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Abstract

Policy makers use reference pricing to curb pharmaceutical expenditures by reducing coverage of expensive branded drugs. In a theoretical analysis we show that the net effect of reference pricing is generally ambiguous when accounting for entry by generic producers. Reference pricing shifts demand towards generics but also induces the branded producer to become more agressive, which triggers price competition and potentially deters entry by generic producers. To investigate the counter- vailing effects, we exploit a policy reform in Norway with a gradual implementation of reference pricing across substances over time. Using a difference-in-differences approach, we find that treated substances have a sharper decline in both branded and generic drug prices and branded market shares. Despite fiercer price competition, the number of generic producers and products increases after exposure to reference pricing, resulting in a reduction of 30 percent in pharmaceutical expenditures. Thus, we find no evidence for a countervailing entry deterring effect of reference pricing.

JEL-Codes: I110, I180, L130, L650.

Keywords: pharmaceuticals, reference pricing, generic competition.

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1 Introduction

Reference pricing (sometimes called internal referencing) is a widely used scheme by insurers and governments to curb expenditures in pharmaceutical markets world wide. Indeed, most European countries has a reference pricing scheme in place.[1] This scheme is mostly used in the off-patent market segment where branded drugs face competition from generic versions.[2] In the US, reference pricing is also well-established for reimbursement of multi-source compounds both by the Medicaid and most managed care programs.[3]

The core idea of reference pricing is to induce cost savings by reducing coverage of expensive branded drugs. Under reference pricing, the insurer defines a maximum price for reimbursement (i.e., a reference price) of a given drug therapy, implying that patients demanding higher-priced branded drugs would have to pay the full price difference out-of-pocket. This surcharge on branded drugs usually comes in addition to the standard copayments on drug consumption. By reducing the coverage of expensive branded drugs, the insurer simply shifts costs to patients, all else equal. However, the insurer also intends to shift demand towards lower-priced generic versions and in turn stimulate price competition between branded and generic drug producers. Thus, reference pricing is expected to reduce total expenditures borne by both insurers and patients by stimulating price competition.

Indeed, several studies have found that reference pricing stimulates price competition and shifts market shares from branded to generic drugs.[4] However, less attention has been devoted to more long-term dynamic effects related to how reference pricing affects the entry decision by the generic drug producers. If reference pricing induces fiercer price competition, this implies lower profit margins for both branded and generic producers and thus, all else equal, lower incentives for entry for the generic producers. In fact, a few studies have reported that reference pricing appears to reduce entry by generic drug producers, though the evidence is sparse and mainly based on correlations rather than causal effects.[5] Our paper contributes to the existing literature in two ways. First, we

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

[2] In Germany and the Netherlands reference pricing 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).

[3] See, for instance, Kelton et al. (2014) or Danzon and Ketcham (2004) for a description. Proposals have also been made for introducing reference pricing in the Medicare program. Some health plans, e.g., the California Public Employees Retirement System, use reference pricing also for reimbursement of health services.

[4] See, for instance, Pavcnik (2002), Brekke et al. (2009, 2011), and Kaiser et al. (2014).

[5] See, for instance, Ekelund (2001), Rudholm (2001), and Moreno-Torres (2009).

bridge the two strands of the literature by looking both at the static (price and demand) effects and the dynamic (entry) effects. Second, we adopt an empirical strategy exploiting a policy reform that allows for causal analysis of the effects of reference pricing.

In a theoretical analysis, we show that reference pricing has ambiguous effects on entry incentives for generic drug producers. On one hand, the surcharge on expensive branded drugs implies a positive demand shift towards generics, which all else equal stimulates entry. On the other hand, reference pricing makes the branded drug producer more price aggressive, which may force the generic producers to reduce prices despite the positive demand effect.[6] Indeed, this is what is typically found by empirical studies.[7] In this case, reference pricing can be less effective and potentially counterproductive in reducing expenditures.[8]

To investigate the potential countervailing effects of reference pricing, we exploit a policy reform in Norway that introduced reference pricing in the off-patent market segment. For administrative reasons, reference pricing was gradually implemented across substances over time.[9] This allows us to use a difference-in-differences (DiD) research design to make causal inference on the impact of reference pricing.

Having detailed product-level data covering all sales of prescription drugs through pharmacies in Norway from 2003 to 2013, we find that treated substances experience a sharper decline in both branded and generic drug prices and a sharper reduction in market shares of branded drugs than untreated substances. Despite depressed profit margins, we find that profits to generic producers increase after exposure to reference pricing, suggesting that the demand effect dominates, whereas profits to branded producers drop significantly. Consistent with this result, we find that treated markets experience a sharper increase in the number of generic producers and products than untreated markets. In fact, the number of generic producers and products more than doubles after the exposure to reference pricing. Consequently, reference pricing results in a significant (more than 30 percent) reduction in pharmaceutical expenditures. Thus, we find no support for a possible countervailing entry deterring effect of the reference pricing scheme introduced in Norway. On the contrary, we find that generic entry is reinforced by the introduction of reference pricing.

These results are robust to alternative empirical specifications. First, we estimate the

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

[7] See for instance Pavcnik (2002), Brekke et al. (2009, 2011), and Kaiser et al. (2014).

[8] 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.

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

effects using only the treated substances, but exploiting the staggered implementation of reference pricing across substances over time. The results are almost identical to the main analysis with a comparison group. Second, we include only substances with generic entry prior to the policy reform in 2005 to account for possible anticipation effects for substances that experience generic entry later. With this alternative sample, we estimate a DiD model using the set of substances that were introduced in the first year after the reform. The effects of reference pricing are highly robust also to this alternative specification.

There is an extensive empirical literature studying entry by generic producers and the dynamics of competition in pharmaceutical markets.[10] However, very few papers focus on the impact of reference pricing on the entry incentives of generic producers. Notable exceptions, though, are Ekelund (2001), Rudholm (2001), and Moreno-Torres et al. (2009).[11] Ekelund (2001) and Rudholm (2001) study the introduction of reference pricing in Sweden. While Ekelund (2001) reports a (weak) negative effect of reference pricing on generic entry, Rudholm (2001) finds no significant effects.[12] Using data from Spain, Moreno-Torres et al. (2009) find a weak negative effect of reference pricing on the number of generic producers. Thus, there appears to be some evidence suggesting an adverse effect of reference pricing on generic competition, but the evidence is sparse, mixed and based on associations derived from before-after estimations rather than causal analysis.

On the contrary, the literature on the more short-term and static effects of reference pricing on prices and demand is quite large.[13] Empirical studies tend to find that reference pricing triggers price competition and results in lower prices of both branded and generic drugs (see e.g., Pavcnik, 2002, Brekke et al., 2009, 2011, Kaiser et al., 2014). There are also a few studies focusing on the effects on the allocation of market shares. While Aronsson et al. (2001) report mixed results based on the introduction of reference pricing in Sweden, Brekke et al. (2011) and Kaiser et al. (2014) report a drop in branded drug market shares based on Norwegian and Danish data, respectively.[14]

[10] The vast majority of studies are on the US market, e.g., Grabowski and Vernon (1992), Frank and Salkever (1997), Scott Morton (1999, 2000), Reiffen and Ward (2005), and Ching (2010a, 2010b). Two non-US studies are Rudholm (2001) and Iizuka (2009) on the Swedish and Japanese markets, respectively.

[11] There is also a cross-country study by Danzon and Ketcham (2004) on the effects of reference pricing schemes on generic competition using cross-sectional data.

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

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

[14] Brekke et al. (2009, 2011) study a different reference pricing policy in Norway than the current paper. They study a pilot reform called 'Index pricing', where only six substances were included, and the reference prices were based on the prices of generic drugs.

The remainder of the paper is structured as follows. In Section 2 we describe the institutional framework of the Norwegian pharmaceutical market, including the policy reform introducing reference pricing. In Section 3 we present a theoretical framework to illustrate the key mechanisms which determine the relationship between reference pricing and generic entry. In Section 4 we describe our empirical strategy using a DiD research design that exploits the gradual implementation of reference pricing across substances over time. In Section 5 we present our data, samples and descriptive statistics. In Section 6 we report our main results regarding the effects of reference pricing on generic competition. In Section 6 we present robustness checks. Section 7 concludes the paper.

2 Institutional background and policy reform

Norway has a mandatory and universal National Health Insurance scheme, financed mainly through general taxation, that covers a large share of the total pharmaceutical expenditures. The pharmaceutical market can be sliced into three different segments depending on sales channel and insurance coverage, which are hospital drugs (100 percent coverage), prescription drugs (partial coverage), and over-the-counter drugs (zero coverage).

The prescription drug segment is clearly the largest one with around 70 percent of the total drug expenditures. The coverage by the national insurance scheme for prescription drugs is around 50 percent.[15] Prescription drugs are sold exclusively through pharmacies and are either reimbursable or not. Drug therapies for short-term, acute conditions (e.g., pain killers, antibiotics) are usually not on the reimbursement list, implying that patients have to pay the full price out of pocket.

In this paper we focus on prescription drugs that are eligible for reimbursement from the insurance scheme. The expenses related to consumption of reimbursable prescription drugs amount for more than 30 percent of the total pharmaceutical expenditures in Norway. The demand-side cost sharing for prescription drugs on the reimbursement list is designed as follows.[16] When purchasing the drug at the pharmacy, patients have to pay out-of-pocket a fixed share of the price of drug, which was 38 percent during the period we study. However, this copayment is constrained by two types of expenditure caps. There is an expenditure cap per script (NOK 520 or €/$ 52) and an expenditure cap per year (NOK 2105 or €/$ 210). Expenditures exceeding these caps are covered

[15] See for instance chapter 9 in the OECD Health at a Glance 2022 report. The EU average of government coverage is around 55 percent.

[16] For details, see the webpages of the Norwegian Medicine Agency; https://legemiddelverket.no/English

100 percent by the insurance scheme, which implies that the *de facto* copayment is lower than 38 percent of the drug price and closer to 10 percent on average.

In 2005 the Norwegian government implemented a policy reform that introduced reference pricing for prescriptions drugs on the reimbursement list, though restricting the scheme to off-patent drugs facing competition from generic drug producers.[17] The aim of the reform was to facilitate cost savings on public budgets by increasing demand-side cost sharing (reducing coverage) and stimulating price competition among brand-name and generic drug producers. The reference pricing scheme is called 'Step Pricing' ('Trinnpris' in Norwegian), which refers to the gradual step-wise reduction in the reference price over time. For a given substance (or more precisely substitution group), the Norwegian Medicine Agency sets the reference price as a fixed percentage discount of the price of the brand-name drug prior to patent expiration and entry by generic drug versions. This percentage discount is then reduced in steps over time, implying a gradually lower reference price for the drug therapy.[18] Thus, this is a so-called *exogenous* reference pricing scheme, where the reference prices are set by the regulator and not endogenously determined by the prices of the generic drug versions entering the market.[19]

The reference price defines the maximum reimbursement that the insurance scheme is offering for a given drug therapy. Patients who purchase a drug that is priced higher than the reference price, which tends to be the brand-name drug version, have to pay out-of-pocket the difference between the actual price of the demanded (brand-name) drug and the reference price, implying zero coverage above the reference price. This surcharge comes in addition to the standard copayment of 38 percent of the drug price. To illustrate, if the reference price is NOK 50 and the brand-name drug is priced NOK 100, the patient has to pay NOK 88 if demanding the brand-name drug and NOK 19 if demanding the generic drug version (assuming this is priced at the reference price). It is important to stress that the above-mentioned expenditure caps per script (NOK 520) and per year (NOK 2105) do not apply to the surcharge related to the reference price. Thus, a patient that has reached the annual cap still has to pay the full price difference between the price of the higher priced (brand-name) drug and the reference price (i.e.,

[17] For details, see the webpage of the Norwegian Medicine Agency; www.legemiddelverket.no

[18] The step price reductions (percentage discounts) have changed over time. During the period we study, the discount was a 35 percent reduction of the price of the brand-name drug for the six first months after generic entry. Then the discount was increased to 60 or 80 percent depending on the sales value of the drug therapy, and eventually to a maximum of 90 percent after 18 months. Today the initial discount is higher. See the webpage of the Norwegian Medicine Agency www.legemiddelverket.no.

[19] See Brekke et al. (2007, 2016) for a discussion of exogenous and endogenous reference pricing schemes. See also Danzon and Ketcham (2004) for wider reference pricing schemes, including therapeutic substitutes.

NOK 50 in the above example) out of pocket.

We should also mention that the pharmacies are obliged by law to have at least one (generic) drug version priced at (or below) the reference price available in the store. They are also obliged to inform patients that enter the pharmacy with a prescription of a higher priced (brand-name) drug version about the cheaper (generic) alternative and the additional surcharge if refusing to substitute to the cheaper (generic) alternative. Physicians are not required to make generic prescriptions and tend to write the brand-name drug on their prescriptions. Physicians can also block generic substitution at the pharmacy by providing a medical reason for this. This practice, which potentially may weaken the effectiveness of the reference pricing scheme, is closely monitored by the health authorities.

The policy reform introducing reference pricing was announced by the government in May 2004, approved by the Parliament in October 2004, and effective from 1st of January 2005. However, the implementation of the new scheme was gradual and applied only to a subsample of the off-patent substances initially. In the first round in January 2005 only 20 substances were included in the reference pricing scheme.[20] The staggered implementation was due to practical reasons and the administrative workload related to computing and implementing reference prices.[21] It was also argued that it was favourable with a gradual roll-out to gain some experience before extending the scheme to more substances. The scheme has been gradually extended over time and includes now more than 100 substances.

Finally, Norway has, as most other European markets, also direct price control regulations. In particular, prescription drugs are subject to price cap regulation. The scheme is based on international reference pricing (external referencing) using a basket of nine Western European countries, where the price cap is set equal to the average of the three lowest prices in the reference countries.[22] The price cap regulation applies to all prescription drugs irrespective of their patent status or whether they are on the reimbursement list or not. Notably, the price caps are set at the substance (or more precisely substitution group) level and are binding usually only for the brand-name drugs if generic competition is in place. Thus, the brand-name drug producers can always lower their prices in response to intensified competition from generic drugs, but there is no

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

[21] 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/

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

scope for raising prices.

3 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 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.

3.1 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:[23]

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

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

Defining $\varepsilon_j := -\left(\partial D_j/\partial c_j\right)\left(c_j/D_j\right)$ 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 $c_b = c_g$.[24]

3.2 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 $p_{gi} < r < p_b$, copayments for the brand-name and the generic drug are given by $c_b^R = \alpha r + p_b - r$ and $c_{g_i}^R = \alpha p_{gi}$, respectively.[25] By applying this copayment scheme and maximizing (1)-(2) with respect

[23] 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.

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

[25] 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.

to p_b and p_{gi}, 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.[26]

3.3 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 reduces the copay-elasticity of generic drug demand for given prices, since $c_b^R\left(p_b\right) > c_b^F\left(p_b\right)$ and therefore $D_g^R\left(p_b, p_g\right) > D_g^F\left(p_b, p_g\right)$, which gives generic producers an incentive to increases prices. On the other hand, the negative price response to RP

[26] 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.

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 $c_g^R\left(p_g\right) = c_g^F\left(p_g\right)$, 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 $c_b^R\left(p_b^R\right) < (>)\, c_b^F\left(p_b^F\right)$.[27] 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

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

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

[27] 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 $\partial^2 D_g/\partial c_b \partial c_g \geq 0$.

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.

3.4 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.[28]

4 Empirical strategy

The empirical analysis aims at estimating the causal effects of reference pricing on the intensity of generic competition and the corresponding effects on market outcomes (prices, market shares, profits) and welfare (expenditures). To do so, we exploit a policy reform that introduced reference pricing for off-patent substances facing generic competition in Norway in 2005. While this reference pricing scheme called *Trinnpris* ('Step pricing') was effective by January 2005, the implementation by the regulator (Norwegian Medicine Agency) was gradual and partial in the sense that substances were included sequentially over time and some substances were never included during this period despite having generic drug sales. The main reason for the gradual implementation is the administra-

[28] In Brekke et al. (2016) 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 reference pricing to stimulate generic entry.

tive workload for the regulator related to defining the reference groups, computing the reference prices, and implementing the scheme for the transactions at pharmacy level, as explained above.

The gradual roll-out of the policy reform enables us to identify the effects of reference pricing by using a difference-in-differences research design with staggered treatment timing. Thus, our empirical strategy relies on a comparison of the development in generic competition and market outcomes for substances exposed to reference pricing (treatment group) with the development for similar substances not exposed to reference pricing (comparison group) over the period we study. Because of the panel structure of the data, we can compare the inter-temporal variation in generic competition before and after the imposition of the reform in each market. The identification does not only rely on a before and after comparison, but also on a comparison of variations in generic competition for markets subject to reference pricing with variation in generic competition for markets not subject to this reform. Notably, in Section 8, we do several robustness checks, including estimations using only the treated substances with identification relying on the staggered implementation. We also do a more standard DiD analysis on substances with generic competition prior to the policy reform, splitting the sample in the treated and untreated substances, to account for possible anticipation effects.

To identify the effects of reference pricing, we estimate the following DiD regression model:

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

where i denotes the market (substance) and t the month of observation starting in January 2003. Y_{it} is the dependent variable, which is either the intensity of generic competition (measured by the number of generic producers, the number of generic products, or the market share of the branded and generic drug producers), market outcomes (measured by the prices of branded and generic drugs, gross profits of the branded and generic drug producers), or welfare (measured by the total drug expenditures for the insurer and the patients).[29] D_{it} is a post-reform (treatment) dummy taking the value 1 for all periods after market i was exposed to reference pricing, and zero otherwise. The gradual roll-out of the reference pricing scheme implies that the post-reform dummy takes the value 1 at different dates across the treated markets (substances). Thus, ρ is our key (DiD) coefficient of interest that captures the impact of reference pricing on competition from generic drug producers and in turn market outcomes and pharmaceutical

[29] Since generic drug versions are considered to be therapeutically equivalent to the branded drug versions, there should be no health loss to patients consuming the generic versions. Thus, changes in total drug expenditures can be considered to be a proxy for welfare effects.

expenditures.

In the regression, we include market (substance) fixed effects (a_i), which capture all time-invariant unobserved (and observed) market-specific heterogeneity, including characteristics of the patient population (e.g., age, gender, chronic, severity), characteristics of the drug therapy (e.g., effectiveness, side-effects, drug administration, technology), characteristics of the prescribing doctor population (e.g., knowledge of drug therapy, information about generic alternatives, professional guidelines), etc. The use of market (substance) fixed effects implies that the effects of reference pricing are estimated using only *within-market* variation over time in our outcome variables, ignoring all sorts of cross-sectional effects.

In addition, the regression includes a vector $\mathbf{X}_{it}$ that contains a set of observed time-varying characteristics. In the baseline model this includes market size (measured by the log of total sales revenues of all products in the therapeutic category) and the intensity of therapeutic competition (measured by the number of therapeutic substitutes at the ATC3 group level). Changes in both market size and the intensity of therapeutic competition may influence the number of generic firms and generic products available in given market i.

Furthermore, to account for the life-cycle of drugs on the market, we include the variable m_{it} which counts the number of months following the first generic entry in market i and is common to all molecules that have experienced generic competition for the same number of periods. Conversely, δ_t is a month-specific effect common to all molecules that captures possible time trends that may influence the intensity of generic competition over time. Finally, ε_{it} is a standard error term.

5 Data and descriptive statistics

To analyse the effects of reference pricing, we have assembled a rich dataset with detailed sales information at product level for a wide range of off-patent prescription drugs with generic competition over an eleven year period from 2003 to 2013.[30] The data source is the Farmapro database of the Norwegian Pharmacy Association, which contains information of all drug purchases across all pharmacies in Norway.[31] From this database, we retrieve monthly information about sales revenues (in Norwegian Crowns) and sales volumes (measured in defined daily doses (DDDs) or the number of packs). The sales

[30] Ideally, we would have liked to have data on a a longer pre-period before the policy reform in 2005, but 2003 is the first year with complete sales data in the Farmapro database.

[31] For more details, see the website of the Norwegian Pharmacy Association; www.apotek.no.

data contain also detailed information about both the product (substance, ATC code, product name, pack size, dosage strength, formula, etc.) and the producer (company name, identity number, etc.). We complement the sales data with regulatory information from the Norwegian Medicine Agency about substances subject to reference pricing, the inclusion date, and the reference prices.[32]

5.1 Sample

Our initial dataset from Farmapro contains the top 222 most selling substances in terms of sales value. Since a large share of these substances are under patent protection, we include only the substances with positive generic sales during the period 2003-2013 and exclude all observations prior to the first generic entry. For each substance, we include all products using the same active ingredient, identified by a unique (5 digit) ATC code. In the main analysis, we include only substances that experience the first generic entry during the period 2003-2013, and thus exclude drugs with generic entry prior to January 2003. This allows us to control for the life-cycle of the drug and to ensure that the drugs in the treatment and comparison groups are fairly similar along this dimension. However, in a robustness check in Section 8, we restrict attention to substances with generic entry prior to the policy reform in 2005, including also drugs with the first generic entry prior to January 2003.

Furthermore, we drop seven substances that were subject to a policy experiment with a different RP scheme from 2003 to 2005.[33] We also exclude all substances that were subject to reference pricing within one year after the first generic entry. This implies that, over at least one year, substances subsequently subject to reference pricing are exposed to the same regulatory framework as the ones that are never subject to reference pricing. We are left with an unbalanced panel of 35 substances for a total of 2,671 month-substance observations over the period 2003-2013. Of the 35 substances in our sample, 11 were subject to reference pricing at least one year after generic entry. This group will be our treatment group. Conversely, 24 substances experiencing generic competition during the period were never subject to reference pricing, and they will constitute our comparison group.

[32] See the Norwegian Medicine Agency's webpage https://legemiddelverket.no/English.

[33] 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).

5.2 Dependent variables

In the analysis, we define each substance as a market. Using the information about actual sales of generic drugs in the data, we identify the date of entry (or exit) of generic drug producers in a given market. The data allow us also to measure the intensity of generic competition, as we observe the number of generic producers and the number of generic products (variants) with positive sales at each date during the period. Based on the sales volumes, we can compute the market share of the brand-name drug producer (or inversely the generic drug producers) for each substance.

Furthermore, by dividing sales revenues (in NOK) by sales volumes (in DDDs), we obtain a monthly (volume-weighted) average price per DDD. We compute this at substance level and for branded and generic drugs separately. The data allow us also to measure the gross profits of the drug producers, which are proxied by the brand-name and generic producers sales revenues at substance level. Assuming production costs are constant over time, changes in sales revenues are likely to reflect changes in the profits of the brand-name and generic drug producers at substance level.

Finally, we compute the total drug expenditures per substance as the sum of the sales values of all products with the same 5 digit ATC code. Given that branded and generic drug versions are therapeutically equivalent, there should be limited or even zero health gains from consuming a branded version instead of a generic version. Thus, changes in total drug expenditures can be considered as a proxy for the welfare effects of a policy reform like reference pricing. We understand that this measure ignores the subjective preferences of individuals for branded drug versions, but policy makers focus primarily on reducing drug expenditures in the off-patent segment, as reflected by a set of policies ranging from simplified approval procedures for generics, requirements for generic substitution, and incentive schemes like reference pricing, which we study in this paper.

5.3 Descriptive statistics

In Table 1 we report the summary statistics for the full sample and split by treated and untreated markets for the period 2003 to 2013.[34] The average number of generic firms and products are 1.8 and 9 per substance, respectively, for the 35 substances. The mean market share of branded producers are 63 percent and the average price per substance

[34] See Table A in the Appendix for a list of all substances in the treated and untreated markets, including summary statistics for the number of generic producers and brand-name market shares for each substance.

is NOK 34 (€/$ 3.4) with the branded drug prices being slightly (8 percent) higher than the generic drug prices on average.[35] The monthly sales revenues are NOK 2.7 (€/$ 0.27) million per substance on average, with the branded drug producers having a substantially larger share than the generic drug producers. Finally, each substance in the sample has on average 9.5 substitutes in therapeutically related markets (same ATC-3 level code).

When splitting the sample in treated and untreated markets, the summary statistics show a few differences across the two groups. Considering generic competition, we see that the average number of generic firms and products per substance are more than twice as high for the 11 substances exposed to reference pricing than for the 24 substances never exposed to reference pricing. Furthermore, the market share of branded drug producers is 48 percent for the treated substances and 72 percent for the untreated substances. However, in Table B in the Appendix, which reports the summary statistics for the treated and untreated markets restricted to the first year after generic entry (and before exposure to reference pricing), we observe that the sample means of these measures of generic competition are almost identical across the two groups.

[Table 1 here]

Table 1 shows that average prices (either at substance level or split by branded and generic drugs) are slightly lower for the treated markets. While the average number of therapeutic substitutes are almost identical across the two groups, we observe some differences in terms of sales revenues and volumes. In particular, the average sales volumes per substance appears to be substantially higher for the treated markets, which may indicate a potential selection issue across the two groups. Table B in the Appendix shows that these differences are somewhat smaller when restricting observations to only one year after generic entry for both the treated and untreated substances.

To account for a potential selection issue, we estimate the effect using only the treated substances in a robustness check in Section 8. However, the validity of the DiD analysis does not depend on the exposure to reference pricing being random across substances. The key identifying assumption for the DiD regression is the parallel trend assumption, i.e., that the trends in the outcomes are similar for the treated and untreated substances prior to the exposure to reference pricing.

[Figure 1 to 3 here]

[35] Note, though, that the generic producers may not necessarily enter the market with the full range of product variants (pack sizes, dosages, etc). Thus, the average prices at substance level may conceal the price differences at product level, especially if generics enter the high-price product variants.

As a first check of the parallel trend assumption, we plot in Figure 1 to 3 the development of our key outcomes on generic competition from the first month of generic entry split by treated (blue line) and untreated (red line) substances.[36] We see that the trends in the number of generic firms (Figure 1) and the number of generic products (Figure 2) are fairly similar prior to inclusion in reference pricing, but depart substantially after the inclusion in the reference pricing scheme. The same pattern is present for the market shares of brand-name drugs in the treated and untreated markets (Figure 3).

5.4 Parallel trend test

For our DiD approach to be valid, the untreated markets need to be comparable to the treated markets in the sense that they capture the counterfactual development in absence of the reference pricing policy. While differences in unobservable (and observable) characteristics that are constant over time can be controlled for by fixed effects, systematic differences in trends in the pre-treatment period are more problematic. In other words, for our DiD coefficient (ρ) in equation (10) to estimate causal effects, the trend in the outcomes prior to the exposure to reference pricing should be similar for the treated and untreated substances.

We cannot implement the usual pre-reform test, due to the fact that reference pricing is introduced at different points in time to the substances in the treatment group. However, we run the parallel trend test on the first year after the first generic entry for the treated and untreated substances. In this period of time, no drugs in our samples were subject to reference pricing. By focusing on the first year of generic entry for the drugs in the treated and untreated markets, we standardise the trend comparisons to account for the life cycle, as depicted by Figure 1 to 3 above.

To test our assumption of common trends for the drugs in the treated and untreated markets, we run a fixed-effects regression where the dependent variable is either the number of generic firms or the number of generic products. We only consider pre-reform observations (i.e., one year after first generic entry) and we include interactions between monthly dummies and a dummy indicating treated substances. 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 2. All interactions are non-significant, both individually and jointly.

[Table 2 here]

[36] The length of the pre-period for the treated substances is at least one year, but may also be longer, as explained previously. This implies that the timing of the inclusion in the reference pricing scheme is not exactly the same for all the treated substances.

6 Results

In this section we report the results from the estimation of the DiD regression model specified in (10) for the different outcome variables. We start with the impact of reference pricing on generic competition before looking at the effects on prices, profits and expenditures. Recall from Section 3 that the theoretical analysis shows that the effect of reference pricing on generic entry is generally ambiguous. While reference pricing shifts demand towards generic drugs due to a surcharge on expensive branded drugs, it also intensifies price competition by making the branded producers more aggressive. Thus, the effect of reference pricing on competition and market outcomes is an empirical question.

6.1 Competition from generic drugs

In Table 3 we report the effects of reference pricing on generic competition measured by the number of generic firms, the number of generic products, and the market share of branded drugs (relative to generic drugs). We see that the DiD coefficients are highly significant both statistically and economically for all three outcomes. Compared with untreated markets, treated markets experience a sharper increase in the number of generic firms, the number of generic products and market shares of generic drugs. The effects are sizeable and consistent with the developments shown in Figure 1 to 3. After exposure to reference pricing, the number of generic firms increases by 2.1 relative to a sample mean of 1.8 per substance, an increase of 168 percent. The number of generic products increases by 7.9 compared to a sample mean of 9 per substance, an increase of 87 percent. Finally, the market share of branded drugs drops by almost 29 percentage points from a sample mean of 63 percent, which is a 45 percent reduction. Market size (monthly sales revenues) and therapeutic competition has the expected signs, but are not significant in most cases.

[Table 3 here]

6.2 Branded and generic drug prices

In the theoretical analysis in Section 3 we show that the branded drug producers respond to reference pricing by becoming more aggressive in their pricing. This is due to the reduced coverage for drugs priced above the reference price, which makes demand more price elastic and branded drugs relatively more expensive at given prices. The effect on the generic drug prices is however ambiguous in general due to countervailing forces.

While reference pricing shifts demand towards generic drugs for given prices, it also makes the branded drug producers more aggressive. The net effect on equilibrium prices is mitigated or reinforced by the incentives for generic entry. In the previous section, we found that reference pricing stimulated generic competition, which should all else equal induce lower prices. The results from the DiD estimation of the model specified in (**10**) on prices are reported in Table 4.

[Table 4 here]

The results show that prices of both branded and generic drugs experience a sharper reduction in the treated markets than in the untreated markets. After the exposure to reference pricing, branded drug prices decline by 24 percent on average, whereas the generic drug prices decline by almost 57 percent. Notice, though, that in absolute value (NOKs) the decline is more similar due to branded drugs being higher priced than generic drugs. Average prices, which are the sales-weighted average of branded and generic drug prices, decline by more than 50 percent on average in the treated markets relative to the untreated markets. Thus, reference pricing induces fiercer price competition partly through the price response from the branded and generic drug producers and partly through increased generic entry, as shown in the previous section.

The empirical evidence described above allows us to better interpret the evidence on generic entry. Reference pricing leads to lower prices but higher demand for generic drugs. Thus, reference pricing shifts demand from brand-name to generic drugs, even after prices have been adjusted. As pointed out in the theoretical analysis in Section 3, the positive demand effect is a necessary condition for reference pricing to encourage entry from generic producers when prices of generic drugs decline due to intensified competition. If both prices and market shares of generic drugs had dropped, then reference pricing would have limited generic entry. However, since the number of generic firms and products increase despite lower prices and profit margins, this suggests that the positive demand effect dominates the negative price effect on generic drugs.

6.3 Profits to branded and generic drug producers

The net effect on equilibrium profits to branded producers should be negative due to lower prices and market shares. However, the net effect on generic firms' equilibrium profits should be positive as reference pricing induces more generic firms to enter the market. In Table 5 we report the results of the DiD regression on branded and generic firms' profits proxied by the monthly sales revenues (expressed in logarithms) at substance level. If we assume that marginal costs (for a given substance) are fairly constant

over time, then changes in sales revenues will be a good proxy for changes in (gross) profits to the drug producers.

[Table 5 here]

Table 5 shows that the profits of branded drug producers are negatively affected by reference pricing. Indeed, after the exposure to reference pricing, the profits of branded drug producers drop by 74 percent on average across the treated markets. However, the generic drug producers experience an increase in profits of more than 200 percent after being exposed to reference pricing. Notice, though, that the pre-reform profits to the generic producers are much lower than to branded producers, so in absolute value (NOKs) the changes in profits are more similar for the two types of producers. In any case, the increased entry by generic drugs after exposure to reference pricing is not sufficient to offset the net effect on their profits, implying that reference pricing shifts equilibrium profits from branded to generic drug producers, which is due to the shift in market shares (as prices and profit margins drop).

6.4 Pharmaceutical expenditures

The main motivation for policy makers of introducing reference pricing is to curb pharmaceutical expenditures and induce cost savings. The above results indicate that the reference pricing scheme in Norway is effective in doing so by shifting market shares towards generic drugs and stimulating price competition. The worry that entry effects might make reference pricing 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. The only countervailing factor is a possible increase in total demand (sales volumes) as a consequence of the lower prices.

In Table 5 we report the results of the DiD regression on drug expenditures measured by monthly total sales revenues (in logs) per substance. Total sales revenues are simply the sum of expenditures borne by patients and insurer (government in our case) for a given drug therapy. The results show a sharper decline in total sales revenues for the treated markets compared to the untreated markets. After exposure to reference pricing, pharmaceutical expenditures drop by 31 percent. This is a sizeable reduction, but the magnitude is lower than the reduction in average prices (at 50 percent), which is likely due to a demand increase in treated markets. The reduction in drug expenditures

can be interpreted as a welfare improvement if we ignore subjective preferences for branded drugs, as typically done by policy makers and insurers. Generic drug versions are therapeutically equivalent to the branded drugs, and there is limited evidence suggesting any health losses to patients from consuming generic versions in terms of treatment efficiency or possible side effects.

7 Robustness checks

In this section we check the robustness of our empirical findings from the main model along two dimensions. First, we estimate the effects using only the treated markets (substances) exploiting the gradual implementation of reference pricing. The aim is to investigate whether the results are sensitive to the choice of a comparison group. Second, we estimate the effects using only substances with generic competition prior to the policy reform in 2005. The aim is to investigate whether the results are sensitive to inclusion of substances that experience generic entry after the policy reform, which may possibly imply anticipation effects.

7.1 Only treated markets and shorter time window

A standard issue with DiD-type studies is the validity of the comparison group. In our setting, the question is whether the substances in the comparison group are comparable in the sense that they capture the counterfactual development in outcomes for the treated substances in the absence of reference pricing. The gradual implementation of the policy reform generates time variation in the exposure to reference pricing, which allows us to estimate the effects using only the treated markets. Assuming the timing of the inclusion in the reference pricing scheme is exogenous to the outcomes, this approach is a DiD-type analysis. We report the results on the effects of reference pricing on the number of generic firms and products in Table 6 and 7, respectively. To investigate the short-term effects of reference pricing, we estimate the model using a shorter post-period of either two or three years.

[Table 6 and 7 here]

The results using only the treated substances are almost identical to the results using the full sample with a comparison group of untreated markets. The effect of reference pricing on the number of generic firms is 2.4 when using only treated substances compared to 2.1 for the full sample (cf. Table 3). The same is true for the number of

generic products, where the coefficient is 7.4 for the only treated estimation and 7.9 for the full sample estimation.

In Table 6 and 7 we also report the effects for a shorter post-period. Interestingly, we see the effects are weaker closer to the exposure to reference pricing. In the model using only two years after the inclusion, we see that reference pricing results in one additional generic producer, whereas the effect for the full after period is an average increase of 2.4 generic firms. The same picture is true for the number of generic products. The weaker short-term effects are likely to be related to the step-wise cuts in the reference prices as explained Section 2. In addition, generic entry may take some time in case generic producers need to increase capacity and set up new production lines. It might also be that generic firms not present on the Norwegian market may find it profitable to enter given the introduction of the reference pricing scheme.

7.2 Only markets with generic competition prior to policy reform

In this robustness check, we relax the restriction that only markets that experience generic entry during the sample period (i.e., after January 2003) are included in the sample. This restriction was imposed to ensure that treated and untreated markets are comparable and to allow us to control for the life cycle of the substances. In this robustness check, we instead include only substances with generic competition prior to the policy reform in 2005 and thus exclude all substances that experience generic entry later.

The purpose of this analysis is to check whether the results in the main model are sensitive to a possible anticipation effect in the pre-period before exposure to reference pricing. In particular, substances that lose patent protection after 2005 are candidates for inclusion in the reference pricing scheme conditional on generic entry and a regulatory decision. This means that generic drug producers may expect the substance to be exposed to reference pricing at some point in time, which may influence their entry decision. If this is the case, then the pre-period (of at least one year) can include an anticipation effect that might bias our results.

However, for the substances with generic competition prior to the policy reform in 2005 there is by definition no anticipation effect. Thus, restricting the sample of treated (and untreated) substances to those having generic competition before reference pricing was introduced in Norway should account for possible anticipation effects. To ensure a sufficient pre-period, we exclude substances that experience generic competition later than May 2004. For the treated substances, we include only those that were included in

the reference pricing scheme in the first year, i.e., during 2005.

Since we change the inclusion criteria, this implies that we have an alternative sample of drugs, with 14 treated substances and 17 untreated substances, all with existing generic competition prior to the policy reform. Table C in the Appendix provides a list of the substances in this alternative sample, including summary statistics on the number of generic producers and the market share of the branded drug producers.

We estimate the following fixed-effect DiD model:

$$Y_{it} = \beta \mathbf{X}_{it} + \rho D_{it} + \delta_t + a_i + \varepsilon_{it}, \tag{11}$$

which differs from the DiD model in the main analysis, as specified in (**10**), in that we do not control for the life cycle (age) of the substances. In addition, all treated substances are now included during 2005, implying much less variation in time regarding the exposure to reference pricing. Otherwise, the variables are identical to those specified in (**10**).

The summary statistics are reported in Table D in the Appendix for the full sample and split by treated and untreated markets, similar to Table 1 for the main analysis. Comparing these tables, the figures are fairly similar. In Table D, the average number of generic producers are slightly higher (2.5 vs. 1.8) and the branded drug producer market share slightly lower (58 vs. 63 percent), but otherwise not much differs. The results of the estimation of the DiD model in (**11**) are reported in Table 8 to 10 for the various outcomes.

[Table 8, 9 and 10 here]

Table 8 shows that treated markets experience a sharper increase in the number of generic firms and products and a sharper drop brand-name market shares than untreated markets, which is consistent with the results from the main analysis, reported in Table 3. The effects are weaker in magnitude for the number of generic firms and products, but stronger for the market share of branded producers. A possible explanation is that the substances in this alternative sample are essentially older and closer to the end of their life cycle, which may imply a different pattern in terms of entry (or exit) decisions.

Table 9 reports the effects on prices, and these results are highly consistent with the results from the main analysis also in terms of magnitude, cf. Table 4. The average price reduction at substance level is almost identical, but the effect on generic drug prices relative to branded drug prices are stronger in the main analysis, which may suggest that generic competition is more mature in the alternative sample. Finally, Table 10 reports

the effects on gross profits and total drug expenditures. Again we see that the results are highly consistent with the main analysis. Reference pricing induces a profit shifting effect from branded to generic drug producers, with the magnitude of the effects being somewhat weaker. The same applies to total expenditures, where the effect is 26 percent compared to 31 percent in the main analysis. Thus, we conclude that the results in the main model are highly robust to alternative estimations and sample inclusion criteria.

8 Conclusion

Policy makers world wide has made widely use of reference pricing to curb pharmaceutical spending in the off-patent market segment. The aim of reference pricing is to stimulate price competition from generic drug producers by limiting the coverage for expensive branded drugs in the reimbursement scheme. In this paper we have pointed out that the expectation of fierce price competition may weaken entry incentives for generic drug producers, which in turn may make reference pricing less effective and possibly counter-productive in reducing pharmaceutical expenditures. In a theoretical analysis we show that this is indeed a possible outcome and that the net effect of reference pricing is generally ambiguous.

To investigate this further, we exploit a policy reform in Norway that introduced reference pricing. The gradual implementation of the reform allows for a DiD research design which allows us to draw causal inferences about the effects of reference pricing. We find that markets (substances) exposed to reference pricing experience fiercer price competition as both branded and generic drug prices drop significantly after being included in the scheme. At the same time, we also find that reference pricing implies a significant shift in market shares from branded to generic drug producers. Thus, the net effect on profits and thus entry incentives for generic drug producers is a priori ambiguous. Our estimations, however, show that the gross profits of generic drug producers increases in treated markets after being exposed to reference pricing, and more importantly we also identify a strong positive entry effect in the treated markets. The number of generic firms more than doubles in treated markets compared to untreated markets. The same is true for the number of generic products. This result is highly robust to different estimation approaches, including using only treated markets, shorter time windows, and only markets with generic entry prior to the policy reform that were included the first year. Our estimates show that the Norwegian reference pricing scheme reduces pharmaceutical expenditures by more than 30 percent. We therefore conclude that the potential countervailing entry deterring effect due to the expectation of fiercer

price competition and smaller profit margins are dominated by the positive demand effect of reference pricing for generic drugs.

By way of conclusion, let us make a few remarks. First, we include only substances where we observe actual generic competition, i.e., where generic entry has occurred. If we had accurate information about patent expiration dates, we could also have included substances where generic entry did not take place even though the patent had expired. However, we would not know whether this substance would have been included in the reference pricing scheme if entry occurred. More importantly, we believe the issue of complete entry deterrence is primarily an issue for very small markets, where entry from generic drug producers can be blocked. For the vast majority of markets, generic entry will not be completely deterred, but instead limited in the sense that fewer generic drug producers find it profitable to enter. This is in line with the strategic entry deterrence study by Ellison and Ellison (2011).

Second, as pointed out in the literature review, a few studies find a negative effect of reference pricing on entry by generic producers, though the results are weak (usually correlations and often non-significant results). Our contribution is to expand the sparse literature and provide more robust results with potential for causal inference. The policy reform with the gradual implementation facilitates a DiD research design that allows for this. However, we should stress that the results may be due to different institutional settings. The previous studies where mainly based on reference pricing schemes in Sweden and Germany. The Norwegian market differs in that there is stricter price control on prescription drugs. While this could imply a lower profitability for generic drug producers, the incentive to enter a given market is obviously based on the expected post-entry equilibrium outcome. The price cap scheme in Norway is in practice not binding for the generic drug producers' price setting. It limits the branded drug producers scope for increasing their prices, but as we showed in the theoretical analysis, the branded drug producers have an incentive to lower (not increase) their prices when being exposed to reference pricing. Thus, we do not think that our results are particular to the Norwegian institutional setting in this respect.

Finally, we do not provide a welfare analysis on the effects of reference pricing. We only focus on whether reference pricing is effective in curbing pharmaceutical expenditures borne by both patients and the insurer (the government). This implies that we ignore possible utility losses due to patients' subjective preferences for branded drug versions relative to the generic drug versions. This is an obvious limitation, but we argue that it is of less importance in the off-patent drug market segment. The main reasons are that the generic versions are required to be therapeutically equivalent and thus sup-

posed to have objectively the same health effect as the branded version. This is also supported by lack empirical evidence of any significant health losses due to lower efficacy or possible side effects. Furthermore, the reduction in profits to branded producers could be a possible concern in terms of innovation incentives, but this is better fixed by improving patent regulation than granting extra profits after the patents have expired. Thus, lower pharmaceutical expenditures may be a good proxy for welfare effects in the off-patent market segment, and is clearly in line with policy makers' objectives when imposing regulations in this segment.

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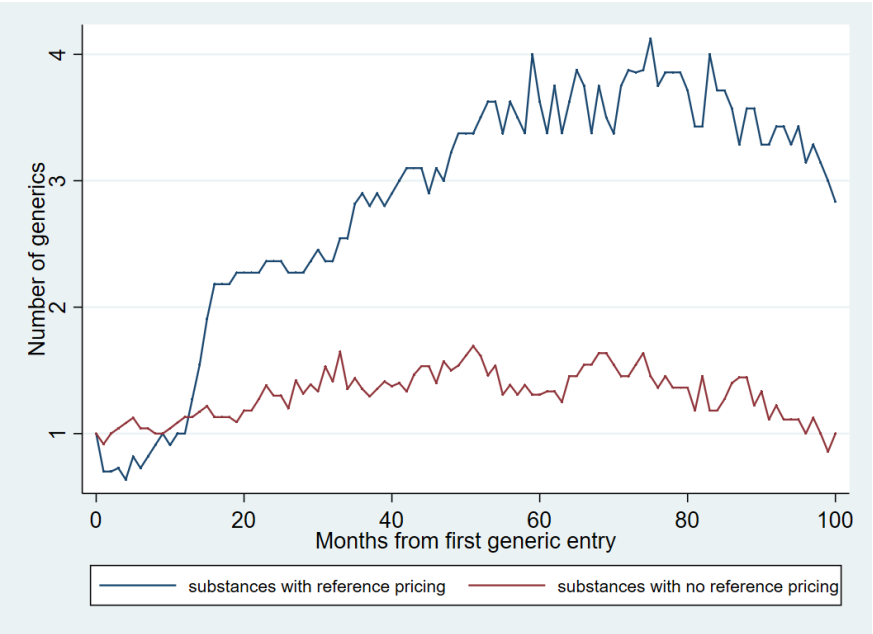
Appendix

[Table A to D here]

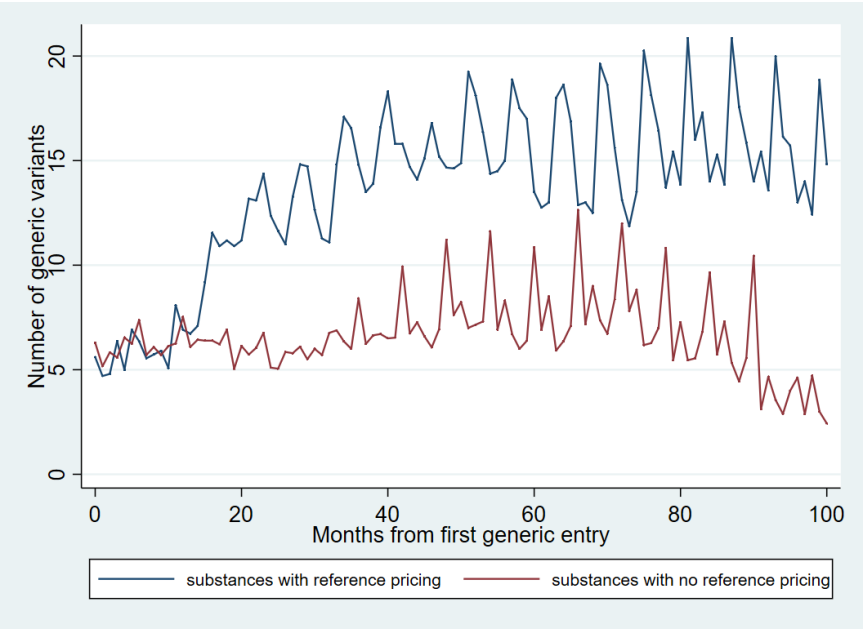
Figures

Figure 1. Average number of generic firms for substances with or without reference pricing



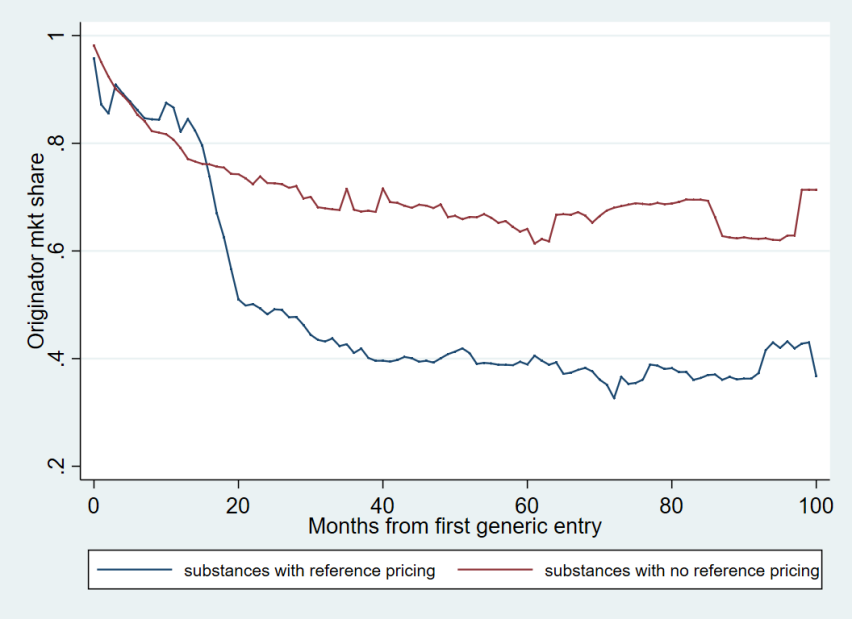
Notes: Figure reports the average number of generic firms per substance for 11 treated substances (blue line) and 24 untreated substances (red line) starting from the first month of generic entry and 100 months forward.

Figure 2. Average number of generic products for substances with and without reference pricing



Notes: Figure reports average number of generic products (variants) per substance for 11 treated substances (blue line) and 24 untreated substances (red line) starting from the first month of generic entry and 100 months forward.

Figure 3. Average brand-name market share for substances with and without reference pricing



Notes: Figure reports average market share of branded drug producer per substance for 11 treated substances (blue line) and 24 untreated substances (red line) starting from the first month of generic entry and 100 months forward.

Tables

Table 1. Summary statistics

Full sample	Mean	Std. Dev.	Min	Max	Markets	Obs.
No. of generic producers	1.793	1.620	0	9	35	2671
No. of generic products	8.979	9.640	0	69	35	2671
Brand-name market share	0.629	0.360	0	1	35	2671
Average molecule price (NOK)	34.788	61.531	0.920	370.891	35	2671
Brand-name price	37.514	64.440	1.262	368.676	35	2523
Generics price	34.734	63.787	0.821	701.400	35	2241
Revenues per month (mill. NOK)	2.719	2.720	0.094	30.200	35	2671
Brand-name monthly revenues	2.030	2.645	0.001	30.100	35	2523
Generics monthly revenues	0.955	1.262	0.001	9.688	35	2241
Volumes per month (1,000 DDDs)	507.105	974.213	5.798	6,383.492	35	2671
No. of therapeutic substitutes	9.554	7.598	1	48	35	2671
Treatment group	Mean	Std. Dev.	Min	Max	Markets	Obs.
No. of generic producers	2.640	1.778	0	9	11	1045
No. of generic products	13.073	10.497	0	56	11	1045
Brand-name market share	0.483	0.276	0.127	1	11	1045
Average molecule price	31.071	41.605	0.920	194.781	11	1045
Brand-name price	36.584	46.602	1.262	197.725	11	1045
Generics price	30.474	42.576	0.869	168.787	11	996
Revenues per month (mill. NOK)	3.161	3.054	0.421	30.200	11	1045
Brand-name monthly revenues	1.813	2.886	0.102	30.100	11	1045
Generics monthly revenues	1.413	1.407	0.001	9.688	11	996
Volumes per month (1,000 DDDs)	822.528	140.597	10.757	6,383.492	11	1045
No. of therapeutic substitutes	9.367	8.110	1	48	11	1045
Comparison group						
No. of generic producers	1.248	1.235	0	8	24	1626
No. of generic products	6.347	8.011	0	69	24	1626
Brand-name market share	0.722	0.376	0	1	24	1626
Average molecule price	37.175	71.374	1.463	370.891	24	1626
Brand-name price	38.173	74.527	1.573	368.676	24	1478
Generics price	38.249	76.482	0.821	701.400	24	1245
Revenues per month (mill. NOK)	2.435	2.357	0.094	17.519	24	1626
Brand-name monthly revenues	2.183	2.449	0.001	17.000	24	1478
Generics monthly revenues	0.588	989.689	0.001	5.321	24	1245
Volumes per month (1,000 DDDs)	304.389	429.363	5.798	3,331.384	24	1626
No. of therapeutic substitutes	9.657	7.216	1	48	24	1626

Notes: Summary statistics cover the full sample of substances (35) and split by treated (11) and untreated (24) substances over the period 2003 to 2013.

Table 2. Pre-reform test, fixed-effect models with robust standard errors.

	No. of generic producers		No. of generic products	
Interaction 1	-0.011	(0.335)	-0.249	(1.860)
Interaction 2	-0.157	(0.355)	-0.342	(1.950)
Interaction 3	-0.187	(0.308)	-1.248	(1.979)
Interaction 4	-0.215	(0.288)	-0.677	(2.006)
Interaction 5	-0.259	(0.365)	-1.115	(1.954)
Interaction 6	-0.010	(0.303)	0.938	(2.545)
Interaction 7	0.050	(0.278)	-0.045	(1.420)
Interaction 8	0.071	(0.236)	-0.401	(2.005)
Interaction 9	0.052	(0.279)	-0.808	(2.011)
Interaction 10	0.295	(0.310)	0.373	(1.777)
Interaction 11	0.196	(0.163)	0.577	(1.827)
Interaction 12	0.153	(0.134)	0.751	(1.827)
No. of therapeutic substitutes	-0.001	(0.007)	-0.122	(0.109)
Revenues (in logs)	0.240	(0.238)	1.470	(1.330)
Constant	-2.3050	(3.299)	-1.650	(19.910)
Joint significance interaction test	0.461		0.898	
Molecule dummies	Yes		Yes	
Month dummies	Yes		Yes	
Month from generic entry dummies	Yes		Yes	
No. of markets	35		35	
Observations	450		450	
R^2	0.444		0.540	

Notes: Pre-test covers the full sample of substances (35) split by treated (11) and untreated (24) substances covering one year after first generic entry and before inclusion in the reference pricing scheme. The reference group is the number of generic producers and products, respectively, in period 1 (i.e., first month when generic entry takes place). Robust standard errors in parentheses. ***p<0.01, **p<0.05, *p<0.1

Table 3. Estimated effects of reference pricing on generic competition. Fixed-effect models

	No. of generic producers	No. of generic products	Brand-name market shares
Reference pricing	2.095***	7.859***	-0.288***
	(0.470)	(1.188)	(0.062)
No. of therapeutic substitutes	0.001	-0.234**	0.001*
	(0.003)	(0.100)	(0.001)
Sales revenues (in logs)	0.393	1.235	0.029
	(0.377)	(1.381)	(0.075)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Month from generic entry dummies	Yes	Yes	Yes
Number of markets	35	35	35
Observations	2,671	2,671	2,671
R^2	0.357	0.467	0.623

Note: Time period is 2003 to 2013. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). ***p<0.01, **p<0.05, *p<0.1

Table 4. Estimated effects of reference pricing on prices (logged). Fixed-effect models.

	Brand-name prices	Generics prices	Average prices
Reference pricing	-0.241***	-0.569***	-0.506***
	(0.083)	(0.122)	(0.095)
No. of therapeutic substitutes	0.001	-0.001	-0.001
	(0.001)	(0.001)	(0.001)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Month from generic entry dummies	Yes	Yes	Yes
Number of markets	35	35	35
Observations	2,523	2,241	2,671
R^2	0.639	0.673	0.697

Note: Time period is 2003 to 2013. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). ***p<0.01, **p<0.05, *p<0.1

Table 5. Estimated effects of reference pricing on profits and expenditures. Fixed-effect models.

	Brand-name profits	Generics profits	Expenditures
Reference pricing	-0.742***	2.054***	-0.311*
	(0.208)	(0.555)	(0.154)
No. of therapeutic substitutes	0.001	-0.006	-0.004***
	(0.002)	(0.005)	(0.001)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Month from generic entry dummies	Yes	Yes	Yes
Number of markets	35	35	35
Observations	2,523	2,241	2,671
R^2	0.451	0.371	0.494

Note: Time period is 2003 to 2013. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). ***p<0.01, **p<0.05, *p<0.1

Table 6. Robustness check: Estimated effects of reference pricing on the number of generic producers. Only treated substances. Fixed effect models.

	Full sample	3 years after RP	2 years after RP
	(1)	(2)	(3)
Reference pricing	2.406***	1.265**	1.098**
	(0.416)	(0.450)	(0.449)
No. of therapeutic substitutes	0.003	-0.003	-0.007**
	(0.009)	(0.005)	(0.003)
Revenues (logged)	2.456*	0.273	-0.129
	(1.141)	(0.483)	(0.234)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Month from generic entry dummies	Yes	Yes	Yes
Number of markets	11	11	11
Observations	1,045	633	524
R^2	0.614	0.805	0.830

Notes: Sample includes only the 11 treated substances exposed to reference pricing. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). Model 1 covers the period from 2003 to 2013. Models 2 and 3 use only observations 3 and 2 years, respectively, after exposure to reference pricing. ***p<0.01, **p<0.05, *p<0.1

Table 7. Robustness check: Estimated effects of reference pricing on the number of generic products. Only treated substances. Fixed effect models.

	Full sample	3 years after RP	2 years after RP
	(1)	(2)	(3)
Reference pricing	7.474***	5.095**	4.227*
	(1.927)	(2.127)	(2.058)
No. of therapeutic substitutes	-0.278***	-0.227**	-0.249
	(0.054)	(0.075)	(0.102)
Revenues (logged)	7.185*	0.318	-2.217
	(3.601)	(1.377)	(1.479)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Month from generic entry dummies	Yes	Yes	Yes
Number of markets	11	11	11
Observations	1,045	633	524
R^2	0.745	0.785	0.795

Notes: Sample includes only the 11 treated substances exposed to reference pricing. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). Model 1 covers the period from 2003 to 2013. Models 2 and 3 use only observations 3 and 2 years, respectively, after exposure to reference pricing. ***p<0.01, **p<0.05, *p<0.1

Table 8. Robustness check: Estimated effects of reference pricing on generic competition. Only substances with generic entry prior to policy reform in 2005. Fixed effect models.

	No. of generic producers	No. of generic products	Brand-name market shares
Reference pricing	0.938*	5.359***	-0.305***
	(0.554)	(1.948)	(0.080)
No. of therapeutic substitutes	-0.192	-0.962	0.062
	(0.349)	(1.242)	(0.060)
Sales revenues (in logs)	-0.054	0.255	-0.064
	(0.158)	(0.618)	(0.042)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Number of markets	31	31	31
Observations	2,140	2,140	2,140
R^2	0.130	0.197	0.444

Notes: Time period 2003 to 2008. Sample includes substances with generic entry at least 7 months before policy reform in January 2005 and for treated substances only those that were included in the reference pricing scheme during 2005. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). ***p<0.01, **p<0.05, *p<0.1

Table 9. Robustness check: Estimated effects of reference pricing on prices. Only substances with generic entry prior to policy reform in 2005. Fixed effects models.

	Brand-name prices	Generics prices	Average prices
Reference pricing	-0.390***	-0.372***	-0.528***
	(0.074)	(0.055)	(0.058)
No. of therapeutic substitutes	0.029	0.055	0.031
	(0.057)	(0.054)	(0.045)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Number of markets	31	31	31
Observations	2,128	1,900	2,140
R^2	0.513	0.495	0.673

Notes: Time period 2003 to 2008. Sample includes substances with generic entry at least 7 months before policy reform in January 2005 and for treated substances only those that were included in the reference pricing scheme during 2005. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). ***p<0.01, **p<0.05, *p<0.1

Table 10. Robustness check: Estimated effects of reference pricing on profits and expenditures. Only substances with generic entry prior to policy reform in 2005. Fixed-effect models.

	Brand-name profits	Generics profits	Expenditures
Reference pricing	-0.642**	1.043	-0.265*
	(0.253)	(0.661)	(0.127)
No. of therapeutic substitutes	0.011	-0.627	-0.040
	(0.166)	(0.445)	(0.102)
Molecule dummies	Yes	Yes	Yes
Month dummies	Yes	Yes	Yes
Number of markets	31	31	31
Observations	2,128	1,900	2,140
R^2	0.396	0.170	0.275

Notes: Time period 2003 to 2008. Sample includes substances with generic entry at least 7 months before policy reform in January 2005 and for treated substances only those that were included in the reference pricing scheme during 2005. Fixed effect models are estimated with robust standard errors clustered at substance level (in parathesis under coefficients). ***p<0.01, **p<0.05, *p<0.1

Table A. Sample characteristics for the main analysis

ATC code	Substance name	Reference pricing	Number of generic producers		Branded drug market share		No. of obs.
			Mean	St. dev.	Mean	St. dev.	
A04AA01	Ondansetron	Yes	4.500	2.405	0.502	0.246	100
B01AC04	Clopidogrel	Yes	1.531	0.504	0.477	0.199	49
C02CA04	Doxazosine	No	0.083	0.278	0.999	0.000	108
C08CA01	Amlodipine	Yes	3.313	1.514	0.333	0.247	131
C08CA02	Felodipine	Yes	3.024	1.236	0.389	0.232	126
C09BA03	Lisinopril & diur.	Yes	2.138	1.368	0.350	0.254	130
C09CA03	Valsartan	Yes	1.711	0.458	0.455	0.177	45
C09CA04	Irbesartan	Yes	0.722	0.454	0.728	0.274	36
C10AA02	Lovastatin	No	1.218	0.414	0.181	0.240	124
D10BA01	Isotretinoine	No	1.000	0.000	0.082	0.227	64
G03AA07	Levonorgestrel&ethinyl.	No	1.000	0.000	0.903	0.038	27
G03AA12	Drospirenone&ethinyl.	No	1.488	0.746	0.969	0.040	41
G03HB01	Cyproterone&estrogen	No	1.865	0.344	0.564	0.080	96
H01CB02	Octreotide	No	0.852	0.573	0.995	0.007	61
J01FA09	Clarithromycin	Yes	1.582	0.641	0.617	0.137	122
J01FA10	Azythromycine	No	0.103	0.310	0.999	0.000	29
J02AC01	Fluconazole	Yes	4.256	2.093	0.368	0.182	117
J05AB04	Ribavirine	No	0.930	0.851	0.921	0.107	86
L02BB03	Bicalutamide	Yes	2.013	0.786	0.384	0.262	77
L04AA06	Mycophenolic acid	Yes	1.714	0.972	0.878	0.151	112
L04AA13	Leflunomide	No	0.097	0.301	0.999	0.000	31
L04AD02	Tacrolimus	No	1.347	0.495	0.960	0.019	24
M01AX01	Nabumetone	No	0.327	0.474	0.986	0.024	49
M01AX05	Glucosamine	No	4.843	1.305	0.134	0.213	108
N02AE01	Buprenorphine	No	1.000	0.000	0.186	0.206	98
N03AX09	Lamotrigine	No	1.777	0.969	0.980	0.016	103
N03AX11	Topiramate	No	1.218	0.416	0.923	0.024	87
N03AX12	Gabapentin	No	1.268	0.790	0.971	0.036	132
N03AX14	Levetiracetam	No	1.000	0.000	0.977	0.010	19
N05AA02	Levonepromazine	No	1.000	0.000	0.913	0.042	11
N05BA12	Alprazolam	No	0.200	0.402	0.997	0.008	125
N06DA04	Galantamine	No	1.000	0.000	0.695	0.081	23
R01AD05	Budesonide	No	1.000	0.000	0.702	0.028	47
R03BA02	Budesonide inhal.	No	1.175	0.406	0.998	0.002	103
V03AE02	Sevelamer	No	1.000	0.000	0.282	0.328	39

Notes: Time period 2003 to 2013. Covers treated and untreated substances in the main sample including substances that experience first generic entry during the years 2003 to 2013.

Table B. Summary statistics. One year after first generic entry

Treatment group	Mean	Std. Dev.	Min	Max	Markets	Obs.
No. of generic producers	0.843	0.638	0	3	11	140
No. of generic products	5.943	7.410	0	27	11	140
Brand-name market share	0.871	0.217	0.331t	1	11	140
Average molecule price	48.715	60.000	2.881	194.781	11	140
Brand-name price	49.840	61.222	2.885	197.725	11	140
Generics price	61.082	63.539	1.246	168.787	11	98
Revenues per month (mill. NOK)	5.906	5.714	0.873	30.200	11	140
Brand-name monthly revenues	5.226	5.610	0.594	30.100	11	140
Generics monthly revenues	0.972	1.646	0.001	6.965	11	98
Volumes per month (1,000 DDDs)	697.403	1,054.782	11.145	5,751.660	11	140
No. of therapeutic substitutes	9.250	7.425	1	47	11	140
Comparison group						
No. of generic producers	1.039	0.657	0	5	24	310
No. of generic products	6.184	6.713	0	42	24	310
Brand-name market share	0.868	0.197	0.002	1	24	310
Average molecule price	44.776	79.285	1.624	366.877	24	310
Brand-name price	44.701	79.324	1.651	366.400	24	310
Generics price	44.289	84.072	0.821	440.054	24	268
Revenues per month (mill. NOK)	2.664	2.464	0.193	17.500	24	310
Brand-name monthly revenues	2.471	2.476	0.002	17.000	24	310
Generics monthly revenues	0.224	0.319	0.001	2.118	24	268
Volumes per month (1,000 DDDs)	343.498	589.055	6.559	2,996.700	24	310
No. of therapeutic substitutes	9.855	7.443	1	47	24	310

Notes: Summary statistics include only observations for the first year after generic entry occurred for the individual substance during the period 2003 to 2013 for the 35 substances in the main sample.

Table C. Sample characteristics for substances with generic entry prior to policy reform in 2005.

ATC-code	Substance name	Reference pricing	Number of generic producers		Branded drug market share		No. of obs.
			Mean	Std. dev.	Mean	Std. dev.	
A02BA02	Ranitidine	Yes	4.292	1.569	0.422	0.086	72
A02BA03	Famotidine	No	1.569	0.499	0.543	0.152	72
A03FA01	Metoclopramide	No	1.152	0.561	0.498	0.349	66
C03CA01	Furosemide	No	3.819	0.387	0.930	0.014	72
C03EA01	Hydrochorothiazide	No	0.866	0.457	0.989	0.012	67
C07AB03	Atenolol	Yes	5.694	2.127	0.380	0.097	72
C08CA02	Felodipine	Yes	3.652	1.364	0.470	0.299	66
C08CA05	Nifedipine	No	0.153	0.362	0.999	0.002	72
C08DA01	Verapamil	No	0.211	0.411	1.000	0.000	71
C09AA05	Ramipril	Yes	2.444	0.825	0.567	0.257	57
C09BA02	Enalapril & diur.	Yes	2.208	0.604	0.475	0.141	72
C09BA03	Lisinopril & diur.	Yes	2.814	1.477	0.451	0.308	70
C10AA02	Lovastatin	No	1.422	0.4980	0.351	0.228	64
J01CE02	Phenoxymethylpenicillin	No	2.000	0.000	0.056	0.014	72
J01FA09	Clarithromycin	Yes	1.661	0.723	0.637	0.190	62
J01MA02	Ciprofloxacin	Yes	3.236	1.419	0.534	0.347	72
J02AC01	Fluconazole	Yes	1.414	0.497	0.408	0.230	58
L02BA01	Tamoxifen	No	0.070	0.640	0.985	0.034	71
M01AB05	Diclofenac	Yes	3.000	0.000	0.648	0.157	72
M01AC01	Piroxicam	No	4.833	0.949	0.008	0.005	72
M01AE02	Naproxen	No	6.222	0.843	0.092	0.059	72
M05BA04	Alendronic acid	Yes	1.328	0.962	0.526	0.364	58
N02AX02	Tramadol	No	5.292	1.054	0.377	0.051	72
N05BA12	Alprazolam	No	0.358	0.490	0.990	0.019	65
N05CD02	Nitrazepam	No	1.000	0.000	0.273	0.027	72
N05CF02	Zolpidem	No	1.528	0.804	0.613	0.074	72
N06AB03	Fluoxetine	Yes	3.500	0.692	0.431	0.205	72
N06AB05	Paroxetine	Yes	2.797	1.399	0.517	0.287	69
N06AX03	Mianserin	Yes	1.000	0.000	0.872	0.136	72
R03AC02	Salbutamol	No	4.125	0.373	0.932	0.006	72
R03AC13	Formoterol	No	2.466	1.874	0.993	0.002	72

Notes: Time period 2003 to 2008. Covers treated and untreated substances in the sample for the robustness check using substances that experience first generic entry (at least seven months) prior to policy reform in January 2005 and for treated substances include only those that were exposed to reference pricing during 2005.

Table D. Summary statistics for substances with generic entry prior to policy reform in 2005

Full sample	Mean	Std. Dev.	Min	Max	Markets	Obs.
No. of generic producers	2.466	1.874	0	9	31	2140
No. of generic products	8.483	6.826	0	30	31	2140
Brand-name market share	0.580	0.340	0	1	31	2140
Average molecule price (NOK)	7.427	12.573	0.648	126.418	31	2140
Brand-name price	8.057	14.205	0.667	128.947	31	2128
Generics price	7.492	12.070	0.631	116.993	31	1900
Revenues per month (mill. NOK)	1.835	1.796	0.001	16.400	31	2140
Brand-name monthly revenues	1.135	1.660	0.001	16.400	31	2128
Generics monthly revenues	0.797	0.946	0.001	0.832	31	1900
Volumes per month (1,000 DDDs)	508.101	598.685	0.001	6,185.363	31	2140
No. of therapeutic substitutes	8.255	4.228	1	15	31	2140
Treatment group	Mean	Std. Dev.	Min	Max	Markets	Obs.
No. of generic producers	2.823	1.694	0	9	14	944
No. of generic products	9.482	5.879	0	26	14	944
Brand-name market share	0.524	0.266	0.132	1	14	944
Average molecule price	10.202	18.130	0.648	126.418	14	944
Brand-name price	11.683	20.338	0.667	128.947	14	944
Generics price	9.424	16.964	0.631	116.993	14	893
Revenues per month (mill. NOK)	2.257	2.124	0.449	16.400	14	944
Brand-name monthly revenues	1.358	1.997	0.124	16.400	14	944
Generics monthly revenues	0.950	0.980	0.001	8.318	14	893
Volumes per month (1,000 DDDs)	680.765	782.359	9.454	5,185.363	14	944
No. of therapeutic substitutes	9.647	5.072	1	15	14	944
Comparison group						
No. of generic producers	2.184	1.960	0	8	17	1196
No. of generic products	7.695	7.398	0	30	17	1196
Brand-name market share	0.623	0.382	0	1	17	1196
Average molecule price	5.778	3.563	0.780	14.533	17	1196
Brand-name price	5.165	3.768	0.779	16.997	17	1184
Generics price	5.778	3.685	0.779	15.997	17	1007
Revenues per month (mill. NOK)	1.503	1.401	0.001	7.247	17	1196
Brand-name monthly revenues	0.957	1.307	0.001	6.729	17	1184
Generics monthly revenues	0.660	0.892	0.001	4.154	17	1007
Volumes per month (1,000 DDDs)	371.818	341.195	0.001	1,849.560	17	1196
No. of therapeutic substitutes	7.156	2.993	1	11	17	1196

Notes: Summary statistics cover to the period from 2003 to 2008. Covers the sample for the robustness check based on substances with generic entry (at least seven months) before the policy reform in January 2005 and for treated substance only those that were included during 2005.