Reforming the Swedish pharmaceuticals market – Consequences for costs per defined daily dose

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Abstract

In 2009 and 2010, the Swedish pharmaceuticals market was reformed. One of the stated policy goals was to achieve low costs for pharmaceutical products dispensed in Sweden. We use price and sales data for off-patent brand-name and generic pharmaceuticals to estimate a log-linear regression model, allowing us to assess how the policy changes affected the cost per defined daily dose**.** The estimated effect is an 18 percent cost reduction per defined daily dose at the retail level and a 34 percent reduction in the prices at the wholesale level (pharmacies' purchase prices). The empirical results suggest that the cost reductions were caused by the introduction of a price cap, an obligation to dispense the lowest-cost generic substitute available in the whole Swedish market, and the introduction of well-defined exchange groups. The reforms thus reduced the cost per defined daily dose for consumers while being advantageous also for the pharmacies, who saw their retail margins increase. However, pharmaceutical firms supplying off-patent pharmaceuticals experienced a clear reduction in the price received for their products.

Keywords: Pharmaceutical industry, national pharmacy monopoly, pharmacy deregulation, competition, generics, pricing

JEL codes : D80, D83, L65, I11

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1. Introduction

All European governments have regulated their pharmaceutical markets more or less extensively. Safety-in-use regulation is ubiquitous as is some form of economic regulation. A common argument for the latter is that a free market would lead to inequalities in access and out-of-pocket costs for pharmaceuticals (Almarsdottir et al., 2000a). Both in the Nordic countries and in the rest of Europe, different measures to control prices have been implemented. During the last decade approximately ¾ of EU-countries used either some form of reference pricing (including mandatory substitution systems), price cap regulations, or both (Puig-Junoy, 2010; Kaiser et al., 2014) to control expenditures.

Most studies find that reference pricing effectively curtails prices of prescription drugs (Aronsson et al., 2001; Pavcnik, 2002; Puig-Junoy, 2007; Kanavos et al., 2008; Brekke et al., 2009, 2011). However, Bergman and Rudholm (2003) found that reference pricing in Sweden mainly affected pharmaceuticals that were already on the market in 1993, when the system was introduced, and hence that suppliers' ability to adjust their behaviour made the long-term price effects more ambiguous. Kaiser et al. (2014) also found that internal reference prices are more effective than external.

There are fewer studies of the effects of price-cap regulation on pharmaceutical prices. Brekke et al. (2011) analyse a natural experiment in Norway, in which price-cap regulation was replaced by reference pricing for some products, and their findings suggest that reference pricing is more efficient in bringing down price than is price-cap regulations. A possible reason is that the price cap tends to act as a focal point for prices, and that dynamic price competition is reduced by price-cap regulation (Anis, 2003).

In 2009 and 2010, the Swedish pharmaceuticals retail market was fundamentally reformed. The Swedish government set up five policy goals for the reform (Statskontoret, 2013): 1) increased availability of pharmaceuticals, 2) higher service standard at the pharmacies, 3) low costs for pharmaceuticals, 4) maintained competence and safety in pharmaceutical supply and, finally, 5) a better use of pharmacies to promote a more efficient use of pharmaceuticals.

The means used to achieve these goals were privatization of pharmacies, a price-cap for products going off patent, more stringent rules for generic substitutions - in combination with a widening of the spread between the retail and wholesale prices, i.e., the pharmacies' margin (Tillväxtanalys, 2012). Effectively, the reform package shifted net revenues from the suppliers of pharmaceuticals to the pharmacies, in the expectation that this would boost the number of pharmacies.

The reform resulted in a 40 percent increase of the number of pharmacies four years after the reform; more in the larger cities and less in more sparsely populated regions; and in a significant lengthening of average opening hours (Vårdanalys, 2014). The purpose of this paper, however, is to investigate if and to what extent the policy reforms made in Sweden in 2009 and 2010 achieved another of the stated goals of the reform, that of low costs for pharmaceuticals in the Swedish market. We will thus empirically study how the reforms affected the costs per dispensed defined daily dose (DDD) in Sweden.[1] Since the reform mainly had consequences for the generics market (i.e., the market for off-patent drugs), we focus on this segment. We are able to divide the total reform effect into four parts, corresponding to: the introduction of a price cap for off-patent pharmaceuticals in July 2009, the obligation to substitute towards the lowest-cost generic available in the Swedish market rather than at the individual pharmacy introduced in October 2009, changes in the definitions of the exchange groups in February 2010, and changes, in May 2010, of which pharmaceuticals the pharmacies were allowed to dispense if and when a national stock-out of the first-hand choice had been declared.

The introduction of the price cap for products going off patent meant that Sweden joined the approximately ¾ of EU-countries that have some form of price-cap regulation on pharmaceuticals (Puig-Junoy, 2010). The motive for the regulation was to lower pharmaceutical prices, and in this paper we are able to estimate the short-run effect on prices of the price cap. It should, however, be noted that a price-cap regulation can have adverse long-run effects on competition as suggested by Anis (2003). An investigation of such effects is outside the scope of this paper, and would be difficult to undertake with our data due to rather few products going off patent in both the pre- and post-reform periods.

Another part of the reform, which did not directly affect pharmaceutical prices, but that certainly changed the structure of the Swedish pharmaceutical market, was that the national monopoly on pharmaceutical retailing was abolished. Similar reforms had previously been made in Iceland in 1996 and in Norway in 2001. After the deregulation, the number of pharmacies increased by 41 percent in Iceland as a whole, and by as much as 67 percent in Reykjavik (Almarsdottir et al., 2000a). However, a related study also reports that the out-of-pocket costs for pharmaceuticals did not decrease as expected after the reform (Almarsdottir et al., 2000b). The effect of the Norwegian reform has been studied by several authors (Anell and Hjelmgren, 2002; Holmberg et al., 2003; Anell, 2004). The findings indicate that neither pharmacy costs nor pharmaceutical prices have decreased, but that access to pharmacy services increased through an increase in the number of pharmacies and their opening hours. However, in a related study (Econ, 2004), the majority of the pharmacists surveyed reported

[1] The prices set by the pharmacies are equal all over Sweden, and the cost of products sold in the pharmacies are equal to the list prices determined in the auction to become product of the month. As such, there is a high degree of equivalence between price and cost in the Swedish pharmaceuticals market.

that the workload had increased significantly after the deregulation of the market, and 40 percent of the pharmacists surveyed considered the workload to be "unacceptable" after the reform.

Our results show that the Swedish reform was effective in delivering lower costs. The retail price per DDD fell by 18 percent and the wholesale price fell by 34 percent. The results also indicate that the introduction of the price cap, the modified and stricter rules for generic substitution, and introduction of the well-defined exchange groups all had significant effects reducing the cost per DDD. Allowing the pharmacies to dispense also the second- or third-lowest-cost generic did not, however, have any significant effects on the cost per DDD. The price cap had a larger relative effect on retail prices than on wholesale prices, but this is partially a mechanical consequence of how the pharmacy (retail) margin is calculated, and partially due to the decision to increase the retail margin by 10 SEK per package (10 SEK ≈ 1.10 EURO, exchange rate 2014-06-02) for off-patent products exposed to generic competition. This increase corresponds to about 13 percent of the net revenues for all Swedish pharmacies combined on sales of pharmaceuticals within the pharmaceuticals insurance system (Vårdanalys, 2014).

2. Material and methods

2.1 The reform

Between 1969 and January 2010 pharmaceuticals were sold exclusively in Sweden through a nationwide government-owned monopoly, the National Corporation of Swedish Pharmacies (NCSP). The NCSP's retail margin for prescription pharmaceuticals was regulated by the Swedish Dental and Pharmaceutical Benefits Board (DPBA) and the private as well as the government-owned pharmacies' margins remain regulated. As for the pharmaceutical firms in Sweden, they have since long the formal right to set prices. However, for a pharmaceutical to be included in the Swedish pharmaceuticals insurance (or patient reimbursement) system the prices have to pass a social cost-benefit test in order to receive authorization from the DPBA. How the price is set for off-patent products will be discussed below. One implication of the regulation of pharmaceutical prices is national pricing; another that transaction prices have to be identical to official prices.

On February 19, 2009, the government presented its reform a bill to the parliament and the law was passed on April 29, 2009.[2] The reform consisted of a series of steps (Tillväxtanalys, 2012). First, in July 2009, the price of off-patent products was capped at 35 percent of the price during the patent period if three conditions were fulfilled. The criteria are that i) an equivalent generic must have been sold at a price below 30 percent of the price during patent protection by a firm that achieved at least 10 percent of the sales within the exchange group; ii) there must have been positive generic sales each

[2] Ministry of Health and Social Affairs, 2009a, b.

month for at least 4 months; and iii) at least six months must have passed since generic competition was first established in the exchange group. Only when all three conditions are met will the price cap become effective and the price of the original article will then be capped at 35 percent of the original product's price at the time of generic entry.

In the second reform step, effective since October 1, 2009, the obligation to substitute towards the lowest-cost generic available at the individual pharmacy was changed to an obligation to dispense the lowest-cost generic substitute available in the Swedish market. The lowest-cost product, called "product of the month", is determined by the DPBA in an auction where the lowest bid wins. Simultaneously and as mentioned, the retail margin for prescription pharmaceuticals was increased with 10 SEK per package dispensed of exchangeable pharmaceutical products at the pharmacy. The retail margin for articles that have a defined exchange group (i.e. have competition from generics) is after the reforms thus set according to the following formulas;

Wholesale price (WP) ≤ 75.00 SEK	Retail price = (WP x 1,20) + 31.25 SEK + 10.00 SEK
Wholesale price > 75,00 - 300,00 SEK	Retail price = (WP x 1,03) + 44,00 SEK + 10,00 SEK
Wholesale price > 300,00 - 6000,00 SEK	Retail price = (WP x 1,02) + 47,00 SEK + 10,00 SEK
Wholesale price > 6000,00 SEK	Retail price = WP + 167,00 SEK + 10,00 SEK

while for products without competition (and for all products prior to the reform), the last 10 SEK is not added to the retail margin. These formulas show that the minimum retail margin is 31.25 SEK (≈ 3.43 EURO, exchange rate 2014-06-02) and the maximum is 177 SEK (≈ 19.45 EURO, exchange rate 2014-06-02) per package dispensed at the pharmacy during the period under study.

Third, in February 2010, the groups within which substitution should be made were defined in an unambiguous way. Before the 2009 reforms, the exchange groups used in the substitution system were defined relative to the prescribed article, which normally means the original article. An exchange group comprised all articles with the same active ingredient, strength and form, for package sizes that deviated no more than 12 percent from that of the original article. However, this way of defining the exchange group was considered to be somewhat arbitrary and sometimes ambiguous. Since February 1, 2010, the DPBA therefore pre-define exchange groups with fixed package-size limits (e.g., packages with 14-16 pills constitute exchange group T14; packages with 40-45 pills belong to exchange group T19, etc.).

In February 2010, following a decision by the Swedish parliament in April 2009, entry into pharmacy retailing was also allowed and two thirds of all existing pharmacies where privatized. The majority of the privatized pharmacies were sold in blocks to private investors, while a fraction was reserved for

small investors and one third remained government owned. The change in ownership became effective as of February 2010.

Prices on prescription pharmaceuticals are still regulated in Sweden[3] and consequently pharmacies mainly compete in location and service quality, e.g. opening hours and in-store availability of pharmaceuticals, but also in the pricing of OTC-drugs and non-drug products.

Finally, in May 2010, following complaints that the manufacturer of the lowest-cost generic alternative sometimes ran out of stock, the pharmacies were allowed to dispense the second- or even third-lowest-cost generic if the regulating authority declared a national stock-out of the first-hand choice.

2.2 Data

The dataset used in this study was collected by IMS Sweden and covers off-patent prescription pharmaceuticals, branded as well as generics, sold through pharmacies during the period January 1, 2006 through December 31, 2011. Prices and volumes are measured at the article level, i.e., a product with a certain active ingredient, strength, form and package size, supplied by a certain firm. Data also identify multi-dose dispensed drugs (MD drugs; see below). For any given article, retail prices are identical at all pharmacies. The volumes sold could, in principle, be measured at the individual pharmacy level, but were aggregated to the national level by IMS.

For each article, besides price and quantity, we know whether it belongs to the preferred (lowest price) provider (i.e. is the "product of the month") or the second- or third-hand choice; whether it was previously sold under a patent, is a branded generic or a true generic; and, if the product went off patent in 2004 or later, at what date this happened**.**

2.3 Descriptive statistics

Table 1 shows the average (sales-weighted) cost per defined daily dose (Cost/DDD) by exchange group in SEK for different time periods. In order not to let changes in the composition of drugs affect the statistics, values in this table are only reported for the two-thirds of the observations that belong to exchange groups that had positive sales each month during the study-period. The averages are calculated at the retail and wholesale level, either including or excluding MD drugs. MD drugs are

[3] Wholesale prices of off-patent products are set in the monthly national tender process. Retail prices are regulated at a level determined by the outcome of the tender in combination with the formula regulating the retail margin.

individualized dosage bags, where each bag contains all pharmaceuticals that a particular individual need to consume at one specific moment in time. Every dosage bag is marked with the name of the patient, the content and the time at which it should be consumed. This segment comprises about 10 percent of the total market in retail prices, with the remaining 90 percent consisting of regular prescriptions. The enhanced possibility to use package sizes and products that minimize costs when preparing the dosage bags may explain why the average cost per DDD, at least in the pre-reform period, is somewhat lower when MD is included. The averages presented in the table indicate that the cost per DDD is lower and decreasing after the reform.

Table 1 about here.

2.4 Empirical model

When evaluating one specific reform, as in this paper, some methodological choices need to be made and motivated. First, the purpose of our paper is to evaluate the effects of the reforms made on the cost per DDD in the Swedish pharmaceuticals market, and our econometric framework is thus based on modeling cost per DDD as a function of several covariates and reform indicator variables. Similar models have previously often been used in evaluation studies of pharmaceutical markets (e.g., Pavcnik, 2002; Ganslandt and Maskus, 2004; Yfantopoulos, 2008; Breeke et al., 2009; Granlund and Rudholm, 2011; Granlund and Köksal-Ayhan, 2014; Ghislandi et al., 2013).

One alternative would be to estimate full supply and demand models as in the papers by Granlund (2010), Breeke et al. (2011), Kaiser et al. (2014), and Duso (2014). However, the main motivation for using such models is that it facilitates calculation of the welfare effects of the reforms, which is clearly outside the scope of the present paper. Also, as argued by Granlund (2010), since there is no product-specific cross-sectional variation in pharmaceutical prices in the Swedish market, demand functions must be identified from variations in pharmaceutical prices over time and across exchange groups only. Previous studies (e.g., Granlund) have shown that this gives less robust estimates of the demand function than in other countries where there is more variation in the price data.

Another alternative would be to use time-series modeling (e.g. Barros and Nunes, 2010; Anderson et al., 2006; Lee et al., 2006; Ong et al., 2003). Barros and Nunes (2010) and Ong et al. (2003) use sophisticated time-series techniques that allow data to identify structural breaks, and then relate these structural breaks to the timing of reforms. Anderson et al. (2006) and Lee et al. (2006) instead use more traditional techniques where the timing of the assumed structural breaks in the time series are postulated by the researcher.

Although we find the time-series approach compelling for situations where one does not have access to panel data, the use of panel data, as in our study, will allow using both time-series and exchange-group cross-sectional variation to identify parameters of interest, making it possible to also control for time-invariant differences between exchange groups in the estimations.

We restrict our evaluation period to January 1, 2006 through December 31, 2011. This evaluation period gives us approximately 20 000 observations that can be used to identify the reform-effect parameters. This should suffice to estimate the reform effects on the cost per DDD; adding observations from a longer period of evaluation would likely not contribute significantly to the identification of the reform parameters.

It should also be noted that a longer evaluation period does not necessarily increase the reliability of the reform-effect estimates, due to in the accumulation of measurement error over time (Mian and Sufi, 2012). In the long run, measurements of the effects of any experiment or program change will approach zero due to the accumulation of random shocks that increase measurement errors; coefficients will become increasingly biased toward zero simply due to an increased noise to signal ratio.

The following log-linear regression model has been estimated:

$$\text{Ln Cost/DDD}_{et} = \alpha_e + \beta_1 Trend_t + \beta_2 DPS2009_{et} + \beta_3 Oct2009_t + \beta_4 Feb2010_t + \beta_5 May2010_t + \beta_6 PatentTr_{st} + \beta_7 Dpatent6_{st} + \beta_8 Dpatent24_{st} + \sum_k \gamma_k \mathbf{W}_{k,et} + \sum_l \delta_l \mathbf{Z}_{l,st} + \varepsilon_{et} \quad (1)$$

The dependent variable is the natural logarithm of the cost per DDD for exchange group *e* at time *t*. Here, an exchange group consists of all articles with the same active ingredient, strength and form, and within each exchange group there may be different package sizes.

The parameters to be estimated are α, β, γ and δ. Subindex *s* indicates pharmaceutical-substance level and thus takes the same value for all exchange groups with the same active substance. Parameters α_e capture exchange-group-specific fixed effects, included to ensure that our estimated reform effect has not been affected by the introduction or withdrawal of exchange groups from the market and *Trend* is a linear time trend. The indicator variable *DPS2009* equals 1 for observations that could potentially be affected by the price cap. It is set equal to 1 for substances and months after June 2009 when at least six months have passed since patent expiration. I.e., we choose not to condition on whether the price cap is actually in effect, since this depends on generic entry and generic prices and is, therefore,

endogenous.[4] *Oct2009*, *Feb2010* and *May2010* are indicator variables taking the value 1 from October 2009, February 2010 and May 2010, respectively. These variables thus indicate when the different components of the reform package, as described in Section 2.1, became effective. The indicator variable *Oct2009* represents the onset of a stricter interpretation of availability for the lowest-cost generic, *Feb2010* represents the switch to unambiguously defined exchange groups and *May2010* equals 1 in periods when pharmacies were allowed to dispense the second- or third-lowest-cost generic when a national stock-out of the first-hand choice had been declared. Together with *DPS2009*, these three indicator variables are included to capture the different components of the reform.

PatentTr is the number of months since patent expiration. Due to lack of reliable data on patent expirations before 2004, it is truncated at 24 months. *Dpatent6* and *Dpatent24* are indicator variables set equal to 1 if more than 6 or 24 months, respectively, have passed since patent expiration and 0 otherwise. The patent expiration variables have been included to capture potential short-term and long-term effects of patent expiration on the cost per DDD, in addition to the effect of the price cap. Note also that since no exchangeable products are under patent protection there is no need to control for current patent status.

The most general specification of our model, presented in eq. 1 above, also includes a vector $\boldsymbol{W}=(W_1, W_2, W_3, W_4)$ of variables that are included to control for the effects of different aspects of competition on the cost per DDD. The following variables are included: the number of package sizes per exchange group, the number of exchange groups per pharmaceutical substance, the average number of firms for each package size in the exchange group and the number of firms per pharmaceutical substance. The vector $\boldsymbol{Z}$, finally, includes measures (at the substance level) of the number of therapeutic competitors and the number of therapeutic alternatives with generic versions.

The first vector of competition-related variables is potentially endogenous. Excluding $\boldsymbol{W}$ alleviates the potential endogeneity problem and makes it possible to estimate a total reform effect, including effects through changes in the competitive environment. However, excluding $\boldsymbol{W}$ might cause missing-variable bias, since we cannot control for the exogenous variation in these variables. Consequently we estimate and present results from versions of the model both with and without these variables. A comparison of the estimates suggests how the exclusion of $\boldsymbol{W}$ affects the estimated reform effect. In our opinion, the models without these variables gives a better measure of the total reform effect on the cost per DDD.

Equation (1) is estimated separately, first for retail and then for wholesale prices, with and without the vector of possibly endogenous variables, $\boldsymbol{W}$, as well as with and without MD. All estimations are made with a fixed-effect estimator where the error terms are allowed to be correlated within exchange

[4] In the Appendix, we show that the estimate of the total reform effect remain stable when using two alternative measures instead of DPS2009.

groups.

The estimated total reform effect is the sum of the three direct reform effects, measured by the parameters β_3, β_4 and β_5, and the effect of the price cap, calculated as the β_2 parameter times the weighted average of the price-cap variable from July 2009. It should be noted that the price-cap effect measured in this model is the direct effect of the introduction of the price cap on prices. The total reform effect is thus the weighted average of the effect for those not affected be the price cap and for those that are. The parameter estimate for the total effect is reported at the bottom of the result tables.

3. Results and discussion

Table 2 presents estimation results for retail prices, while results for wholesale prices are presented in Table 3. In the second column of Table 2, our preferred model with MD sales excluded from the analysis, the estimates for the price cap is negative with a parameter estimate of -0.082 and statistically significant at the 5 percent level. The parameter estimate capturing the introduction of more stringent generic substitution rules is -0.068 and statistically significant at the 10 percent level. The parameter estimate for the introduction of well-defined exchange groups equals -0.059, also significant at the 10 percent level. Finally, allowing the pharmacies to dispense also the second- or third-lowest-cost generic does not seem to have had any significant effects on the cost per DDD.

Table 2 about here.

Using the formula for calculating the effect in percentage terms, 100*[exp(β)-1], this means that the estimated effect of the price cap equals a 7.87 percent decrease in cost per DDD. The stricter obligation to switch to the lowest-priced product in the whole market reduces costs per DDD by 6.57 percent and the introduction of more well-defined exchange groups lowered the cost per DDD by an estimated additional 5.72 percent. The total reform effect corresponds to a 18.37 percent decrease in cost per DDD.[5] The formula presented above is used throughout the paper to calculate the percentage price effects.

As mentioned, *PatentTr* is the number of month since patent expiration, truncated at 24, while *Dpatent6* and *Dpatent24* are indicator variables set equal to 1 if more than 6 or 24 months,

[5] Excluding observations from February, 2009, when the reform bill was presented to parliament, until July 2009, when the first elements of the reform became effective, resulted in a slightly more negative estimate of the time trend and reduced the absolute value of the point estimates for the reform effect with 1-2 percentage points for retail prices and with 3-4 percentage points for wholesale prices. As another sensitivity analysis, we included separate time trends for each exchange group. When estimated on the subsample of exchange groups with positive sales throughout the whole period, results remain stable. For the full sample, the estimated reform effect falls, e.g. from -0.42 to -0.34 in the regression on wholesale prices excluding W and MD, but we believe one reason for this is overfitting.

respectively, have passed since the patent expired for substance *s*. These variables were included to capture potential effects of patent expiration on the cost per DDD. The parameter estimate related to *PatentTr* is negative and statistically significant at the 1 percent level in all estimated models. In our preferred model specification, the parameter estimate for *PatentTr* indicates that the cost per DDD decreases with about 4 percent per month during the first two years after patent expiration. The negative point estimate for *Dpatent6*, while not statistically significant in our preferred specification, indicates that the cost declines more rapidly the first few months after patent expiration and that the price fall then slows down. Our preferred model does, however, not indicate that there are any further cost reductions after 24 months. Also, some additional estimations, controlling for the time since patent expiration more flexibly using, e.g., 24 indicator variables, result in very similar estimates for the coefficients of main interest, i.e., those associated with the different steps of the reform.

Turning to the last two columns of Table 2, where the pharmaceutical products that are sold as multi-dose dispensed drugs, MD, are also included in the sample, we find a slightly larger total reform effect, around 20 percent. Note also the similarities in the parameter estimates in all four specifications, indicating that our results are not sensitive to changes in specification and/or the inclusion of MD in the sample.

Estimation results for wholesale prices are presented in Table 3. The main difference between Table 2 (retail prices) and Tables 3 (wholesale prices) is that the latter point estimates are larger for the general effects of the reform and for the effects of the price cap, hence suggesting a larger total reform effect for wholesale prices. This is to be expected, since the reform package included an intentional increase in the retail margin by 10 SEK per dispensed package at the pharmacy, and since the algorithm used to calculate the retail margin (described in Section 2.1) results in a less-than-proportional effect on retail prices when wholesale prices change.

The parameter estimates for the direct reform effects and the effect of the price cap corresponds to a total reform effect on the wholesale price of about 34 percent. Finally, we see that including the MD part of the market again has a negligible effect on the parameter estimates.

Table 3 about here.

4. Conclusion

In 2009 and 2010, the Swedish pharmacy market was reformed. The reform package contained several regulatory changes, such as the introduction of a price cap on off-patent products, stricter rules for

generic substitution, and a widened retail margin for pharmacies. Also, during the period 1969 until 2010, pharmaceuticals were sold exclusively in Sweden through a nationwide government-owned monopoly, but in February 2010 the previous monopoly was exposed to competition when entry into pharmacy retailing was allowed and two thirds of all existing government-owned pharmacies where privatized. One of the stated objectives of the reform was to achieve low costs for pharmaceutical products dispensed in Sweden (Statskontoret, 2013). The purpose of our paper has been to investigate whether this goal has been met.

We are able to divide the total reform effect into four parts. The introduction of a price cap for off-patent pharmaceuticals lowered the cost per DDD by 7.8 percent. An obligation to substitute towards the lowest-cost generic available in the whole Swedish market lowered costs by 6.6 percent. Changes in the definitions of the exchange groups, in February 2010, reduced costs with an additional 5.7 percent, while the changes in May 2010, since when pharmacies are allowed to dispense alternative products if and when a national stock-out of the first-hand choice has been declared, had no significant effects on the costs per DDD. In total, the reform effect corresponds to a reduction of the cost per DDD by 18 percent at the retail level and by 34 percent at the wholesale level. The difference between these two measures is partly due to the regulatory algorithm that determines the retail margin, but it is also in part caused by the intentional increase of the retail margin that was part of the reform package.

Overall, the reform seems to have reduced pharmaceutical costs per DDD, hence benefiting consumers and tax payers, and it seems also to have been advantageous for the pharmacies via the increase of the retail margin that was part of the package. However, the reform also clearly reduced prices for the manufacturers of off-patent pharmaceuticals, through the introduction of the price cap as well as through other price-reducing effects stemming from the reform.

Finally, it should be noted that although lowering prices in the short run, the price-cap regulation could have negative long-term effects on competition. Although approximately ¾ of EU countries have some form of price-cap regulation of pharmaceuticals, few studies have addressed the long-term effects of price-cap regulations in the pharmaceuticals market (Puig-Junoy, 2010). Price-cap regulations can lead to less price competition and higher pharmaceutical prices in the long run, for example by providing focal points for pharmaceutical prices (Anis, 2003) or by discouraging entry. Thus, an interesting avenue for future research would be to investigate how price-cap regulation affects dynamic price competition in the long run.

Appendix

The indicator variable *DPS2009* is based on the last of the three criteria for the price cap to become effective (see Section 2.1), so that the indicator takes the value 1 six months after patent expiration for the period after July 2009. As a sensitivity analysis, we have also performed estimations with two alternative variables, *Generics4_2009* and *DPS2009_Binding*. *Generics4_2009*, is based on the second criteria of the price cap and takes the value 1 from July 2009 if there have been positive generic sales for at least four months. *DPS2009_Binding* takes the value 1 if the brand-name drug actually lowered its price in the summer of 2009 and six months had passed since patent expiration. *DPS2009_Binding* is thus intended to indicate if the price cap were binding. Note that both *Generics4_2009* and *DPS2009_Binding* are potentially endogenous; the first since generic entry and exit depends on prices and the second since the price cap can only be binding if the second criteria is fulfilled, if generics are sold at below 30 percent of the patent price, and if the brand-name drug had not already reduced its price with more than 65 percent.

For the model where MD sales and the vector of potentially endogenous variables, $\boldsymbol{W}$, are excluded, key results are reported in Table A1. To facilitate comparisons, corresponding results from estimates with *DPS2009* are also presented in the table. As can be seen, the estimated total reform effect remains nearly unchanged under the alternative specifications. This is true also for models with MD sales and/or $\boldsymbol{W}$ included. Similarly, individual estimates are not very sensitive to choice between *DPS2009* and *Generics4_2009*. However, the estimates for *DPS2009_Binding* are significantly different from the other two. Using this variable also reduced the estimates of *Oct2009* with nearly one standard error. Yet the estimated total reform effect remains relatively unaffected, since this variable only take the value 1 for about 25 percent of the observations after July 2009, while the corresponding figures for *DPS2009* and *Generics4_2009* are 95-96 percent.

Table A1 about here.

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Table 1: Descriptive statistics, SEK per DDD

Period	Retail Excl. MD	Retail Incl. MD	Wholesale Excl. MD	Wholesale Incl. MD
Pre reform: Jan. 2006 – June 2009	4.92	4.73	3.42	3.33
Post reform				
May 2010 -April 2011	4.00	3.90	2.38	2.38
May 2010 -Dec. 2011	3.95	3.86	2.34	2.35
Jan. 2011 - Dec. 2011	3.90	3.82	2.29	2.31
Total sales, million of SEK, 2011, sample	2264.26	2511.22	970.80	1155.95

Note: The values in this table are only reported for observations that belong to exchange groups that had positive sales each month during the study-period.

Table 2: Estimation results, Cost per DDD, Retail prices, excluding and including sales of MD drugs.

	Including *W*, excluding MD	**Excluding *W* and MD**	**Including *W* and MD**	**Excluding *W*, including MD**
Trend	0.000	-0.000	0.002**	0.002**
	(0.001)	(0.001)	(0.001)	(0.001)
DPS2009	-0.083**	-0.082**	-0.080**	-0.075*
	(0.037)	(0.040)	(0.038)	(0.040)
Oct2009	-0.065*	-0.068*	-0.097**	-0.097**
	(0.036)	(0.037)	(0.040)	(0.039)
Feb2010	-0.056*	-0.059*	-0.055*	-0.062**
	(0.032)	(0.033)	(0.029)	(0.025)
May2010	0.015	0.002	0.012	0.008
	(0.027)	(0.031)	(0.026)	(0.029)
PatentTr	-0.038***	-0.043***	-0.039***	-0.042***
	(0.008)	(0.008)	(0.010)	(0.009)
Dpatent6	-0.155*	-0.152	-0.150	-0.144
	(0.094)	(0.093)	(0.098)	(0.095)
Dpatent24	-0.031	0.043	-0.066	-0.025
	(0.065)	(0.056)	(0.065)	(0.060)
Reform effect	-0.185***	-0.203***	-0.215***	-0.222***
	(0.048)	(0.056)	(0.055)	(0.058)
NOBS	21513	21513	21544	21544
R^2within	0.531	0.493	0.485	0.474

*Note: The regressions "Including **W**" includes all variables that control for competition, while all regressions include the measures of therapeutic competition. The 2008 levels of sales in the exchange groups are used as weights. 15210 of the observations used belong to exchange groups that had positive sales each month during the study-period. Standard errors, robust to correlations within exchange groups, are given in parenthesis. ***, **, * indicate that the coefficient is statistically significant different from zero on the 1%, 5% and 10% significance levels, respectively.*

Table 3: Estimation results, Cost per DDD, Wholesale prices, excluding and including MD sales.

	Including *W*, excluding MD	**Excluding *W* and MD**	**Including *W* and MD**	**Excluding *W*, including MD**
Trend	-0.001	-0.001	0.002	0.001
	(0.001)	(0.001)	(0.001)	(0.001)
DPS2009	-0.134***	-0.137**	-0.128***	-0.128**
	(0.050)	(0.056)	(0.049)	(0.053)
Oct2009	-0.169***	-0.174***	-0.186***	-0.185***
	(0.043)	(0.044)	(0.046)	(0.045)
Feb2010	-0.084**	-0.086**	-0.073**	-0.079***
	(0.037)	(0.041)	(0.032)	(0.030)
May2010	-0.002	-0.026	-0.003	-0.014
	(0.035)	(0.042)	(0.032)	(0.037)
PatentTr	-0.044***	-0.049***	-0.045***	-0.048***
	(0.010)	(0.010)	(0.011)	(0.011)
Dpatent6	-0.166	-0.155	-0.154	-0.143
	(0.124)	(0.123)	(0.123)	(0.119)
Dpatent24	-0.055	0.042	-0.086	-0.036
	(0.109)	(0.100)	(0.104)	(0.101)
Reform effect	-0.382***	-0.416***	-0.384***	-0.400***
	(0.060)	(0.071)	(0.058)	(0.065)
NOBS	21513	21513	21544	21544
R^2within	0.576	0.538	0.543	0.530

See note to table 2.

Table A1: Estimation results, Cost per DDD, Retail and Wholesale prices, excluding MD sales and ***W***.

	Retail prices			**Wholesale prices**		
	Baseline: DPS2009	**Generics4-_2009**	**DPS2009-_Binding**	**Baseline: DPS2009**	**Generics4-_2009**	**DPS2009-_Binding**
DPS2009	-0.082**			-0.137**		
	(0.040)			(0.056)		
Generics4_2009		-0.091**			-0.143***	
		(0.037)			(0.051)	
DPS2009_Binding			-0.401***			-0.513***
			(0.093)			(0.115)
Oct2009	-0.068*	-0.062*	-0.032	-0.174***	-0.170***	-0.149***
	(0.037)	(0.034)	(0.035)	(0.044)	(0.040)	(0.047)
Feb2010	-0.059*	-0.061*	-0.057*	-0.086**	-0.088**	-0.082*
	(0.033)	(0.032)	(0.034)	(0.041)	(0.039)	(0.042)
May2010	0.002	0.004	-0.006	-0.026	-0.025	-0.035
	(0.031)	(0.031)	(0.030)	(0.042)	(0.041)	(0.040)
Reform effect	-0.203***	-0.207***	-0.197***	-0.416***	-0.419***	-0.396***
	(0.056)	(0.057)	(0.042)	(0.071)	(0.071)	(0.053)
NOBS	21513	21513	21513	21513	21513	21513
Clusters	363	363	363	363	363	363
R^2within	0.493	0.495	0.541	0.538	0.539	0.577

See note to table 2.