Does Reference Pricing Drive Out Generic Competition in Pharmaceutical Markets? Evidence from a Policy Reform*

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Abstract

Reference pricing (RP) is intended to reduce pharmaceutical expenditures by making demand more price elastic and thereby stimulating generic competition. However, expectation of fiercer price competition may weaken generic firms' incentive to enter, potentially making RP counterproductive. In this paper we study the effect of RP on generic competition both at the extensive (number of generic firms) and at the intensive margin (generic firms' market share). To identify causal effects, we exploit a policy reform that implemented RP for a subset of drugs in Norway in 2005 providing us with a treatment and a comparison group. Using detailed register data for the period 2003-2013, we find that RP increased both the number of generic competitors and their market share relative to brand-name producers. Similar results are obtained using an alternative identification strategy based on regression discontinuity. Thus, the pro-competitive effect of RP is reinforced by increased generic entry.

Keywords: Pharmaceuticals; Reference pricing; Generic competition

JEL classifications: I11; I18; L13; L65

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1 Introduction

Reference pricing (RP) of pharmaceuticals has become a widely used regulatory scheme. In Europe, almost every country has now introduced RP schemes in the market segment for off-patent drugs.[1] In the US, RP is a well-established practice through the Maximum Allowable Cost (MAC) programs that are used by Medicaid and some managed-care programs to reimburse multi-source compounds.[2] An RP scheme defines a maximum price that will be reimbursed by the insurer for a set of drugs with similar therapeutic effects. Consumers can purchase a drug priced above the reference price, but will then have to pay out-of-pocket the difference between the reference price and the actual drug price. The intention of RP is to curb pharmaceutical expenditures by increasing the demand elasticity and stimulating price competition between drug producers. In this paper we study whether RP has its intended effects.

RP schemes apply in most cases to substances where the original brand-name drug has lost patent protection and faces competition from generic versions of the drug.[3] Given that RP enhances price competition between brand-name and generic drug producers, then RP can in principle have a negative effect on the expected profits of generic drug producers and thus reduce generic entry.[4] If the negative effect on generic entry is sufficiently large, then RP may in fact *dampen* price competition and potentially *increase* pharmaceutical expenditures.[5] In the extreme case where generic entry is fully deterred by the expectation of fierce price competition, RP would be counterproductive in containing medical costs. Thus, knowledge about the competitive effects of RP has potentially major policy implications.

In this paper we conduct an empirical analysis of the impact of RP on generic competition and the corresponding effects on drug prices, sales, and expenditures. To motivate our empirical analysis, we develop a general theoretical model that allows us to identify the key effects of RP on

[1] According to Carone et al. (2012) at least 20 member states in the European Union have introduced RP.

[2] See, for instance, Danzon and Ketcham (2004) or a recent study by Kelton et al. (2014). In the US, there have been suggestions of extending the use of RP to Medicare. Interestingly, some plans also use RP for health services, e.g., the California Public Employees Retirement System.

[3] In some countries, such as Germany or the Netherlands, RP is applied more broadly including also drugs with similar therapeutic effects but different substances (see, e.g., Danzon and Ketcham, 2004, or Carone et al., 2012).

[4] The idea that potential ex post competition may reduce entry is well illustrated in Dasgupta and Stiglitz (1988).

[5] The study by Danzon and Chao (2000) was perhaps the first to make this argument, but focused mainly on the effect of direct price regulation on generic competition.

generic entry. The theoretical analysis shows that the impact of RP on generic entry depends on the relative strength of two counteracting effects. On the one hand, for given prices, RP increases the demand for generic drugs due to a higher brand-name copayment, which provides the generic drug producers with an incentive to set higher prices and in turn makes generic entry more profitable. On the other hand, RP pushes the brand-name producer to reduce its price to counteract the (expected) reduction in demand. If the brand-name producer's price response to RP is sufficiently aggressive, so that the generic drug producers also reduce their prices, the net effect on generic entry may be negative. Thus, the competitive effects of RP are theoretically ambiguous and consequently an empirical question.

To identify the causal effect of RP on generic competition, we exploit a policy reform in Norway that introduced an RP scheme called *Trinnpris* in 2005.[6] Importantly, the scheme was gradually implemented for administrative reasons and included initially a limited set of off-patent substances. This allows us to establish a comparison group of drugs not subject to RP and to use a difference-in-difference approach to identify the effect of RP on generic competition. In the analysis we estimate the competitive effect of RP both on the extensive margin, i.e., the number of generic competitors, and the intensive margin, i.e., the market share of generic firms relative to the original brand-name producers. The effect is identified by selecting a sample of substances which all had generic competition prior to the policy reform in 2005, and comparing the change in generic competition for the substances that were exposed to RP with those that were not exposed to RP.

Estimating a fixed-effect model making use of detailed product-level data from 2003 to 2013, we find that the introduction of RP substantially *increased* the number of generic producers and their market shares. We also find that RP triggered price competition, resulting in lower prices of both the brand-name and the generic drugs. Thus, our results suggest that RP led to a demand increase for generic drugs that outweighs the corresponding price reductions, and therefore stimulated generic entry. We also find a negative effect (albeit weakly significant) of RP on total drug expenditures. The reduction in total expenditures is relatively smaller than the average price reduction, which reflects the fact that lower prices stimulate total demand for pharmaceuticals.

[6] See the Norwegian Medicine Agency's website www.legemiddelverket.no/trinnpris for more details.

Our main result – that RP led to increased generic competition both at the extensive and the intensive margins – is also confirmed by an alternative empirical strategy. Focusing only on drugs that were included in the RP scheme at some point during the period of observation, we exploit the fact that the exact time of inclusion was to a large extent random, which allows us to apply a regression discontinuity set-up when estimating the effects of RP on generic competition. Our estimations from this alternative approach are qualitatively identical, and quantitatively very similar, to the ones obtained from the difference-in-difference approach, which reinforces the robustness of our main results.

Despite the rich empirical literature on generic entry in pharmaceutical markets[7], very few papers investigate the impact of RP on generic entry. Ekelund (2001), Rudholm (2001), and Moreno-Torres et al. (2009) are, to our knowledge, the only studies that address the relationship between RP and generic entry.[8] Ekelund (2001) and Rudholm (2001) analyze the introduction of RP in the Swedish pharmaceutical market. Whereas Ekelund (2001) reports a (weak) negative effect of RP on generic entry, Rudholm (2001) finds no effect of RP.[9] A more recent study by Moreno-Torres et al. (2009) on the Spanish pharmaceutical market finds a negative effect of RP on generic entry. In the present study we arrive at the opposite result, namely that RP tends to stimulate generic competition, which implies that the positive demand effect for generic firms dominates the negative price effect. The differences in results can be due to the empirical strategy that allows us to identify the causal effect of RP. While the previous studies only use a before-after estimation, we also exploit the gradual implementation of RP to estimate the effect on generic competition. However, since the effect of RP on generic competition is theoretically ambiguous, the opposing results may also be due to differences in market characteristics and regulatory framework that may influence the demand and price effects of RP.[10]

The literature on the effects of RP on pharmaceutical prices, sales, and expenditures is fairly

[7]See, for instance, Grabowski and Vernon (1992), Frank and Salkever (1997), Scott Morton (1999, 2000), Reiffen and Ward (2005), and Ching (2010a, 2010b) for generic entry in the more unregulated US pharmaceutical market, and Rudholm (2001) and Iizuka (2009) for generic entry in the more regulated Swedish and Japanese markets, respectively.

[8]There is also a cross-country study by Danzon and Ketcham (2004) on the effects of different RP schemes on generic competition using one-year cross-sectional data.

[9]Bergman and Rudholm (2003) also study the impact of RP in Sweden, but focus on the impact of actual and potential generic competition on pharmaceutical prices.

[10]In a theoretical model, Brekke et al. (2015) find that RP reduces generic entry, but the effect is weaker and may be reversed in the presence of price regulation.

large.[11] The empirical studies tend to find that RP results in price reductions on both brand-name and generic products, with the price reductions being stronger for brand-name producers than for generic producers (see e.g., Pavcnik, 2002, Brekke et al., 2009, 2011, Kaiser et al., 2014). Our results are consistent with these findings. There are also a few studies focusing on the impact of RP on market shares. While Brekke et al. (2011) and Kaiser et al. (2014) find a positive effect of RP on generic firms' market shares, Aronsson et al. (2001) report weaker and more mixed results. The contribution of our study in relation to this literature is two-fold: First, we directly estimate the impact of RP on generic entry per se. Second, we estimate the effect of RP on market outcomes explicitly accounting for generic entry. Our results show that RP had a positive effect on generic entry, and this effect reinforced the direct effect of RP on prices and sales.

The remainder of the paper is structured as follows. In Section 2 we present a general framework to illustrate the main theoretical mechanisms which determine the relationship between RP and generic entry. In Section 3 we describe the institutional framework of the Norwegian pharmaceutical market. In Section 4 we present our data and descriptive statistics. In Section 5 we describe our empirical strategy based on difference-in-difference estimation and report our main results regarding the effects of RP on generic competition. In Section 6 we confirm our results from the previous section by using an alternative identification strategy based on regression discontinuity. In Section 7 we report the estimated effects of RP on prices and total expenditures when generic entry effects are taken into account. Section 8 closes the paper with some concluding remarks.

2 Theoretical framework

To motivate our empirical analysis, we present a general theoretical framework for assessing the impact of different reimbursement schemes on pharmaceutical price setting, which in turn affect incentives for generic entry. Consider a pharmaceutical market with a brand-name drug (denoted b) which has lost patent protection and potentially faces competition from generic producers (denoted g and indexed by $i = 1, ..., n$) that can enter the market by incurring a fixed

[11] See Galizzi et al. (2011) for a review of the literature on RP in pharmaceutical markets.

cost f. Without loss of generality, we abstract from other production costs.

Consumers are partially insured and face copayments c_b if purchasing the brand-name drug and c_{gi} if purchasing generic drug i. Demand for the two drug versions are given by $D_b(c_b, c_{g1}, ..., c_{gn}, n)$ and $D_{gi}(c_b, c_{g1}, ..., c_{gn}, n)$, with $\partial D_b/\partial c_b < 0$, $\partial D_b/\partial c_{gi} > 0$, $\partial D_{gi}/\partial c_{gi} < 0$, $\partial D_{gi}/\partial c_b > 0$, $\partial D_b/\partial n \leq 0$, and $\partial D_{gi}/\partial n < 0$. We also assume that the demand functions of all generic drugs are symmetric, and that $\partial D_{gi}/\partial c_{gj} > 0 \; \forall i \neq j$. Finally, we assume that $D_b > D_{gi}$ if $c_b = c_{gi}$, implying that (at least some) consumers strictly prefer the brand-name drug over a generic alternative if copayments are identical. The profits of brand-name and generic producers, respectively, are then given by

$$\pi_b = p_b D_b(c_b, c_{g1}, ..., c_{gn}, n), \tag{1}$$

$$\pi_{gi} = p_{gi} D_{gi}(c_b, c_{gi}, ..., c_{gn}, n) - f, \quad i = 1, ..., n. \tag{2}$$

where p_b and p_{gi} are the prices set by the brand-name producer and generic producer i, respectively. We consider a two-stage game where the generic entry decisions are followed by simultaneous price setting.

2.1 Fixed percentage reimbursement (FPR)

Suppose first that the copayment is a fixed percentage of the price of the demanded product. If we let $\alpha \in (0, 1)$ be the coinsurance rate, the copayments for the brand-name and the generic drug i are $c_b^F = \alpha p_b$ and $c_{gi}^F = \alpha p_{gi}$, respectively. Suppose that n generic firms have entered the market. Because of the assumed symmetry among the generic producers, the Nash equilibrium in the price game has equal prices (and therefore equal demand) for all generic drugs. Let us denote the equilibrium brand-name and generic prices by p_b^F and p_g^F, respectively. These prices

are implicitly defined by the following system of equations:[12]

$$D_b\left(c_b^F\left(p_b^F\right), c_g^F\left(p_g^F\right), n\right) + c_b^F \frac{\partial D_b\left(c_b^F\left(p_b^F\right), c_g^F\left(p_g^F\right), n\right)}{\partial c_b^F} = 0, \tag{3}$$

$$D_g\left(c_b^F\left(p_b^F\right), c_g^F\left(p_g^F\right), n\right) + c_g^F \frac{\partial D_g\left(c_b^F\left(p_b^F\right), c_g^F\left(p_g^F\right), n\right)}{\partial c_g^F} = 0. \tag{4}$$

Defining $\varepsilon_j := -\frac{\partial D_j}{\partial c_j}\frac{c_j}{D_j}$ as the copay-elasticity of demand for drug j, the equilibrium conditions (3)-(4) imply

$$\varepsilon_b\left(c_b^F\left(p_b^F\right), c_g^F\left(p_g^F\right), n\right) = \varepsilon_g\left(c_b^F\left(p_b^F\right), c_g^F\left(p_g^F\right), n\right) = 1. \tag{5}$$

Thus, in equilibrium, each producer will price its drug such that the copay-elasticity of demand is equal to one. From the second order conditions of profit maximization, it can be shown that the copay-elasticity of demand is increasing in the price of the drug. Thus, in equilibrium, the brand-name drug is priced higher than the generic drugs ($p_b^F > p_g^F$), under the assumption that $\varepsilon_b < \varepsilon_g$ for $c_b = c_g$.[13]

2.2 Exogenous reference pricing (RP)

Let us now consider a reference pricing scheme where the insurer defines a maximum reimbursement r, which is assumed to be exogenous in the sense that it does not depend on the pricing of the brand-name and generic producers. This is arguably the best approximation to reimbursement schemes where the reference price is not frequently updated or where updates are not based on predefined rules.

Assuming that the reference price is set such that $p_g^i < r < p_b$, copayments for the brand-name and the generic drug are given by $c_b^R = \alpha r + p_b - r$ and $c_{g_i}^R = \alpha p_g^i$, respectively.[14] By

[12] Assuming the second-order conditions

$$\frac{\partial^2 \pi_b}{\partial p_b^2} = 2\alpha\frac{\partial D_b}{\partial c_b} + c_b\frac{\partial^2 D_b}{\partial c_b^2} < 0,$$

$$\frac{\partial^2 \pi_g^i}{\partial\left(p_g^i\right)^2} = 2\alpha\frac{\partial D_g^i}{\partial c_g} + c_g^i\frac{\partial^2 D_g^i}{\partial\left(c_g^i\right)^2} < 0, \quad i = 1, ..., n$$

are fulfilled.

[13] This assumption is rather mild, since most empirical evidence documents that generics are priced below brand-name drugs.

[14] A reference price outside this interval would either imply that there is no difference between FPR and RP (if $r > p_b$) or that patients are not insured (if $r < p_g^i$). We consider both of these cases to be irrelevant.

applying this copayment scheme and maximizing (1)-(2) with respect to p_b and p_g^i, respectively, we derive the Nash equilibrium in the price game under RP, for a given number (n) of generic producers. Once more, because of symmetry, all generic prices (and market shares) are equal. Let us denote the equilibrium brand-name and generic prices by p_b^R and p_g^R, respectively. These prices are implicitly given by

$$D_b\left(c_b^R\left(p_b^R\right), c_g^R\left(p_g^R\right), n\right) + p_b^R \frac{\partial D_b\left(c_b^R\left(p_b^R\right), c_g^R\left(p_g^R\right), n\right)}{\partial c_b^R} = 0 \tag{6}$$

and

$$D_g\left(c_b^R\left(p_b^R\right), c_g^R\left(p_g^R\right), n\right) + c_g^R \frac{\partial D_g\left(c_b^R\left(p_b^R\right), c_g^R\left(p_g^R\right), n\right)}{\partial c_g^R} = 0. \tag{7}$$

Using once more the definition of copay-elasticity of demand, the equilibrium prices are such that

$$\varepsilon_b\left(c_b^R\left(p_b^R\right), c_g^R\left(p_g^R\right), n\right) = 1 - \frac{(1-\alpha)\, r}{p_b^R} < \varepsilon_g\left(c_b^R\left(p_b^R\right), c_g^R\left(p_g^R\right), n\right) = 1. \tag{8}$$

Thus, in equilibrium prices are set such that the copay-elasticity of demand is lower for brand-name than for generic drugs.[15]

2.3 FPR versus RP

Let us now compare equilibrium pricing under the two reimbursement regimes and deduce the potential implications for generic entry. When comparing the two equilibria, implicitly given by (5) and (8), notice that $c_g^R\left(p_g\right) = c_g^F\left(p_g\right)$, whereas $c_b^R\left(p_b\right) > c_b^F\left(p_b\right)$.

Consider first the pricing of the brand-name drug. Comparing (5) and (8), it is straightforward to see that RP gives the brand-name producer an incentive to reduce its price, compared with FPR. For given prices, RP reduces demand for the brand-name drug while simultaneously making demand more price-elastic. The first effect implies that RP increases the copay-elasticity of brand-name drug demand, whereas the second effect implies that brand-name profits are maximized when the copay-elasticity is less than one. Thus, both effects contribute towards a lower price for the brand-name drug under RP than under FPR.

The price response of generic producers to RP is more ambiguous. On the one hand, RP

[15]This does not imply that the brand-name price is lower than generic prices in equilibrium, since, for equal copayments, the copay-elasticity is lower for brand-name than for generic drugs.

reduces the copay-elasticity of generic drug demand for given prices, since $c_b^R(p_b) > c_b^F(p_b)$ and therefore $D_g^R(p_b, p_g) > D_g^F(p_b, p_g)$, which gives generic producers an incentive to increases prices. On the other hand, the negative price response to RP by the brand-name producer implies that $c_b^R\left(p_b^R\right) < c_b^R\left(p_b^F\right)$, which has the opposite effect on the copay-elasticity of generic demand and thus generic pricing. Thus, RP has both a positive direct (demand) effect and a negative indirect effect (due to prices being strategic complements) on the pricing of generic drugs. The relative strength of these two counteracting effects determine whether equilibrium generic prices are higher or lower under RP, compared with FPR. Since equilibrium generic prices imply a copay-elasticity equal to one under both reimbursement regimes, and since $c_g^R(p_g) = c_g^F(p_g)$, the effect of RP on generic prices depends ultimately on how RP affects the brand-name copayment, and how this in turn affects the copay-elasticity of generic drug demand. Under the assumption that the elasticity of demand for generics decreases as the brand-name drug's price increases, i.e. $\partial\varepsilon_g/\partial c_b < 0$, we can conclude that $p_g^R < (>)\, p_g^F$ if and only if $c_b^R\left(p_b^R\right) < (>)\, c_b^F\left(p_b^F\right)$.[16] In words, if RP implies a lower brand-name copayment in equilibrium, it also implies lower generic drug prices.

Are incentives for generic entry higher under RP than under FPR? The answer to this question depends on the equilibrium profit difference (for a given number of generic producers) under the two reimbursement regimes. This profit difference can be written as

$$\pi_g^R(n) - \pi_g^F(n) = \left[D_g^R - D_g^F\right] p_g^R + \left[p_g^R - p_g^F\right] D_g^F. \tag{9}$$

The first term represents the demand effect, whereas the second term represents the price effect. Since both effects are *a priori* ambiguous, we can distinguish between four different scenarios:

1. If $p_g^R > p_g^F$ and $D_g^R > D_g^F$, RP unambiguously stimulates generic entry.
2. If $p_g^R > p_g^F$ and $D_g^R < D_g^F$, the effect of RP on generic entry is theoretically ambiguous.
3. If $p_g^R < p_g^F$ and $D_g^R > D_g^F$, the effect of RP on generic entry is theoretically ambiguous.

[16] Since

$$\frac{\partial\varepsilon_g}{\partial c_b} = -\frac{c_g}{D_g}\left(\frac{\partial^2 D_g}{\partial c_b \partial c_g} - \frac{\partial D_g}{\partial c_g}\frac{\partial D_g/\partial c_b}{D_g}\right),$$

a sufficient (but not necessary) condition for $\partial\varepsilon_g/\partial c_b < 0$ is $\partial^2 D_g/\partial c_b \partial c_g \geq 0$.

4. If $p_g^R < p_g^F$ and $D_g^R < D_g^F$, RP unambiguously discourages generic entry.

Since most empirical studies find that RP leads to lower generic prices, we consider the last two scenarios to be the most likely ones. If so, it follows that a necessary (but not sufficient) condition for RP to stimulate generic entry is that it leads to a lower brand-name market share.

2.4 Price cap regulation

In the above analysis, we have assumed that all drug producers can freely choose their prices. However, in many countries (including Norway) drug pricing is, to some extent, restricted by price cap regulation. Let us here briefly consider how the analysis might be affected if a binding price cap is imposed. Given that generic producers have an incentive to price their drugs below the brand-name price, the presence of a price cap will potentially bind only for the brand-name producer. The above described price and demand effects of RP might therefore be modified in one of the following two ways: (i) if the price cap binds under FPR but not under RP, the difference in brand-name prices under the two reimbursement regimes will be smaller than in the absence of price cap regulation, which – all else equal – increases the profitability of RP for generic producers; (ii) if the price cap binds under both reimbursement regimes, then RP has no effect on brand-name prices and will unambiguously boost the profitability of generics through higher demand.

Thus, we expect that the presence of price cap regulation makes it more likely that the introduction of RP will stimulate demand for generics, thereby making generic entry more profitable. In a companion paper (Brekke et al., 2015) we develop a full-fledged model of generic competition in a Salop-type framework and show that the presence of price cap regulation will indeed increase the scope for RP to stimulate generic entry.

3 Institutional background

The total sales of pharmaceuticals in Norway are around 20 billion NOK, where prescription drugs have a market share of around 80 percent.[17] As in most other European markets, the

[17]The total sales of pharmaceuticals were 21.7 billion NOK in 2014, according to the Association of the Pharmaceutical Industry in Norway (LMI). 1 Euro is about 8 NOK, 1 US dollar is about 7 NOK, and 1 British pound is about 11 NOK.

Norwegian pharmaceutical market is subject to regulation.[18] On the supply side, prices of prescription drugs are subject to price cap regulation. The price regulation scheme is based on international reference pricing (or external referencing), where prices are collected from nine Western European countries.[19] The maximum price of a given drug on the Norwegian market is set as the average of the three lowest prices of the (original brand-name) product in the reference countries. Generic drugs obtain the same price cap as the original brand-name product. In practice, this usually implies that the price cap is binding for the original drug, but not for the generic drugs. The price caps are usually revised annually, and change depending on the price development in the reference countries and/or the movements in the exchange rates.

On the demand side, there is cost-sharing of medical expenditures between patients and the National Insurance Scheme for prescription drugs on the reimbursement list.[20] For these drugs, patients pay a standard coinsurance, which is currently 38 percent of the price of the drug, constrained by expenditure caps per script and per year.[21] If the medical expenditures exceed these caps, patients receive 100 percent insurance coverage for any additional medical costs.

To increase demand elasticity and curb pharmaceutical expenditures, Norway introduced in 2005 a reference pricing scheme called *Trinnpris*. This scheme applies to prescription drugs on the reimbursement list that have lost patent protection and are subject to competition from generic drugs.[22] The reference price, which is the maximum reimbursement from the National Insurance Scheme, is set as a fixed discount on the price cap of the original brand-name drug in the period prior to patent expiration and generic entry. The initial discount is 35 percent and effective when generic competition takes place. After six months the discount is increased to around 60 or 80 percent depending on the sales value of the drug. Eventually, after (at least) 18 months the regulator can increase the discount up to a maximum of 90 percent for the substances with the highest sales value.[23]

[18] For details about the regulation of the Norwegian pharmaceutical market, see the website of the Norwegian Medicines Agency; *www.legemiddelverket.no.*

[19] The reference countries for Norway are Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden, and the UK.

[20] For over-the-counter drugs and prescription drugs not listed for reimbursement, which usually are pharmaceuticals aimed at treating short-term conditions, the patients have to pay out-of-pocket 100 percent of the medical costs.

[21] For 2014 the expenditure caps were NOK 520 per script and NOK 2105 per year.

[22] In addition, the Norwegian Medicines Agency has to define the original and generic drug versions as substitutable, see www.legemiddelverket.no/bytteliste.

[23] For more details see the webpage of the Norwegian Medicines Agency www.legemiddelverket.no.

Patients who purchase a product that is priced higher than the reference price have to pay the full price difference out-of-pocket in addition to the standard coinsurance payment. Notably, this part of the patients' copayments have to be paid irrespective of whether the accumulated medical costs exceed the expenditure caps described above. Moreover, pharmacies are through the generic substitution law obliged to offer patients lower priced (generic) products.[24] If patients refuses to accept the generic substitute, then they are charged the price difference between the actual price of the product and the reference price.

The *Trinnpris* scheme, which was effective from 1st of January 2005, was announced by the government in May 2004 and later approved by the Norwegian Parliament in October 2004. However, the implementation of the RP scheme was gradual and applied only to a subsample of off-patent substances. This was mainly due to practical reasons and the administrative workload related to implementing reference prices for the relevant products, but also to gain some experience before extending the scheme to more substances.[25] Thus, from 1 January 2005 the Norwegian Medicines Agency included only 20 off-patent substances that had lost patent protection and faced competition from generic drugs.[26] The scheme has been gradually extended and includes now more than 100 substances. In the next section, we will describe our sample of substances more carefully.

4 Data and descriptive statistics

To study the effects of RP on the entry of generic products and, in turn, on pricing and sales of pharmaceuticals, we have collected information about generic entry, pricing and sales of the 222 best selling molecules from the database of the Norwegian Pharmacy Association. The data contains detailed sales information of all transactions (purchases) made at every pharmacy in Norway.[27] We could retrieve monthly information about sales revenues (in Norwegian Kroner,

[24]The pharmacies are obliged to have at least one drug version priced at (or below) the RP (trinnpris) available for sale.

[25]Details about this can be found in the hearing document from the Norwegian Ministry of Health dated October 6, 2014; https://www.regjeringen.no/nb/dokumenter/horing–trinnpris-for-visse-legemidler/id96490/

[26]For the list of substances subject to *Trinnpris*, with details about when they were included, see www.legemiddelverket.no/trinnpris.

[27]Sales that are channeled through the hospitals to hospitalized patients and over-the-counter drugs sales taking place outside pharmacies (at, say, grocery stores) are not covered by this database. For more details, see the website of the Norwegian Pharmacy Association; www.apotek.no.

NOK) and volumes (number of packs and defined daily doses (DDDs)) for all products over the eleven year period 2003-2013. The data also contains information about substance name, producer (seller), pack size, dosage strength, whether the drug is branded or generic, etc.

Using the information about actual generic sales in our data, we can identify the date of entry (or exit) of generic products for each molecule in our sample. The data also allows us to measure the intensity of generic competition, as we can observe the number of generic products with positive sales at each date during the sample period. By dividing sales revenues by sales volumes measured in DDDs, we obtain a monthly (sales-)weighted average price per DDD of the brand-name and generic drugs for each month, which enables us to study the price responses to the implementation of RP. Information about the date for inclusion of a molecule in the RP scheme is obtained from the Norwegian Medicines Agency.

In our analysis, each market (i.e., molecule) includes all products using the same active ingredient, identified by a unique Anatomical Therapeutic Chemical (ATC) code. We only include markets with generic competition before the reform was announced, in May 2004, and exclude all observations prior to the first recorded generic entry. This allows us to exclude molecules potentially under patent protection. We dropped 7 molecules that were subject to a policy experiment with a different RP scheme from 2003 to 2005.[28] Moreover, we dropped all non-tablets products. The reason to focus on tablets only is twofold. First, no molecules commercialized in non-tablet form only have been subject to RP during our sample period. Second, focusing on tablets only ensures that the market defined by each molecule includes comparable products. Within the same molecule one can have non-tablet and tablet products, and they may not be substitutable. We are left with an unbalanced panel of 36 molecules for a total of 4,576 month-molecule observations over the period 2003-2013. Of the 36 molecules in our sample, 19 were subject to RP in some periods after the reform was introduced, in January 2005. This group will be our treatment group. Conversely, 17 molecules were never subject to RP, and they will constitute our comparison group.

In Table 1, we report descriptive statistics for both the treatment and the comparison group. time of the variables of interest. According to Table 1, drug prices in the treatment group are

[28] Under this scheme, called *Indekspris*, the reference price was set as a weighted average of brand-name and generic prices. For more details, see Brekke et al. (2009, 2011).

relatively high compared with the ones in the comparison group. Similarly, the markets in the treatment group are characterized by higher volumes (measured in DDDs) and sales. Thus, there is some evidence that the regulator included in the RP scheme larger markets with higher prices. However, as Figures A1-A4 suggest, the trends of average prices and of the sales revenues are fairly similar in the treatment and comparison groups before the reform was announced.[29] Furthermore, we will show below that there is no evidence that drugs were included in the RP scheme according to the evolution of generic competition in the pre-reform period. It is also worth noting that, according to Table 1, generics' prices are slightly higher than brand-name drugs' prices in the comparison group (1 NOK per DDD on average). This is due to the fact that generics tend to enter the market with a more limited sample of product variants (e.g., pack sizes, dosage strengths) that are higher priced and more profitable than the full range provided by the original producer.

We are particularly interested in the evolution of our competition variables (number of generics and market shares of the brand-name drug). In Table 2, we report these measures, computed for the periods before and after these drugs were included in the RP scheme (a more detailed description of generic competition is reported in Table A1, where the information is disaggregated by market). For drugs never subject to RP, we calculate averages before and after the reform was introduced, in 2005, in order to provide some comparisons. The drugs in the treatment group display an increase in the number of generics present on the market after the introduction of RP (from 1.9 to 2.5 per market). For drugs in the comparison group, the number of generics decreases over time (from 2.5 to 1.7). In line with this piece of evidence, the market shares of the brand-name drug decrease substantially for molecules in the treatment group after the inclusion in the RP scheme (from 75% to 40%). Conversely, molecules in the comparison group display rather stable market shares of the brand-name drug (from 65% before 2005 to 61% after 2005). Figures 1 and 2 display the development over time of the competition variables, for both the treatment and the comparison group.[30] Following a drop before 2005,

[29]Figure A1 registers a large upward jump in the treatment group average prices in March 2004. This does not appear to be a strategic response of drug producers, but to be due to the unbalanced nature of the panel. Some molecules are included in the sample only after 2003 (after the first generic enters the market), and this causes jumps in the average price. Figure A2 reports average prices for drugs with generic competition in January 2003, and display a much smother evolution for the treatment group.

[30]Note that, in Table 1, averages for the treatment group are calculated in the pre-inclusion and the post-inclusion period. For some molecules, inclusion occurs after 2005. This explains why Table 1 suggests an increase

the number of generics in the treatment group seems to be relatively stable. Conversely, the number of generics in the comparison group falls over the full sample period, following a trend that is consistent with the general trend in the Norwegian pharmaceutical market, as Figure A5 suggests. Treated molecules seem to have resisted such a downward trend, and the market shares of brand-name drugs have decreased dramatically over time.

[Insert Table 1 here]

[Insert Table 2 here]

[Insert Figure 1 here]

[Insert Figure 2 here]

5 Empirical strategy and results

Our aim is to test for the effect of RP on generic competition, both at the extensive and intensive margin. Thus, we estimate the effect of RP on (i) the number of generic products and on (ii) the market shares of the brand-name drug. As mentioned above, we limit our analysis to markets with generic competition prior to the announcement of the RP reform. Thus, our estimates of the effect of RP are conditional on competition being already present in the market.

Since the RP scheme was implemented gradually (see Section 3), our empirical strategy relies on a comparison of the molecules affected by RP (treatment group) to similar molecules that were never subject to RP (comparison group). Thus, we can evaluate the effect of the regulatory change with a difference-in-difference approach. Because of the panel structure of the data, we can compare the inter-temporal variation in the number of generic competitors before and after the imposition of the reform for each molecule. The identification does not only rely on a before and after comparison, but also on a comparison of variations in the number of generic products for molecules subject to RP with variation in outcomes for molecules not subject to this reform.

The model to be estimated is

$$Y_{it} = \beta \mathbf{X}_{it} + \rho D_{it} + \delta_t + a_i + \epsilon_{it}, \tag{10}$$

in the number of generics in the treatment group after inclusion, while Figures 1 displays a flatter picture.

where Y_{it} is the variable of interest (number of generics or market share of brand-name drugs) at time t in market i. D_{it} is a dummy variable equal to one if molecule i is subject to RP at time t, and the vector $\mathbf{X}_{it}$ contains observed time-varying characteristics. In the baseline model these include the number of therapeutic substitutes in the same ATC3 group and market size (captured by the log of sales revenues of all the product in the therapeutic group). a_i is a molecule fixed effect, whereas δ_t is a month-specific effect common to all molecules. The coefficient of interest is ρ, which captures the effect of RP.

5.1 Pre-reform test

For our approach to be valid in identifying the causal effect of RP on generic entry, the treatment and the comparison group need to be comparable. While differences in characteristics that are constant over time can be controlled for by fixed effects, systematic differences in trends in the pre-reform period are more problematic. In other words, for our parameter ρ to estimate causal effects, the trend of the number of generic products before the introduction of RP should be similar in the treatment and comparison group. We cannot implement the usual pre-reform tests, due to the fact that RP is introduced at different points in time to the molecules in the treatment group. However, we run the test on the period before the reform was announced, in May 2004. By that point, the producers of molecules soon to be included in the RP scheme could have been already informed (at least informally).[31]

The average numbers of generics for the comparison and the treatment group in the pre-reform period are plotted in Figure 3. The figure suggests that the evolutions in the number of generics are fairly similar across the two groups in the pre-reform period. To test our assumption of common trends, we also run a fixed effects regression where the dependent variable is the number of generics. We only consider pre-reform observations (January 2003-May 2004) and we include interactions between monthly dummies and a dummy indicating treated molecules. If these interactions do not have a significant coefficient, this indicates that pre-reform trends are not significantly different, and that the comparison group is legitimate. The results of the test are presented in Table 3. All interactions are non-significant, both individually and jointly.

[31] Of the 19 molecules in the treatment group, 14 were included in the RP scheme already in 2005, while 5 were included later on.

[Insert Figure 3 here]

[Insert Table 3 here]

We run a similar test for the brand-name drugs' market shares. Figure 4 shows their evolution in the pre-reform period for molecules in the treatment and comparison group. The trends appear to be similar prior to the reform announcement. A pre-reform test similar to the one described above is performed for market shares, and yields similar results (see Table 4).

[Insert Figure 4 here]

[Insert Table 4 here]

5.2 Effects of RP on generic competition

The main results on generic entry are reported in the first column of Table 5. The number of generics in a given market is significantly higher after the introduction of RP. The effect (1.2) is quite high if compared with the average number of generics the pre-reform period (1.8). As our descriptive statistics and Figure A5 illustrate, this positive and strongly significant effect is mostly due to a decline in the number of generics for molecules in the comparison group, which was much less pronounced for drugs in the treatment group. The decline in generic competition seems to be pervasive in the Norwegian pharmaceutical market, as is evident from Figure A2 in the Appendix, which shows the average number of generics for all tablets markets with some generic competition in our sample period. Thus, our findings suggest that, for the treated markets, the introduction of RP has slowed down, and to some extent reversed, an otherwise downward trend in the number of generics.

In order to be consistent with our pre-reform test, we also consider the possibility that producers may be informed early about the inclusion in the RP scheme. Thus, we define a different treatment dummy, taking value one in all periods with RP and in the 7 months prior to the inclusion of the drug in the RP scheme. The results, presented in column (2) of Table 5, indicate that our parameter of interest is robust to this alternative specification. The estimated effect of RP is slightly lower in this case, suggesting that entry decisions are responsive to the expected inclusion of the drug in the RP scheme.

Controlling for RP inclusion, we do not find any significant effect of the number of therapeutic substitutes and of the market size (captured by market revenues) on the number of generics in each market. While this is somehow surprising, if compared with the previous literature (see Grabowski and Vernon, 1992, and Scott-Morton, 1999 and 2000), it is probably due to the fact that these variables display little variation over time. The effects of molecule-specific market conditions may thus be captured by the fixed effects.

[Insert Table 5 here]

Our results are robust to different model specifications. First, since the number of generics is a count variable, we run a Poisson regression. The results, reported in the first column of Table 6, are quantitatively similar to the linear ones. Second, to check whether the results are specific to tablets, we also run both the linear and the Poisson regressions on the full set of products, including non-tablets. In this case, the treatment group is the same as in our main sample, but the comparison group is now larger, including 29 molecules. Again, the main results, reported in the second and third column of Table 5, are confirmed, and the coefficient of interest has a similar magnitude.

[Insert Table 6 here]

We now turn to the analysis of market shares. The results on the effect of RP on the market shares of the brand-name drug are presented in Table 7. In columns (1) and (2) we do not control for the number of generics, and we find that the introduction of RP reduces the market shares of the brand-name drug by 34 percentage points (32 points if we lag the introduction of RP to take announcement effects into account). This coefficient is statistically and economically significant. However, it may capture two effects. On the one hand, RP shifts demand from the brand-name drugs to generics, and this may lead to a reduction in brand-name market shares for a given number of generics. On the other hand, we have previously shown that RP also encourages generic entry, and this may also have a negative effect on the brand-name drugs' market shares. In order to disentangle these two effects, in columns (3) and (4) we control for the number of generics. Not surprisingly, the coefficient is negative and significant. In line with our economic intuition, controlling for the number of generics reduces the estimated coefficient

for the RP dummy. This result is comparable with the one of the existing literature, which takes the number of generics as given in assessing the impact of RP.

[Insert Table 7 here]

All in all, our results suggest that RP had a positive impact on the number of generics and on the market shares of generic drugs. More specifically, it seems to have countered a downward trend detectable in the comparison group and more generally in the Norwegian pharmaceutical market. In light of these results, we expect the profits of the brand-name drug producers to decline, and the joint profits of generic producers to increase, once we control for the number of generics in the market. If this was not the case, it would be difficult to explain the positive effect of RP on generic entry. In Table 8, we explore the effect of RP on profits. Our measure of profitability is given by the sales of brand-name drugs and generics (expressed in logarithms). We assume that the variable costs of producing all drugs have not changed over time, so that sales revenues can be interpreted as a proxy for profits. As expected, the profits of brand-name drug producers are negatively affected by RP. The coefficient is very high, 87%, even when controlling for the number of generics. The joint profits of generic producers are positively affected by RP (the increase equals 184%), for a given number of generics present in the market. This is direct evidence of the fact that expected profits are higher in markets with RP, implying that RP stimulates generic entry.

[Insert Table 8 here]

6 Results from an alternative identification strategy

The validity of the results obtained from the difference-in-difference approach relies crucially on the validity of the comparison group. Although our pre-reform test seems to confirm the validity of our chosen comparison group, as shown in Section 5.1, we also provide here a different type of validation by presenting results from an alternative identification strategy based on data for the treated molecules only. Our approach is to exploit the fact that, for molecules included in the RP scheme during the period of observation, the exact date of inclusion is to a large extent random. This allows us to adopt a regression discontinuity (RD) set-up.

The nature of the RD approach necessitates the adoption of slightly different criteria for sample selection. We now limit the analysis to molecules with generic competition at least one year prior to inclusion in the RP scheme. For molecules with generic competition in the first period of the sample (January 2003), we do not know at which prior date generic entry took place. Thus, in order to avoid any bias related to drug life cycles, we only include molecules for which the first registered generic entry occurs after January 2003. As before, all observations prior to generic entry are excluded. This leaves us with a group of 18 'treated' molecules; i.e., molecules that were included in the RP scheme during the period 2003-2013 and for which first generic entry is observed after January 2003.

The average time between generic entry and inclusion in the RP scheme is around 30 months for the 18 molecules in our selected sample. However, it is important to observe that the variance in the lag between generic entry and RP inclusion is very high.[32] This is readily seen in Figure 5, were we report the distribution of this lag across the 18 molecules. Thus, there is no evidence that the timing of inclusion in the RP scheme is related to the life cycle of pharmaceuticals, a key observation that serves as a justification for estimating the effects of RP by using an RD design.

[Insert Figure 5 here]

Some visual evidence on the effects of RP on the number of generics is displayed in Figure 6, where the average number of generics is plotted 3 years before and 3 years after RP inclusion, and with a quadratic fit estimated separately on each side of the cutoff date. Similar evidence for the average market share of the brand-name drug is presented in Figure 7. Based on a visual inspection of these figures, there seems to be a clear discontinuity at the time of RP inclusion with a sharp increase in the number of generics (from around 1.5 to 2) and an equally strong drop in brand-name market shares (from 70% to 50%).

[Insert Figure 6 here]

[Insert Figure 7 here]

[32] The mean lag is 30.33 months, with a standard deviation of 21.92 months. Across the 18 molecules, the lag between generic entry and RP inclusion varies from 14 to 89 months.

In order to test whether the apparent discontinuities revealed in Figures 6 and 7 reflect statistically significant effects of RP inclusion, we estimate six different parametric models and one nonparametric model. The estimated parametric models are the following:

$$(1a): Y_{it} = \beta_0 + \beta_1 T_{it} + \beta_2 R_{it} + a_i + \delta_t + \epsilon_{it}$$

$$(1b): Y_{it} = \beta_0 + \beta_1 T_{it} + (\beta_2 + \beta_3 T_{it}) R_{it} + a_i + \delta_t + \epsilon_{it}$$

$$(2a): Y_{it} = \beta_0 + \beta_1 T_{it} + \beta_2 R_{it} + \beta_3 R_{it}^2 + a_i + \delta_t + \epsilon_{it}$$

$$(2b): Y_{it} = \beta_0 + \beta_1 T_{it} + (\beta_2 + \beta_3 T_{it}) R_{it} + (\beta_4 + \beta_5 T_{it}) R_{it}^2 + a_i + \delta_t + \epsilon_{it}$$

$$(3a): Y_{it} = \beta_0 + \beta_1 T_{it} + \beta_2 R_{it} + \beta_3 R_{it}^2 + \beta_4 R_{it}^3 + a_i + \delta_t + \epsilon_{it},$$

$$(3b): Y_{it} = \beta_0 + \beta_1 T_{it} + (\beta_2 + \beta_3 T_{it}) R_{it} + (\beta_4 + \beta_5 T_{it}) R_{it}^2 + (\beta_6 + \beta_7 T_{it}) R_{it}^3 + a_i + \delta_t + \epsilon_{it},$$

where Y is the dependent variable (number of generics or brand-name market share), T_{it} is a dummy variable equal to one if RP applies for drug i at date t, and $R_{it} := t - RPdate_i$ is the number of months since the inclusion of drug i in the RP scheme. Thus, β_1 estimates the effect of RP on the dependent variable at the date of RP inclusion ($t = RPdate_i$). In addition to a linear equation (1a/b), we also estimate second-order (2a/b) and third-order (3a/b) polynomials in R_{it}, which allows us to rule out the possibility that a detected discontinuity might be attributed to non-linearities in the trend. In the b-version of each model, we also allow the trend to depend on the treatment (i.e., we allow the trend to differ before and after RP inclusion). Finally, we control for time dummies (δ_t) and for molecule-fixed effects (a_i). The inclusion of time dummies controls for the possibility that RP inclusion happened in particular time periods that might correlate with generic entry. Since treated molecules experienced generic entry on average 3 years prior to RP inclusion, we estimate the above specified models in a time window ranging from 3 years before to 3 years after the cutoff date.

Regarding the effect of reference pricing on the number of generics, the results from our 6 models are presented in Table 9. The coefficient of interest, β_1, is positive and strongly significant in all 6 models. A Wald test of joint significance performed on the models with interactions (the b-models) suggests that the third-degree polynomial (Model 3b) is the best fit for the data. In

this model, the estimated effect of RP is an increase in the number of generics of 0.6. There is, however, a possibility that information about RP inclusion of a particular molecule might have reached the market (shortly) before RP inclusion was actually implemented. If potential generic producers were able to anticipate RP inclusion, the estimates reported in Table 9 might be affected by some responses or adjustments to an anticipated RP inclusion. In order to correct for such anticipation effects, we also report results (in Table 10) from 'donut' estimations where we have excluded all observations within one month of the cutoff date. The estimated RP-coefficient is still positive and strongly significant in all 6 models, and has somewhat larger magnitudes. The best fitted model is now the first-degree polynomial (Model 1b), where the estimated effect of RP is an increase in the number of generics of 1.1. Notice that this magnitude is very close to the corresponding coefficient in the difference-in-difference regression reported in Table 5.

[Insert Table 9 here]

[Insert Table 10 here]

Tables 11 and 12 show similar estimations as Tables 9 and 10, but with brand-name market share as the dependent variables. Once more, the effect of RP is strongly significant in all models, with market share responses ranging from 24 to 39 percentage points (Table 11) depending on the estimated model. Quantitatively, these effects are highly comparable to estimated effects from the difference-in-difference regressions, as presented in Table 7. These effects are even stronger if we use a one-month donut model (Table 12), where RP inclusion yields an estimated drop in brand-name market shares of around 42 percentage points in the most preferred model (which in this case is Model 2b).[33]

[Insert Table 11 here]

[Insert Table 12 here]

Finally, Table 13 displays our results from a nonparametric estimation, for the effect of RP on the number of generics as well as brand-name market shares. We use a triangular kernel and

[33] As robustness checks, we have also estimated two- and three-month donut models (for number of generics and brand-name market share), which yield – qualitatively and quantitatively – very similar results. Details are available upon request.

control for a first-degree polynomial in time, which is allowed to differ on each side of the cutoff. The triangular kernel attributes larger weights to the values closer to the cutoff. The bandwidth is selected using a cross-validation procedure that minimizes the mean squared error between the prediction of two models: a local linear regression and a fourth-order polynomial model. As is evident from Table 13, the estimates have the expected sign and are, in quantitative terms, fairly consistent with the estimates obtained from the parametric (no-donut) models.

[Insert Table 13 here]

7 Effects of RP on prices and expenditures

Our main result reported above is that RP increases the number of generics and reduces the market shares of the brand-name drug. In other words, RP increases generic competition both at the extensive and the intensive margin. For public policy, though, the main interest ultimately lies in how RP affects prices and total drug expenditures. The worry that entry effects might make RP a less potent (and potentially counterproductive) instrument for curtailing pharmaceutical expenditures is not supported by our empirical findings. On the contrary, our results suggest that, if anything, the effects of RP on prices and expenditures are *reinforced* when the endogeneity of generic entry is taken into account. In this penultimate section of the paper we will more precisely quantify these effects and explore the role of generic entry in the process. All results in this section are based on the difference-in-difference approach detailed in Section 5.

7.1 Effect of RP on prices

According to our theoretical model, while it is reasonable to expect that the price of brand-name drugs might decline in response to RP, the effect on generics' prices is ambiguous. On the one hand, RP shifts demand towards generic producers, as Table 7 shows, providing incentives to increase prices. On the other hand, RP increases price competition, both through the brand-name producer's price response and through generic entry.

Table 14 presents the results from estimation of (10) with, respectively, brand-name and generic (logged) prices as dependent variables. In columns (1) and (4) we do not control for the number of generics. The estimated effect of RP on prices is negative for both the brand-name

drugs (an estimated 32% reduction) and generics products (an estimated 43% reduction). The fact that generic prices drop more than the prices of brand-name drugs does not imply that the decline for generics is higher in absolute terms, since generics typically have lower prices. In columns (2) and (5), we control for the number of generics on the market. We do not find a significant coefficient associated with this variable, and the estimated effect of RP on prices does not seem to be strongly affected by its inclusion in the regression.

In columns (3) and (6), we use the dummy associated with the announcement of RP. The estimated effect of RP is slightly lower in this specification. Differently from entry decisions, price adjustments seem to be implemented once the new regulation is in place, rather than at the time of the policy announcement.[34]

In Table 15, we present estimates on the effect of RP on (sales-weighted) average prices. Not surprisingly, the effect is negative. This is due both to the shift in demand towards cheaper generic drugs, and to price responses of both brand-name and generic firms.

[Insert Table 14 here]

[Insert Table 15 here]

The empirical evidence described above allows us to better interpret the evidence on generic entry. RP leads to lower prices but higher demand for generic drugs. Thus, RP shifts demand from brand-name to generic drugs, even after prices have been adjusted. This is a necessary condition for RP to encourage entry in the case where RP leads to lower generic prices. Indeed, our results on the effect of RP on generic entry show that the positive demand effect is sufficiently large to outweigh the negative price effect. Even if post-RP prices are lower, the expected profit of selling a generic drug increases because of the demand effect.

7.2 Effects of RP on expenditures

In light of our results regarding the price effect of RP, the effect of RP on total pharmaceutical expenditures (borne both by the government and by consumers) is *a priori* ambiguous: since prices have been reduced for molecules with RP, demand might have increased, thus offsetting potential savings.

[34] This result is consistent with Bergman and Rudholm (2003) who find that the effect of RP has an impact on drug prices only when actual (not potential) generic competition occurs.

Our measure of expenditures are the logarithmic transformations of total sales (prices multiplied by volumes) of all drugs in the therapeutic group. Table 16 summarizes the results. We find a negative effect (statistically significant at the 10% confidence level) of RP on overall expenditures. This is in line with previous literature, showing that RP is successful in curbing pharmaceutical expenditures. However, the reduction in total expenditures (24%) is relatively smaller than the reduction in average prices (50%), which reflects the fact that lower prices stimulated demand. In order to take into account seasonality in sales data, we also included month dummies. The results, reported in columns (3) and (4), are robust to this alternative specification.

[Insert Table 16 here]

8 Conclusion

This paper constitutes an attempt to assess the effect of RP on generic competition and ultimately on prices and expenditures. Theoretically, the effect of RP on generic competition is ambiguous and depends on the relative strength of two opposing effects. Whereas RP shifts demand towards generic drugs for given drug prices, which (all else equal) stimulates generic entry, RP also induces the brand-name producer to reduce its price, which has the opposite effect on the profitability of selling generic drugs.

Exploiting a Norwegian policy reform, we compare drugs subject and not subject to RP, and find that the introduction of an RP scheme had a positive effect on generic competition, measured both at the extensive margin (the number of generic products) and the intensive margin (the market share of generic products relative to branded products). Although RP led to lower prices for both branded and generic drugs, the positive effect on demand for generic drugs was sufficiently large to stimulate generic entry. Thus, our results suggest that focusing on short-term price responses to RP might lead to an underestimation of the pro-competitive effects of RP, since the initial price reductions caused by RP (for a given number of generics) were reinforced by increased generic entry. Our empirical results also show that the price reductions caused by RP contributed to a reduction in overall drug expenditures (although the effect is only weakly significant). Nevertheless, since lower prices stimulated total demand, the reduction

in overall expenditures is much smaller than the price reduction (in relative terms).

Our results on RP and generic competition differ from the results of previous empirical studies, and suggest that market-specific factors and the regulatory framework are important in assessing the impact of RP. For instance, in Norway, the existence of price caps may have contributed to the pro-competitive effect of RP.

One important limitation of our study is that we only consider generic entry/exit in markets where generic competition is already present. An interesting line of future research would be to include in the analysis all off-patent drugs, in order to look at the effect of RP on the probability and lags of entry. To this purpose, detailed patent data would be needed.

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Appendix

[Insert Table A1 here]

[Insert Figures A1 - A5 here]

Tables and Figures

Table 1: Descriptive statistics.

Treatment group						
	Mean	Std. Dev.	Min	Max	Markets	Obs.
Number of generics	2.314	1.493	0	9	19	2,413
Brand-name Market Share	0.487	0.278	0.002	1.000	19	2,413
Average Price	9.045	14.767	0.477	126.418	19	2,413
Brand-name Price	10.633	16.445	0.471	128.947	19	2,413
Generics Price	7.997	13.636	0.478	116.993	19	2,205
Revenues (in mill. NOK/month)	3.168	3.760	0.4005	25.542	19	2,413
Volumes (in K ddd/month)	985.697	1238.433	9.453	5277.170	19	2,413
Number of ther. substitutes	9.724	4.812	1	15	19	2,413
Comparison group						
	Mean	Std. Dev.	Min	Max	Markets	Obs.
Number of generics	1.835	1.789	0	8	17	2,158
Brand-name Market Share	0.624	0.401	0.000	1.000	17	2158
Average Price	4.718	3.189	0.523	14.533	17	2,158
Brand-name Price	4.592	3.428	0.523	16.997	17	1,956
Generics Price	5.362	3.348	0.728	15.696	17	1,640
Revenues (in mill. NOK/month)	1.483	1.525	0.001	7.698	17	2,158
Volumes (in K ddd/month)	380.770	371.070	0.014	1975.000	17	2,158
Number of ther. substitutes	7.353	2.917	1	12	17	2,158

Table 2: Generic competition: Means and standard deviations (in parenthesis)

VARIABLES	RP. Before	RP. During	No RP. Before 2005	No RP. After 2005
Number of generics	1.860 (1.863)	2.497 (1.269)	2.487 (2.032)	1.692 (1.699)
Brand-name Market Share	0.723 (0.285)	0.392 (0.210)	0.664 (0.356)	0.616 (0.410)
Number of markets	19	19	17	17
Number of Observations	694	1,719	386	1,772

Table 3: Pre-reform test, fixed effects with model with robust standard error.

	Number of generics	
Interaction 1	-0.386	(0.429)
Interaction 2	-0.312	(0.410)
Interaction 3	0.085	(0.310)
Interaction 4	-0.226	(0.401)
Interaction 5	-0.214	(0.344)
Interaction 6	-0.219	(0.378)
Interaction 7	-0.064	(0.314)
Interaction 8	-0.045	(0.321)
Interaction 9	0.021	(0.262)
Interaction 10	0.081	(0.227)
Interaction 11	-0.016	(0.303)
Interaction 12	0.117	(0.233)
Interaction 13	0.230	(0.224)
Interaction 14	0.160	(0.184)
Interaction 15	0.115	(0.166)
Number of therapeutic substitutes	-0.133	(0.248)
LogRevenues	-0.045	(0.190)
Constant	4.321	(3.187)
Joint significance Interaction 1-15 (F-Test)	0.614	
Time dummies	Yes	
Molecule dummies	Yes	
Number of Markets	36	
Observations	462	
R^2	0.059	

Robust standard errors in parentheses

Table 4: Pre-reform test, fixed effects with model with robust standard error.

	Brand-name Market Shares	
Interaction 1	0.041	(0.048)
Interaction 2	0.033	(0.047)
Interaction 3	0.015	(0.040)
Interaction 4	-0.001	(0.038)
Interaction 5	-0.007	(0.034)
Interaction 6	0.011	(0.031)
Interaction 7	0.005	(0.029)
Interaction 8	0.008	(0.024)
Interaction 9	8.74e-05	(0.029)
Interaction 10	0.001	(0.024)
Interaction 11	0.027	(0.019)
Interaction 12	0.019	(0.016)
Interaction 13	0.011	(0.014)
Interaction 14	0.017	(0.015)
Interaction 15	-0.006	(0.009)
Number of therapeutic substitutes	-0.023	(0.052)
LogRevenues	0.049*	(0.028)
Constant	0.191	(0.634)
Joint significance Interaction 1-15 (F-Test)	0.791	
Time dummies	Yes	
Molecule dummies	Yes	
Number of markets	36	
Observations	462	
R^2	0.169	

Robust standard errors in parentheses

Table 5: Estimated effects of reference pricing on the number of generics. Fixed effect models

	(1)	(2)
Reference Pricing	1.243***	
	(0.429)	
Reference Pricing, 7 month lagged		1.330***
		(0.374)
Number of therapeutic substitutes	-0.218	-0.235
	(0.219)	(0.219)
LogRevenues	-0.00595	-0.0348
	(0.183)	(0.192)
Constant	4.425	4.954*
	(2.733)	(2.932)
Time dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of markets	36	36
Observations	4,571	4,571
R^2	0.175	0.176

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 6: Estimated effects of reference pricing on the number of generics. Robustness checks

	(1) Poisson Regression	(2) All Molecules	(3) All Molecules Poisson reg.
Reference Pricing	0.625***	1.126**	0.505**
	(0.215)	(0.505)	(0.208)
Number of therapeutic substitutes	-0.0487	-0.303	-0.114
	(0.0975)	(0.283)	(0.0986)
LogRevenues	0.0704	0.208	0.154
	(0.123)	(0.330)	(0.133)
Constant		2.116	
		(5.517)	
Time dummies	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes
Number of markets	36	48	48
Observations	4,571	6,218	6,218
R^2		0.102	

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 7: Estimated effects of reference pricing on the market shares of the brand-name drug. Fixed effect models

	(1)	(2)	(3)	(4)
Reference Pricing	-0.340***		-0.279***	
	(0.072)		(0.067)	
Reference Pricing, 7 month lagged		-0.325***		-0.257***
		(0.069)		(0.066)
Number of therapeutic substitutes	0.0270	0.0297	0.0165	0.0177
	(0.031)	(0.031)	(0.030)	(0.030)
LogRevenues	-0.004	0.006	-0.004	0.004
	(0.048)	(0.051)	(0.045)	(0.047)
Number of generics			-0.049***	-0.051***
			(0.009)	(0.010)
Constant	0.576	0.413	0.791	0.665
	(0.708)	(0.752)	(0.678)	(0.712)
Time dummies	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36
Observations	4,571	4,571	4,571	4,571
R^2	0.390	0.356	0.451	0.423

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 8: Estimated effects of reference pricing on profits. Fixed effect models

	(1) Brand	(2) Brand	(3) Generics	(4) Generics
Reference Pricing	-0.870***		1.836*	
	(0.206)		(0.982)	
Reference Pricing, 7 month lagged		-0.757***		2.158*
		(0.190)		(1.139)
Number of therapeutic substitutes	0.058	0.058	-0.344	-0.380
	(0.126)	(0.125)	(0.290)	(0.305)
Number of generics	-0.096*	-0.106*	0.242***	0.244***
	(0.049)	(0.053)	(0.065)	(0.064)
Constant	13.73***	13.75***	14.35***	14.59***
	(1.126)	(1.118)	(2.547)	(2.674)
Time dummies	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36
Observations	4,369	4,369	3,845	3,845
R^2	0.408	0.387	0.198	0.212

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 9: Regression discontinuity. Number of generics. Molecules with generic competition at least one year before RP and entry after January 2003.

	Number of generics					
	(1)	(2)	(3)	(4)	(5)	(6)
Reference Pricing	1.109***	0.974***	1.125***	0.853***	0.947***	0.604***
	(0.227)	(0.238)	(0.221)	(0.143)	(0.162)	(0.112)
Months from RP	0.030***	0.035***	0.029***	0.079***	0.041***	0.157***
	(0.004)	(0.009)	(0.004)	(0.016)	(0.005)	(0.028)
(Months from RP)2			8.16e-05	0.002***	0.0001	0.008***
			(0.0002)	(0.001)	(0.0002)	(0.002)
(Months from RP)3					-1.26e-05*	0.0001***
					(6.01e-06)	(3.81e-05)
RP*(Months from RP)		-0.014		-0.046*		-0.103*
		(0.014)		(0.024)		(0.053)
RP*(Months from RP)2				-0.002**		-0.009***
				(0.001)		(0.003)
RP*(Months from RP)3						-0.0001
						(6.39e-05)
Constant	-0.095	1.101***	-0.145	0.177	-0.053	0.291*
	(0.122)	(0.156)	(0.133)	(0.169)	(0.131)	(0.155)
Observations	988	988	988	988	988	988
R^2	0.780	0.655	0.780	0.786	0.783	0.789
Number of markets	18	18	18	18	18	18
Time dummies	Yes	Yes	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes	Yes	Yes
Wald test for nested models				(4) vs (2)		(6) vs (4)
Joint significance, p-value				0.0130		0.0056

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 10: Regression discontinuity. Brand-name market shares. Molecules with generic competition at least one year before RP and entry after January 2003.

	Brand-name market shares.					
	(1)	(2)	(3)	(4)	(5)	(6)
Reference Pricing	-0.391***	-0.375***	-0.385***	-0.302***	-0.329***	-0.238***
	(0.045)	(0.042)	(0.044)	(0.045)	(0.045)	(0.054)
Months from RP	-0.005***	-0.007**	-0.005***	-0.019***	-0.009***	-0.035**
	(0.001)	(0.002)	(0.001)	(0.006)	(0.002)	(0.014)
(Months from RP)2			3.22e-05	-0.0004**	1.74e-05	-0.002
			(4.20e-05)	(0.0002)	(4.17e-05)	(0.001)
(Months from RP)3					3.92e-06**	-2.54e-05
					(1.58e-06)	(1.79e-05)
RP*(Months from RP)		0.005		0.012		0.020
		(0.003)		(0.009)		(0.018)
RP*(Months from RP)2				0.001**		0.002*
				(0.0002)		(0.001)
RP*(Months from RP)3						1.48e-05
						(2.01e-05)
Constant	0.983***	0.807***	0.964***	0.872***	0.935***	0.848***
	(0.028)	(0.031)	(0.041)	(0.053)	(0.041)	(0.054)
Observations	988	988	988	988	988	988
R^2	0.842	0.785	0.843	0.851	0.847	0.853
Number of markets	18	18	18	18	18	18
Time dummies	Yes	Yes	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes	Yes	Yes
Wald test for nested models				(4) vs (2)		(6) vs (4)
Joint significance, p-value				0.0423		0.2438

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 11: Regression discontinuity (1 months donut). Number of generics. Molecules with generic competition at least one year before RP and entry after January 2003.

	Number of generics					
	(1)	(2)	(3)	(4)	(5)	(6)
Reference Pricing	1.295***	1.103***	1.339***	1.190***	1.241***	1.104***
	(0.263)	(0.264)	(0.251)	(0.195)	(0.203)	(0.202)
Months from RP	0.030***	0.028***	0.028***	0.045**	0.034***	0.066
	(0.005)	(0.009)	(0.004)	(0.018)	(0.005)	(0.042)
(Months from RP)2			0.0002	0.001	0.0002	0.002
			(0.000219)	(0.001)	(0.0002)	(0.003)
(Months from RP)3					-5.80e-06	2.84e-05
					(5.55e-06)	(4.82e-05)
RP*(Months from RP)		-0.008		-0.009		-0.025
		(0.015)		(0.027)		(0.061)
RP*(Months from RP)2				-0.001		-0.003
				(0.001)		(0.003)
RP*(Months from RP)3						-2.28e-05
						(6.89e-05)
Constant	0.061	0.991***	-0.020	0.091	0.028	0.149
	(0.140)	(0.172)	(0.138)	(0.191)	(0.129)	(0.209)
Observations	934	934	934	934	934	934
R^2	0.796	0.671	0.798	0.799	0.799	0.799
Number of markets	18	18	18	18	18	18
Time dummies	Yes	Yes	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes	Yes	Yes
Wald test for nested models				(4) vs (2)		(6) vs (4)
Joint significance, p-value				0.4051		0.7970

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 12: Regression discontinuity (1 months donut). Brand-name market shares. Molecules with generic competition at least one year before RP and entry after January 2003.

	Brand-name market shares.					
	(1)	(2)	(3)	(4)	(5)	(6)
Reference Pricing	-0.455***	-0.418***	-0.451***	-0.403***	-0.418***	-0.410***
	(0.045)	(0.046)	(0.045)	(0.053)	(0.050)	(0.084)
Months from RP	-0.003***	-0.005*	-0.003**	-0.009	-0.005**	-0.001
	(0.001)	(0.002)	(0.001)	(0.007)	(0.002)	(0.021)
(Months from RP)2			1.33e-05	-0.0001	7.13e-06	0.0003
			(4.40e-05)	(0.0002)	(4.34e-05)	(0.001)
(Months from RP)3					1.95e-06	9.98e-06
					(1.62e-06)	(2.21e-05)
RP*(Months from RP)		0.003		0.003		-0.009
		(0.003)		(0.011)		(0.023)
RP*(Months from RP)2				0.0002		3.62e-05
				(0.0002)		(0.001)
RP*(Months from RP)3						-1.59e-05
						(2.37e-05)
Constant	1.012***	0.842***	1.006***	0.970***	0.990***	0.990***
	(0.031)	(0.034)	(0.042)	(0.068)	(0.044)	(0.085)
Observations	934	934	934	934	934	934
R^2	0.868	0.809	0.868	0.869	0.869	0.869
Number of markets	18	18	18	18	18	18
Time dummies	Yes	Yes	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes	Yes	Yes
Wald test for nested models				(4) vs (2)		(6) vs (4)
Joint significance, p-value				0.5195		0.7468

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 13: RD estimates

Dependent variable	Coefficient	Std.Err.	Bandwith (months)	Obs.
Number of generics	0.755***	0.163	22.450	988
Brand-name market shares	-0.305***	0.033	17.5	988

Table 14: Estimated effects of reference pricing on prices (logged). Fixed effect models

	(1) Brand	(2) Brand	(3) Brand	(4) Generics	(5) Generics	(6) Generics
Reference Pricing	-0.323***	-0.307***		-0.427***	-0.423***	
	(0.065)	(0.072)		(0.074)	(0.074)	
Reference Pricing, 7 month lagged			-0.235***			-0.328***
			(0.075)			(0.083)
Number of therapeutic substitutes	0.019	0.017	0.015	0.054*	0.052	0.053
	(0.032)	(0.034)	(0.037)	(0.031)	(0.032)	(0.035)
Number of generics		-0.014	-0.020		-0.007	-0.013
		(0.018)	(0.022)		(0.014)	(0.016)
Constant	1.707***	1.761***	1.788***	1.278***	1.312***	1.318***
	(0.267)	(0.291)	(0.325)	(0.273)	(0.293)	(0.322)
Time dummies	Yes	Yes	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36	36	36
Observations	4,369	4,369	4,369	3,845	3,845	3,845
R^2	0.518	0.521	0.480	0.556	0.556	0.492

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 15: Estimated effects of reference pricing on average prices (logged). Fixed effect models

	(1)	(2)
Reference Pricing	-0.499***	
	(0.069)	
Reference Pricing, 7 month lagged		-0.414***
		(0.073)
Number of therapeutic substitutes	0.023	0.022
	(0.026)	(0.031)
Number of generics	-0.036**	-0.044*
	(0.017)	(0.022)
Constant	1.703***	1.723***
	(0.227)	(0.276)
Time dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of markets	36	36
Observations	4,571	4,571
R^2	0.700	0.638

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 16: Estimated effects of reference pricing on expenditures (logged). Fixed effect models

	(1)	(2)	(3)	(4)
Reference Pricing	-0.240*		-0.240*	
	(0.136)		(0.136)	
Reference Pricing, 7 month lagged		-0.175		-0.175
		(0.122)		(0.122)
Number of therapeutic substitutes	0.012	0.011	0.012	0.011
	(0.065)	(0.066)	(0.065)	(0.066)
Number of generics	-0.001	-0.007	-0.001	-0.007
	(0.034)	(0.035)	(0.034)	(0.035)
Constant	14.15***	14.18***	14.15***	14.18***
	(0.564)	(0.578)	(0.577)	(0.593)
Number markets	36	36	36	36
Time dummies	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes
Month dummies	No	No	Yes	Yes
Observations	4,571	4,571	4,571	4,571
R^2	0.325	0.318	0.325	0.318

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Figure 1: Average number of generics. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

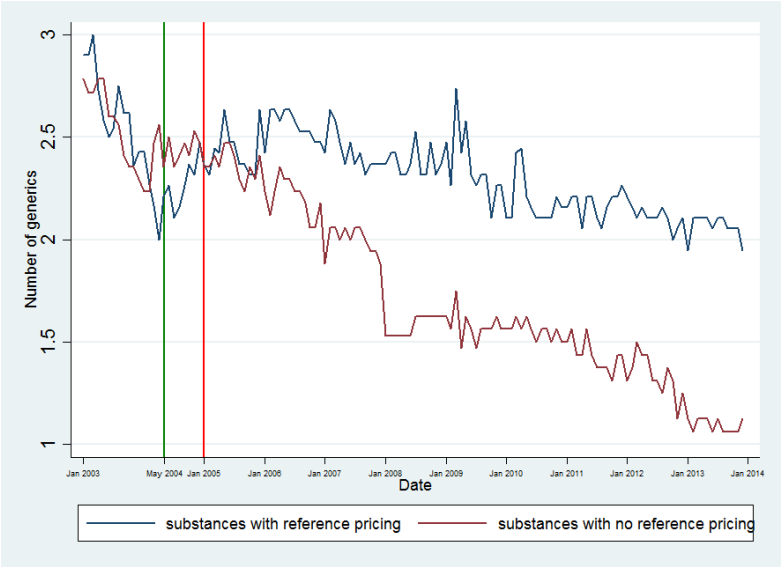

Figure 2: Average market shares of the brand-name drug. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

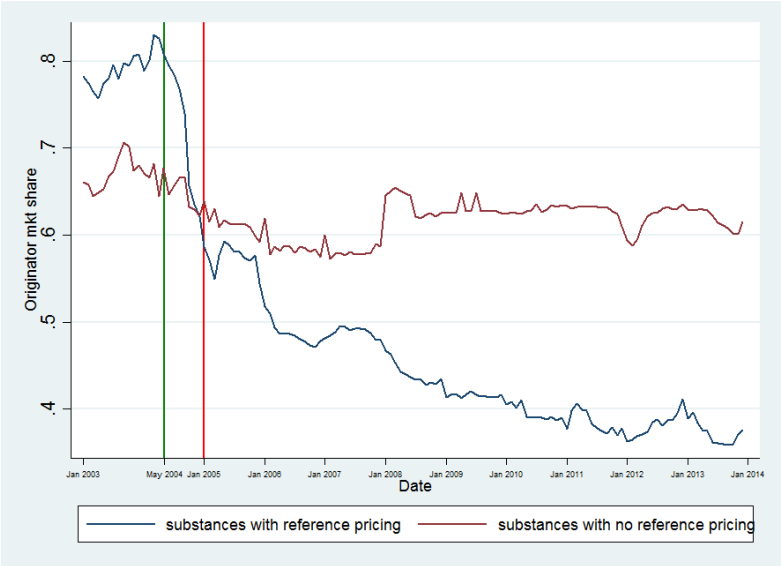

Figure 3: Average number of generics. Pre-reform development for substances subject to reference pricing (RP) and not subject to reference pricing (CR)

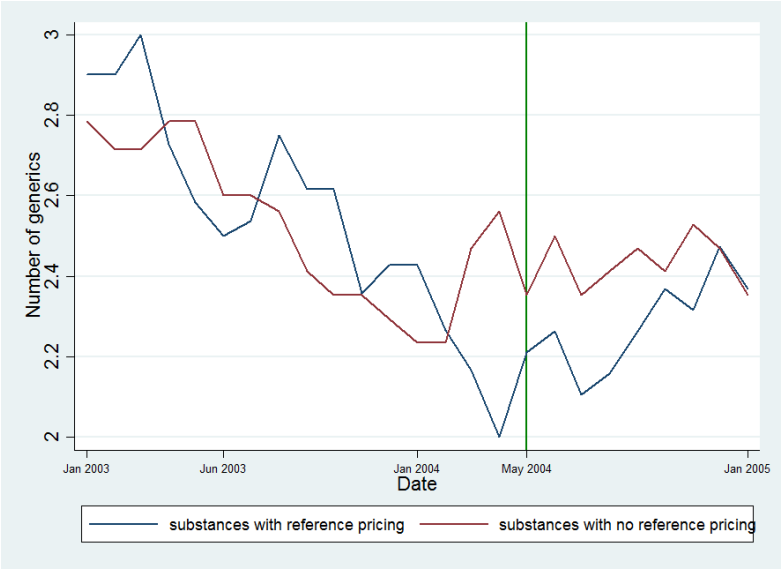

Figure 4: Average market shares of the brand-name drug. Pre-reform development for substances subject to reference pricing (RP) and not subject to reference pricing (CR)

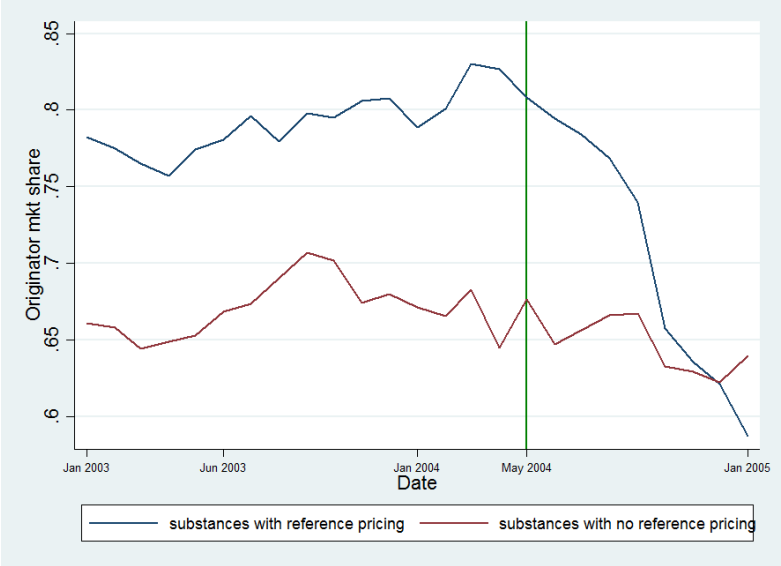

Figure 5: Distribution of the lag between first entry and RP. Molecules with entry registered after Jan. 2013.

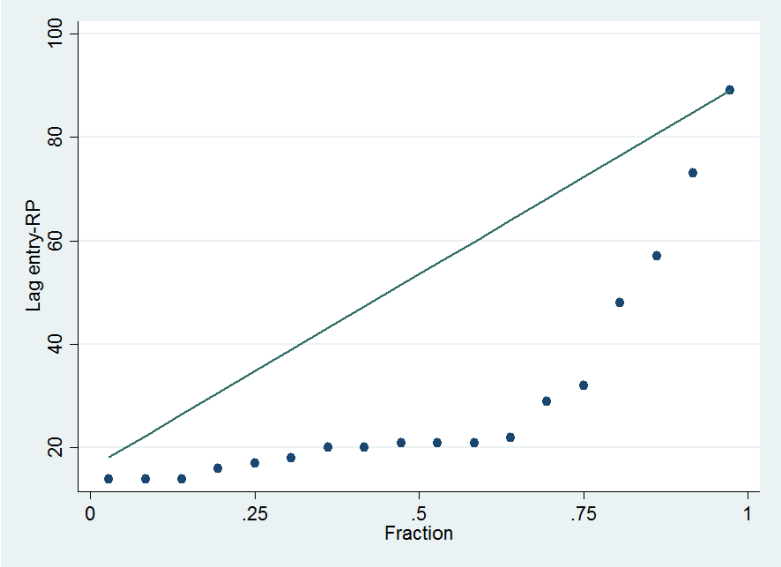

Figure 6: Average number of generics, treated molecules with generic entry at least one year before RP and entry after January 2003.

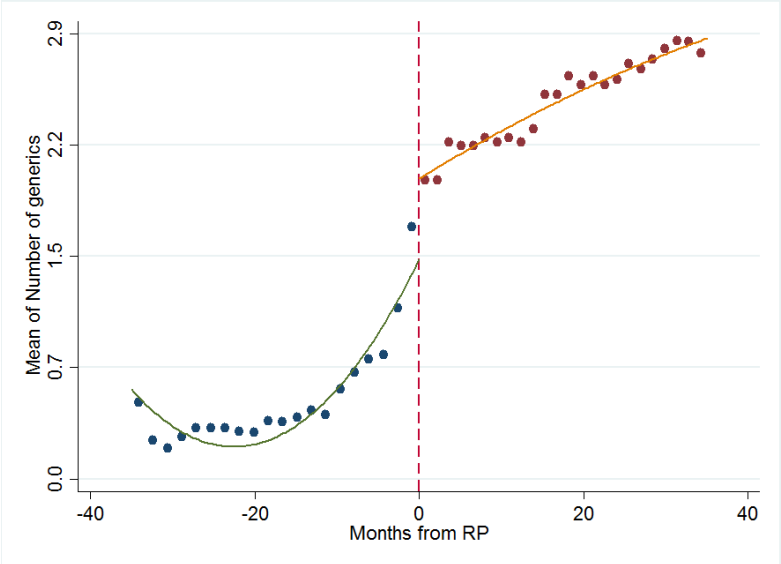

Figure 7: Average Brand-name market shares, treated molecules with generic entry at least one year before RP and entry after January 2003.

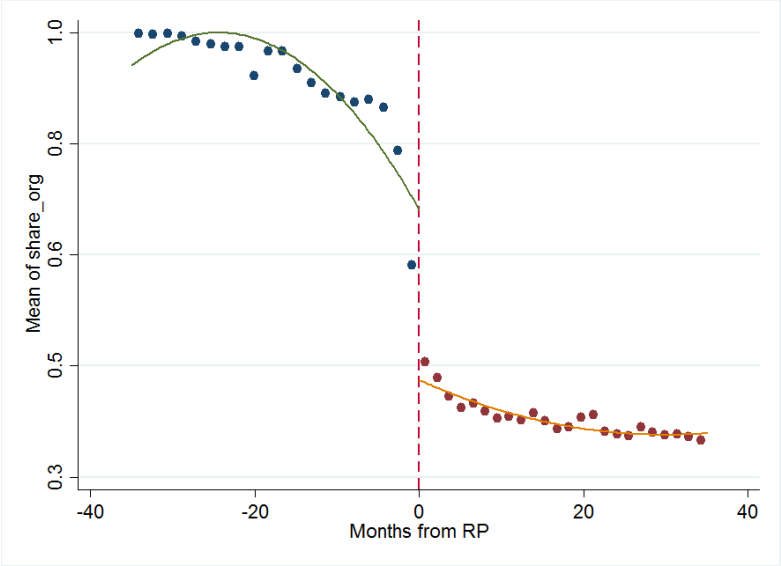

Table A1: Sample characteristics: number of generics

			N. of Generics		**Brand Mkt Shares**		
ATC-code	Molecule Name	Reference Pricing	Mean	Standard Deviation	Mean	Standard Deviation	N. of Obs.
A02BA02	Ranitidine	Yes	2.947	1.923	0.428	0.065	132
A02BA03	Famotidine	No	1.333	0.473	0.559	0.332	132
A03FA01	Metoclopramide	No	1.118	0.587	0.513	0.354	68
C03CA01	Furosemide	No	2.902	1.097	0.928	0.014	132
C03EA01	Hydrochorothiazide	No	0.457	0.546	0.994	0.010	127
C07AB02	Metoprolol	Yes	1.094	0.342	0.676	0.284	128
C07AB03	Atenolol	Yes	3.909	2.540	0.354	0.078	132
C08CA02	Felodipine	Yes	3.024	1.236	0.389	0.232	126
C08CA05	Nifedipine	No	0.083	0.277	1.000	0.002	132
C08DA01	Verapamil	No	0.115	0.320	1.000	0.000	131
C09AA05	Ramipril	Yes	2.444	0.875	0.496	0.195	117
C09BA02	Enalapril & diur.	Yes	1.826	0.715	0.447	0.109	132
C09BA03	Lisinopril & diur.	Yes	2.138	1.368	0.350	0.254	130
C09CA03	Valsartan	Yes	0.692	0.868	0.795	0.286	120
C10AA02	Lovastatin	No	1.218	0.414	0.181	0.240	124
J01CE02	Phenoxymethylpenicillin	No	1.977	0.150	0.095	0.066	132
J01FA09	Clarithromycin	Yes	1.582	0.641	0.577	0.149	122
J01MA02	Ciprofloxacin	Yes	3.250	1.333	0.351	0.326	132
J02AC01	Fluconazole	Yes	2.009	0.771	0.312	0.192	117
L02BA01	Tamoxifen	No	0.588	0.711	0.992	0.026	131
M01AB05	Diclofenac	Yes	3.083	0.277	0.601	0.130	132
M01AC01	Piroxicam	No	3.886	1.288	0.004	0.005	132
M01AE02	Naproxen	No	5.212	1.483	0.052	0.064	132
M05BA04	Alendronic acid	Yes	2.932	1.871	0.356	0.306	118
N02AX02	Tramadol	No	4.583	1.146	0.355	0.050	132
N05AH02	Clozapine	Yes	1.811	0.554	0.180	0.210	132
N05AH03	Olanzapine	Yes	1.585	1.469	0.638	0.312	118
N05BA12	Alprazolam	No	0.200	0.402	0.995	0.014	125
N05CD02	Nitrazepam	No	1.008	0.087	0.359	0.235	132
N05CF01	Zopiclone	Yes	2.629	0.976	0.576	0.108	132
N05CF02	Zolpidem	No	1.288	0.648	0.619	0.069	132
N06AB03	Fluoxetine	Yes	3.144	0.743	0.340	0.182	132
N06AB05	Paroxetine	Yes	2.938	1.102	0.476	0.232	129
N06AX03	Mianserin	Yes	0.697	0.461	0.930	0.118	132
R03AC02	Salbutamol	No	3.886	0.519	0.931	0.006	132
R03AC13	Formoterol	No	0.788	0.410	0.995	0.003	132

Figure A1: Average prices. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

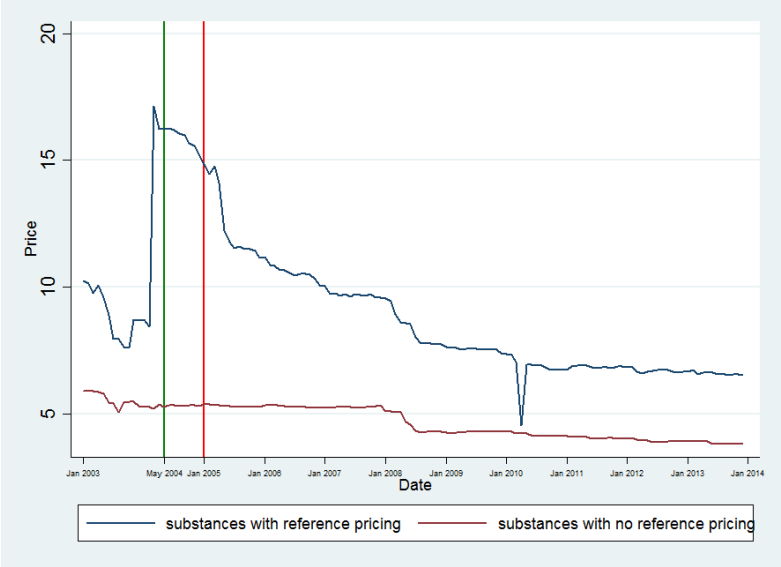

Figure A2: Average prices. Substances subject to reference pricing (RP) and not subject to reference pricing (CR) with generic competition prior to January 2003

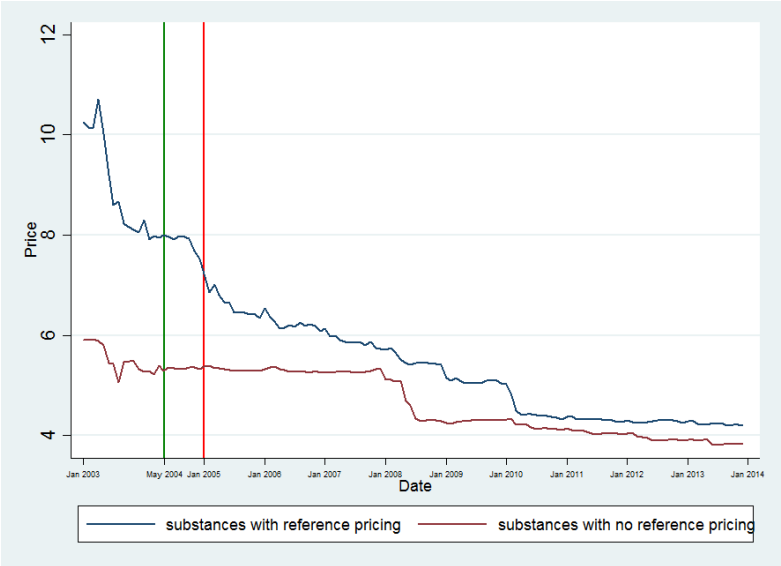

Figure A3: Average revenues. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

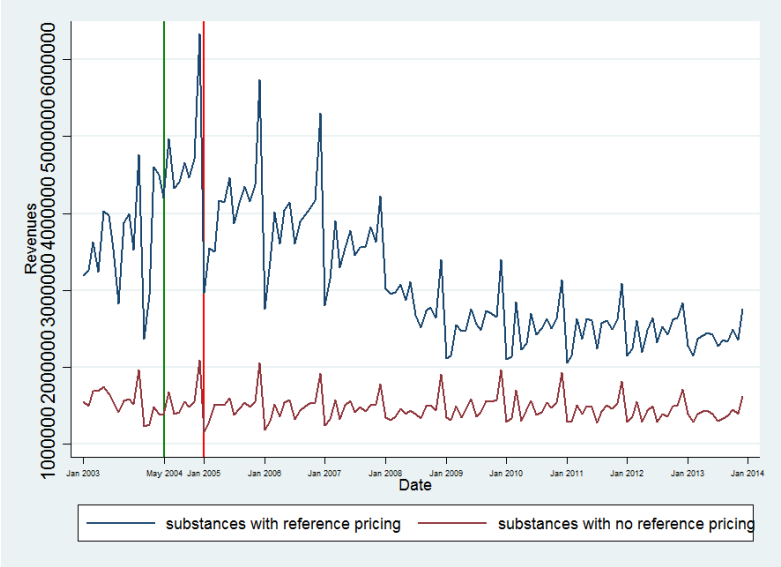

Figure A4: Average volumes, in DDD. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

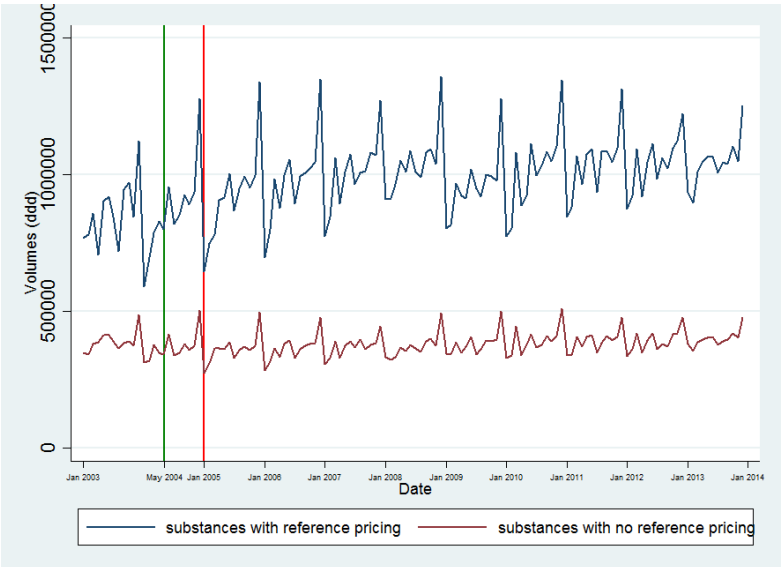

Figure A5: Average number of generics. All tablets (87 markets), conditional on generic competition