it is preferable to treat this variable as exogenous rather than employing an instrumental variable method.

⁹These changes could be caused, for example, by the introduction of new pharmaceuticals that lower the demand for pharmaceutical for which they are substitutes and by changes in pharmaceutical markets in other countries (e.g., regarding price-controls).

As mentioned above, the break-points in the pharmaceutical benefits scheme were increased by SEK 500 in June 1999. One might expect that this would have made consumers more price sensitive by increasing their copayment rates, which, in turn, might have encouraged pharmaceutical firms to lower their prices. However, due to the construction of Swedish pharmaceutical benefits scheme and due to the skewed distribution of consumers' pharmaceutical consumption, most of the pharmaceuticals were bought by consumers who, regardless of this increase, had zero marginal cost for pharmaceuticals.¹⁰ Therefore, this change likely had, at most, minor effects on prices. Estimations including controls for the increased break-points, and for delayed responses to this increase and to the benefits scheme changes of January 1997, indicated no price effects and gave only marginally different results for the parameters of interest, so these results are not reported.

Letting the parameter estimates differ between the four pharmaceutical groups will improve the efficiency of the estimators, if these groups are differently affected by the substitution reform, and makes it possible to test, for example, whether the substitution reform also affected the prices of pharmaceuticals for which there are no generic substitutes. To do this by splitting the population, instead of by using interaction variables, keeps the models nonlinear in only one variable – the adjustment variable $D/(t - R)$ – which allows the specification to be easily estimated using a grid-search estimation strategy. This method is employed for each model by setting μ equal to values ranging from 0 to 5 and then estimating the remaining parameters using a Prais-Winsten estimator that corrects for first-order serial correlation in the error terms. Finally, likelihood values were used to discriminate between the different parameter values. The likelihood values were also used to calculate 95% confidence intervals for the adjustment parameter, μ .

In all estimations, the observations are assigned weights that equal the products' total sales values in the study period; if the reform effects are correlated with sales values, this is necessary when estimating how the substitution reform affected the pharmaceutical price levels. As for price indexes, there are several alternate sets of weights that can be used, so I have reported the results

¹⁰Data from the county of Västerbotten show that 54–61% of the pharmaceuticals in 2000 were bought by consumers, who had reached the new highest break-point of the insurance before, or on, the current purchasing occasion. Since at the time of purchasing, consumers are on average approximately 6 months into the 12-month insurance period, a higher share than this had a marginal cost of zero after the reform as well.

obtained also when using pre-reform sales as weights.

3.2 Demand and welfare estimation

Hausman (1981) demonstrated that knowledge of the uncompensated (i.e., the Marshallian) demand function is all that is needed to establish an exact measure of the welfare effects caused by changed prices. The welfare effects can be expressed either in terms of compensating variation (CV) or, as here, in terms of equivalent variation (EV).

In this context, the EV formula derived by Hausman is written

$$EV = - \left\{ \frac{(1 - \gamma_2)}{(1 + \gamma_1) I^{\gamma_2}} [P_{ref} Q(P_{ref}, I) - P_{alt} Q(P_{alt}, I)] + I^{(1 - \gamma_2)} \right\}^{1/(1 - \gamma_2)} + I,$$

where γ_1 is the price elasticity of demand and γ_2 is the income elasticity of demand, both of which must be estimated. P_{ref} is the index for pharmacies' selling prices of pharmaceuticals, and P_{alt} is given by $P_{alt} = P_{ref}(1 - ARE)$. *ARE* is short for the average reform effect and is obtained by weighting together the predicted reform effects for the four pharmaceutical groups. The difference between the coefficient of GC_{it} after and before the substitution reform in October 2002 is treated as part of the reform effects. Finally, $Q(\cdot)$ is the predicted annual pharmaceutical demand at various price levels and I is annual income.

If both the price and the income elasticity equal zero, the EV measures equal the extra amount that consumption after the substitution reform would have cost without the price-lowering effect of the substitution reform. Since P_{ref} is an index for the full prices of pharmaceuticals, and not only the out-of-pocket prices paid by the consumers, the EV will measure the welfare effects of the price cuts for the whole consumer side of the market, both directly for the consumers and for the insurers. The cost of the pharmaceutical benefits scheme is still paid for by the consumers – in the Swedish case, by income taxes – but the distinction is still important if, for example, one wishes to consider the distributional effects of the substitution reform.

Bear in mind that the reform effects are estimated using the pharmacies' purchase prices. Nevertheless, I have still chosen to use the pharmacies' selling prices in the EV measures and in estimating the price elasticity (γ_1). The justification is that pharmaceutical demand is most closely related to the selling prices. If the pharmacies' margins are affected by the substitution reform, however, the choice may cause an inconsistency in the EV measures. As reported in

the Results section, the Pharmaceutical Benefits Board has allowed increased margins because the substitution reform has increased pharmacies' costs. However, it is impossible to know whether some of these increases would have been allowed in any case, even without the substitution reform, and then justified on other grounds. In the Results section, I therefore focus on the EV measures obtained by assuming that margins were unaffected by the substitution reform, but also report EV measures obtained by adjusting the average reform effect (*ARE*) in line with the margin changes justified by the substitution reform.

Since I want to calculate the EV for the substitution reform that has affected the entire pharmaceutical market, and not just the prices of a few drugs, the price and income elasticity should be estimated on an aggregated level.¹¹ Since the elasticities might differ between countries, the estimation should preferably be done using Swedish data. As mentioned above, no cross-sectional variation in pharmaceutical prices was allowed in Sweden in the study period, implying that the demand function (or at least the price elasticity) must be identified using only variation over time. As discussed below, several difficulties are associated with this, so I will also calculate the EV measures based on demand estimates made for other countries.

The uncompensated pharmaceutical demand in Sweden are estimated using aggregated quarterly data provided by the National Corporation of Swedish Pharmacies, the Riksbank, and Statistics Sweden. The estimations are performed using the following two specifications

$$\begin{aligned} \Delta \ln Q_t = & \alpha + \gamma_1 \Delta \ln P_t + \gamma_2 \Delta \ln I_t + \gamma_3 \Delta Trend_t \\ & + \sum_{q=2}^4 \theta_q \Delta Quarter_{qt} + \gamma_4 \Delta Hoard_t + \varepsilon_t, \end{aligned} \quad (D1)$$

$$\begin{aligned} \ln Q_t = & \alpha + \gamma_1 \ln P_t + \gamma_2 \ln I_t + \gamma_3 Trend_t + \sum_{q=2}^4 \theta_q Quarter_{qt} \\ & + \gamma_4 Hoard_t + \gamma_5 \ln Q_{t-1} + \gamma_6 \ln Q_{t-4} + \varepsilon_t, \end{aligned} \quad (D2)$$

which both are inspired by a specification in Alexander et al. (1994). Q_t is defined as the pharmacies' total purchase of pharmaceuticals in quarter t ,

¹¹Deriving the price elasticity of aggregated consumption from demand estimates based on product level data is unfeasible since it would require the estimation of all relevant cross-price elasticities between the nearly 15,000 pharmaceutical products.

measured in SEK per 1000 inhabitants and working day, and divided by an index for pharmacies' purchase prices. P_t is the index for pharmacies' selling prices of pharmaceuticals and I is GDP per capita in SEK 1000. $\ln$ indicates that the natural logarithms of the variables are used and Δ indicates that the first differences of the variables are used (e.g., $\Delta \ln Q_t = \ln Q_t - \ln Q_{t-1}$). A trend variable is included and complemented by three quarter-dummies, since Andersson et al. (2007) report that there are seasonal variations in the sales values of pharmaceuticals.¹²

The variable *Hoard* is included to capture the hoarding that is observed in the quarters before increases in the patients' copayment shares and the corresponding decline in sales in the quarters directly after the changes. For a quarter after changed rules that increased patients' copayment shares, *Hoard* equals the percentage increase in the consumer price index for pharmaceuticals compared with the preceding quarter; *Hoard* equals the negative value of that increase for a quarter preceding such a change and 0 otherwise. Hence, the parameter for this variable will estimate the demand shift between subsequent quarters induced by stockpiling. When calculating the consumer price index for pharmaceuticals, Statistics Sweden ignores the fact that the consumers' copayment shares are decreasing functions of pharmaceutical prices. The effects of changed pharmaceutical prices on consumer prices are therefore exaggerated in the consumer price index for pharmaceuticals. This might result in some measurement error of *Hoard* and more severe measurement errors in the index itself, so it is not included in the specifications.

According to Dickey-Fuller tests, it cannot be rejected that the time series $\ln Q$, $\ln P$ and $\ln I$ have unit roots. Since this non-stationarity might result in spurious regression it should be addressed. In this paper, two alternate approaches, each with different flaws and merits, are used to address non-stationarity. The first is to make a first-difference transformation (specification D1) and the second is to include lagged values of pharmaceutical consumption (specification D2). The choice to include the first and fourth lags ($\ln Q_{t-1}$ and

¹²The main differences between these specifications and the one in Alexander et al. (1994) are that I do not take the natural logarithm of the trend variable, since this would mean that the percentage change in the pharmaceutical consumption is assumed to decline with time, and that I either make a first-difference transformation or include lagged consumption. I have also estimated a specification similar to that of Alexander et al., and then obtained results similar to theirs, but concluded that the results likely were spurious, since statistical tests suggested that the included time series were non-stationary and not cointegrated.

$\ln Q_{t-4}$) is based on the Akaike information criterion (Greene, 2003, Chapter 8).

Both specifications ensure that the error terms are stationary and that the results are therefore not spurious. The first specification addresses the non-stationarity of all variables and is suitable for estimating short-term effects. However, if $\ln P$ is endogenous, this approach is difficult to use since it is inherently hard to find strong instruments for the first difference of $\ln P$. Regarding the second specification, it should be noted that the coefficients for lagged consumption can easily capture the effects of omitted variables and therefore should not be interpreted as estimates of persistency in pharmaceutical consumption. Hence, the long-term effects cannot be estimated using this specification.¹³ Due to the auto-regressive processes of $\ln P$ and $\ln I$, there is also a risk that some of the effects of these variables will be attributed to the coefficients for lagged pharmaceutical consumption. A conclusion that can be drawn from this discussion is that the second specification is useful in investigating whether or not $\ln P$ is endogenous, but if $\ln P$ is not endogenous, or only weakly so, the first specification is preferable.

Endogeneity has been discussed previously in this context. For example, Reekie (1978) assumed that sellers of pharmaceuticals set prices each period and offer to sell indefinitely large amounts at that price in the period, arguing that prices are therefore determined largely by non-demand-related factors and thus can be treated as exogenous. It should, however, be noted that even if prices are predetermined, as they are on the Swedish market, demand expectations might play a role in the price setting, which might cause some endogeneity problems.

The specifications are estimated using both OLS and IV estimators and the error terms are allowed to be correlated within calendar years. In the IV estimations, $\ln P$ is instrumented with its second and fourth lag and with the first and second lag of the variable $\ln TCW$. TCW is the total competitiveness weights index, which measures the value of the Swedish crown (SEK) against a basket of other currencies. The lags of $\ln TCW$ are included as instruments mainly to capture the sharp declines in the value of the Swedish crown that occurred when it was devaluated in September 1981 (-10%) and October 1982 (-16%) and when Sweden abandoned the fixed exchange rate in November 1992, which

¹³I have tried to estimate long-term elasticities using error-correction models, but failed to obtain reliable estimates, likely because $\ln Q$, $\ln P$ and $\ln I$ are not cointegrated; at least a residual-based test provides no support for cointegration.

resulted in a depreciation of approximately 21% within three months. These events were likely unexpected when pharmaceutical prices were set and therefore likely caused price changes. Several other instruments, and combination of instruments, have also been tested. The choice of instrument-set is based on the Kleibergen-Paap weak identification statistic, which measures the strength of the instruments, and the Hansen J statistic, which tests the validity of the instruments.

3.3 Descriptive statistics

Table 1 presents descriptive statistics for the variables used when estimating the reform effects on prices. The means of $\ln Price$ are not easily comparable between the four groups since they represent the prices of very heterogeneous products. Still, it is not surprising to find the highest average in the *BrandM* population, consisting of brand-name pharmaceuticals that did not face generic competition 1 October 2002 when the substitution reform came into effect.

In the *BrandM* population 810 of the 6,267 products gained generic competition at some time after the substitution reform, but Table 1 shows that the weighted frequency of observations facing competition is only 4%. In the *BrandC* population, consisting of brand-name pharmaceuticals that faced generic competition at the time of reform, 364 of the 989 products gained generic competition first after the beginning of the study period, but the weighted frequency of observations without competition is only 19%. The market shares show that *BrandM* is by far the most important population in terms of sales values.

Table 1. Weighted means of variables used in the price estimations

Variable	<i>Generics</i>	<i>BrandC</i>	<i>BrandM</i>	<i>Others</i>
$\ln Price$	4.56	5.22	6.80	5.79
<i>D</i>	0.52	0.46	0.53	0.50
<i>GC</i>	0.00	0.81	0.04	0.00
<i>Trend</i>	69.80	65.01	70.91	68.23
Observations	228 730	83 462	405 086	152 708
Products	4 232	989	6 267	3 216
Market share	0.13	0.09	0.65	0.13

Note: The products' total sales values in the study period are used as weights.

Descriptive statistics for the variables used in the demand specifications are given in Table 2. Figure 1 illustrates how the three main variables have changed

over time, indicating, for example, that there is seasonal variation in both GDP per capita and the purchase of pharmaceuticals.

Table 2. Means of variables used in the demand estimations

Variable	Level	First-difference
$\ln Q$	3.34	0.02
$\ln P$	5.35	-0.01
$\ln I$	4.12	0.00
<i>Trend</i>	56.5	1.00
<i>Hoard</i>	0.00	0.00
$\ln TCW$	4.71	0.00
Observations	112	111

Note: No data are missing, so 25% of the observations are from each quarter

Figure 1. Depictions of three time series used in the demand estimations

4 Results

4.1 Estimated reform effects

Table 3 first reports the predicted instantaneous effect of the substitution reform (Ref_{inst}), the mean reform effect for October 2002 through October 2007 (Ref_{mean}), and the reform effect as of the last month of the study period (Ref_{end}). These three all express the percentage effects the substitution reform has had on pharmaceutical prices in each population. Ref_{inst} equals $100 * [\exp(\beta_1 + \beta_2) - 1]$ and does not depend on μ , since $t - R$ takes the value of one in the first month of the substitution reform (October 2002), while Ref_{mean} and Ref_{end} are calculated also using the estimates of μ in accordance

with specification (R1). The substitution reform effects at different points in

Table 3. Estimation results, percentage effect on prices

	<i>Generics</i>	<i>BrandC</i>	<i>BrandM</i>	<i>Others</i>
$Ref_{inst}(\beta_2, \mu)$	-1.98** (-2.32:-1.65)	-2.45** (-2.72:-2.17)	-0.76** (-0.96:-0.57)	-0.62** (-0.80:-0.43)
$Ref_{mean}(\beta_1, \beta_2, \mu)$	-8.72** (-9.83:-7.62)	-13.97** (-14.86:-13.08)	-10.26** (-10.83:-9.68)	-4.52** (-5.17:-3.86)
$Ref_{end}(\beta_1, \beta_2, \mu)$	-11.22** (-11.99:-9.23)	-17.31** (-18.41:-16.20)	-12.95** (-13.66:-12.23)	-5.68** (-6.50:-4.85)
$GC(\beta_3)$		-0.45* (-0.81:-0.10)	-4.78** (-5.22:-4.35)	
$Trend(\beta_4)$	0.15** (0.13:0.18)	0.33** (0.25:0.42)	0.21** (0.20:0.23)	0.62** (0.59:0.64)
$D/(t-R)(\mu)$	2.9^{-4**} ($0.0 < : 8.5^{-3}$)	2.3^{-4**} ($0.0 < : 7.0^{-3}$)	1.5^{-4**} ($0.0 < : 1.4^{-3}$)	2.3^{-4**} ($0.0 < : 6.0^{-3}$)
Observations	224,498	82,472	398,800	149,490
Products	4,191	988	6,236	3,175
Log likelihood	273,402	155,962	572,372	298,956

Notes: The products' total sales values in the study period are used as weights.

Robust 95% confidence intervals are shown in parentheses. The confidence intervals for μ are not symmetrical, which is expected, since a value of μ equaling zero leads to an empirical model where the adjustment variable equals the reform indicator variable.

** and * denote significance at the 1% and 5% levels, respectively.

time are also illustrated in Figure 2.

The estimates of Ref_{mean} indicate that the substitution reform has had significant effects on the prices in all pharmaceutical groups in the study period. The largest relative price cut, 14%, is found in the population of brands that faced generic competition at the time of the substitution reform (*BrandC*); the second largest amounts to 10% and is found for brands that lacked generic competition at that time (*BrandM*). A comparison of the estimates for GC in these two populations reveals another reform effect: the price-effect of getting generic competition goes from being merely -0.45% before the substitution reform to -4.78% after the substitution reform. Together, these results for brand-name pharmaceuticals indicate that the eventual reform effect for those brands that gained generic competition sometime after the substitution reform is similar in

size to the effect for those that faced generic competition before the substitution reform.

The lowest estimated average reform effect is -5% for *Others*, while the estimated average reform effect is -9% for *Generics*. Using the market shares from Table 1 as weights, the average reform effect over the four pharmaceutical groups is -9.87% (95% C.I. $-10.29\%:-9.45\%$) or -9.66% (95% C.I. $-10.07\%:-9.24\%$) when the effect on *GC* is not included.

The results also clearly indicate that the pharmaceutical firms had not fully adjusted their prices to the substitution reform already by October 2002: for the different populations, the instantaneous price cuts were 1–2%, compared with declines of 6–17% by the end of the study period. This conclusion is also strengthened by the fact that both β_2 and μ differ significantly from zero. As expected, the results indicate that the adjustment was fastest for *Generics*.

The estimates for μ assume values below 0.001 in all populations which results in correlations between D and $D/(t-R)^\mu$ of above 0.99. Due to these high correlations, the estimates for β_1 and β_2 should not be interpreted separately and are therefore not reported. Fortunately, these high correlations do not affect the reliability of the joint effect of D and $D/(t-R)^\mu$ within the study period (Verbeek, 2008, Chapter 2). The estimates of Ref_{inst} , Ref_{mean} , and Ref_{end} as well as the predictions depicted in Figure 2 are thus still reliable and retain small confidence intervals despite these correlations.

The time trend estimate is positive in all populations and largest for *Others*. When the products' pre-reform sales values are used as weights, instead of the sales values for the entire study period, Ref_{mean} shrinks in absolute size for *Generics* and for *BrandM* to -6.86% and -9.31% , while it increases in absolute size to -15.89% for *BrandM* and to -5.91% for *Others*. In total, the weighted average reform effect is reduced in absolute size by half a percentage point.¹⁴

¹⁴The weighted average reform effect is considerably larger when using a specification that allows the slope of the time trend to change at the time of the substitution reform. There is, however, reason to believe that this specification is inappropriate. Quite apart from the reasons mentioned previously in the text, the results obtained using this specification cast doubt on its validity. For example, the results for brands indicate that the reform effect is of the same size irrespective of whether or not the product faces generic competition.

Note: The estimated reform effects illustrated here do not include the effect that the substitution reform has by amplifying the effect of generic competition.

Figure 2. Estimated reform effects

4.2 Estimated demand and welfare effects

The first column of Table 4 presents the OLS results for specification (D1) (the first-difference), while the second and third columns present the OLS and IV results for specification (D2). No strong and valid instruments are found for $\Delta \ln P$, so the IV results for the first-difference specification are not reported.

Let us start by noting that the estimates obtained using specification (D1) differ quite substantially from those obtained using specification (D2). This is expected, since the estimates of specification (D1) describe how changes in the independent variable affect the change in demand, while the estimates of specification (D2) – given the high coefficients for lagged consumption – more or less describe how the level of the independent variable affects the change in demand. As discussed above, the coefficients for lagged consumption can easily capture the effects of omitted variables and should therefore not be interpreted as estimates of persistence in pharmaceutical consumption.

Table 4. Estimation results for pharmaceutical demand, multiplied by 100

	Specification D1	Specification D2	
	OLS (first-diff.)	OLS	IV
$\ln P$	-75.83** (-130.51:-21.15)	-32.86* (-57.56:-8.16.)	-35.23* (-64.71:-5.75.)
$\ln I$	45.49* (8.75:82.24)	8.14 (-28.39:44.66)	10.11 (-23.23:43.45)
<i>Trend</i> [Ⓐ]	1.08* (0.18:1.98)	-0.10 (-0.55:0.35)	-0.14 (-0.61:0.34)
<i>Quarter</i> ₂	4.01** (2.40:5.64)	3.11** (1.05:5.17)	3.04** (1.20:4.87)
<i>Quarter</i> ₃	-7.36** (-11.50:-3.23)	-9.69** (-14.27:-5.11)	-9.46** (-13.81:-5.11)
<i>Quarter</i> ₄	-2.60 (-5.47:0.27)	6.34** (2.20:10.47)	6.23** (2.85:9.61)
<i>Hoard</i>	-0.30** (-0.50:-0.10)	-0.52** (-0.84:-0.21)	-0.53** (-0.82:0.24)
$\ln Q_{t-1}$		59.99** (47.94:72.05)	60.23** (48.95:71.51)
$\ln Q_{t-4}$		35.09** (25.42:44.76)	35.48** (26.51:44.46)
Observations	111	108	108
AIC	-341.58	-365.48	-365.45
R ²	0.8642	0.9955	0.9955
Kleibergen-Paap			30.32
Hansen J (P-value)			0.22

Notes: Robust 95% confidence intervals are shown in parentheses.

** and * denote significance at the 1% and 5% percent levels, respectively.

[Ⓐ]Note that *Trend* only becomes a constant in the first-difference specification.

The OLS and IV estimates for specification (D2) differ less from each other. If prices are endogenous, one would expect the OLS estimate in the second column to be larger than the IV estimate for $\ln P$. Table 4 shows that this is the case, but the difference is quite small and not statistically significant. The difference might still indicate that there is an endogeneity problem, but the problem seems small in relation to the problem caused by including lagged consumption. Therefore, I view the results for specification (D1) as the most

reliable ones, and will focus my discussion on these estimates.

The price and income elasticity estimates for specification (D1) are both significantly different from zero and have the expected signs, indicating that consumption decreases with prices but increases with income. The results for specification (D1) also indicate a considerable seasonal variation, and growth over time, in pharmaceutical demand. The estimate of -0.003 for the variable *Hoard* suggests that a change in pharmaceutical benefits scheme that increases consumer prices for pharmaceuticals by 10% is preceded by a temporary increase of 3% in the demand.

Based on the estimated reform effects one can calculate that, without the price-lowering effect of the substitution reform, Sweden's pharmaceutical consumption after the substitution reform would have cost on average SEK 2.80 billion more per year in the study period. This can be compared with total Swedish pharmaceutical sales that averaged SEK 25.50 billions during this period, but this is not a very exact measure of the importance of the substitution reform, since the pharmaceutical consumption would have been lower without the price-lowering effect of the substitution reform.

A better measure is equivalent variation (EV). Using the price and income elasticities of specification (D1), the average annual EV measure in the study period is estimated to be SEK 2.68 billion. The increase in welfare is estimated to be SEK 1.80 billion in 2003 and SEK 3.30 billion in 2006. Using a real discount rate of 3%, the present value in 2002 of the welfare effects for October 2002 through October 2007 amounts to SEK 12.42 billion.

Since the estimates reported in Table 4 are not very robust, I have also calculated the EV measures using other values for the price and income elasticities. Zero is a logical upper bound for the price elasticity and gives a present value of the welfare effects of SEK 12.96 billion. Economic theory provides no natural lower bound for the price elasticity; instead I report that the present value becomes SEK 12.05 billion when the price elasticity is set to -1.31 (the lower limit of the 95% confidence interval of specification (D1)), and SEK 10.86 billion when it is set to -3.25 (the estimate reported by Alexander et al.).¹⁵

¹⁵I share the opinion of Alexander et al., who found their estimate on -3.25 "very surprising". If pharmaceutical products are substitutes for each other, the own-price elasticity of individual products should be below that of pharmaceuticals as a group. This, in combination with pharmaceutical firms' high mark-ups over marginal cost, suggests that a price elasticity of -3.25 is not in accordance with the behavior of well-informed profit-maximizing pharmaceutical firms: such an elastic demand suggests that the firms could raise profits by

The EV measures are only marginally affected by the income elasticity: if the income elasticity is set to 1.55 (the estimate reported by Alexander et al.), the present value remains at SEK 12.42 billion, and if it is set to 0 it becomes SEK 0.01 billion higher.

The welfare estimate reported above measures the value for the whole consumer-side of the market, both directly for the consumers and for the insurers. That the estimated price elasticity is above -1 implies that the substitution reform has reduced pharmaceutical expenditures. The average reduction for October 2002 through October 2007 is 2.5% and the present value of the reduced expenditures amounts to SEK 3.00 billion. In this period, approximately 75% of the pharmaceutical expenditures were paid by the insurer (the National Corporation of Swedish Pharmacies). This means that the insurers' costs have decreased by approximately SEK 2.25 billion (75% of the SEK 3.00 billion, actually somewhat more than this due to the non-linear construction of Swedish pharmaceutical benefits scheme), meaning that approximately SEK 10 billion of the discounted welfare improvement accrues directly to the consumers.

In view of increased costs due to the substitution reform, the Pharmaceutical Benefits Board allowed the National Corporation of Swedish Pharmacies to increase its annual margins by SEK 56 million in 2003, and by an additionally SEK 20 million in 2006 (the National Corporation of Swedish Pharmacies, 2003; the Pharmaceutical Benefits Board, 2005). If the estimated average reform effect is adjusted for these increases, the estimated average annual EV measure shrinks from SEK 2.68 billion to SEK 2.62 billion and the discounted welfare effect goes from SEK 12.42 billion to SEK 12.15 billion.

5 Other welfare effects

The substitution reform of October 2002 of course has other welfare effects besides those on the consumer-side in the form of reduced prices. Below, I briefly discuss other important welfare effects, though it is beyond the scope of this paper to provide estimates of these.

The substitution of cheaper versions for prescribed pharmaceuticals has not

reducing prices. For example, if the price elasticity of a firm's products is -3 , a price cut of 1% would increase revenues by nearly 2%. If the marginal costs are constant, this would raise the variable costs by 3% and thus increase the firms profit if the variable costs are less than $2/3$ of the revenues.

only led to increased price competition but also to direct savings. A rough estimate of these savings is SEK 0.6 billion per year.¹⁶ There are, however, reasons not to consider the entire savings as constituting a welfare improvement for consumers. Andersson et al. (2005) and Granlund and Rudholm (2008) reported that significant shares of Swedish consumers refused substitution and paid extra to get the prescribed instead of the generic (or parallel-imported) pharmaceutical, indicating that they viewed the substitutes as inferior. Similarly, the Medical Products Agency (2004) reports that some consumers feel generic substitutes are less effective than brand-name pharmaceuticals; generic substitution might therefore affect patient willingness to follow physician recommendations. Generic substitution might also increase the risk that some consumers confuse different drugs.

Since the substitution reform has made consumers and physicians more familiar to generic pharmaceuticals, it might have affected physicians' prescribing pattern. Generic substitution might also have increased the costs for the Pharmaceutical Benefits Board, which must make more decisions regarding price changes, and for physicians, who might have to answer questions about generic substitution from their patients.¹⁷

The total producer surplus of the pharmaceutical firms has clearly been reduced by the substitution reform: the revenues have declined and the costs have increased due to higher quantities. Some generic producers have likely benefited from the substitution reform due to increased market shares, while the profits of brand-name producers have been affected most negatively. Generic substitution also reduces the expected profits arising from new pharmaceuticals and thus the incentive to invest in research and development. However, since the Swedish pharmaceutical market is small from a global perspective, this effect is also small.

¹⁶This estimate is obtained by extrapolating to the whole of Sweden from data for the county of Västerbotten for January 2003–October 2006; see Granlund (2009) for a description of this data. The National Corporation of Swedish Pharmacies et al. (2003) estimated these savings to be SEK 0.5 billion based on national data for the first six months after the reform.

¹⁷Andersson et al. (2006) investigated physicians' opinions on and experiences of the Swedish substitution reform.

6 Discussion

In this paper, the Swedish substitution reform was estimated to have reduced the average price of pharmaceuticals during October 2002 through October 2007 by 10%. The reform effect was found to be significantly greater for brand-name than for generic products. The results also suggest that the substitution reform amplified the effect of generic entry on brand-name prices by a factor of ten. This in turn has contributed to the reform effect being of similar size for brand-name products, irrespective of whether a product gained generic competition before or after the substitution reform.

The results confirm the conclusion of Granlund and Rudholm (2007), that pharmaceutical firms gradually adjusted their prices after the substitution reform, and that prices of generics were reduced less than those of brands that faced generic competition is in accordance with their theoretical predictions. The estimated reform effects reported here, however, were significantly larger than those obtained by Granlund and Rudholm. One important explanation is that the observations here were weighted to obtain estimates of welfare effects due to increased price competition. This paper also differs from Granlund and Rudholm (2007) by, for example, studying the effects on all pharmaceutical products sold in Sweden, by using longer time series, and by studying the effect on the prices charged by the pharmaceutical firms, instead of those charged by the pharmacies.

The reform effects reported here are also considerably larger than those that Buzzelli et al. (2006) estimated for 16 OECD countries. This difference could be because the Swedish substitution reform was more successful in reducing prices than were the substitution reforms of the other 15 countries Buzzelli et al. studied. The difference could also be because I, unlike them, used a specification that allowed for gradual price adjustments after the substitution reform.

The results of this paper support the theoretical predictions of Frank and Salkever (1992) by indicating that the effect of generic competition changes significantly when consumers become more price sensitive, as they did with the Swedish substitution reform. How a substitution reform influences the effects of generic entry has, to my knowledge, never been tested before.

The price elasticity was estimated to -0.76, which is more negative than most price elasticities for pharmaceuticals reported in the literature, but not directly

comparable to many of those, since they measure the elasticities of pharmaceutical demand with respect to out-of-pocket prices for pharmaceuticals. If physicians' prescribing behavior is also affected by the costs to the insurers, this reduces the effect that changed copayments have on pharmaceutical demand. The price elasticity estimate is, however, considerably less negative than that reported by Alexander et al. (1994). The income elasticity of 0.45 indicates that pharmaceutical consumption is a necessity in the short run. This can be compared with the long-term estimate reported by Alexander et al. (1994) and those summarized by Getzen (2000), indicating that pharmaceuticals and healthcare on a national level are a luxuries. One explanation of these differences is that pharmaceutical demand reacts slowly to changes in income. The estimations of the demand for pharmaceuticals were, however, troubled by the non-stationarity of the key variables, so these elasticity estimates should be interpreted with caution. Fortunately, the welfare estimates expressed in equivalent variation are not very sensitive with respect to price and income elasticities, so the present value of the welfare effects remains between SEK 12 and 13 billion for reasonable values of the elasticities.

To conclude, this paper has demonstrated that the substitution reform has reduced pharmaceutical prices considerably. Even though more research is needed into other consequences of the substitution reform, the substitution reform has likely been welfare improving from a Swedish perspective. The result may differ from a global perspective, since most brand-name producers are located outside Sweden and since consumers all over the world are affected by reduced incentives for pharmaceutical research and development.

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