NHH

INSTITUTT FOR SAMFUNNSØKONOMI

DEPARTMENT OF ECONOMICS

SAM 11 2015

ISSN: 0804-6824

June 2015

Discussion paper

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

BY

Kurt R. Brekke, Chiara Canta AND **Odd Rune Straume**

This series consists of papers with limited circulation, intended to stimulate discussion.

Norges Handelshøyskole

NORWEGIAN SCHOOL OF ECONOMICS

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

Kurt R. Brekke†, Chiara Canta‡, Odd Rune Straume§

June 2015

Abstract

In this paper we study the impact of reference pricing (RP) on entry of generic firms in the pharmaceutical market. For given prices, RP increases generic firms' expected profit, but since RP also stimulates price competition, the impact on generic entry is theoretically ambiguous. In order to empirically test the effects of RP, we exploit a policy reform in Norway in 2005 that exposed a subset of drugs to RP. Having detailed product-level data for a wide set of substances from 2003 to 2013, we find that RP increased the number of generic drugs. We also find that RP increased market shares of generic drugs, reduced the prices of both branded and generic drugs, and led to a (weakly significant) decrease in total drug expenditures. The reduction in total expenditures was relatively smaller than the reduction in average prices, reflecting the fact that lower prices stimulated total demand.

Keywords: Pharmaceuticals; Reference pricing; Generic entry

JEL classifications: I11; I18; L13; L65

*We are grateful for comments by Jon Andersen, Eleonora Fichera, Giovanni Mellace, Marianne Simonsen, and by participants at the Workshop on Pharmaceutical Economics at the University of Southern Denmark, Odense, 2014, and to seminars at the Norwegian Pharmacy Association, Oslo, 2015, and at the University of Lausanne, 2015.

†Department of Economics, Norwegian School of Economics (NHH), Helleveien 30, N-5045 Bergen, Norway. E-mail: kurt.brekke@nhh.no

‡Department of Economics, Norwegian School of Economics (NHH), Helleveien 30, N-5045 Bergen, Norway. E-mail: chiara.canta@nhh.no

§Department of Economics/NIPE, University of Minho, Campus de Gualtar, 4710-057 Braga, Portugal; and Department of Economics, University of Bergen, Norway. E-mail: o.r.straume@eeg.uminho.pt.

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) programmes that are used by Medicaid and some managed-care programmes to reimburse multisource 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 effects of RP on generic entry has potentially major policy implications.

In this paper we conduct an empirical analysis of the impact of RP on generic entry 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 generic entry. The theoretical analysis shows that the impact of RP on generic entry depends

[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).

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

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 impact of RP on generic entry is theoretically ambiguous and consequently an empirical question.

To estimate the effect of RP on generic entry, we exploit a policy reform in Norway that introduced an RP scheme called *Trinnpris* in 2005.[6] Importantly, the scheme was gradually implemented due to administrative reasons and included initially only a limited set of off-patent substances. This allows us to use a difference-in-difference approach to estimate the effect of RP on generic entry. 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 the number of generic firms 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 (i) substantially *increased* the number of generic producers, (ii) *intensified* price competition, resulting in lower prices of both brand-name and generic drugs, and (iii) *increased* the market share of generic producers. 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.

The literature on the effects of RP on pharmaceutical prices, sales, and expenditures is fairly large.[7] The empirical studies tend to find that RP intensifies price competition between brand-name and generic producers, with the price response being stronger for brand-name drugs than for generic drugs (see e.g., Pavcnik, 2002, Brekke et al., 2009, 2011, Kaiser et al., 2014). Most

[6] For details about this scheme, see the website of the Norwegian Medicines Agency; www.legemiddelverket.no/trinnpris.

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

empirical studies also report that the brand-name market share is reduced by the introduction of RP (see e.g., Aronsson, 2001, Brekke et al. 2011, Kaiser et al., 2014). Despite the findings of intensified price competition, this literature tends to ignore the effect of RP on generic entry. 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.

Despite the rich empirical literature on generic entry in pharmaceutical markets[8], 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.[9] Ekelund (2001) and Rudholm (2001) analyse 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.[10] A more recent study by Moreno-Torres et al. (2009) on the Spanish pharmaceutical market finds a negative effect of RP on generic entry. Our study reports the opposite result, namely that RP stimulated generic entry. This is due to the fact that the positive demand effect on generic sales more than offset the negative price effect induced by RP. One possible reason for this result is the presence of price cap regulation, which weakens the price response by original brand-name producers.[11] However, as pointed out above, the impact of RP on generic entry is theoretically ambiguous, and this may explain different results in different markets. Our study also contributes to the existing studies in that we exploit the gradual implementation of RP in Norway, which enables us to estimate the causal effect of RP on generic entry using a difference-in-difference approach.

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

[8]See, for instance, Grabowski and Vernon (1992), Frank and Salkever (1997), Scott Morton (1999, 2000), Reiffen and Ward (2005) 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.

[9]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.

[10]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.

[11]Using a Salop-type 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.

pharmaceutical market. In Section 4 we present our data and descriptive statistics. In Section 5 we explain our empirical strategy and report our results. Section 6 concludes the paper.

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 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_g^i if purchasing generic drug i. Demand for the two drug versions are given by $D_b\left(c_b, c_g^1, ..., c_g^n, n\right)$ and $D_g^i\left(c_b, c_g^1, ..., c_g^n, n\right)$, with $\partial D_b/\partial c_b < 0$, $\partial D_b/\partial c_g^i > 0$, $\partial D_g^i/\partial c_g^i < 0$, $\partial D_g^i/\partial c_b > 0$, $\partial D_b/\partial n \leq 0$ and $\partial D_g^i/\partial n < 0$, and where all demand functions for generic drugs are symmetric. Finally, we assume that $D_b > D_g^i$ if $c_b = c_g^i$, 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

$$\pi_b = p_b D_b\left(c_b, c_g^1, ..., c_g^n, n\right), \tag{1}$$

$$\pi_g^i = p_g^i D_g^i\left(c_b, c_g^1, ..., c_g^n, n\right) - f, \quad i = 1, ..., n. \tag{2}$$

where p_b and p_g^i 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 $c_{g_i}^F = \alpha p_g^i$, 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.

[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.

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 applying this copayment scheme and maximising (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 $c_g^R(p_g) = c_g^F(p_g)$, whereas $c_b^R(p_b) > c_b^F(p_b)$.

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 max-

[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.

[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.

imised 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 $c_b^R(p_b) > c_b^F(p_b)$ 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:

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

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.

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 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

[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.

[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.

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]

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 irrespectively 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.

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

[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.

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 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. In absence of reliable patent data, our study focuses on the effect of RP on generic competition at the intensive margin, i.e., intensity of generic competition, rather than at the extensive margin, i.e., probability of generic entry. 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

[27] Sales that are channeled through the hospitals to hospitalised 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.

[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).

only is twofold. First, no molecules commercialised 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 control group.

In Table 1, we report the mean and the standard deviations of the dependent variables in our empirical models, for drugs with generic competition. Figures 2-8 in the Appendix display the development over time of the variables of interest. For drugs subject to RP, we calculate these measures for the periods before and after these drugs were included in the RP scheme. For drugs never subject to RP, we calculate averages before and after the reform was introduced, in 2005, in order to provide some comparison. 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 control group, the number of generics decreased over time (from 2.5 to 1.7). A more detailed description of generic competition is reported in Table 2, where the information is disaggregated by market.

According to Table 1, drug prices in the treatment group before the introduction of RP are relatively high compared with the ones in the control group. Similarly, the markets in the treatment group are characterised by higher sales and higher originator's market shares. Thus, there is some evidence that the regulator included in the RP scheme larger markets with higher prices. However, as Figures 4-7 suggest, the trend in market shares, average prices, and revenues were not substantially different in the treatment and control groups before the reform was announced.[29] The average price for treated drugs decreases after the introduction of RP, whereas the average price of drugs in the control group does not decline substantially over time. A similar pattern can be found for the market shares of the originator.

[29]Figure 5 registers a large upward jump in the treatment group average prices in March 2004. This is due to the fact that at this date Fluconazole, an antifungal drug displaying a very high price per DDD, is included in the sample due to the first generic entering the market. Figure 6 reports average prices when Fluconazole is excluded from the sample. All our results are robust to the exclusion of this drug from the sample.

[Insert Table 1 here]

[Insert Table 2 here]

5 Empirical strategy and results

Our aim is to test for the effect of RP on the number of generic products in the market. 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. As discussed in Section 2, a necessary condition for RP to stimulate generic entry in the case where RP leads to lower generic prices, is that demand shifts away from the originator. For this reason, we also test the effect of RP on market shares and on market prices.

Our empirical strategy relies on a comparison of the molecules affected by RP (treatment group) to similar molecules that were never subject to RP (control group). Since the RP scheme was implemented gradually, as described in Section 3, the effect of the regulatory change can be evaluated with a difference-in-difference approach. Because of the panel structure of the data, we can compare 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

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

where Y_{it} is the variable of interest (i.e., number of generics, prices, sales, or market shares) 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 control 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 control 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).[30]

The average numbers of generics for the control and the treatment group in the pre-reform period are plotted in Figure 1. 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 control group is legitimate. The results of the test are presented in Table 3. All interactions are non-significant, both individually and jointly.

[Insert Figure 1 here]

[Insert Table 3 here]

5.2 Effects of RP on generic entry

The main results on generic entry are reported in the first column of Table 4. The number of generics in a given market is significantly higher after the introduction of RP. The effect (1.4) is quite high if compared with the average number of entrants in the pre-reform period (1.6). As our descriptive statistics and Figure 2 in the Appendix illustrate, this positive and strongly

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

significant effect is mostly due to a decline in the number of generics for molecules in the control 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 3 in the Appendix, which shows the average number of generics for all tablets markets with some generic competition present in our sample. Thus, our finding suggests 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 the 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 2, 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.

[Insert Table 4 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 5, 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 control 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.

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]

All in all, our results suggest that RP had a positive impact on the number of generics. More specifically, it seems to have countered a downward trend detectable in the control group and more generally in the Norwegian pharmaceutical market. In light of these results, we expect the profits of the originator 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 6, 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 the originators are negatively affected by RP. The coefficient is very high, 85%, even when controlling for the number of generics. The joint profits of generic producers are positively affected by RP (the increase equals 185%), 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.

These findings are consistent with a decline in prices and in the market shares of the originator for molecules with RP, which is supported by our descriptive statistics. In the next section we further explore the impact of RP on market shares and prices.

[Insert Table 6 here]

5.3 Effects of RP on market shares and prices

Based on our main result reported above, that RP increases the number of generics, we expect RP to affect negatively the market share of brand-name drugs. Theoretically, the effect of RP on brand-name prices is unambiguously negative, whereas the effect on generic prices is ambiguous. Below we explore these two issues by analysing the effect of RP on market shares and prices. We estimate two groups of models similar to the previous one, but where the dependent variables are market shares and prices, respectively.

The results on the effect of RP on the originator's market share 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 originators by 37 percentage points (35 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 originators' 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 literature, that takes the number of generics as given in assessing the impact of RP.

[Insert Table 7 here]

We now turn to analysing the effect of RP on prices. The results for the price model, for both brand-name drugs and generics, are presented in Table 8. The dependent variables are logged prices, so that the coefficients can be interpreted in terms or relative changes. 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 42% 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 (5), 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 and thus de fact competition are in place, rather than at the time of the policy announcement.[31]

In Table 9, 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

[31]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.

generic drugs, and to price responses of both brand-name and generic firms.

[Insert Table 8 here]

[Insert Table 9 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.

5.4 Effects of RP on expenditures

In the previous sections, we have shown that RP reduces prices, and shifts demands towards generics. Overall, the effect on generic entry is positive. We now turn to analysing the effect of RP on total pharmaceutical expenditures (borne both by the government and by consumers). The effect on expenditures is *a priori* ambiguous: since prices have been reduced for molecules with RP, demand might have increased, thus offsetting potential savings.

Our measure of expenditures are the logarithmic transformations of total sales (prices multiplied by volumes) of all drugs in the therapeutic group. Table 10 summarises 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 stimulate demand. As reported in Table 11, RP is associated with an increase in the total volume of drugs sold (in DDDs). The increase is non-negligible, amounting to approximately 30%.

[Insert Table 10 here]

[Insert Table 11 here]

6 Conclusion

This paper constitutes an attempt to assess the effect of RP on the number of generics and ultimately on prices. Theoretically, the effect of RP on generic entry 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.

Using Norwegian data, we compare drugs subject and not subject to RP, and find that the introduction of an RP scheme had a positive effect on the number of generic products present in the market. Although RP led to lower prices for all 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).

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.

References

[1] Aronsson T., Bergman M.A., and N. Rudholm (2001), The impact of generic drug competition on brand name market shares - evidence from micro data, *Review of Industrial Organization*, 19, 425–435.

[2] Bae J.P. (1997), Drug patent expirations and the speed of generic entry, *Health Services Research*, 32, 87–101.

[3] Bergman M.A., and N. Rudholm (2003), The relative importance of actual and potential competition: empirical evidence from the pharmaceuticals market, *Journal of Industrial Economics,* 51, 455–467.

[4] Carone G., Schwierz C., and A. Xavier (2012), Cost-containment policies in public pharmaceutical spending in the EU, European Economy, Economic Papers 461, European Commission.

[5] Brekke, K.R, Canta, C., and O.R. Straume (2015), Reference pricing with endogenous generic entry, NIPE Working Paper 02/2015.

[6] Brekke K.R., Grasdal A.L., and T.H. Holmås (2009), Regulation and pricing of pharmaceuticals: Reference pricing or price cap regulation?, *European Economic Review*, 53, 170–185.

[7] Brekke K.R., Holmås T.H., and O.R. Straume (2011), Reference pricing, competition, and pharmaceutical expenditures: Theory and evidence from a natural experiment, *Journal of Public Economics*, 95, 624–638.

[8] Brekke, K.R., Königbauer I., and O.R. Straume (2007), Reference pricing of pharmaceuticals, *Journal of Health Economics*, 26, 613–642.

[9] Danzon P.M. and L-W. Chao (2000), Does regulation drive our competition in pharmaceutical markets?, *Journal of Law & Economics*, 43, 311–357.

[10] Danzon P.M. and J.D. Ketcham (2004), Reference pricing of pharmaceuticals for Medicare: evidence from Germany, the Netherlands and New Zealand. In Cutler D.M. and A.M. Garber (Eds.), Frontiers in Health policy research, vol. 7, NBER and MIT Press.

[11] Dasgupta P. and J.E. Stiglitz (1988), Potential competition, actual competition, and economic welfare, *European Economic Review*, 32, 569–577.

[12] Ekelund M. (2001), Generic entry before and after the introduction of reference prices. In M. Ekelund (Ed.), Competition and innovation in the Swedish pharmaceutical market (Chap. 4, pp. 1–17). Dissertation, Stockholm School of Economics.

[13] Frank R.G. and D.S. Salkever (1997), Generic Entry and the Pricing of Pharmaceuticals, *Journal of Economics and Management Strategy*, 6, 75–90.

[14] Kelton C.M., Chang L.V., Guo J.J., Yu Y., Berry E.A., Bian B. and P.C. Heaton (2014), Firm- and drug-specific patterns of generic drug payments by US medicaid programs: 1991-2008. *Applied Health Economics Health Policy*, 12, 165-177.

[15] Galizzi M.M., Ghislandi S., and M. Miraldo (2011), Effects of reference pricing in pharmaceutical markets, PharmacoEconomics, 29, 17-33.

[16] Grabowski H.G. and J.M. Vernon (1992), Brand loyalty, entry, and price competition in pharmaceuticals after the 1984 Drug Act, *Journal of Law & Economics*, 2, 331–350.

[17] Hudson J. (2000), Generic take-up in the pharmaceutical market following patent expiry. A multi-country study, *International Review of Law & Economics*, 20, 205–221.

[18] Iizuka T., (2009), Generic entry in a regulated pharmaceutical market. *Japanese Economic Review,* 60, 63-81.

[19] Kaiser U., Mendez S.J., Ronde T., and H. Ullrich (2014), Regulation of pharmaceutical prices: evidence from a reference price reform in Denmark, *Journal of Health Economics*, 36, 174–187.

[20] Moreno-Torres I., Puig-Junoi J., and J-R. Borrel (2009), Generic entry into the regulated spanish pharmaceuitical market, *Review of Industrial Organization*, 34, 373–388.

[21] Pavcnik N. (2002), Do pharmaceutical prices respond to potential patient out-of-pocket expenses? *RAND Journal of Economics*, 33, 469–487.

[22] Reiffen D., and M.E. Ward (2005), Generic Drug Industry Dynamics, *Review of Economics and Statistics*, 87, 37–49.

[23] Rudholm N. (2001), Entry and the number of firms in the Swedish pharmaceutical market, *Review of Industrial Organization*, 19, 351–364.

[24] Scott Morton F.M. (1999), Entry decisions in the generic pharmaceuitical industry, *RAND Journal of Economics*, 30, 421–444.

[25] Scott Morton F.M. (2000), Barriers to entry, brand advertizing, and generic entry in the US pharmaceutical market, *International Journal of Industrial Organization*, 18, 1085–1104.

Appendix

[Insert Figures 2-8 here]

Tables and Figures

Table 1: Descriptive statistics. Means and standard deviations (in parenthesis)

VARIABLES	RP. Before	RP. During	No RP. Before 2005	No RP. After 2005
Number of generics	1.855 (1.859)	2.497 (1.269)	2.486 (2.030)	1.692 (1.699)
Average Price	12.3605 (18.981)	7.714 (12.432)	5.440 (3.698)	4.561 (3.044)
Market shares of the originator	.724 (.285)	.391 (.213)	.665 (.356)	.694 (.367)
Revenues (in mill. NOK/month)	5.715 (5.189)	2.153 (2.332)	1.551 (1.294)	1.467 (1.571)
Number of markets	19	19	17	17

Table 2: Sample characteristics: number of generics

ATC-code	Molecule Name	Reference Pricing	Mean	Standard Deviation	min	Max	Number of Obs.
A02BA02	Ranitidine	Yes	2.947	1.923	1	7	132
A02BA03	Famotidine	No	1.333	.473	1	2	132
A03FA01	Metoclopramide	No	1.118	.587	0	2	68
C03CA01	Furosemide	No	2.902	1.097	1	4	132
C03EA01	Hydrochorothiazide	No	.457	.546	0	2	127
C07AB02	Metoprolol	Yes	1.091	.337	0	2	132
C07AB03	Atenolol	Yes	3.909	2.540	1	9	132
C08CA02	Felodipine	Yes	3.024	1.236	0	5	126
C08CA05	Nifedipine	No	.083	.277	0	1	132
C08DA01	Verapamil	No	.115	.320	0	1	131
C09AA05	Ramipril	Yes	2.444	.875	1	4	117
C09BA02	Enalapril & diur.	Yes	1.826	.715	1	3	132
C09BA03	Lisinopril & diur.	Yes	2.138	1.368	0	4	130
C09CA03	Valsartan	Yes	.692	.868	0	2	120
C10AA02	Lovastatin	No	1.218	.414	1	2	124
J01CE02	Phenoxymethylpenicillin	No	1.977	.150	1	2	132
J01FA09	Clarithromycin	Yes	1.582	.641	0	3	122
J01MA02	Ciprofloxacin	Yes	3.250	1.333	1	5	132
J02AC01	Fluconazole	Yes	2.008	.768	1	3	118
L02BA01	Tamoxifen	No	.598	.719	0	2	132
M01AB05	Diclofenac	Yes	3.083	.277	3	4	132
M01AC01	Piroxicam	No	3.886	1.288	2	6	132
M01AE02	Naproxen	No	5.212	1.483	2	8	132
M05BA04	Alendronic acid	Yes	2.932	1.871	0	6	118
N02AX02	Tramadol	No	4.583	1.146	3	7	132
N05AH02	Clozapine	Yes	1.811	.554	1	3	132
N05AH03	Olanzapine	Yes	1.585	1.469	0	5	118
N05BA12	Alprazolam	No	.200	.402	0	1	125
N05CD02	Nitrazepam	No	1.008	.087	1	2	132
N05CF01	Zopiclone	Yes	2.629	.976	2	5	132
N05CF02	Zolpidem	No	1.288	.648	1	3	132
N06AB03	Fluoxetine	Yes	3.144	.743	1	5	132
N06AB05	Paroxetine	Yes	2.938	1.102	0	5	129
N06AX03	Mianserin	Yes	.697	.461	0	1	132
R03AC02	Salbutamol	No	3.886	.519	3	5	132
R03AC13	Formoterol	No	.788	.410	0	1	132

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

	Number of generics
Interaction 1	-.386 (.429)
Interaction 2	-.311 (.409)
Interaction 3	.085 (.310)
Interaction 4	-.213 (.310)
Interaction 5	-.214 (.344)
Interaction 6	-.219 (.344)
Interaction 7	-.064 (.314)
Interaction 8	-.045 (.313)
Interaction 9	.021 (.262)
Interaction 10	.082 (.192)
Interaction 11	-.016 (.303)
Interaction 12	.118 (.233)
Interaction 13	.228 (.221)
Interaction 14	.160 (.184)
Interaction 15	.115 (.166)
Number of terapeutic substitutes	-.134 (.248)
Log Revenues	-.050 (.190)
Joint Significance (Ftest)	.5551
Time dummies	Yes
Molecule dummies	Yes
Number of markets	36
Observations	465
R^2	.059

Table 4: Estimated effects of reference pricing on the number of generics. Fixed effect models

	(1)	(2)
Reference Pricing	1.245***	
	(0.427)	
Reference Pricing, 7 month lagged		1.330***
		(0.372)
Number of therapeutic substitutes	-0.218	-0.235
	(0.218)	(0.218)
LogRevenues	-0.005	-0.034
	(0.183)	(0.192)
Constant	4.403	4.935
	(2.730)	(2.930)
Observations	4,576	4,576
R^2	0.175	0.177
Time dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of markets	36	36

Robust standard errors in parentheses

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

Table 5: 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	0.627***	1.120**	0.501**
	(0.215)	(0.503)	(0.208)
Number of therapeutic substitutes	-0.049	-0.298	-0.112
	(0.097)	(0.284)	(0.099)
LogRevenues	0.072	0.185	0.142
	(0.123)	(0.317)	(0.126)
Constant		2.402	
		(5.356)	
Observations	4,576	6,224	6,224
R^2		0.102	
Time dummies	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes
Number of markets	36	48	48

Robust standard errors in parentheses

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

Table 6: Estimated effects of reference pricing on profits. Fixed effect models

	(1) Originator	(2) Originator	(3) Generics	(4) Generics
Reference Pricing	-0.851***		1.836*	
	(0.206)		(0.982)	
Reference Pricing, 7 month lagged		-0.734***		2.158*
		(0.191)		(1.139)
Number of therapeutic substitutes	0.046	0.046	-0.344	-0.380
	(0.123)	(0.123)	(0.290)	(0.305)
Number of generics	-0.102**	-0.112**	0.242***	0.244***
	(0.047)	(0.051)	(0.065)	(0.064)
Constant	13.09***	13.05***	14.35***	14.59***
	(1.105)	(1.098)	(2.547)	(2.674)
Observations	4,484	4,484	3,845	3,845
R^2	0.442	0.422	0.198	0.212
Time dummies	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36

Robust standard errors in parentheses

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

Table 7: Estimated effects of reference pricing on the originator's market shares. Fixed effect models

	(1)	(2)	(3)	(4)
Reference Pricing	-0.371***		-0.313***	
	(0.071)		(0.066)	
Reference Pricing, 7 month lagged		-0.350***		-0.285***
		(0.068)		(0.065)
Number of therapeutic substitutes	0.032	0.034	0.024	0.025
	(0.031)	(0.031)	(0.031)	(0.031)
LogRevenues	-0.039	-0.025	-0.041	-0.029
	(0.039)	(0.045)	(0.035)	(0.040)
Number of generics			-0.051***	-0.053***
			(0.010)	(0.011)
Constant	1.064*	0.843	1.287**	1.110*
	(0.603)	(0.680)	(0.573)	(0.629)
Observations	4,376	4,376	4,376	4,376
R^2	0.429	0.383	0.498	0.459
Time dummies	Yes	Yes	Yes	Yes
Molecule dummies	Yes	Yes	Yes	Yes
Number of markets	36	36	36	36

Robust standard errors in parentheses

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

Table 8: Estimated effects of reference pricing on prices (logged). Fixed effect models

	(1) Originator	(2) Originator	(3) Originator	(4) Generics	(5) Generics	(6) Generics
Reference Pricing	-0.322***	-0.306***		-0.421***	-0.417***	
	(0.065)	(0.073)		(0.070)	(0.071)	
Ref. Pricing, 7 month lagged			-0.234***			-0.320***
			(0.075)			(0.078)
N. of therapeutic substitutes	0.019	0.016	0.014	0.048	0.046	0.047
	(0.032)	(0.034)	(0.037)	(0.031)	(0.032)	(0.035)
Number of generics		-0.0141	-0.0198		-0.00644	-0.0120
		(0.0185)	(0.0219)		(0.0137)	(0.0163)
Constant	1.711***	1.765***	1.791***	1.327***	1.358***	1.365***
	(0.265)	(0.291)	(0.325)	(0.270)	(0.292)	(0.323)
Observations	4,374	4,374	4,374	3,850	3,850	3,850
R^2	0.518	0.521	0.480	0.481	0.481	0.424
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

Robust standard errors in parentheses

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

Table 9: Estimated effects of reference pricing on average prices (logged). Fixed effect models

	(1)	(2)
Reference Pricing	-0.498***	
	(0.069)	
Reference Pricing, 7 month lagged		-0.413***
		(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	1.706***	1.726***
	(0.227)	(0.276)
Observations	4,576	4,576
R^2	0.700	0.638
Time dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of markets	36	36

Robust standard errors in parentheses

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

Table 10: Estimated effects of reference pricing on expenditures (logged). Fixed effect models

	(1)	(2)
Reference Pricing	-0.237*	
	(0.137)	
Reference Pricing, 7 month lagged		-0.171
		(0.123)
Number of therapeutic substitutes	0.012	0.010
	(0.065)	(0.067)
Number of generics	-0.001	-0.006
	(0.034)	(0.036)
Constant	14.16***	14.18***
	(0.566)	(0.579)
Observations	4,576	4,576
R^2	0.324	0.318
Time dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of markets	36	36

Robust standard errors in parentheses

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

Table 11: Estimated effects of reference pricing on volumes (measured in DDD, logged). Fixed effect models

	(1)	(2)
Reference Pricing	0.282**	
	(0.121)	
Reference Pricing, 7 month lagged		0.268**
		(0.113)
Number of therapeutic substitutes	-0.020	-0.022
	(0.060)	(0.061)
Number of generics	0.035	0.036
	(0.033)	(0.034)
Constant	12.72***	12.44***
	(0.530)	(0.557)
Observations	4,686	4,686
R^2	0.165	0.160
Time dummies	Yes	Yes
Molecule dummies	Yes	Yes
Number of markets	36	36

Robust standard errors in parentheses

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

Figure 1: Average number of generics. Pre-reform development for substances subject to reference pricing (RP) and not subject to reference pricing (CR)

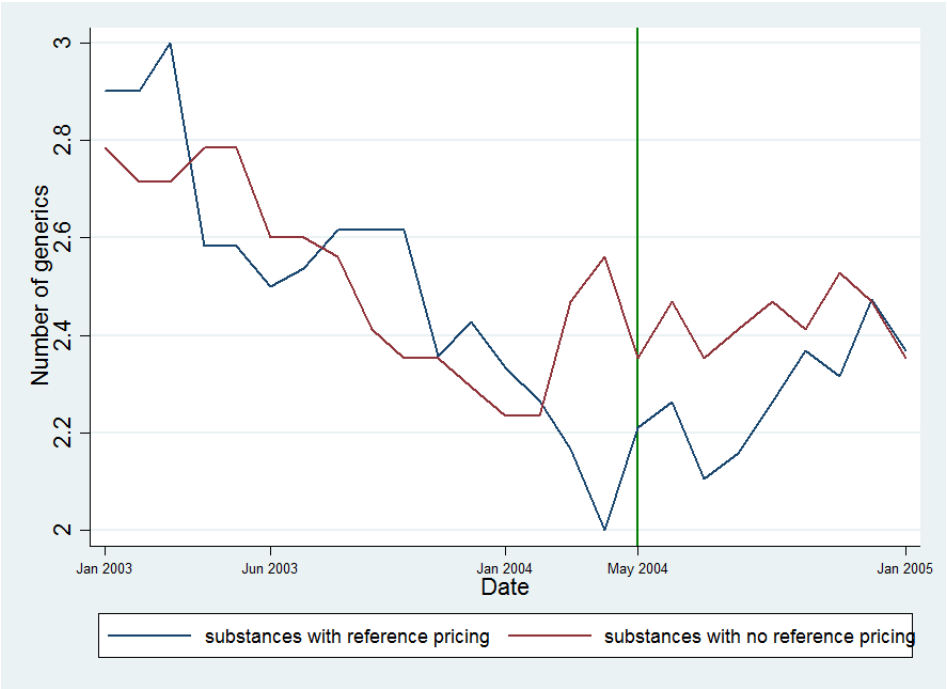


Figure 2: Average number of generics. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

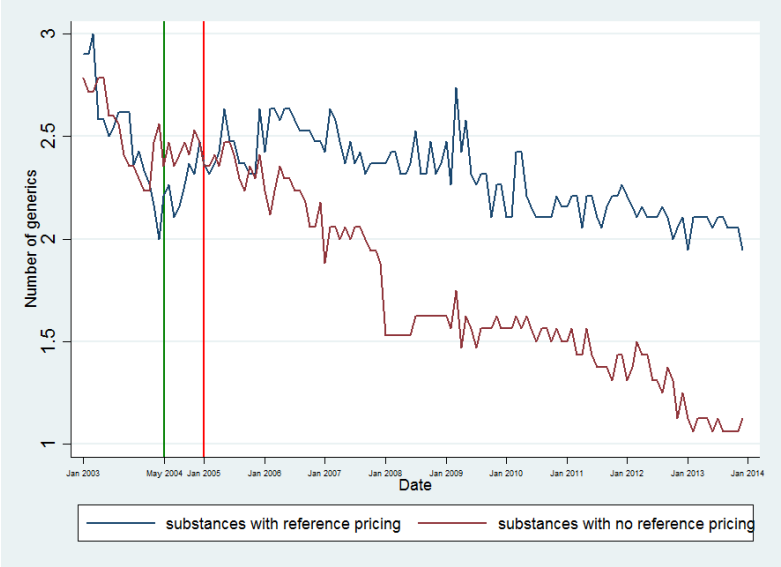


Figure 3: Average number of generics. All tablets (87 markets), conditional on generic competition

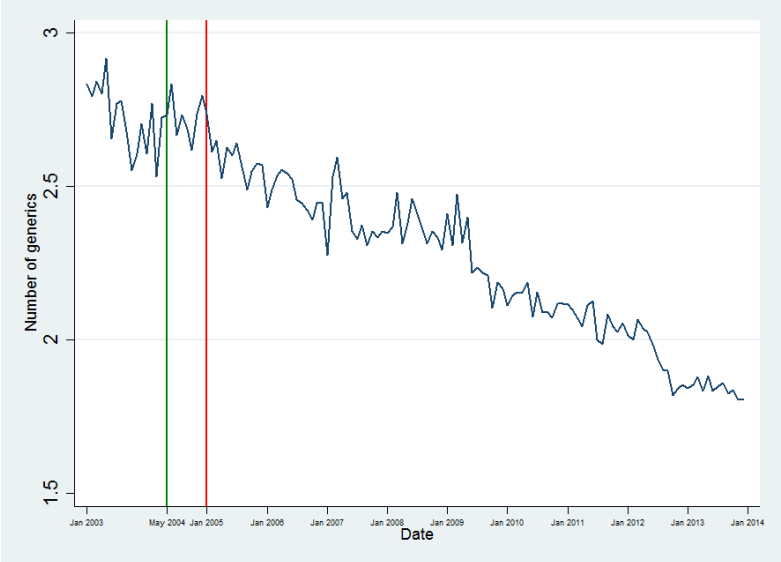


Figure 4: Average market shares of the originator. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

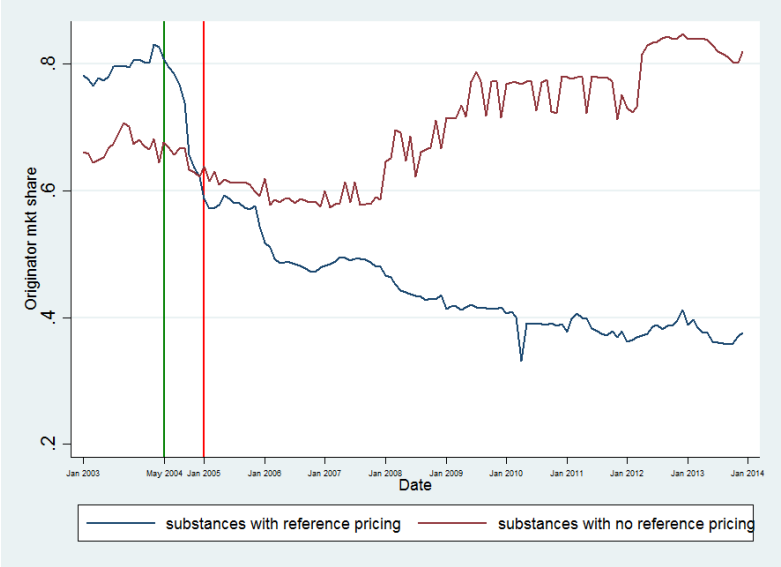


Figure 5: Average prices. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

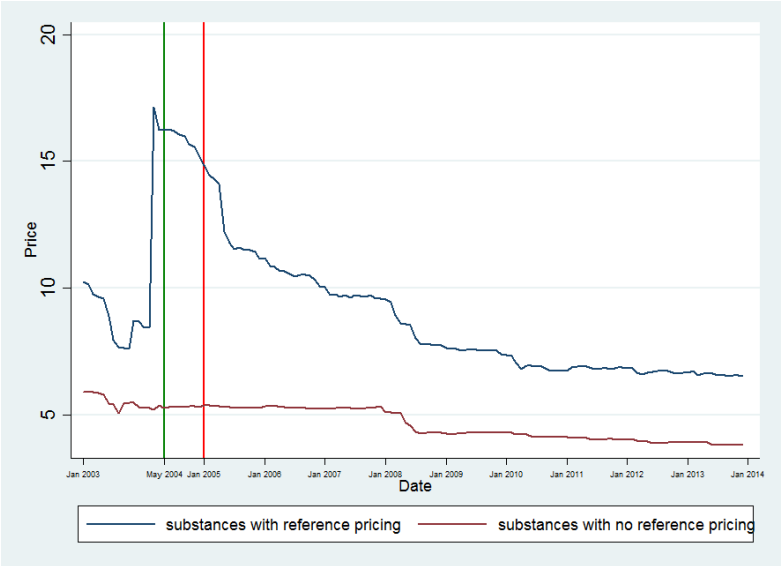


Figure 6: Average prices. Substances subject to reference pricing (RP) and not subject to reference pricing (CR), excluding Fluconazole

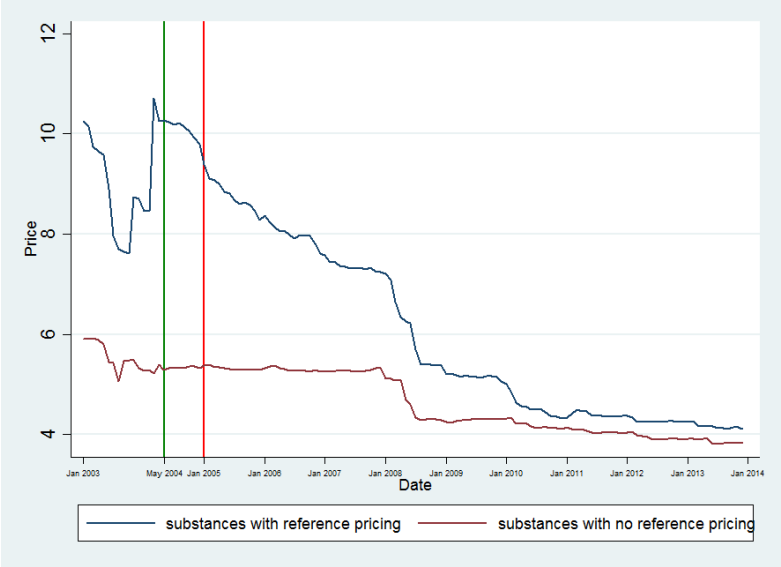


Figure 7: Average revenues. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)

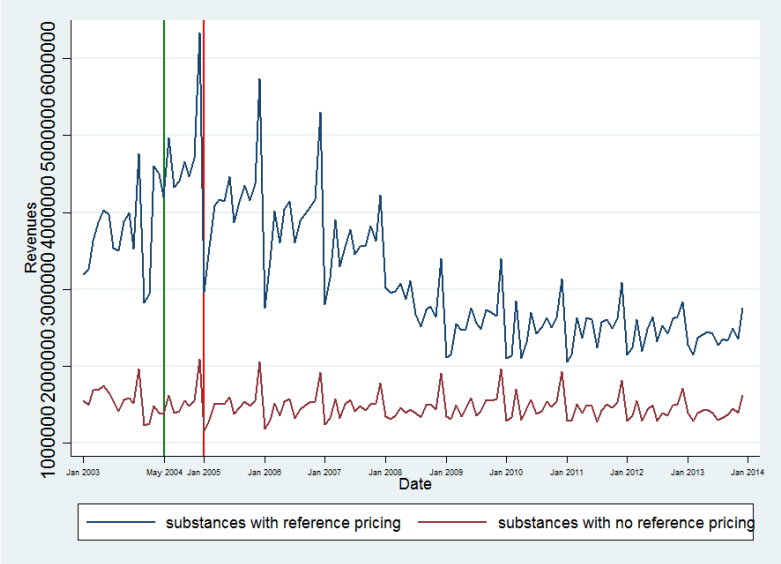
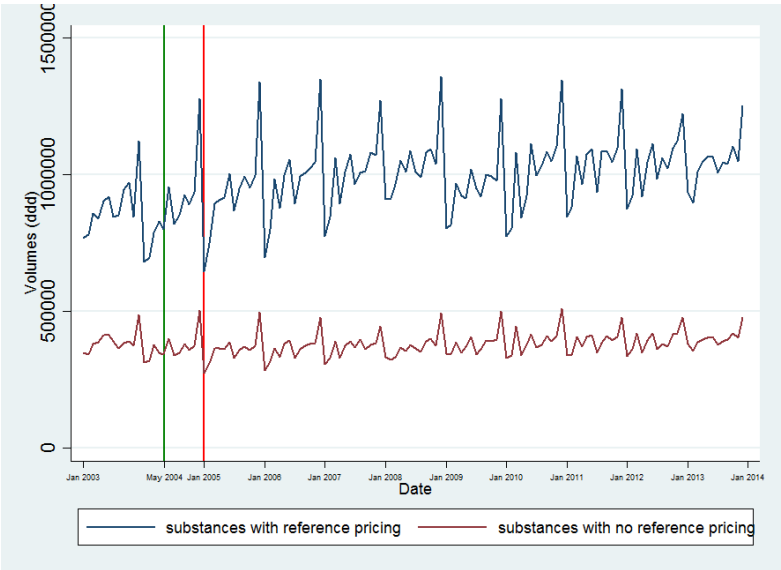


Figure 8: Average volumes, in DDD. Substances subject to reference pricing (RP) and not subject to reference pricing (CR)



Issued in the series Discussion Papers 2014

2014

01/14 January**, Kurt R. Brekke**, Tor Helge Holmås, and Odd Rune Straume, "Price Regulation and Parallel Imports of Pharmaceuticals".

02/14 January, **Alexander W. Cappelen, Bjørn-Atle Reme, Erik Ø. Sørensen,** and **Bertil Tungodden, "**Leadership and incentives".

03/14 January, **Ingvild Almås, Alexander W. Cappelen, Kjell G. Salvanes, Erik Ø. Sørensen**, and **Bertil Tungodden**, "Willingness to Compete: Family Matters".

04/14 February, **Kurt R. Brekke**, Luigi Siciliani, and Odd Runde Straume, "Horizontal Mergers and Product Quality".

05/14 March, **Jan Tore Klovland**, "Challenges for the construction of historical price indices: The case of Norway, 1777-1920".

06/14 March, Johanna Möllerström, **Bjørn-Atle Reme**, and **Erik Ø. Sørensen**, "Luck, Choice and Responsibility".

07/14 March, Andreea Cosnita-Langlais and **Lars Sørgard**, "Enforcement vs Deterrence in Merger Control: Can Remedies Lead to Lower Welfare?"

08/14 March, **Alexander W. Cappelen, Shachar Kariv, Erik Ø. Sørensen**, and **Bertil Tungodden**, «Is There a Development Gap in Rationality?"

09/14 April, **Alexander W. Cappelen**, Ulrik H. Nielsen, **Bertil Tungodden**, Jean-Robert Tyran, and Erik Wengström, "Fairness is intuitive".

10/14 April, **Agnar Sandmo**, "The early history of environmental economics".

11/14 April, **Astrid Kunze**, "Are all of the good men fathers? The effect of having children on earnings".

12/14 April, **Agnar Sandmo**, "The Market in Economics: Behavioural Assumptions and Value Judgments".

13/14 April, **Agnar Sandmo**, "Adam Smith and modern economics".

14/14 April, Hilde Meersman, **Siri Pettersen Strandenes**, and Eddy Van de Voorde, "Port Pricing: Principles, Structure and Models".

15/14 May, **Ola Honningdal Grytten**, "Growth in public finances as tool for control: Norwegian development 1850-1950"

16/14 May, **Hans Jarle Kind**, Tore Nilssen, and **Lars Sørgard**, "Inter-Firm Price Coordination in a Two-Sided Market".

17/14 May, **Stig Tenold**, "Globalisation and maritime labour in Norway after World War II".

18/14 May, **Tunç Durmaz,** "Energy Storage and Renewable Energy"

19/14 May, **Elias Braunfels**, "How do Political and Economic Institutions Affect Each Other?"

20/14 May, Arturo Ormeño and **Krisztina Molnár**, "Using Survey Data of Inflation Expectations in the Estimation of Learning and Rational Expectations Models"

21/14 May, **Kurt R. Brekke**, Luigi Siciliani, and Odd Rune Straume, "Hospital Mergers with Regulated Prices".

22/14 May, **Katrine Holm Reiso**, "The Effect of Welfare Reforms on Benefit Substitution".

23/14 June, Sandra E. Black, Paul J. Devereux, and **Kjell G. Salvanes**, "Does grief transfer across generations? In-utero deaths and child outcomes"

24/14 June, Manudeep Bhuller, Magne Mogstad, and **Kjell G. Salvanes**, «Life Cycle Earnings, Education Premiums and Internal Rates of Return".

25/14 June, **Ragnhild Balsvik**, **Sissel Jensen**, and **Kjell G. Salvanes**, "Made in China, sold in Norway: Local labor market effects of an import shock".

26/14 August, **Kristina Bott, Alexander W. Cappelen, Erik Ø. Sørensen**, and **Bertil Tungodden**, "You've got mail: a randomized field experiment on tax evasion"

27/14 August, **Alexander W. Cappelen, Sebastian Fest, Erik Ø. Sørensen**, and **Bertil Tungodden**, "The freedom to choose undermines the willingness to redistribute."

28/14 August, Marianne Bertrand, Sandra Black, **Sissel Jensen**, and Adriana Lleras-Muney, "Breaking the Glass Ceiling? The Effect of Board Quotas on Female Labor Market Outcomes in Norway."

29/14 August, **Astrid Kunze**, "The family gap in career progression".

30/14 September, **Ragnhild Balsvik** and **Morten Sæthre**, "Rent Sharing with Footloose Production. Foreign Ownership and Wages Revisited".

31/14 October, **Nicola D. Coniglio** and Giovanni Pesce, "Climate Variability and International Migration: an empirical analysis"

32/14 November, **Kurt R. Brekke**, Armando J. Garcia Pires, Dirk Schindler, and Guttorm Schjelderup, "Capital Taxation and Imperfect Competition: ACE vs. CBIT"

33/14 November, **Jan I. Haaland** and Anthony J. Venables, "Optimal trade policy with monopolistic competition and heterogeneous firms".

34/14 December, Rolf Aaberge, **Kai Liu**, and Yu Zhu, "Political Uncertainty and Household Savings".

2015

01/15 January**,** Antonio Mele**, Krisztina Molnár,** and Sergio Santoro, "On the perils of stabilizing prices when agents are learning".

02/15 March, **Liam Brunt**, "Weather shocks and English wheat yields, 1690-1871".

03/15 March, **Kjetil Bjorvatn, Alexander W. Cappelen**, Linda Helgesson Sekei, **Erik Ø. Sørensen**, and **Bertil Tungodden**, "Teaching through television: Experimental evidence on entrepreneurship education in Tanzania".

04/15 March**, Kurt R. Brekke**, **Chiara Canta**, Odd Rune Straume, "Reference pricing with endogenous generic entry".

05/15 March, Richard Gilbert and **Eirik Gaard Kristiansen**, "Licensing and Innovation with Imperfect Contract Enforcement".

06/15 March, **Liam Brunt** and Edmund Cannon, "Variations in the price and quality of English grain, 1750-1914: quantitative evidence and empirical implications".

07/15 April, Jari Ojala and **Stig Tenold**, "Sharing Mare Nostrum: An analysis of Mediterranean maritime history articles in English-language journals".

08/15 April, **Bjørn L. Basberg**, "Keynes, Trouton and the Hector Whaling Company. A personal and professional relationship".

09/15 April, Nils G. May and **Øivind A. Nilsen**, "The Local Economic Impact of Wind Power Deployment".

10/15 May, **Ragnhild Balsvik** and Stefanie Haller, "Ownership change and its implications for the match between the plant and its workers".

11/15 June, **Kurt R. Brekke**, **Chiara Canta**, Odd Rune Straume, "Does Reference Pricing Drive Out Generic Competition in Pharmaceutical Markets? Evidence from a Policy Reform".

NHH

Norges Handelshøyskole

Norwegian School of Economics

NHH
Helleveien 30
NO-5045 Bergen
Norway

Tlf/Tel: +47 55 95 90 00
Faks/Fax: +47 55 95 91 00
nhh.postmottak@nhh.no
www.nhh.no