Does Increased Price Competition Affect Entry of New Pharmaceutical Products?*

David Granlund† and Niklas Rudholm‡

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Abstract

In October 2002 a substitution reform was introduced in the Swedish Pharmaceuticals market. In this note, the effects of increased price competition due to the reform on the entry of new pharmaceutical products were studied. The results show that the reform did affect the entry behavior of generic manufacturers as they became more prone to enter new package sizes into the market after the reform, but also that there is considerable heterogeneity in entry behavior between different ATC-code groups for both brand name and generic products.

Keywords: pharmaceutical industry; generic competition; generic drugs; brand name drugs.

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*A research grant from the Swedish Competition Authority is gratefully acknowledged. Corresponding author: (N. Rudholm) nru@du.se

†The Swedish Retail Institute, SE-103 29 Stockholm, Sweden; and Department of Economics, Umeå University, SE-901 87 Umeå, Sweden

‡The Swedish Retail Institute, SE-103 29 Stockholm, Sweden; and Department of Economics, Dalarna University, SE-781 88 Borlänge, Sweden.

1 Introduction

A substitution reform that came into effect on October 1, 2002 increased the price competition at the Swedish pharmaceuticals market.[1]. When the reform was introduced, there was a debate in Sweden that pharmaceutical firms would increase product diversity with more different types of pharmaceutical products (more drugs being sold as pills, oral fluids, etc instead of just as pills) and more different package sizes. The reason for this belief was that pharmaceutical firms by doing so could avoid the increased price competition between exchangeable products since the rules state that exchange is only possible for products of the same type and package size.

In this note, this reform will be used as a natural experiment to study the causal effect of increased price competition on product diversity. More precisely, we study whether or not pharmaceutical firms have responded to the reform by launching products in new segments of the market. Our focus is thus on entry of new exchange groups as defined by the Swedish Medical Products Agency, or alternatively, on entry of new package sizes into already existing exchange groups.

As mentioned above, the substitution reform will affect the profitability of pharmaceutical products since it makes consumers within an exchange group more cross-price-sensitive and this affects revenues. Among products that are exchangeable, generic substitution has also decreased the market share of the, normally more expensive, brand name product (Granlund and Rudholm, 2007). As for the costs of entering and being active in an exchange group, the application fees for entering a product into a new exchange group is SEK 70 000 and SEK 40 000 for additional products in the same application. For firms entering an already existent exchange group that fee is SEK 20 000. The yearly administrative fee for being active in the market is SEK 16 000 for each additional product in each exchange group (SFS 1993:595).

Firms will choose to enter a new product into the market (or to introduce a new package size for an already existing product) if they believe that they can make an economic profit doing so. Both before and after the reform, brand name producers are able to, at least temporarily, increase total sales and the

[1] The reform, the characteristics of the reform that made consumers more price sensitive and the effect that this has had on pharmaceutical prices is described in detail in Granlund and Rudholm (2008) and Granlund (2009).

average price of their products by launching products that are not exchangeable to their competitors' products. The reason is that part of the sales of their new product comes on the expense of sales of generics that are close substitutes to their existing products (and not on the expense on their own existing products), and that they are able to charge higher prices for products for which no close substitutes exists. Since the reform increases the market shares of generics and reduces prices among exchangeable products, the reform enhances the increase in total sales and average price that brand name producers can achieve by launching products that are not exchangeable to generic products. The downside for brand name producers is that as soon as their new products face generic competition, the revenues from them is lower after the substitution reform than before. Hence, whether or not the reform will make a brand name producer more likely to launch a new product depends on the time it expects will pass before generic competitors launch exchangeable products. For generics, the increased market share works for that the reform make them more likely to launch products that are (or will be) exchangeable to brand name products, while the lower pharmaceutical prices works in the opposite direction. If generic firms enter exchange groups without existing products, the probability of rapid brand name entry into the same exchange group would be considerable bearing in mind that brand name producers have profits from the time as monopolist that can help finance entry costs.

Brand name firms can launch new product either before or after the patent expires. Entering new products before patent expiration has two advantages, it leaves the brand name producer as monopolist until patent expiration and it helps create consumer loyalty to the brand name product which is valuable to the firm (for a discussion regarding consumer loyalty see e.g. Granlund and Rudholm, 2007). Both of these effects increases the probability that establishing a new exchange group (i.e. entering a new product) will be profitable for the brand name firm.

The purpose of this paper is twofold. First, to test is the substitution reform has affected the probabilities of brand name and generic producers, respectively, launching new product and/or new package sizes. Second, to test the hypotheses that brand name producers should be more prone to establish new exchange groups before patent expiration rather than after due to the threat of rapid generic entry after patent expiration.

2 The Swedish pharmaceuticals market and the substitution reform

The substitution reform came into effect on October 1, 2002. The reform required that pharmacists inform the consumers if there are substitute products available, as well as that the cheapest available substitute product would be provided within the Swedish pharmaceuticals insurance system. The pharmacist must also inform the consumers that they can buy the prescribed pharmaceutical product instead of the generic if they pay the difference in price between the products themselves. Finally, the reform requires that pharmacists substitute the prescribed pharmaceutical product to the cheapest available generic in cases when neither the prescribing physician prohibits the switch 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 switch due to medical reasons the consumer is still reimbursed.

Pharmaceutical firms decide which prices they charge for pharmaceuticals in Sweden, but for products to be included in the Swedish pharmaceuticals insurance system the price charged by the pharmaceutical firms has to be authorized by the Pharmaceutical Benefits Board. Pharmaceuticals are sold through a nation wide government owned monopoly, the National Corporation of Swedish Pharmacies (NCSP), which has a margin on the pharmaceutical products that is determined by the Pharmaceutical Benefits Board. The regulations also imply that the NCSP is required to charge a nation wide uniform price for each pharmaceutical product in Sweden.

Before the substitution reform, a reference price system introduced in January 1993 was in effect.[2] Under that system, the Swedish National Social Insurance Board set a reference price equal to 110 percent of the price of the cheapest available generic product, and all costs exceeding this reference price were to be borne by the consumer (RFFS 1992:20, 1996:31).

Also under the reference price system, a prescribed pharmaceutical product could be substituted for a cheaper version if the prescribing physician had given his/her consent to this on the prescription, or if the patient requested

[2] The effects of the reference price system on pharmaceutical prices have been analyzed previously, see e.g. Aronsson et al. (2001), Rudholm (2001) and Bergman and Rudholm (2003).

substitution. In the latter case there was, however, a recommendation that the physician be contacted before substituting products if possible, and a requirement that the prescribing physician be informed about the substitution after. This means that the transaction cost of generic substitution was lowered when the substitution reform was introduced in 2002. Also, the out-of-pocket cost for patients changed when the reference price was abolished. Under the substitution reform costs up to 100 percent of the cheapest generic alternative is included in the pharmaceutical insurance system, compared to 110 percent during the reference price system. This increased the patients' out-of-pocket costs for choosing to buy the prescribed pharmaceutical with 0-10 percent of the price of the cheapest generic version, depending on the patient's copayment rate in the insurance system. On average this means an extra out-of-pocket cost of approximately 19 SEK ($\approx$ 2 EURO).[3]

3 The empirical analysis

IMS Sweden has provided a dataset containing information on all pharmaceutical products sold in Sweden during the period January 1997 until October 2007. In this paper, our focus is on entry of new exchange groups as defined by the Swedish Medical Products Agency. As such, the data is aggregated so that an observation of our dependent variable equal to one represents the entry of one (or more) new exchange groups within a given seven-figure ATC-code[4], or entry of one (or more) new package sizes into an already existing exchange group, in a given month.[5] The estimations are conducted for both brands and generics, and the total number of observations in the dataset used in the estimation for brand name drugs equals $40,973$, while the number of observations

[3] The calculation is based on the fact that the average price of the prescribed products and the available substitute products in the substitution system was approximately 300 SEK and 250 SEK, respectively, and a patient co-payment rate of 25 percent. 9.51 SEK = 1 EURO, exchange rate 2008-09-12.

[4] In the World Health Organization's Anatomical Therapeutic Chemical (ATC) classification system, the drugs are divided into different groups according to the organ or system on which they act, and their chemical, pharmacological and therapeutic properties. In the ATC-groups used here, drugs which share the same chemical substances are grouped together.

[5] We choose to study the probability of one or more entrants within a specific month instead of the number of entrants since entry of more than one new exchange group within a specific month is rare in our sample.

related to generics equals 14,108. Descriptive statistics for both types of dependent variable (exchange group and package size) and the variables used in the estimation of equation (1) are presented in Table 1 for both brand name and generic products.

Table 1 about here.

The following equation is then estimated for both brand name products and generics;

$$\Pr(entry_{it}) = \beta_0 + \beta_1 t + \beta_2 reform_t + \beta_3 patent_{it} + u_{it}, \tag{1}$$

where *entry* represents the establishment of a new exchange group (entry of a new type of pharmaceutical product) as defined by the Swedish Medical Products Agency or entering a new package size into an existing exchange group. t is a time trend, $reform$ is a indicator variable taking the value one after the introduction of the Swedish substitution reform in October 2002, *patent* represents our proxy for patent expiration[6], and u_{it} is the residual term. The time trend is included to capture possible time trends in entry behavior (due to, for example, time-trends in revenues and/or profits, costs etc.).

One could consider other potential covariates such as the number of generic competitors, revenues etc. However, using these variables introduces econometric problems, due to the fact that these variables are endogenous in the sense that they will be correlated with the error term of the regression. Instead of including these problematic covariates, we opt for using a random effects, random coefficient model to account for heterogeneity between ATC-code groups in both average entry behavior and the effects of the reform on entry behavior. The residual (or heterogeneity) term is specified as

$$u_{it} = v_i + \gamma_i reform_t + \varepsilon_{it}, \tag{2}$$

where $v_i \sim iid\ N(0, \sigma_v^2)$ is an ATC-code random effect, $\gamma_i \sim iid\ N(0, \sigma_\gamma^2)$ is an ATC-code specific random coefficient term related to the introduction of the substitution reform, and $\varepsilon_{it} \sim iid\ N(0, \sigma_\varepsilon^2)$ is the within ATC-code group

[6] In this paper, the time of generic entry is used as a proxy for patent expiration. Thus, the variable *patent* is an indicator variable taking the value one befor entry of the first generic competitor into each exchange group.

residual. The specific random effects are assumed independent of each other, and the model to be estimated can thus be written

$$\Pr(entry_{it}) = \beta_0 + \beta_1 t + v_i + (\gamma_i + \beta_2) reform_t + \beta_3 patent_{it} + \varepsilon_{it}. \quad (3)$$

The main advantages of this type of model is that it accounts for ATC-code specific unobserved heterogeneity in entry behavior, while also allowing for heterogeneity in how the reform affected different ATC-code groups with respect to entry behavior.[7] The results from the estimations are presented in Table 2.

Table 2 about here.

The population mean coefficient for the average effect of the exchange reform on entry of new exchange groups for brand name drugs and generics are 0.0020 and 0.022, respectively. Neither of these parameter estimates is statistically significant at conventional levels. We can also use the estimation results to calculate an interval within which 95% of the estimated coefficients $(\gamma_i + \beta_2)$ related to the reform effect are expected to lie (Rabe-Hesketh and Skrondal, 2008, p. 159). Doing this we obtain $0.0026 \pm (1.96 * 0.016)$ for brands and $-0.0017 \pm (1.96 * 0.018)$ for generics. As such, 95 percent of the coefficients $(\gamma_i + \beta_2)$ for the effects of the reform on entry of brand name product exchange groups will be between -0.029 and 0.034. The same numbers for generics are -0.037 and 0.034. For entry of new package sizes within an already existing exchange group, the estimate of the average effect for all ATC-code groups is statistically insignificant for brands, but significant on the 5 percent level for generics. The size of the parameter estimate indicates that the probability of a generic entering a new package size into an already established exchange group is increased by 2.9 percent by the substitution reform. Calculating the same type of confidence interval as above, the results show that 95 percent of the coefficients for the effects of the reform will be between -0.071 and 0.13, respectively. As such, the results show that there is considerable heterogeneity between ATC-code groups in how the reform has affected both the establishment of new exchange groups and the entry of new package sizes in already established

[7] Conventional random effects models have also been estimated. All qualitative results presented in this paper remain the same.

exchange groups. It should also be noted that the variance components for both random effects and random coefficients are statistically significant, indicating that not including these in the estimations would lead to biased parameter estimates.

4 Discussion

In this paper, the substitution reform implemented in Sweden in October 2002 has been used to study the causal effect of increased price competition on product diversity. When the reform was introduced, there was a debate in Sweden that pharmaceutical firms would increase product diversity with more different types of pharmaceutical products and more different package sizes. The reason for this belief was that the pharmaceutical firms by doing this could avoid the increased price competition due to the reform since the rules state that exchange is only possible for products of the same type and package size.

The results in this paper show that the reform has not, on average, affected the entry behavior of brand name pharmaceutical firms. This indicate that, on average, brand name firms expected that the time new products can avoid generic substitution is to short for the reform to make it more profitable to launch new products. For generics, the reform made generic firms on average 2.9% more likely to launch products of new package size, indicating that the increase in their market shares are, on average, more important than the increased price competition. For both brand name pharmaceuticals and generics the results show that there is considerable heterogeneity in how the reform has affected both the establishment of new exchange groups and the entry of new package sizes in already established exchange groups.

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Table 1: Descriptive statistics.

	Brand name drugs		Generic drugs	
Variable	Mean	Std. dev.	Mean	Std.dev.
entry (*new exchange group*)	0.0078	0.88	0.0099	0.099
entry (*new package size*)	0.026	0.16	0.059	0.24
t	69.14	36.90	74.02	37.56
$reform$	0.51	0.49	0.57	0.49
patent	0.63	0.44	n.a.	n.a.
Observations	40973		14108	

Table 2: Estimation results.

	Brand name drugs				Generic drugs			
	New group		New size		New group		New size	
Parameter (variables)	Estimate	S.e.	Estimate	S.e.	Estimate	S.e.	Estimate	S.e.
β_0	0.012*	0.0017	0.036*	0.0030	0.020*	0.0042	0.061*	0.026
$\beta_1(t)$	-4.9E^{-5}*	2.3E^{-5}	-1.1E^{-4}*	4.3E^{-5}	-6.0E^{-5}	-4.6E^{-5}	-5.8E^{-4}*	1.0E^{-4}
$\beta_2(reform)$	0.0026	0.0019	0.0030	0.0035	-0.0017	0.0038	0.029*	0.0095
$\beta_3(patent)$	0.0033	0.0020	0.0024	0.0034	n.a.	n.a.	n.a.	n.a.
Random effect/random coefficient parameters (variable)								
v_i	0.026*	0.0012	0.043*	0.0021	0.042*	0.0040	0.078*	0.0072
$\gamma_i(reform)$	0.016*	0.0013	0.033*	0.0023	0.018*	0.0032	0.051*	0.0065
Log-likelihood	42609		18172		12782		798	
Observations	40973		40973		14108		14108	
ATC-codes	391		391		178		178	

* Significant at the 5 percent level.