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# Regulation, generic competition and pharmaceutical prices: Theory and evidence from a natural experiment\*

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## Abstract

We study the impact of regulatory regimes on generic competition and pharmaceutical pricing using a unique policy experiment in Norway, where reference pricing (RP) replaced price cap regulation in 2003 for a sub-sample of off-patent products. We exploit a detailed panel dataset at product level covering a wide set of off-patent drugs before and after the policy reform. Off-patent drugs not subject to reference pricing serve as our control group. We find that RP leads to lower relative prices, with the effect being driven by strong brand-name price reductions, and not increases in generic prices. We also find that RP increases generic competition, resulting in lower brand-name market shares. Finally, we show that RP has a strong negative effect on average prices at molecule level, suggesting significant cost-savings.

*Key words:* Pharmaceuticals; Regulation; Generic Competition

*JEL Classifications:* I11; I18; L13; L65

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# 1 Introduction

In pharmaceutical markets new innovations are protected by patents that restrict competing firms from copying the innovation within a certain period. When the patent expires, competing firms may enter the market with generic products. The generic versions contain exactly the same active chemical ingredient and must prove therapeutic equivalence before they can be launched on the market. Since generics have the same therapeutic effect as the brand-name, one would expect that only relative prices matter for the consumers' (or physicians') choice of drug, and thus that generic entry would trigger fierce competition between brand-names and generics. This is, however, not what is happening. A robust empirical regularity is that the brand-names charge a higher price than their generic versions and still obtain positive market shares (e.g., Scherer, 2000). Some studies show that brand-name prices even increase when the patent expires and generics enter the market (Grabowski and Vernon, 1992, Frank and Salkever, 1997). This phenomenon has been labelled the "generic paradox".

Given that profits earned under the patent period are sufficient for the brand-name producer to recoup its R&D costs, the efficient outcome in the post-patent period should be prices equal to marginal production costs, taking into account that brand-names and generics are identical products and provide similar health gains to consumers. Thus, from a policy perspective, the large market share of higher priced brand-names relative to their generic versions is an unsatisfactory outcome.

Most Western countries, except for the US, regulate pharmaceutical prices directly or indirectly in order to control pharmaceutical expenditures.<sup>1</sup> The recent extension of Medicare to prescription drugs has spurred a debate of price controls also in the US.<sup>2,3</sup> The rationale for regulation is that price competition in pharmaceutical markets is weak, mainly

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<sup>1</sup>Danzon (1997) provides a thorough overview of theory and practice of price regulation in the pharmaceutical industry. See also Kanavos (2001) for a comprehensive overview of pharmaceutical regulation practices in 14 EU countries.

<sup>2</sup>For example, Kanavos and Reinhardt (2003) discuss whether reference pricing is suitable for the US pharmaceutical market, while Frank and Newhouse (2008) discuss the need for price negotiations for prescription drugs in the Medicare plan in light of the increasing pharmaceutical expenditures.

<sup>3</sup>Notably, there are some price control mechanisms in the US system. For example, (generic) reference pricing is well-established through the "maximum allowable charge" programs used by, e.g., Medicaid.

due to substantial medical insurance. Danzon and Chao (2000) argue, however, that regulation drives out competition and is thus counter-productive in obtaining cost-savings. They base their conclusion on a cross-national study using data for 1992, showing that price competition between generic competitors is stronger in unregulated or less regulated markets (United States, United Kingdom, Canada, and Germany) than in countries with strict price or reimbursement regulations (France, Italy, and Japan).

Our research agenda is highly parallel. In the present paper we analyze the relationship between regulation, competition and pharmaceutical prices both theoretically and empirically. The theory model allows us to analyze price competition between brand-names and generics under price cap regulation and reference pricing, as well as the benchmark case of free pricing, and to derive empirically testable hypotheses. The empirical part of the paper exploits a unique policy experiment in Norway, where the government exposed a subsample of the off-patent drugs on the market to reference pricing. The policy reform is thus a natural experiment that provides us with a comparison group consisting of off-patent drugs subject to price cap regulation throughout the whole period. We use a rich product level panel data set covering a four-year period from 2001 to 2005 that gives us variation over time (before and after the reform) and across products that are subject to different regulatory regimes (price cap or reference pricing).

Our empirical analysis is divided into three parts. First, we examine the impact of reference pricing on relative prices, measured as the ratio of brand-name and generic prices. Our results show a negative, though weak, significant effect on relative prices. A possible explanation could be price convergence towards the reference price, as suggested by, e.g., Danzon and Liu (1996) and Danzon and Ketcham (2004). However, when we decompose the effect by looking at brand-name and generic prices separately, we find that reference pricing not only reduces brand-name prices but also generic prices. The reason that relative prices decline due to reference pricing is that brand-name prices drop more than generic prices.

In the theory section, we show that price convergence towards the reference price

happens only if the reference price is *exogenous*, i.e., fixed at a some level between brand-name and generic prices. However, if the reference price is a function of the prices, and thus *endogenous*, a generic producer has a strategic incentive to lower its price in order to reduce the reference price, making the brand-name drug relatively more expensive. Since the reference price in Norway was calculated as a weighted average of brand-name and generic prices, this would explain why we do not observe price convergence in our data.<sup>4</sup>

Second, we analyze the impact of reference pricing on generic competition, measured inversely by brand-name market shares, as, for instance, Aronsson et al. (2001).<sup>5</sup> The effect of reference pricing on generic competition is not *a priori* evident. Reference pricing changes the copayment structure, making the brand-name drug relatively more expensive than the generics, which increase generics' market share *for given prices*. However, the brand-names respond to reference pricing by lowering their prices in order to retain their market shares. The net effect on market shares is thus determined by the relative strengths of these two counteracting effects.

Our estimations show that reference pricing leads to a significant and substantial (almost 14 percent) reduction in brand-name market shares, controlling for changes in relative prices. We can thus interpret this result as a *direct demand response* (for given drug prices) to the change in copayment structure brought about by the introduction of reference pricing. The brand-name price reductions pull in the opposite direction. We find, however, no significant effect of changes in relative branded–generic prices on brand-name market-shares. Thus, the direct demand response of the radical change in the copayment structure due to reference pricing by far outweighs any indirect effect via the price responses.

Finally, we quantify the effect reference pricing has on average prices at molecule level, using the market shares of brand-names and generics as weights. Qualitatively, the impact on average prices is evident, since we have established that reference pricing leads to lower brand-name and generic prices and lower brand-name market shares. However,

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<sup>4</sup>In most countries that adopt reference pricing, the reference price is determined endogenously as a function of one or more drug prices in the relevant market (see, e.g., Lopez-Casasnovas and Puig-Junoy, 2000).

<sup>5</sup>Alternatively, we could measure the effect on the number of generic competitors, the Herfindahl-index, etc. The measures are, however, highly correlated and provide qualitatively similar results.

for policy implications it is of interest to quantify the effect. Our estimations show that reference pricing lowers average molecule prices by more than 30 percent. This is an impressive reduction, especially taking into account that Norway has a relatively strict price cap regime. Provided that total drug demand is relatively price inelastic, this result suggests significant cost-savings.<sup>6</sup> There are two different effects that contribute to these cost-savings: as described above, we find that the introduction of reference pricing leads to (i) a reduction of both brand-name and generic drug prices, and (ii) a shift in demand from brand-names to generics. The decomposed effects suggest that a substantial part of the cost-savings can be attributed to the second effect: a shift in demand from brand-name to generic drugs. Thus, reference pricing stimulates generic competition and reduces pharmaceutical prices, and is therefore clearly favorable compared with price cap regulation in the off-patent market.

A highly related paper is Aronsson et al. (2001) who use Swedish data to analyze the impact of relative brand-name and generic prices, as well as reference pricing, on brand-name market shares.<sup>7</sup> They find only weak effects of relative prices and reference pricing on brand-name market shares. Estimating the effects on the whole sample (12 molecules) provides no significant impact of reference pricing or relative prices on brand-name market shares. They therefore run regressions at molecule level, finding significant effects for only 5 out of 12 molecules.

Our study differ from theirs in several ways. First, the policy reform in Norway is a natural experiment, which provides us with a control group of pharmaceuticals. In Sweden reference pricing was introduced for all substances with generic competition, implying that Aronsson et al. (2001) must rely on before-after estimation. Second, we make use of a much more extensive dataset, comprising 24 molecules with monthly price and volume data. Third, we extend their analysis by estimating the effect on brand-name and generic

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<sup>6</sup>Several empirical studies have documented that demand for pharmaceuticals are quite price inelastic (e.g., Newhouse, 1993). This suggests that average prices at the molecule level are good proxies for potential cost savings (see also Danzon and Chao, 2000).

<sup>7</sup>Aronsson et al. (2001) interpret relative prices as a measure of generic competition. This seems highly imprecise since lower relative prices might be due to higher generic prices, which would hardly be equivalent to stronger generic competition. We follow the mainstream by measuring generic competition by either the generic market share or the number of generic competitors.

prices separately, such that we can identify the driving force behind relative price changes. More importantly, we address the policy implications more directly by looking at the effects on average prices at molecule level, which is not a part of their study. Finally, in contrast to Aronsson et al. (2001), our analysis finds strong effects of reference pricing on generic competition (market shares) and pharmaceutical prices.

Our paper is also related to the literature on the impact of regulation on pharmaceutical firms' pricing strategies. Pavcnik (2002) studies the introduction of (therapeutic) reference pricing in Germany in 1989, focusing on the change in patients' out-of-pocket expenses. Using data for two different therapeutic fields (oral antidiabetics and antiulcerants) for 1986 to 1996, she identifies significant price reductions of the reference price system on both brand-names and generics, with the effect being stronger for brand-names. She also finds that brand-names with more generic competitors reduced prices more. Brekke et al. (2007a) provide a similar type of study, exploiting the same policy experiment as the present paper, but using a dataset with on-patent products and substantially fewer off-patent molecules. Their findings are similar to Pavcnik (2002) with respect to brand-name and generic price responses to reference pricing. However, Brekke et al. (2007a) also considers cross-price effects on therapeutic substitutes not exposed to reference prices, finding that price reductions on referenced drugs trigger lower prices on their therapeutic substitutes, a result that is relevant for patent protection and innovation, as well as the trade-off between copayments and health gains (see also Brekke et al. 2007b).<sup>8</sup>

While the above-mentioned studies are related, they obviously focus on different aspects than we do in the present paper. Importantly, they are not concerned with the impact of regulation on generic competition. This is an important aspect when evaluating the performance of regulatory reforms in terms of cost-savings, which is the primary policy goal in the pharmaceutical off-patent market. Our study, thus, complements the mentioned studies by estimating the effects of reference pricing relative to price cap regula-

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<sup>8</sup>There is also a paper by Bergman and Rudholm (2003) that studies the price effects of the Swedish reference price system, providing similar figures as Pavcnik (2002) and Brekke et al. (2007a). Distinguishing between actual and potential generic competition, they find that reference pricing only reduced prices of those brand-names that faced actual generic competition.



tion on generic competition. Here, we also make a theoretical contribution by highlighting in particular the importance of exogenous versus endogenous reference pricing. We also extend the previous literature by estimating the effects of regulation on average prices at molecule level, so that potential cost-savings can be analyzed, and thus policy implications can be discussed more directly.

The rest of the paper is organized as follows. In Section 2 we develop a theoretical model and derive predictions for the empirical analysis. In Section 3 we present some institutional background by describing the price cap regulation and the policy experiment with reference pricing in Norway. In Section 4 we present our data and some descriptive statistics. In Section 5 we present the empirical method and results with respect to relative prices, brand-name market shares, and average prices at molecule level. Finally, Section 6 concludes the paper.

## 2 A theoretical model

We can capture some main mechanisms of generic drug competition by applying a simple vertical product differentiation model. Consider a therapeutic market with products offered by two firms. Firm  $B$  offers the original (off-patent) brand-name drug  $b$ , while firm  $G$  offers a generic substitute  $g$ . Consumers are heterogeneous with respect to the gross valuation of drug treatment, represented by a parameter  $\tau$  which is uniformly distributed on the interval  $[0, t]$ . It would be natural to think of the heterogeneity of gross valuations as reflecting differences in severity levels, but it could also be interpreted as differences in prescription practices among physicians.<sup>9</sup> The total mass of consumers is given by  $M$ . Each consumer demands either one or zero units of the most preferred drug. The utility derived from no drug consumption is zero, while a consumer who buys one unit of drug  $i$  obtains a net utility

$$U_i = \begin{cases} \theta\tau - c_b & \text{if } i = b \\ \tau - c_g & \text{if } i = g \end{cases}, \quad (1)$$

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<sup>9</sup>For example, pharmaceutical detailing might influence a physician's willingness to prescribe a cheaper generic substitute.

where  $\theta > 1$  is the (perceived) quality difference – e.g., due to differences in advertising intensity – between the brand-name and the generic drug, and  $c_i$  is the patient copayment for drug  $i$ .<sup>10</sup>

A consumer with a positive net utility of drug consumption will choose the most preferred drug version by trading off drug quality against drug copayment. The higher the gross valuation of drug treatment, the more the consumer is willing to pay in order to purchase the (high-quality) brand-name drug. A consumer who is indifferent between the two drug versions has a gross valuation equal to  $\hat{\tau}$ , given by  $\theta\hat{\tau} - c_b = \hat{\tau} - c_g$ , yielding

$$\hat{\tau} = \frac{c_b - c_g}{\theta - 1}. \quad (2)$$

Consumers with a gross valuation higher than  $\hat{\tau}$  demand the brand-name drug, while the remaining consumers demand the generic drug, as long as the net utility of drug consumption is non-negative. Total demand for the two drug versions are thus given by

$$D_b = \frac{M}{t} (t - \hat{\tau}), \quad (3)$$

$$D_g = \frac{M}{t} (\hat{\tau} - c_g). \quad (4)$$

From these demand functions we can define the market share of the generic drug,

$$\gamma_g = \frac{D_g}{D_b + D_g}. \quad (5)$$

Assuming, for simplicity, that marginal production costs of both drug versions are zero, profits are given by

$$\pi_i = p_i D_i, \quad (6)$$

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<sup>10</sup>As mentioned in the Introduction, there is strong empirical evidence that generic drugs are not perceived to be perfect substitutes to the original brand-name drug, despite being chemically identical. The findings of substantial and persistent branded-generic price differences after generic entry (see, e.g., Grabowski and Vernon, 1992, Frank and Salkever, 1997, Scott Morton, 2000) fit well with predictions of vertical differentiation models. Two recent papers applying this approach to branded-generic competition are Königbauer (2007) and Brekke et al. (2007b).

where  $p_i$  is the price of drug  $i$ ;  $i = b, g$ . Given the restrictions imposed by the regulatory regime in place, we assume that the two firms play a Bertrand game, simultaneously choosing drug prices to maximize profits.

## 2.1 No regulation

As a benchmark for comparison, consider the case of no regulation, where firms are free to choose drug prices and patient copayment is given by

$$c_i = f + \alpha p_i, \quad (7)$$

where  $f > 0$  is a fixed fee and  $\alpha \in (0, 1)$  is the coinsurance rate.<sup>11</sup> To make sure that both firms are active in equilibrium, we impose the condition  $f < \frac{t}{2}$ .

The first-order conditions for profit maximizing drug prices yield the following best-response functions for the producers of the brand-name and generic drug, respectively:

$$p_b(p_g) = \frac{1}{2} \left[ p_g + \frac{t(\theta - 1)}{\alpha} \right], \quad (8)$$

$$p_g(p_b) = \frac{1}{2\theta} \left[ p_b - \frac{f(\theta - 1)}{\alpha} \right]. \quad (9)$$

The best-response functions confirm that drug prices are strategic complements; a higher brand-name drug price induces a higher generic drug price, and vice versa.

Under free pricing, equilibrium drug prices are found by simultaneously solving (8)-(9), yielding

$$p_g^* = \frac{(\theta - 1)(t - 2f)}{\alpha(4\theta - 1)}, \quad (10)$$

$$p_b^* = \frac{(\theta - 1)(2t\theta - f)}{\alpha(4\theta - 1)}. \quad (11)$$

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<sup>11</sup>A copayment system with a fixed and a variable component is common for many countries (see, e.g., Kanavos, 2001). Notice, however, that the parameters  $\alpha$  and  $f$  can be given several alternative interpretations. For example,  $\alpha$  could be interpreted as the prescribing physician's price consciousness (see, e.g., Hellerstein, 1998), while  $f$  can be interpreted also as the (non-monetary) cost of attending a GP to obtain a prescription.

Since the brand-name drug is perceived to be of higher quality than the generic drug, firm  $B$  will set the higher price,  $p_b^* > p_g^*$ , and serve the consumers with higher gross valuation of drug treatment. The larger the degree of perceived vertical differentiation,  $\theta$ , the larger the branded-generic price difference in equilibrium.

## 2.2 Price cap regulation

The equilibrium outcome under price cap regulation is a straightforward modification of the free pricing equilibrium derived above. If the producer of the brand-name drug faces a binding price cap,  $\bar{p}_b$ , set by a regulator, the equilibrium generic drug price is given by (9), with  $p_b = \bar{p}_b$ . Stricter price regulation makes the brand-name drug less expensive for consumers, inducing – all else equal – a shift in demand towards drug  $b$ . However, since prices are strategic complements, firm  $G$  will respond by lowering the price of the generic drug. An assessment of the total effect shows that the former (direct) effect dominates the latter (indirect) effect:

$$\frac{\partial \gamma_g}{\partial \bar{p}_b} = \frac{2\theta^2 \alpha (t - f)}{(\theta - 1) (f (1 + \theta) - 2t\theta + \alpha \bar{p}_b)^2} > 0. \quad (12)$$

**Proposition 1** *Under price cap regulation, a reduction in the (binding) price cap reduces the equilibrium market share of generics.*

In other words, stricter price cap regulation dampens generic competition. If price cap regulation is sufficiently strict, generic competition will be completely eliminated. The critical price cap, below which the generic producer will exit the market, is given by  $\bar{p}_b = \frac{f(\theta-1)}{\alpha}$ . We see that the likelihood of price cap regulation driving out generic competition is increasing in the degree of perceived vertical differentiation and the fixed cost of drug consumption, while decreasing in the degree of coinsurance.

## 2.3 Reference pricing

Under a reference pricing (RP) system, firms are free to set drug prices, but patient copayment is based on a reference price,  $r$ , that is set by a regulator. More specifically,

if a consumer chooses a drug that is priced higher than the reference price, she has to pay the full difference between the reference price and the actual drug price. Usually, the reference price is set at a level somewhere between the lowest and highest drug price in the market. For a reference price  $r \in (p_g, p_b)$ , the copayment schedule is given by

$$c_b = \alpha r + (p_b - r) + f, \quad (13)$$

$$c_g = \alpha p_g + f. \quad (14)$$

In order to illustrate the decomposed effects of RP on drug pricing and generic competition, we will do the analysis in two steps. Assume first that the firms perceive the reference price to be exogenously given. For  $r \in (p_g, p_b)$ , equilibrium prices are then given by

$$p_g^{rp}(r) = \frac{(t - 2f)(\theta - 1) - r(1 - \alpha)}{\alpha(4\theta - 1)}, \quad (15)$$

$$p_b^{rp}(r) = \frac{(\theta - 1)(2t\theta - f) + r(2\theta - 1)(1 - \alpha)}{4\theta - 1}. \quad (16)$$

We can analyze the effects of RP by considering a marginal reduction in  $r$ . RP implies that the brand-name drug becomes relatively more expensive, and that drug demand becomes more elastic for prices above  $r$ . The resulting price responses are easily derived from (15)-(16):  $\partial p_g^{rp}/\partial r < 0$  and  $\partial p_b^{rp}/\partial r > 0$ .

**Proposition 2** *Under reference pricing, if the firms perceive the reference price to be exogenous, a reduction in the reference price leads to a reduction (increase) in the brand-name (generic) drug price.*

This result is in line with the price convergence hypothesis: The introduction of reference pricing leads to a price convergence towards the reference price; the generic drug becomes more expensive, while the brand-name drug becomes cheaper.<sup>12</sup>

However, this hypothesis ignores the fact that, in most reference pricing systems, the reference price is determined as a function of actual drug prices and is thus endogenous. If

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<sup>12</sup>See, e.g., Danzon and Liu (1996) and Danzon and Ketcham (2004).

the reference price is frequently updated, the drug producers know that their price setting is going to affect the reference price, and thereby demand and profits, in the future. A simple way to capture this effect is to define the reference price as a weighted average of the brand-name and generic drug prices:

$$r = \beta p_g + (1 - \beta) p_b. \quad (17)$$

When the firms are able to influence the reference price through their price setting, a new and counteracting incentive for the generic producer is introduced. As before, reference pricing makes the brand-name drug more expensive, giving the generic producer an incentive to raise prices. However, the generic producer can make the brand-name drug even more expensive by lowering the price of the generic drug, since this automatically reduces the reference price. Equilibrium prices are now given by

$$p_g^{rp} = \frac{(t - 2f)(\theta - 1)}{3\beta(1 - \alpha) + \alpha(4\theta - 1)}, \quad (18)$$

$$p_b^{rp} = \frac{(\theta - 1)(\alpha(2t\theta - f) + \beta(1 - \alpha)(2t - f))}{(\alpha + \beta(1 - \alpha))(3\beta(1 - \alpha) + \alpha(4\theta - 1))}. \quad (19)$$

We can analyze the effects of reference pricing by considering a marginal increase in  $\beta$ . The equilibrium price responses of RP are given by

$$\frac{\partial p_g^{rp}}{\partial \beta} = -\frac{3(\theta - 1)(t - 2f)(1 - \alpha)}{(\alpha(4\theta - 1) + 3\beta(1 - \alpha))^2} < 0, \quad (20)$$

$$\frac{\partial p_b^{rp}}{\partial \beta} = -\frac{(\theta - 1)(1 - \alpha)[2t\Omega - 3f\Phi]}{\Phi(\alpha(4\theta - 1) + 3\beta(1 - \alpha))^2} < 0, \quad (21)$$

where

$$\Omega := \alpha^2 + 3\beta^2(1 - \alpha)^2 + 2\theta\alpha^2(2\theta - 1) + 6\theta\alpha\beta(1 - \alpha)$$

and

$$\Phi := (\alpha + \beta(1 - \alpha))^2 < \Omega.$$

Thus, endogenizing the reference price completely reverts the price response of the generic producer, implying that RP leads to price reductions for brand-name *and* generic drugs. Since both drugs become cheaper, the effect of RP on relative prices is *a priori* uncertain. Equilibrium relative prices are given by

$$\omega^{rp} := \frac{p_b^{rp}}{p_g^{rp}} = \frac{\alpha(2t\theta - f) + \beta(1 - \alpha)(2t - f)}{(t - 2f)(\alpha(1 - \beta) + \beta)}. \quad (22)$$

Thus, the effect of RP on relative prices is given by

$$\frac{\partial \omega^{rp}}{\partial \beta} = -\frac{2t\alpha(\theta - 1)(1 - \alpha)}{(t - 2f)(\alpha(1 - \beta) + \beta)^2} < 0, \quad (23)$$

implying that the price reduction is stronger, in absolute terms, for the brand-name drug. A closer scrutiny of (23) shows that the fall in relative prices is stronger the lower the degree of coinsurance ( $\alpha$ ) and the higher the fixed cost of drug consumption ( $f$ ).

What is the effect of RP on generic competition, measured by the generic market share? The above analysis suggests that there are two counteracting forces:

(i) For given relative drug prices, RP generally leads to an increase in the relative copayment rate, which is given by

$$\mu(p_b, p_g) := \frac{c_b(p_b, p_g)}{c_g(p_b, p_g)} = \frac{f + \alpha p_b + \beta(p_b - p_g)(1 - \alpha)}{f + \alpha p_g}. \quad (24)$$

The effect of RP is then given by

$$\frac{\partial \mu(p_b, p_g)}{\partial \beta} = \frac{(p_b - p_g)(1 - \alpha)}{f + \alpha p_g} > 0. \quad (25)$$

The strength of this effect is decreasing in both  $f$  and  $\alpha$ . Indeed, in the absence of insurance, i.e.,  $\alpha \rightarrow 1$ , there is obviously no effect of RP on relative copayments. Generally, though, as long as  $\alpha < 1$ , RP induces a shift in consumption – for given drug prices – from brand-name to generic drugs.

(ii) The positive relationship between RP and relative copayments is, at least partly,

compensated for by a reduction in relative drug prices, as shown by (23). All else equal, this effects leads to a shift of consumption from generic to brand-name drugs. The overall effect on market shares is thus a priori ambiguous.

Combining the two above mentioned effects, the overall impact of RP on generic competition is

$$\frac{\partial \gamma_g^{rp}}{\partial \beta} = \frac{f\alpha(\theta - 1)(1 - \alpha)(t - 2f)}{(\alpha(3t\theta - f(1 + 2\theta)) + 3\beta(1 - \alpha)(t - f))^2} > 0. \quad (26)$$

Thus, in our parameterized model, the increase in the relative copayment rate is not outweighed by the drop in relative drug prices, implying that RP leads to an increase in the generic market share. It is also straightforward to confirm that the positive effect of RP on generic market shares is weaker the higher the degree of coinsurance, i.e.,  $\partial^2 \gamma_g^{rp} / \partial \alpha \partial \beta < 0$ . Notice also that the net effect of RP on generic market shares is zero if  $f = 0$ . Thus, in the special case of no fixed costs of drug consumption, the direct effect of RP on relative copayments is fully offset by a subsequent drop in relative drug prices.

We summarize as follows:

**Proposition 3** *Assume that the reference price is endogenously determined as a function of the drug prices in the market. A higher weight attached to the low-priced generic drug, implying all else equal a reduction in the reference price, will then generally lead to (i) a reduction in both brand-name and generic drug prices, (ii) a reduction in relative drug prices, (iii) an increase in the market share of generic drugs.*

When assessing the effect of RP on generic competition, we have, by considering marginal changes in  $\beta$ , implicitly compared the outcome with the free pricing equilibrium, since this equilibrium coincides with the RP equilibrium in the limit  $\beta \rightarrow 0$ . However, notice that, since a binding price cap reduces generic competition (compared with free pricing), the positive effect of RP on generic market shares would be even larger if we compared with a price cap equilibrium. The drug pricing responses of replacing price cap regulation with RP are less clear, and depends on the strictness of price cap regulation.



If the price cap is sufficiently low, we cannot rule out the possibility that replacing this regulatory system with RP will increase drug prices. However, the fact that we observe generic competition in markets with price cap regulation suggests that, in reality, the price cap is generally set well above marginal production costs. Furthermore, the descriptive data from the policy experiment we exploit in the subsequent empirical analysis does not suggest that this is a relevant case.

Thus, based on the above theoretical analysis and discussion, the hypotheses we postulate for the empirical analysis follows from Proposition 3:

- (i) Switching from price cap regulation to RP leads to an increase in generic market shares.
- (ii) Given that price cap regulation is not excessively strict, switching from price cap regulation to RP leads to a reduction in brand-name and generic drug prices and a reduction in relative drug prices.

### 3 Institutional background

The Norwegian pharmaceutical market is, as most other Western pharmaceutical markets, extensively regulated. The regulatory body is the Norwegian Ministry of Health and Care Services and its agency called the Norwegian Medicines Agency. Norway has adopted the European patent law system to a large extent, implying that all new chemical entities are subject to patent protection for a given period. To launch their products on the Norwegian market, pharmaceutical firms need a government approval. The approval is based on (clinical) evidence showing that the drug is not dangerous and has a positive health effect. To get the drug listed for reimbursement ("blue list"), the pharmaceutical firms must in addition provide evidence of a positive cost-benefit analysis.

All prescription drugs (reimbursable or not) are subject to price control. The current system is a *price cap* scheme based on international reference pricing, also called external referencing. This system was introduced in 2000, and covers all prescription drugs, both

on-patent and off-patent, except for those included in the reference price system. The government requires that a producer that sells a prescription drug on the Norwegian market, reports the *foreign* prices of this drug in a defined set of "comparable" countries.<sup>13</sup> The price cap, which is the maximum *domestic* price a producer can charge for its product, is then set equal to the average of the three lowest reported foreign prices of this drug. Generic versions receive the same price cap as the brand-names, but the price cap rarely binds as they are typically priced lower than the brand-name. The price cap is imposed at the wholesale level. The government then defines the maximum mark-up the pharmacies can charge, which in turn determines the price cap at the retail level for each product.

The *reference price* system, called "index pricing", was introduced in March 2003 for a subsample of off-patent pharmaceuticals facing generic competition. Initially, the index price system covered six chemical substances: Citalopram (depression), Omeprazol (antiulcer), Cetirizin (allergy), Loratadin (allergy), Enalapril (high blood pressure) and Lisinopril (high blood pressure). In June 2004 Simvastatin (high cholesterol) was included. The choice of drugs were based on two criteria: first, they should cover a wide set of diseases, and not be concentrated within one particular disease type; second, the selected drugs should be high-volume drugs.<sup>14</sup> The government decided to terminate the system by the end of 2004, arguing that the price reductions and cost savings were lower than expected.<sup>15</sup> Thus, in total the system ran for almost two years.

In calculating the index (reference) price, the government first clustered together drugs with the same chemical substance. Within each substance group, drugs were classified into subgroups depending on package size and dosage in order to adjust for cost variation. Then the government calculated the index price, defined as the sales weighted average

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<sup>13</sup>The Norwegian basket of "comparable" countries consists of Austria, Belgium, Danmark, Finland, Germany, Irland, the Netherlands, Sweden and the UK. Southern and Eastern European countries, as well as France and Switzerland, are excluded. If the product is not yet launched in any of the countries in the basket, the price cap will be determined by negotiations between the producer and the regulator.

<sup>14</sup>The first criterion is helpful for identification purposes since it provides us with a proper control group. The second criterion could potentially be a problem if the selected drugs differ from the non-selected drugs. In Section 4, we therefore perform a pre-test, showing no significant differences in prices and market shares for the treatment (reference priced drugs) and the control (price capped drugs) group.

<sup>15</sup>The decision was based on an evaluation report, using data until February 2004. As will be shown below, our analysis strongly indicates that the evaluation was carried out too early. Price and market share effects became substantial after some time, especially during 2004.

brand-name and generic price, for each subgroup. For the six chemical substances initially included, there were 16 index prices in total. The government repeated this exercise every three months, resulting in a revised index price for every quarter of a year. Thus, if generics increase their market share and/or there is a reduction in brand-name or generic prices, this would induce a lower index price for the next period. In other words, the index price system can be classified as an *endogenous* reference price system, as explained in the theory section (Section 2).

The index price system provided strong incentives for generic substitution at pharmacy level. The pharmacies obtained the positive margin of selling a (generic) drug priced lower than the reference price. However, they also faced the negative margin of selling a (brand-name) drug priced higher than the reference price. Thus, we would expect that the pharmacies would suggest a generic substitute to patients unless the physicians made reservations on the prescriptions, which they could do if they provided a particular reason (e.g., drug compliance for old patients).

However, if the patients refused generic substitution, they had to cover the price difference between the higher priced brand-name drug and the index price, as common under reference pricing. In addition, patients in Norway are required to pay coinsurance, which is currently 36 percent of the price of the drug chosen, with an expenditure cap of 400 NOK per script and 1,350 NOK per year. All drug expenditures above these caps would be fully covered by the social security scheme.

## 4 Data and descriptive statistics

In the empirical analysis we use data from Farmastat.<sup>16</sup> Their database includes information on sales value and volume for each package of drugs sold at the Norwegian pharmaceutical market. Values are in pharmacy purchase prices and volumes in defined daily doses (DDD) for the active substance according to the ATC-code system.<sup>17</sup> The

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<sup>16</sup>Farmastat is a company specialised in provision of pharmaceutical statistics. The company is owned by the Norwegian Association of Pharmaceutical Manufacturers.

<sup>17</sup>The ATC-code system is used by the World Health Organization to classify pharmaceutical substances according to their chemical, pharmacological and therapeutic properties. Pharmaceuticals sharing the same

database also provides detailed information about product name, manufacturer, launch date, whether the product is a brand-name or a generic drug, package size, dosage, etc.

From this database we have information on all off-patent prescription drugs within the 40 largest ATC groups (in terms of sales volume) over a four year period from 1st of January 2001 to 31st of December 2004. Our empirical strategy relies on a comparison of drugs subject to reference pricing with drugs under price cap regulation. Since most of the drugs in the index price system faced generic competition for a relatively short period before they came subject to the reform, we only include molecules with generic entry after 1st of January 1998 in our sample. This leaves us with 24 ATC groups. Table 1 lists main characteristics of these molecules.

[ Table 1 about here ]

The "Market share" variable in Table 1 gives the proportion of sales of brand-names compared to sales of generics within each ATC group. The "Relative price" variable is calculated as brand-name prices divided by the quantity weighted average of generic drug prices for each substance. All prices are deflated using the consumer-price index. The table also provides information about the number of generic competitors within each of the 24 substances, as well as the degree of therapeutic competition, measured by the number of ATC groups having the same three first digits in their ATC code. In the analysis we divide time into periods of one month. Substances that face generic competition over the total sample period are therefore represented with 48 observations in the dataset. Finally, there is a column indicating whether or not the substance is exposed to reference pricing.<sup>18</sup>

The main objective in the empirical analyses is to test the hypotheses following from Proposition 3 in Section 2. The first hypothesis postulates that when switching from price cap regulation to reference pricing one would expect an increase in generic market shares.

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seven-digit ATC-code have the same ingredients and are considered equivalent in the treatment of a given disease.

<sup>18</sup>Notice that the ATC group C10AA01 (Simvastatin) was included in the reference price system in June 2004, while the rest of the ATC groups subject to reference pricing was included when the reform was initiated in March 2003.

In Table 2 we compare average market shares for brand-names subject to reference pricing before and during the reference pricing period with average market shares for brand-names subject to price cap regulation over the same period. From the table we see that while there has been a decrease in brand-name market shares for both groups, the decrease is substantially larger for the drugs subject to reference pricing.

[ Table 2 about here ]

Our second hypothesis postulates that when switching from price cap regulation to reference pricing, one would expect a reduction in brand-name and generic drug prices, and a reduction in relative drug prices. The descriptive statistics in Table 2 seem to confirm this. For drugs subject to reference pricing, we see a reduction in the average price for both brand-names and generics, with the effect being stronger for the brand-names, resulting in an 8.5 percent decrease in relative prices. The changes in relative and average prices for drugs subject to price cap regulation are much more modest over the same period.

## 5 Empirical method and results

In this section we analyze the effect of introducing reference pricing on three different outcomes. First, we focus on how reference pricing affects relative branded-generic prices in order to test whether prices tend to converge towards the reference price. We also estimate the effects on average brand-name prices and average generic prices separately, such that we can determine which prices that drive potential changes in the relative prices. Second, we analyze the impact of reference pricing on generic competition, measured inversely by brand-name market shares. Finally, we estimate the impact of reference pricing on average prices at molecule level, which enable us to draw some policy implications of the policy reform.

Our estimating strategy relies on a comparison of the eight molecules affected by

reference pricing (the treatment group) to similar molecules not subject to reference pricing (the control group). Having panel data, we are able to compare inter-temporal variation in outcomes before and after the imposition of the reform. Therefore, identification relies not only on before-after comparison, but also on comparison of variations in outcomes for molecules subject to reference pricing with variation in outcomes for molecules not subject to this reform.

In the analyses, we estimate different versions of the following fixed effect model:

$$Y_{it} = \mathbf{X}'_{it}\boldsymbol{\beta} + a_i + \delta_t + \alpha D_{it} + \varepsilon_{it}, \quad (27)$$

where  $Y_{it}$  is one of three outcomes (relative prices, brand-name market share, or average molecule prices) described above for molecule  $i$  at time  $t$ ,  $a_i$  is a molecule fixed effect,  $\delta_t$  is a period specific effect common to all molecules,  $\varepsilon_{it}$  represents unobserved time varying factors that affect outcomes,  $\mathbf{X}'_{it}$  contains observable variables, and  $D_{it}$  is a dummy variable indicating whether or not molecule  $i$  is subject to reference pricing at time  $t$ . The effect of introducing reference pricing is captured by  $\alpha$  and the effect of the control variables by the vector  $\boldsymbol{\beta}$ .

An important assumption is that  $\varepsilon_{it}$  is uncorrelated with  $D_{it}$  (as well as with  $\mathbf{X}'_{it}$  and  $\delta_t$ ). This implies that, after controlling for covariates and molecule specific effects in the pre-reform period, the price trends for drugs subject to reference pricing should not differ from price trends for drugs subject to price cap regulation. A test of this assumption is presented in Table 3.

[ Table 3 about here ]

Here we only use observations *prior to* the reference price reform. In order to compare the pre-reform trends in prices and market shares for drugs in the treatment and control group, we include interactions between the period dummies and a variable indicating treated molecules (in the post-reform period). If the interactions are insignificant, this is an indication of a legitimate control group, i.e., that unobservable factors affecting

prices are uncorrelated with the probability that a given molecule is in the treatment group. As evident from Table 3, all interactions are statistically insignificant in all three models. In addition, F-tests suggest that the interactions are jointly insignificant. These results indicate that market shares, relative prices and average prices for drugs in the two different groups are following the same general trend before the reference pricing reform was implemented. We therefore conclude that the comparison group is legitimate.

## 5.1 Relative prices

We start out by examining the impact of reference pricing on relative prices, where relative prices are measured as the ratio of brand-name prices and the volume-weighted average generic prices. The results from this regression are presented in column 2 in Table 4. Controlling for the number of therapeutic competitors, and period and molecule specific effects, we find that reference pricing has a negative, though weak, significant effect on relative prices.

[ Table 4 about here ]

A possible explanation for the decline in relative prices could be price convergence towards the reference price, as suggested by Danzon and Liu (1996) and Danzon and Ketcham (2004). However, as shown in the theory section, such price convergence only happens if the reference price is exogenous, i.e. fixed at some level between the brand-name and the generic price. If the reference price is endogenous, then the generic producers have a strategic incentive to lower their price in order to reduce the reference price, which makes the brand-name relatively more expensive. If this is the case, the reduction in relative prices must be caused by a larger reduction in brand-name prices than in generic prices.

To decompose the effect of reference pricing on relative prices, we estimate a fixed effect model where we use the logarithm of average prices of brand-names and generics as the dependent variable (thus having two price observations per molecule per time period). By including an interaction term between the reference price indicator and the brand-name

indicator, we can separate the effect of reference pricing on brand-names from the price effect on generics:

$$\ln P_{it} = \mathbf{X}'_{it}\boldsymbol{\beta} + a_i + \delta_t + \alpha_1 D_{it} + \alpha_2 D_{it} * B_i + \varepsilon_{it}, \quad (28)$$

where  $B_i$  is a dummy that equals one if product  $i$  is a brand-name. In the regression we further include a brand-name dummy and control for the number of generic and therapeutic competitors. The results from the regression are reported in Table 5.

[ Table 5 about here ]

From the table we see that reference pricing leads to a reduction in both brand-name and generic prices. The estimated decrease in average prices is quite substantial; around 21 percent for generics (measured by  $\alpha_1$ ) and 36 percent for brand-names (measured by  $\alpha_1 + \alpha_2$ ). Thus, the (weak) negative impact of reference pricing on relative prices is due to a larger drop in brand-name than generic prices. Since the reference price in Norway was calculated as a weighted average of brand-name and generic prices, this can explain why we do not observe price convergence in our data.

## 5.2 Generic competition

We then turn to the analysis of the impact of reference pricing on generic competition. The effect of reference pricing on generic competition is not *a priori* evident, as pointed out in the theory section. Reference pricing changes the copayment structure, making the brand-name drug relatively more expensive than the generics, which increases the generics' market share for given prices. However, the brand-names respond to reference pricing by lowering their prices in order to retain their market shares. The net effect on market shares is thus determined by the relative strength of these two counteracting effects.

The dependent variable in the analysis is the brand-names' market shares (as a percentage). This measure of generic competition has been used in previous work, for instance,



Aronsson et al. (2001).<sup>19</sup> In the regressions we control for molecule and period specific effects, as well as the number of therapeutic competitors, and the relative price between brand-names and generics. The results are presented in column 3 in Table 4 above.

We find that the imposition of reference pricing leads to a significant (13.8 percent) reduction in brand-name market shares. Since we control for relative prices in the regression, we can interpret this decrease as a direct demand response to reference pricing and the corresponding change in the copayment structure. The brand-name price responses pull in the opposite direction, but we find that the effect is negligible, and that changes in relative prices have no significant impact (at the five percent level) on the brand-name market shares in the regression.

A potential problem in this regression is that relative prices might be endogenous. While relative branded-generic prices might explain market shares, market shares might also influence firms' price setting and thus relative prices. We therefore employ a *fixed effect IV-model* where we use relative prices in period  $t - 1$  as an instrument. The results from the IV-regression are, however, quite similar to the results presented in Table 4 (see Table A.1 in Appendix A). We therefore choose not to focus on the results from this regression.

### 5.3 Average prices

Finally, we quantify the effect of reference pricing on average molecule level prices. Qualitatively, the impact on average prices is evident, since we have established that reference pricing leads to lower brand-name and generic prices as well as lower brand-name market shares. However, for policy implications it is of interest to quantify the effect.

The dependent variable in the regression is the logarithm of the average price at molecule level, where we use the market shares of brand-names and generics as weights. We control for molecule and time period specific effects, as well as the number of generic and

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<sup>19</sup> Alternatively, we could measure the effect on the number of generic competitors, the Herfindahl-index, etc. The measures are, however, highly correlated and provide qualitatively similar results.

therapeutic competitors within each ATC code.

[ Table 6 about here ]

As evident from Table 6, we find that reference pricing lowers average molecule prices by more than 30 percent. This is an impressive price reduction, especially when taking into account that Norway has a relatively strict price cap regime, as explained in Section 3. Since total demand for prescription drugs is quite price inelastic, a 30 percent reduction in average molecule prices indicates substantial cost savings from introducing reference pricing in the pharmaceutical off-patent market. It follows from the above analysis that these cost savings are explained partly by drug price reductions and partly by an increase in generic market shares.

## 6 Concluding Remarks

In this paper, we have analyzed the relationship between regulation, generic competition and pharmaceutical prices. In the theoretical part of the paper, we have applied a vertical differentiation model to derive two main predictions for the subsequent empirical study: (i) Switching from price cap regulation to RP leads to an increase in generic market shares; (ii) Given that price cap regulation is not excessively strict, switching from price cap regulation to RP leads to a reduction in brand-name and generic drug prices and a reduction in relative drug prices. In the empirical part of the paper, we have exploited a natural policy experiment – where reference pricing replaced price cap regulation for only a sub-sample of the off-patent drugs on the Norwegian market – to identify price and competition effects of the two regulatory regimes.

Our paper provides three main findings. Compared with price cap regulation, (i) RP leads to price reductions of both brand-names and generics, with the effect being stronger for the former group of drugs, resulting in (slightly) lower relative prices; (ii) RP stimulates generic competition by substantially lowering the brand-names' market shares; and (iii)

RP results in considerably lower average prices at molecule level, suggesting substantial cost savings. Thus, for the off-patent market, reference pricing is clearly more favorable than price cap regulation.

By way of conclusion, we would like to identify a couple of aspects that might potentially reduce the strength of our conclusions. First, there might be unintended cross-price effects of reference pricing to non-referenced, therapeutic substitutes, as shown – theoretically and empirically – by Brekke et al. (2007a,b). If the therapeutic substitutes also are off-patent, this might not be a problem. However, if the therapeutic substitute is an on-patent product, then reference pricing might negatively affect the patent rent by inducing lower prices. Second, reference pricing might also induce unintended trade-off between patient health gains and copayments (see, e.g., Lopez-Casasnovas and Puig-Junoy, 2000). If patients trade off health gains of drug therapy against copayments, then radical changes in copayments induced by reference pricing might lead some patients to choose a less suitable and/or lower quality drug. This problem is perceived to be more severe under therapeutic than generic reference pricing. However, Brekke et al. (2007b) show, in a theoretical analysis, that this is not necessarily correct.

Effects of regulatory regimes, like price cap regulation and reference pricing, on innovation incentives and health outcomes are two very important issues that deserve to be examined much more carefully.<sup>20</sup> However, both issues are clearly beyond the scope of the present study, so we leave them for future research.

## Appendix A: Fixed effect IV-model

[ Tabel A.1 here ]

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<sup>20</sup>There is a recent theoretical paper by Bommier et al. (2006) on the impact of (therapeutic) reference pricing on pharmaceutical innovation.

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## Tables

Table 1. Sample characteristics

ATC-code	Market share	Relative price	Subject to ref. pricing	Number of generics <sup>1</sup>	Number of therapeutic competitors. <sup>2</sup>	Number of Observations
A02BC01	68.86 (14.03)	1.28 (0.09)	Yes	1	9	48
A10BA02	81.84 (4.72)	1.23 (0.13)	No	5	9	48
A10BB01	95.24 (7.81)	1.26 (0.11)	No	1	9	33
C08CA01	50.39 (15.14)	1.35 (0.15)	Yes	5	1	10
C09AA02	71.03 (21.77)	1.54 (0.16)	Yes	6	4	48
C09AA03	71.93 (21.92)	1.54 (0.14)	Yes	5	4	48
C09BA02	58.48 (10.96)	1.32 (0.05)	No	2	1	24
C10AA01	58.12 (17.92)	1.28 (0.12)	Yes	5	4	21
C10AA02	53.19 (19.63)	1.36 (0.15)	No	1	4	17
H02AB02	30.25 (5.78)	0.98 (0.09)	No	2	8	12
J01FA01	75.74 (4.19)	1.76 (0.10)	No	1	0	48
J01MA02	95.93 (8.28)	1.18 (0.12)	No	2	0	26
M01AB05	80.11 (8.00)	1.24 (0.75)	No	3	14	48
N03AF02	98.74 (1.34)	2.06 (0.49)	No	1	14	12
N05AH02	50.09 (20.10)	1.31 (0.03)	No	1	6	48
N05BA12	97.67 (1.01)	1.59 (0.10)	No	1	3	17
N05BE01	55.29 (15.69)	1.37 (0.05)	No	3	6	48
N05CF02	71.99 (13.02)	1.87 (0.21)	No	2	3	32
N06AB03	77.69 (21.37)	1.30 (0.16)	No	1	15	36
N06AB04	67.37 (29.81)	1.23 (0.16)	Yes	5	15	32
N06AB05	64.70 (25.33)	1.18 (0.07)	No	4	15	18
N06AG02	73.77 (13.12)	1.41 (0.04)	No	2	15	27
R06AE07	49.92 (18.05)	1.19 (0.12)	Yes	6	11	34
R06AX13	74.51 (18.03)	1.13 (0.08)	Yes	6	17	48

<sup>1</sup> Largest number of generics through the sample period. <sup>2</sup> Largest numbers of therapeutic competitors through the sample period.

Table 2. Market shares, relative prices and average prices before and during the reference pricing period.

	Drugs subject to reference pricing		Drugs subject to price cap regulation	
	Before the reference pricing period	During the reference pricing period	Before the reference pricing period	During the reference pricing period
Market shares brand names	87.26 (12.13)	50.16 (13.17)	79.86 (17.86)	67.66 (21.29)
Relative prices	1.40 (0.21)	1.28 (0.21)	1.41 (0.44)	1.37 (0.25)
Average prices brand names	5.10 (3.88)	3.91 (2.78)	7.46 (6.48)	7.74 (6.41)
Average prices generics	3.92 (2.81)	3.42 (2.31)	6.39 (5.43)	6.40 (5.75)

Table 3. Testing for pre-reform differences in price and market share trends. Fixed effect results with robust standard errors.

	Relative prices	Ln_mean prices	Market shares
Interaction period 1	-0.14 (0.35)	0.01 (0.16)	4.84 (4.94)
Interaction period 2	-0.06 (0.29)	-0.07 (0.18)	7.08 (5.73)
Interaction period 3	-0.27 (0.25)	-0.07 (0.14)	8.72 (6.03)
Interaction period 4	-0.27 (0.33)	-0.09 (0.17)	4.66 (4.60)
Interaction period 5	-0.30 (0.33)	-0.14 (0.17)	3.25 (4.11)
Interaction period 6	-0.06 (0.14)	0.02 (0.09)	8.14 (7.36)
Interaction period 7	-0.09 (0.13)	0.01 (0.09)	2.63 (4.29)
Interaction period 8	-0.07 (0.13)	-0.03 (0.09)	2.16 (4.14)
Interaction period 9	0.05 (0.14)	-0.02 (0.09)	1.26 (3.95)
Interaction period 10	-0.04 (0.32)	-0.07 (0.08)	1.30 (3.88)
Interaction period 11	0.03 (0.12)	-0.03 (0.08)	3.03 (5.93)
Interaction period 12	0.01 (0.12)	-0.04 (0.08)	2.01 (5.68)
Interaction period 13	-	-	-
Interaction period 14	-0.01 (0.11)	0.01 (0.07)	0.55 (4.97)
Interaction period 15	-0.01 (0.11)	0.03 (0.07)	6.05 (5.93)
Interaction period 16	-0.03 (0.11)	0.04 (0.07)	2.59 (4.76)
Interaction period 17	-0.02 (0.11)	0.04 (0.07)	0.51 (3.99)
Interaction period 18	-0.01 (0.12)	0.03 (0.07)	-1.04 (4.28)
Interaction period 19	0.09 (0.11)	0.07 (0.07)	-1.77 (4.50)
Interaction period 20	0.12 (0.11)	0.06 (0.07)	0.18 (4.39)
Interaction period 21	0.13 (0.12)	0.07 (0.07)	-3.64 (4.08)
Interaction period 22	0.10 (0.10)	0.06 (0.07)	-6.02 (5.17)
Interaction period 23	0.14 (0.11)	0.08 (0.07)	-2.06 (4.73)
Interaction period 24	0.16 (0.11)	0.09 (0.07)	-0.76 (5.12)
Interaction period 25	0.13 (0.11)	0.06 (0.07)	-6.16 (5.00)
Interaction period 26	0.05 (0.13)	0.07 (0.08)	-3.53 (5.29)
Relative prices	-	-	-0.10 (0.45)
Number of generics	-	-0.04* (0.02)	-
Number of therapeutic competitors	-0.02 (0.01)	-0.02 (0.01)	-0.17 (0.45)
Molecule dummies	Yes	Yes	Yes
Period dummies	Yes	Yes	Yes
Joint insignificance of interactions (Prob>F)	.866	.877	.711
Number of observations	334	334	334
Number of products	20	20	20
R-squared	.15	.25	.40

\*\* : significant at the 1 percent level, \* : significant at the 5 percent level.

Table 4. Effects of reference pricing on relative prices and market shares. Fixed effect models with robust standard errors.

	Relative price	Market share
Relative price	-	-1.7576 (1.0690)
Products subject to reference pricing	-0.0896** (0.0238)	-13.7988** (1.6785)
Number of therapeutic competitors	-0.0396* (0.0168)	2.7148** (0.3938)
Constant	1.9194** (0.2640)	69.7341** (4.2673)
Period dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of observations	783	783
Number of ATC groups	24	24
R-squared	0.13	0.72

\*\* : significant at the 1 percent level, \* : significant at the 5 percent level.



Table 5. Effects of reference pricing on log of average brand-name and generic prices. Fixed effect models with robust standard errors.

Generics subject to reference pricing	-0.2113 <sup>**</sup> (0.0196)
Brand names subject to reference pricing	-0.1479 <sup>**</sup> (0.0194)
Brand names	0.2625 <sup>**</sup> (0.0084)
Number of therapeutic competitors	-0.0264 <sup>**</sup> (0.0056)
Number of generics	0.0073 (0.0052)
Constant	1.6956 <sup>**</sup> (0.0814)
Period dummies	Yes
Molecule dummies	Yes
Number of observations	1536
Number of ATC groups	24
R-squared	0.61

<sup>\*\*</sup>: significant at the 1 percent level, <sup>\*</sup>: significant at the 5 percent level.

Table 6. Effects of reference pricing on log of average prices. Fixed effect models with robust standard errors.

Drugs subject to reference pricing	-0.3028 <sup>**</sup> (0.0236)
Number of therapeutic competitors	-0.0392 <sup>**</sup> (0.0087)
Number of generics	0.0061 (0.0068)
Constant	2.1622 <sup>**</sup> (0.1292)
Period dummies	Yes
Molecule dummies	Yes
Number of observations	783
Number of ATC groups	24
R-squared	0.64

<sup>\*\*</sup>: significant at the 1 percent level, <sup>\*</sup>: significant at the 5 percent level.

Table A.1. Effects of reference pricing on market shares. Fixed effect IV-model.

	First step	Second step
Relative price	-	0.0508 (1.9383)
Products subject to reference pricing	-0.0155 (0.0202)	-12.8326 <sup>**</sup> (1.4689)
Number of therapeutic competitors	0.0006 (0.0054)	2.9695 <sup>**</sup> (0.3904)
Relative price (t-1)	0.7797 <sup>**</sup> (0.0208)	-
Constant	0.1198 (0.0706)	65.5888 <sup>**</sup> (4.7145)
Period dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of observations	759	759
Number of molecules	24	24
R-squared	0.71	0.72

<sup>\*\*</sup>: significant at the 1 percent level, <sup>\*</sup>: significant at the 5 percent level.

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