Regulation and Pricing of Pharmaceuticals: Reference Pricing or Price Cap Regulation?*

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Abstract

We study the relationship between regulatory regimes and pharmaceutical firms' pricing strategies using a unique policy experiment from Norway, which in 2003 introduced a reference price (RP) system called "index pricing" for a sub-sample of off-patent pharmaceuticals, replacing the existing price cap (PC) regulation. We estimate the effect of the reform using a product level panel dataset, covering the drugs exposed to RP and a large number of drugs still under PC regulation in the time before and after the policy change. Our results show that RP significantly reduced both brand-name and generic prices within the reference group, with the effect being stronger for brand-names. We also identify a negative cross-price effect on therapeutic substitutes not included in the RP-system. In terms of policy implications, the results suggest that RP is more effective than PC regulation in lowering drug prices, while the cross-price effect raises a concern about patent protection.

Keywords: Pharmaceuticals; Price Regulation; Branded-Generic competition

JEL Classification: I11; L13; L51; L65

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1 Introduction

Pharmaceutical markets are characterised by price inelastic demand, mainly due to extensive medical insurance, and supply-side market power associated with the patent system protecting new chemical entities from being copied within a given period. This combination has lead most countries to exert various means to curb the pharmaceutical firms' market power and to control the growth in medical expenditures.[1]

Two of the most commonly used price control mechanisms in pharmaceutical markets are price cap regulation and reference pricing. While the two systems share the same purpose, namely to contain (the growth in) medical expenditures, they differ substantially in nature. Price cap regulation limits the pharmaceutical firms' ability to exploit market power by charging high prices, while reference pricing aims at stimulating competition by making demand for pharmaceuticals more price elastic. The link between regulatory regimes and pharmaceutical firms' pricing strategies has received surprisingly little attention in the literature, and the main purpose of this paper is to fill this gap.[2]

We exploit a unique policy experiment from Norway to assess the relative performance of reference pricing and price cap regulation. In 2003 the Norwegian government introduced a reference price system called "index pricing" to a set of off-patent pharmaceuticals, replacing the existing price cap regime, which was based on international price comparisons. Since only a sub-sample of the off-patent drugs was exposed to reference pricing, the policy reform can be classified as a quasi-natural experiment. We exploit a rich product level panel dataset covering a four-year period from 2001 to 2005. Besides having data on all drugs exposed to the reference price system, we also have data on a substantial number of drugs still subject to the existing price cap regulation. This latter group of drugs consists of drugs that are either therapeutic substitutes or unrelated in consumption to the drugs exposed to reference pricing. In addition to exploiting the before-after reform variation in prices, we make use of the non-included drugs

[1] The US is the exception among Western countries. However, the recent inclusion of prescription drugs in Medicare has spurred a debate of price controls also in the US (e.g., Huskamp et al, 2000, Kanavos and Reinhardt, 2003). In addition, (generic) reference pricing is well-established through the "maximum allowable charge" programs used by, e.g., Medicaid.

[2] Danzon (1997) provides an excellent overview over issues and related literature on price regulation in pharmaceutical markets. For reference price systems, see the literature surveys by Lopez-Casasnovas and Puig-Junoy (2000), Danzon (2001) and Puig-Junoy (2005).

as a comparison group to identify the price effects on the drugs subject to the policy experiment, as well as any cross-price effects on therapeutic substitutes not exposed to the experiment.

Under price cap regulation, the regulator sets a maximum price that can be charged for each product. The price cap is set when a new patent-protected drug enters the market. To be effective (binding), the price cap needs to be lower than the firms' profit-maximising (monopoly) price. Competition can, however, induce the firms to reduce the price on the original brand-name drug below the price cap level. First, if a new drug with similar therapeutic properties enters the market, the original drug can be forced to set a lower price to avoid loosing too much of its market share. Second, when the original drug looses its patent protection, generic substitutes can enter the market with lower prices to capture market shares from the original drug. Our dataset allows us to identify the price effects due to therapeutic competition (first type) and generic competition (second type).[3]

Under reference pricing, the regulator enforces no explicit restrictions on the pharmaceutical firms' price setting. The firms are allowed to charge any price they like. Instead the regulator sets a maximum reimbursement price (the reference price) to be paid for a group of drugs ("clusters").[4] Purchase of drugs with price above the reference price results in a surcharge equal to the difference between the drug's price and the reference price.[5] This surcharge may be imposed by the regulator on the consumer, the prescribing physician, or, as in Norway, the dispensing pharmacy. The intention is to make demand more sensitive to prices, which may trigger price competition and, in turn, result in lower prices and medical expenditures.

We find that the reference price system introduced in Norway had a strong price reducing effect on the drugs exposed to this regime, with the effect being stronger for brand-names (18 to 19 percent) than generics (7 to 8 percent). This confirms that reference pricing triggers price competition within the cluster of drugs exposed to the regime. Since the reference price system in Norway included off-patent products only, the identified price effect is solely due to generic

[3] We do not analyse the impact of (generic) entry on drug prices. This has been the subject of several papers, e.g., Caves et al. (1991), Grabowski and Vernon (1992), Frank and Salkever (1997).

[4] The definition of clusters is a controversial issue. It is common to distinguish between generic and therapeutic reference pricing, where the former involves clustering of drugs that are chemically identical (generics), while the latter involves clustering of drugs that have similar therapeutic effects (therapeutic substitutes). We return to this issue in the next section.

[5] Often the reference price is set equal to the lowest priced drug in the cluster. However, if this is not the case, the difference between the reference price and a lower priced drug is often shared between the payer and the dispensing pharmacy to create incentives to also sell those drugs (Lopez-Casanovas and Puig-Junoy, 2000).

competition triggered by the reform.

Interestingly, we also identify a negative cross-price effect of the policy reform on the non-included therapeutic substitutes still under price cap regulation, providing evidence on therapeutic competition in the market. The effect is weaker (2.2 percent), as we would expect, since these drugs have different chemical substances and therefore are only imperfect substitutes to the drugs exposed to reference pricing. When we decompose the effect, we find that it is merely the generics that respond to the reform (by 6.4 percent). An obvious explanation is that the price cap is binding for the brand-names but not for the generics. This implies that we capture any price reductions on the generics, while for brand-names we observe only price reductions *below* the price cap. However, under free pricing, or less strict price regulation, it is likely that also the brand-names will reduce their prices as a response to the lower prices triggered by reference pricing.

The Norwegian policy experiment provides an excellent opportunity to assess the relative performance of two different regulatory regimes; reference pricing and price cap regulation. Our results suggest that reference pricing is more effective than price cap regulation in reducing drug prices. To indicate the economic significance of the reform, we can calculate potential savings in medical expenditures, using 2002, the year before the reform was introduced, as our benchmark. In 2002, the total sales value of the drugs included in the reference price system amounted to 474.4 mill NOK, with a brand-name market share of about 72 percent. Using our estimated price reductions of about 18 percent on brand-names and 8 percent of generics, we obtain cost saving of about 75 mill NOK. This is a conservative figure for two reasons. First, the reference price system is likely to trigger a shift in market shares from the brand-names to the generics (e.g., Aronsson et al., 2001). Second, when extending the reform to the whole generic market segment, the savings (in absolute terms) will be even higher.

A potential downside of the reference price system is related to the negative cross-price effect on non-included therapeutic substitutes, which raises two concerns: first, that reference pricing may reduce patent rent, which in turn can affect national launching decisions and global innovation incentives (if applied in large, high-income countries); and, second, that reference pricing may potentially distort drug consumption towards less effective or suitable drug treatments in order to obtain economic savings (lower patient co-payments) or gains (higher pharmacy margins

or physician budgets).

The rest of the paper is organised as follows. In section 2, we relate our paper to existing literature. In section 3, we present institutional facts about the Norwegian pharmaceutical market, the regulatory regime and the policy reform introducing reference pricing. In section 4, we present our dataset and some descriptive statistics. In section 5, we carry out the econometric analysis and report our empirical results. Finally, in section 6, concluding remarks are presented.

2 Related Literature

The literature on the performance of different regulatory regimes on pharmaceutical price setting is limited, and many of the empirical studies are descriptive.[6] Our paper is a contribution in that respect. There are, however, some notable exceptions. Below we relate our paper to these.

In a theoretical paper, Danzon and Lui (1996) argues that all prices within the cluster will converge towards the reference price, implying a price decrease on the high-price (brand-name) drugs and a price increase on the low-price (generic) drugs, leaving the net price and cost saving effect of reference pricing unclear.[7] Moreover, Zweifel and Grivelli (1997), who provide a theory model and some anecdotal evidence from Germany, suggest that the reference pricing produces an immediate reduction in brand-name prices to the reference price level but has no effect on generics.

However, more recent studies, including ours, find a negative effect of reference pricing not only on brand-names but indeed also on generics. Aronsson et al. (2001) analyse how brand-name market shares are affected by generic competition, in general, and (generic) reference pricing, in particular. Using data from Sweden for the time period 1972-96, they find that the price of brand-name relative to the average price of generics affects the brand-name market share for 5 out of 12 different substances. Extending the model to capture the effect of the reference price system introduced in 1993, they provide evidence that reference pricing had a

[6] See the literature surveys by Danzon (1997), Lopez-Casasnovas and Puig-Junoy (2000), Danzon (2001), and Puig-Junoy (2005).

[7] This result relies on the assumptions that the reference price is set above the lowest price in the reference cluster and that demand is perfectly inelastic below the reference price. However, many countries set the reference price equal to the lowest price, and those that don't often share the benefit from selling a drug with a price below the reference price with the dispensing pharmacy. Moreover, if there is coinsurance, where the patient pay a fraction of the drug price, demand is likely to be elastic also under the reference price.

negative effect on brand-name market share, but only for 3 substances. However, as the authors point out themselves, they have an identification problem because the reference price system is likely to affect the relative prices on brand-names and generics directly. They therefore perform a test on the price effects of reference prices, which indicates a strong negative effect on both brand-names and generics.

A more recent study by Bergman and Rudholm (2003), also based on Swedish data, analyses the impact of actual and potential competition between brand-names and generics, where 'potential competition' is defined as a situation where the brand-name's patent has expired but no generics have entered. Using data on 18 substances for the same period as the previous study (1972-96), they find that the price of the brand-name is lowered by both actual and potential generic competition. Importantly, the reference price system introduced in 1993 also had a strong negative effect (16-21 percent) on brand-name prices, but only for the drugs facing actual competition.

Pavcnik (2002), which is the closest study to ours, analyses the impact of the introduction of (therapeutic) reference pricing in Germany in 1989 on pharmaceutical prices, focusing on the change in patient out-of-pocket expenses. Using data on two different therapeutic fields (oral antidiabetics and antiulcerants) for the time period 1986-96, she identifies strong price decreases for both brand-names and generics, with the price reductions being more pronounced for the brand-names. She also finds that brand-names with more generic competitors reduced prices more.

Finally, there exists a recent paper by Dalen et al. (2005) analysing the same policy reform in Norway (the index price system) as we do. They use a structural approach, with prices as instruments, to estimate the impact of the reform on demand and market power, and concludes that the index price system increased the market shares of generic drugs and reduced overall market power. However, their dataset only covers the six chemical substances subject to the reference price system, as well as a limited number of pharmacies (22 of about 500).

The policy experiment in Norway enables us to advance the literature along several dimensions. First, it allows us to establish a proper comparison group to carefully estimate the net price effect of the reference price system. The previously mentioned studies resort to comparison of prices and/or market shares before and after the introduction of reference pricing. In Sweden

there was no policy experiment since *all* off-patent drugs were exposed to reference pricing in 1993. Dalen et al. (2005) could have made use of the policy experiment in Norway, but did not by focusing only on the drugs exposed to reference pricing. The exception is Pavcnik (2002) who exploits the gradually extension of the reference price system within the oral antidiabetic group in Germany to establish a comparison group. A potential problem with her comparison group is that it consists of therapeutic substitutes to the ones exposed to reference pricing, and, as our results show, there may be cross-price effects that can potentially bias the results.

Second, the policy experiment allows us to analyse generic and therapeutic competition. Generic competition has received substantial attention in the literature, possibly because o the so-called "generic paradox", where empirical studies have shown that brand-name drugs respond to generic entry by *rising* their prices (see e.g., Grabowski and Vernon, 1992, Frank and Salkever, 1997).[8] The evidence from the Swedish market provided by Aaronsson et al. (2001) and Bergman and Rudholm (2003) and the German based study by Pavcnik (2002) do not support the "generic paradox" result. All studies find that generic entry or competition results in lower brand-name prices, which is also confirmed by our study. However, it is very likely that the difference in results may be due to different market structures and regulatory regimes in the US compared with European countries.

The literature on therapeutic competition is much more limited. An important exception is Ellison et al. (1997) that use US data from one therapeutic field (cephalosporin), providing evidence of high elasticities between generic substitutes and also significant, though lower, elasticities between therapeutic substitutes. Consistent with Ellison et al. (1997), we provide evidence of therapeutic competition in the pharmaceutical market, although this competitio is, as one would expect, weaker than competition from generic substitutes.

Finally, our study also contributes to the debate on generic versus therapeutic reference pricing.[9] Generic reference pricing (like in Norway and Sweden) is considered to be uncontroversial in contrast to therapeutic reference pricing (like in Germany) for two reasons: First, since generic reference pricing only concerns drugs with the same active chemical substances, healt

[8] The "generic paradox" have been challenged by, for instance, Caves et al. (1991) who find that generic entry is associated with brand-name prices reductions. However, the reductions are economically small, much smaller than one would expect from products that are supposed to be perfect substitutes.

[9] Lopez-Casasnovas and Puig-Junoy (2000) and Danzon (2001) provide a detailed presentation of the arguments in the debate between generic and therapeutic reference pricing.

risks associated with generic substitution are considered to be very limited. Second, since generic reference pricing applies by definition to off-patent drugs only, it is perceived to not affect the patent protection, and thus market entry and innovation decisions.

A theoretical paper by Brekke et al. (2005) show that this is not necessarily true. Using a model combining generic and therapeutic competition, they find that generic reference pricing triggers lower prices on non-included therapeutic substitutes and exposes patients to *higher* health risks than therapeutic reference pricing. The reason is that generic reference pricing results in larger price differences, and thus copayments, between included (off-patent) drugs and non-included (on-patent) drugs than therapeutic reference pricing, which induces a larger fraction of patients to purchase a cheaper but perhaps less effective/suitable off-patent drug.

Our data does not enable us to test the effect of reference pricing on the patients' health risk or the market entry and innovation incentives of the firms.[10] However, we provide evidence on a negative cross-price effect of the generic reference price system on therapeutic substitutes not subject to this system. This confirms the concern raised by Brekke et al. (2005) that not only therapeutic reference pricing but also generic reference pricing may reduce patent protection and potentially expose patients to health risks.

3 The Norwegian Pharmaceutical Market

The Norwegian pharmaceutical market is extensively regulated, as in most other countries. The regulatory body is the Norwegian Ministry of Health and Care Services and its agency called the Norwegian Medicines Agency. Norway has adopted the European patent law system to a large extent, implying that all new chemical entities are subject to patent protection for a given period. However, the pharmaceutical firms still need government approval to launch a new product in Norway. In addition, they must submit an application providing sufficient evidence of benefits compared with costs from the drug therapy in order to get the drug listed in the reimbursement system (the blue list). Once this is obtained, the prices are subject to price control.

[10] A paper by Danzon and Ketchham (2004) analyses the effect of reference pricing on the availability of drugs in Germany, the Netherlands and New Zealand, providing results that indicate that the strictness of the reference price systems tends to lower the number of drugs available in a country.

The current system is a *price cap* scheme based on international reference pricing. This system was introduced in 2001, and covers all prescription drugs, both on-patent and off-patent, except for those included in the reference price system. The price cap is defined as the weighted sum of the three lowest prices of a specific drug in a basket of countries that is "comparable" to Norway.[11] The price cap is imposed at the wholesale level, leaving the producer prices unregulated. The government then defines a maximum product-specific mark-up, which in turn determines the price cap on the retail price of each product.

The *reference price* system, called index pricing, was introduced in March 2003 for a subsample of off-patent pharmaceuticals facing generic competition. Initially, the index price system covered six chemical substances: Citalopram (depression), Omeprazol (antiulcer), Cetirizin (allergy), Loratadin (allergy), Enalapril (high blood pressure) and Lisinopril (high blood pressure). In June 2004 Simavastatin (high cholesterol) was included. The government decided to terminate the system by the end of 2004, arguing that the price reductions and cost savings were lower than expected.[12] Thus, in total the system run for almost two years.

The index price was calculated as follows. First, the drugs were classified into clusters based on chemical substance. Then within each cluster, the drugs were classified into subgroups depending on the package size and dosage in order to adjust for cost variation. Second, the index price was calculated as the sales weighted sum of producer prices of the drugs included in each subgroup. For the six chemical substances initially included, there were 16 index prices in total. This exercise were repeated every three months, resulting in a revised index price for every quarter of a year. Formally, the index price for a given period t, denoted by I^t, can be defined as:

$$I^t = \sum_{i=1}^{N} \left[M_i^{t-1} \cdot p_i^{t-1} \right], \quad \text{where } M_i^{t-1} = \frac{q_i^{t-1}}{\sum_{j=1}^{N} q_j^{t-1}}.$$

where p_i^{t-1} is the producer price of product i in the previous period $(t-1)$, q_i^{t-1} is the quantity sold of product i in the previous period, measured in tablets or defined daily doses (DDD),

[11] The following countries are included in the Norwegian basket: Austria, Belgium, Danmark, Finland, Germany, Irland, the Netherlands, Sweden and the UK. Thus, Southern and Eastern Europian countries, as well as France and Switzerland, are excluded. If there are no prices yet in these countries, the price is determined by negotiations based on the provided evidence on benefit and costs of the medical treatment in question.

[12] The decision was based on an evaluation report, using data until February 2004. As will be shown below, our analysis strongly indicates that the evaluation was carried out too early. Price reductions became substantial after some time, especially during 2004.

and, thus, M_i^{t-1} is the market share of product i in the previous period. Since each period t lasts for three months, all variables are average values. The index price was the maximum reimbursement for every drug in the reference group. We see that the index price is reduced if lower-priced (generic) drugs increase their market share, and/or if there is a price decrease of the higher-priced (brand-name) drugs and/or the lower-priced (generic) drugs generic in the cluster.

A special feature of the Norwegian reference price system relative to other reference price systems is that the pharmacies were exposed to all incentives. Not only did they keep the margin of selling a (generic) drug with a price lower than the index price, but they also had to bear the full cost of selling a (brand-name) drug with a price higher than the index price. Importantly, generic substitution was allowed in 2001, so the pharmacies could suggest a cheaper (generic) drug, although the physicians had written a brand-name drug on the prescription (which they frequently tend to do). If the patients refused to accept a generic substitution, they had to pay the surcharge associated with the difference between the high-priced (brand-name) drug and the index price, as is common in most other reference price systems. On the other hand, the physicians could blockade generic substitution by actively writing an argument on the prescription of why this particular patient is better off with the brand-name drug. In such cases, the price cap system was reintroduced.

In Norway there is a statutory public health insurance, covering the whole population. Close to 70 percent of the total drug expenses are covered by this insurance scheme. For prescription drugs on the reimbursement list (the blue list), patients pay a fixed share (36 percent) of the drug price, constrained by a maximum amount per prescription (400 NOK) and per year (1.350 NOK). Notably, the index price system did not change the *structure* of the patient copayments, except for the case when the patients refused to accept a cheaper generic drug, as described above. However, the *amount* of the patient copayments may, of course, be affected to the extent that the reference pricing affects prices and choices of pharmaceuticals.

4 Data and Descriptive Results

4.1 Data

In the empirical analysis we use data from Farmastat.[13] Their database includes information on sales value and volume for each package of drugs sold at the Norwegian pharmaceutical market. Values are in pharmacy purchase prices and volumes in defined daily doses (DDD) for the active substance according to the ATC-code system.[14] The database also provides information about product name, manufacturer, launch date, price cap, whether the product is a brand-name or a generic drug, package size and dosage.

From this database we have data on all prescription drugs within the 30 largest ATC-groups (in terms of sales value) over a four year period from 2001 to 2005. Table 1 lists ATC-code, brand-name, and manufacturer of these pharmaceuticals. The table also gives information about whether the drugs within each ATC-code are subject to reference pricing, whether the branded drug faces generic competition, and whether a drug is classified as a therapeutic competitor to a drug in the reference price group. This last classification is based on therapeutic categories. For example, Losec with ATC-code A02BC01 is included in the index price system, and therefore all pharmaceuticals with A02 as the first three characters in the ATC-code are classified as therapeutic competitors to Losec.

[Table 1 about here]

In our analysis, we define a product as all presentations of a given drug produced by given manufacturer. For example, the brand-name Zantac together with five generic product give a total of six products in ATC-group A02BA02. For each product, prices are calculate as total sales values divided by the total volume sold (in DDD). All prices therefore refer t average prices per defined daily dose of the active ingredient; a price measure that enable comparison across different formulations (tablets, capsules, etc.) within each product, and als

[13] Farmastat is a company specialised in provision of pharmaceutical statistics. The company is owned by th Norwegian Association of Pharmaceutical Manufacturers.

[14] The ATC-code system is used by the World Health Organization to classify pharmaceutical substances accord ing to their chemical, pharmacological and therapeutic properties. Pharmaceuticals sharing the same seven-figur ATC-code have the same active ingredients and are considered equivalent in the treatment of a given disease.

across different active ingredients. The prices have been deflated using the consumer-price index. Time is measured in one-month periods, and the average price of each product in each time-period constitutes an observation. The number of observations is not identical in each period, which is due to generic entry during our sample period. In such cases, the product does not appear in our data, leaving us with an unbalanced panel. The number of observations within each ATC-group is given in the last column in Table 1. The total number of observations in our analysis is 2765.

4.2 Descriptive results

A natural starting point for the descriptive analysis is to look at how average prices have developed over time. In Figure 1, we plot average prices for brand-names and generics for the following three groups of pharmaceuticals: (i) the pharmaceuticals subject to reference pricing, (ii) the drugs that are therapeutic substitutes still under price cap regulation, and (iii) the others, which are independent in consumption and exposed to price cap regulation.

[Figure 1 about here]

With time measured in one-month periods, the reference price regulation was introduced in period 27 in the figure. Average prices of pharmaceuticals subject to reference pricing display a pronounced decrease after the implementation of the reform. In Table 2, we have calculated the average price in the periods before and after the implementation of the index price system. We find that average prices in the pre-regulation period is about 4.7 NOK, while average prices during reference pricing is about 3.3 NOK. This implies a price reduction of more than 29 percent. Turning to the therapeutic competitor group, we find a somewhat similar price pattern as in the group of pharmaceuticals subject to reference pricing prior to the reform, but the decrease in average prices after the reform is much smaller, about 12 percent. The average prices in the "others" group show a quite different price pattern; a large decline in the first part of the reference price period is followed by an increase in the second part of this period.

[Table 2 about here]

To get a better understanding of the price patterns depicted in Figure 1, we plot the averag prices of brand-names and generics together with the average price cap for the three groups. I Figure 2, we see that the average price of the brand-name drugs has been steadily decreasin after the implementation of the reference price regulation. Interestingly, in the post-regulatio period, average prices of generic drugs follow almost the same price pattern as brand-nam pharmaceuticals. The large variation in the average price of the generics in the period befor the reform is almost entirely due to entry of new generic drugs. In Figure 1A in the Appendix, we have plotted the same average prices as in Figure 2, but only included generics that hav been in the market during the entire sample period. From this figure, we see that the averag price of generics follows the same trend as the average prices of brand-names.

[Figure 2-4 about here]

From Figure 3 and 4, we see that average prices of brand-names in the therapeutic competito group and the "others" group follow the maximum price over the entire period. This indicate that the reference price regulation had a small, if any effect on the price setting of brand-nam drugs in the group of pharmaceuticals not directly affected by the regulation. However, averag prices of generic drugs in the therapeutic competitor group follow the same pattern as price for generics in the reference pricing group, which indicates that much of the price reduction i the "therapeutic competitor" group is explained by a reduction in prices on generic drugs. A obvious reason is that the price cap is binding for the brand-names but not for the generics. A a consequence, we will observe any price reduction on the generics, while for brand-names w observe only price reductions below the price cap.

5 Empirical Analysis

5.1 Design and econometric model

The descriptive statistics presented in Section 4 suggest a strong, negative price response o pharmaceuticals subject to reference pricing. There are also some indications of a negativ cross-price effect of the reform on non-included therapeutic competitors. In this section, w

present an econometric framework to analyse the price effects of the reform more carefully. Ideally, in order to estimate the effect of introducing reference pricing, we would like to know what the prices on the products affected by the reform would have been had the reform not been imposed on them. Since we only observe prices for these products with the imposed reform, we let the prices from a set of other comparable products represent the counterfactual. Having panel data, we are able to compare inter-temporal variation in prices before and after the imposition of the reform. Therefore, identification relies not only on before-after comparison, but also on comparison of price variation for drugs subject to the reform with price variation for comparable drugs not subject to the reform.

Our econometric framework is based on an application of a model used in numerous evaluation studies (e.g., Ashenfelter 1978; Card and Sullivan 1988; Lavy 2002; Pavcnik 2002), where (permanent) unobserved differences between pharmaceuticals are controlled for by including product fixed effects in the model. Following the convention from this literature, we use the notion 'treatment group' for the pharmaceuticals subject to reference pricing, while pharmaceuticals not subject to the reform are used as a comparison group.

In this section, we closely follow Lavy (2002) and Pavcnik (2002). Let the dummy variable D_{it} indicate treatment status for a given product, and let $P_{it}(0)$ indicate the price of product i in period t if the product is not exposed to treatment ($D_{it} = 0$). The fixed effect model then implies that the price of any untreated product i at time t can be written as

$$P_{it}(0) = \mathbf{X}'_{it}\beta + a_i + \delta_t + \varepsilon_{it}. \tag{1}$$

Here, a_i is a product fixed effect, δ_t is a period specific effect common to all products, ε_{it} represents unobserved time varying factors that affect prices, and $\mathbf{X}'_{it}$ contains observable variables. In the model, the error term ε_{it} is allowed to be correlated with a_i, but not with the treatment status D_{it}.

We assume a constant price effect of the reform, measured by α, and the post-reform prices for pharmaceuticals subject to reference pricing becomes: $P_{it}(1) = P_{it}(0) + \alpha$. Using $P_{it}(1)$,

$P_{it}(0)$ and equation (1), the observed price for product i in time period t can be written as

$$\begin{aligned} P_{it} &= P_{it}(0)(1 - D_{it}) + P_{it}(1) D_{it} \\ &= \mathbf{X}'_{it}\beta + a_i + \delta_t + \alpha D_{it} + \varepsilon_{it}, \end{aligned} \tag{2}$$

where the error term ε_{it} is assumed to be uncorrelated with D_{it}. This assumption has several testable implications: first, any price differences prior to the reform between products in the treatment group and products in the comparison group can be explained by observable variables and the product specific effect a_i. Second, after controlling for observables and the product specific effects, the price trend for drugs in the comparison group should not be significantly different in the post-reform period compared with the pre-reform period.

Since D_{it} is an interaction term[15] equal to 1 for products subject to the reform and 0 for all other drugs, then α is the estimated total effect of introducing reference pricing. However, previous studies have found that prices on brand-names and generics adjust differently to price regulations (e.g., Aronsson et al., 2001, Pavcnik, 2002). To distinguish between brand-names and generics, we therefore interact D_{it} with a dummy B_i that equals 1 if product i is a brand-name.

We are also interested in whether there is a cross-price effect of reference pricing on therapeutic competitors. Pharmaceuticals with different chemical compounds but similar therapeutic effects are typically substitutes in treatment. It is therefore likely that price responses triggered by the reference price system may influence the pricing of non-included therapeutic substitutes.[16] To estimate such effects, we introduce the variables DTC_{it} and $DTC_{it} * B_i$, where DTC_{it} is the interaction between a dummy indicating observations in the post-reform periods and a dummy indicating whether or not a product is a therapeutic competitor. After taking the natural log of prices, our estimating equation thus becomes

$$\begin{aligned} \ln P_{it} &= \mathbf{X}'_{it}\beta + a_i + \delta_t + \alpha_1 D_{it} + \alpha_2 D_{it} * B_i \\ &\quad + \alpha_3 DTC_{it} + \alpha_4 DTC_{it} * B_i + \varepsilon_{it}. \end{aligned} \tag{3}$$

[15] For products within six of the seven therapeutic substances subjected to the reference price system, this variable equals zero for period $t = 1, \ldots, 26$, and one for period $t = 27, \ldots, 48$. For products within the seventh substance, that was included as of June 2004, the variable equals zero up to period $t = 41$ and one thereafter.

[16] Ellison et al. (1997) provide evidence of negative price elasticities between drugs with different chemical compounds but therapeutically similar effects.

Note that we by this specification have two different treatment groups. The first group consists of pharmaceuticals subject to reference pricing, the second group of their therapeutic competitors, while the drugs in the "others" group serve as our comparison group. Excluding the therapeutic competitors from the comparison group enables us to capture potential cross-price effects, and also ensures that the comparison group consists of drugs not affected by the reform. In the next section, we conduct tests that provide evidence that the "others" group is a valid comparison group.

The direct price effect of the reform is measured by α_1 and α_2. α_1 is the estimated price effect of the reform on generics subject to reference pricing, α_2 measures whether reference pricing influences brand-names differently than generics, and thus $\alpha_1 + \alpha_2$ is the price effect on brand-names subject to the reform. In a similar way, the two coefficients α_3 and α_4 measure the cross price effect of the reform on brand-names and generics in the therapeutic competitor group.

Within equation (3), a_i control for time constant product specific factors (both observed and unobserved) that affect prices, while the period specific effect, δ_t, control for time-varying factors that affect prices equally for all pharmaceuticals. $\mathbf{X}'_{it}$ consists of variables controlling for price cap regulation and the degree of competition. To control for price cap regulation, we include the natural log of the average price cap faced by product i at time t, $\ln PCAP$. From the figures in Section 4, we see that the brand-name prices follow the price cap level quite closely. Since the price cap is binding for the brand-names, we expect the sign of this variable to be positive; a lower price cap yields lower average prices, and vice versa. By including the price cap in our regressions, we ensure that the estimated effect of the reference price system is directly compared with the price cap regime.[17]

To control for the degree of competition, we calculate the Herfindahl index, measuring the degree of concentration within a therapeutic substance group. The Herfindal index will be maximised (take the value of 10.000) in case of only one product within substance group, capturing that a drug is still under patent protection and/or there is no (generic) competition. As competition increases, the index becomes lower. We therefore expect the estimated coefficient to have

[17] As explained in Section 3, the price caps were still calculated for the drugs subject to reference pricing in case the physicians restricted generic substitution or the patients refused to purchase a cheaper generic drug.

a positive sign, i.e., that higher market concentration support higher prices.

5.2 Empirical Results

As noted in the previous section, our estimating strategy relies on that drugs in the comparison group are "comparable" to drugs in the treatment groups, except for not being treated. Even though the figures in section 4 showed quite similar price trends for all three groups of pharmaceuticals prior to the reform, this assumption should be tested more thoroughly. We therefore start out this section by presenting results from two tests of the comparison group: first, in the pre-reform period, after controlling for covariates and product specific effects, the price trends for pharmaceuticals subject to reference pricing should not be different from the price trends for pharmaceuticals not included in the reform. Second, after controlling for covariates and product specific effects, the price trends for pharmaceuticals in the comparison group should not be different in the post-reform period compared with the pre-reform period.

In the first test, we run regressions on pre-reform data, where we regress log prices on period dummies and period dummies interacted with a dummy variable indicating treated products. We also control for changes in the price cap level, the degree of competition and product specific effects. If the interactions are jointly insignificant, this is an indication of a legitimate control group, i.e., that unobservable factors affecting price setting are uncorrelated with the probability that a given product is in the treatment group. In column 2-4 in table 3, we present results where price trends for pharmaceuticals subject to reference pricing are compared with price trends for pharmaceuticals in the control group (others group). The first model uses the period just prior to the reform (period 26) as the base group, the second model uses period 13 as the base group, and in the third model we use the first period in our dataset as the base group. The three last columns in table 3 give similar comparisons of the therapeutic competitors and the comparison group. Despite a few significant interactions in model 3 and 6, we find the results from these regressions quite conclusive due to the fact that joint insignificants of the interactions are not rejected in any model.

[Table 3 about here]

In the second test, we restrict our sample to pharmaceuticals in the comparison group and

regress log prices on a dummy variable equalling 1 for the post-reform period and 0 otherwise. In the regression, we control for period dummies, the price cap level, the degree of competition, and a product specific effects. The dummy variable has no significant effect on prices, and clearl indicates that price trends for drugs in the comparison group are not affected by the referenc pricing reform. On the basis of the results from these tests, we conclude that the "others" grou is a legitimate comparison group.

[Table 4 about here]

We start out by estimating a fixed effect model based on a simple version of equation (3), where we focus on pharmaceuticals exposed to reference pricing only, not distinguish betwee brands and generics.[18] We see from model 1 in table 4 that the estimated effect of the reform is a price reduction of about 24 percent. Not surprisingly, this is in line with the results reported i table 2, where we compared the average prices before and after the introduction of the referenc price system. In model 2, we allow for brand-names and generics to be affected differentl by the reform. Similar to Aronsson et al. (2001) and Pavcnik (2002), our results show that reference pricing triggers a stronger price reduction on brand-names (30 percent) than generics (19 percent).

So far we have not taken price cap regulation into account. From figure 1-4 we see that the brand-name prices follow the price cap quite closely. Since the development of the price cap differs among the three groups, it is important to control for changes in the price cap level. We find an estimated elasticity of around 0.74 (model 3), which clearly demonstrates the importance of this variable in the price setting behaviour of pharmaceutical companies. By comparing R-squared in model 2 and 3, we find that this variable accounts for about 50 percent of the explained within-group variation in the dependent variable in our sample. More importantly, after controlling for this variable, we find that the estimated price effect of the reference price system is substantially lower. The price reduction for brand-names is about 18 percent, while generics face a price reduction of about 7 percent. This result is not surprising since we see from

[18] In the models in table 4, we have tested for three different time specifications; year dummies, period dummies and a time trend variable. In terms of R-squared, we found that the best specification was the one with period dummies.

figure 2-4 that the drugs included in the reference price system face a reduction in the price cap, while the price cap for those not included is more stable.

Turning to a potential cross price effect, we find that prices on products that are therapeutic substitutes to those included in the reference price system have responded to the reform as well. On average, prices on therapeutic substitutes are reduced by 2.2 percent (model 4). However, a separation of the effect on brand-names and generics (model 5) reveals that it is merely the prices on therapeutic generics that respond to the reform, by price reduction of 6.4 percent, whereas the effect on branded therapeutic substitutes is statistically insignificant by a F-test and close to zero. A possible explanation is that the price cap is binding for the brand-names but not for the generics. This implies that we capture any price reductions on the generics, while for brand-names we observe only price reductions *below* the price cap. However, under free pricing, or less strict price regulation, it is likely that also the brand-names will reduce their prices as a response to the lower prices triggered by reference pricing.

Finally, in model 6, we control for the degree of competition by using the Herfindahl index. The estimated effect of this variable turns out to be statistically insignificant. However, due to a possible endogeneity problem, the result must be interpreted with some care. For example, the probability of generic entry in a marked segment might be influenced by higher prices because of higher anticipated profit. This suggests a negative correlation between prices and the Herfindahl index, which indicates a downward bias in our estimates. One possible solution to this problem is to instrument for the variable, i.e., finding a variable that affects the market concentration but not directly affects the prices of existing products. However, since the estimated price effects of the reform are unaffected by the inclusion of the competition variable, and since it is hard to find good instruments, we choose not to do so in this study.

To summarize this section, we find that the introduction of reference pricing has led to an average price reduction of about 18 percent on brand names and 8 percent on generics. The reference pricing system also have a negative price effect on generics in therapeutic substitute group of about 6 percent. We have tested the robustness of these results by running a number of regressions, where we experiment with different model specifications, different comparison groups and the length of time periods. For example, we have estimated model 1 to 6 using a comparison group consisting of off-patent drugs facing generic competition only; we have tried

to include different competition variables, like the number of generics and whether or not there is generic competition; we have also estimated the models using two and three month time periods. In all of these different regressions, we got results that did not differ substantially from those reported in Table 4.[19]

6 Concluding remarks

We have analysed the relationship between regulatory regimes and pharmaceutical firms' pricing strategies, focusing on the relative performance of reference pricing and price cap regulation. A unique policy experiment from Norway, where a sub-sample of off-patent drugs was exposed to reference pricing, has been exploited to carefully identify the effects on pharmaceutical prices. Our analysis showed that the reference pricing system induced lower prices of both brand-names and generics exposed to the system. In addition, we identified a negative cross-price effect on therapeutic substitutes still under price cap regulation. Notably, our results are robust to different model specifications and choices of comparison groups, as discussed in the previous section.

We believe these results are interesting for several reasons. First, the results show that pharmaceutical firms' respond to different regulatory regimes. In particular, reference pricing tends to trigger price competition and lead to lower prices than price cap regulation. This price response is not obvious considering the complicated structure of demand and supply in the pharmaceutical industry, including the presence of insurance and informational asymmetries. Some have also questioned whether reference pricing actually triggers competition (e.g., Danzon, 2001, Puig-Junoy, 2005). However, the pro-competitive effect seems very robust, as several recent studies, including ours, report lower prices and/or higher generic market shares due to reference pricing (Aronsson et al., 2001, Pavcnik, 2002, Bergman and Rudholm, 2003, Dalen et al., 2005).

Second, the policy experiment enables us to provide evidence, not only on generic competition, but, importantly, also on therapeutic competition. The negative cross-price effect on the therapeutic substitutes not exposed to the reference price system shows that there exists therapeutic competition in the market. The effect is, though, weaker than the direct price ef-

[19] The results from these regressions are avaiable from the authors upon request.

fect, which is consistent with Ellison et al. (1997) who show that generics are closer substitutes than brand-names with different chemical ingredients but similar therapeutic properties, a very intuitive result.

Third, the results provide some information in terms of policy implications. Reference pricing turns out to be more effective than price cap regulation in lowering drug prices. Assuming that total demand (not individual market shares) is relatively inelastic, this strongly indicates that reference pricing is superior in reducing medical expenditures. To indicate the economic significance of the reform, we can calculate the potential savings in medical expenditures. In 2002 the total sales value of the drugs included in the reference price system amounted to 474.4 mill NOK, with a brand-name market share of about 72 percent. Using our estimated price reductions of about 18 percent on brand-names and 8 percent of generics, we obtain cost saving of about 75 mill NOK. This is a conservative figure of two reasons. First, the reference price system is likely to trigger a shift in market shares from the brand-names to the generics (e.g., Aronsson et al., 2001). Second, when extending the reform to the whole generic market segment, the savings (in absolute terms) will be even higher.

However, the negative cross-price effect on therapeutic substitutes outside the system points at a potential detrimental aspect of reference pricing, namely that it may affect the patent rent and potentially stifle innovation. Clearly, this is not a great concern if only Norway introduced such a system, but reference pricing has become increasingly popular worldwide. In addition, the cross-price effect indicates that even *generic*, not just therapeutic, reference pricing may induce patients to trade-off health gains against lower co-payments.

Finally, we would like to emphasis that our study does not perform a social welfare analysis of the different regulatory regimes. A complete welfare analysis would have to measure the effects of the reference price system on patients' health condition, the pharmaceutical firms' profits and innovation incentives, and, eventually, on the medical expenditures, potentially including the costs of public funds. Although our paper provides some partial information about profits and expenditures, through the price effects, a complete welfare analysis is outside the scope of the current paper and left for future research.

7 Appendix

[Figure 1A about here]

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Table 1. Sample characteristics

ATC-group	Drug subject to reference pricing	Therapeutic competitor	Brand name	Manufacturer	Number of generics	Number of observations
A02BA02	No	Yes	ZANTAC	GLAXOSMITHKLIN	5	254
A02BC01	Yes	No	LOSEC	ASTRAZENECA	1	86
A02BC03	No	Yes	LANZO	WYETH-LEDERLE	0	48
A02BC05	No	Yes	NEXIUM	ASTRAZENECA	0	48
C07AB02	No	No	SELO-ZOK	ASTRAZENECA	3	109
C07AB03	No	No	TENORMIN	PFIZER	5	242
C09AA02	Yes	No	RENITEC	MSD	3	131
C09AA03	Yes	No	VIVATEC	ASTRAZENECA	4	205
			ZESTRIL	MSD		
C09BA02	No	Yes	RENITEC COMP	MSD	1	72
C09CA01	No	Yes	COZAAR	MSD	0	48
C09DA01	No	Yes	COZAAR COMP	MSD	0	48
C10AA01	Yes (1.6.2004)	No	ZOCOR	MSD	2	82
C10AA03	No	Yes	PRAVACHOL	B-MYERS SQUIBB	0	48
C10AA05	No	Yes	LIPITOR	PFIZER	0	48
G04BE03	No	No	VIAGRA	PFIZER	0	48
L02BB03	No	No	CASODEX	ASTRAZENECA	0	48
M01AH01	No	No	CELEBRA	PFIZER	0	48
M01AH02	No	No	VIOXX	MSD	0	45
M05BA04	No	No	FOSAMAX	MSD	0	48
N02BE01	No	No	PANODIL	GLAXOSMITHKLIN	4	240
N02CC01	No	No	IMIGRAN	GLAXOSMITHKLIN	0	48
N05AH03	No	No	ZYPREXA	ELI LILLY	0	48
N06AB04	Yes	No	CIPRAMIL	LUNDBECK	3	112
N06AB05	No	Yes	SEROXAT	GLAXOSMITHKLIN	0	48
N06AB06	No	Yes	ZOLOFT	PFIZER	0	48
N06AX03	No	Yes	TOLVON	ORGANON	1	96
R03AK06	No	No	SERETIDE	GLAXOSMITHKLIN	0	48
R03AK07	No	No	SYMBICORT	ASTRAZENECA	0	44
R06AE07	Yes	No	REACTINE	PFIZER	3	151
			ZYRTEC	UCB		
R06AX13	Yes	No	CLARITYN	SCHERING-PLOUGH	4	176
Total					37	2765

Table 2. Average prices before and after reference pricing.

	Prices before	Prices after	Percentage price change
Drug subject to reference pricing	4.66 (3.18)	3.48 (2.23)	-25.32%
Therapeutic competitors	6.95 (2.78)	6.09 (2.55)	-12.37%
Other drugs	14.21 (16.89)	14.05 (16.34)	-0.01%

Table 3. Testing for pre-reform differences in price trends between groups of products. Fixed effect results with robust standard errors.

	Reference price group vs. others group			**Therapeutic competitors vs. others group**		
	(1)	(2)	(3)	(4)	(5)	(6)
	Period 26 base group	Period 13 base group	Period 1 base group	Period 26 base group	Period 13 base group	Period 1 base group
Interaction period 1	.043 (.045)	.024 (.025)	-	-.009 (.029)	-.022 (.019)	-
Interaction period 2	.026 (.044)	.006 (.023)	-.018 (.029)	-.010 (.029)	-.024 (.019)	-.001 (.018)
Interaction period 3	.031 (.043)	.012 (.021)	-.012 (.027)	-.005 (.028)	-.019 (.018)	.004 (.016)
Interaction period 4	.057 (.046)	.038 (.027)	.014 (.033)	-.008 (.036)	-.022 (.029)	.001 (.028)
Interaction period 5	.023 (.041)	.004 (.017)	-.020 (.024)	-.021 (.032)	-.035 (.025)	-.013 (.023)
Interaction period 6	.016 (.042)	-.003 (.018)	-.027 (.025)	.002 (.034)	-.011 (.027)	.011 (.025)
Interaction period 7	.008 (.040)	-.011 (.016)	-.035 (.024)	.009 (.030)	-.004 (.020)	.018 (.019)
Interaction period 8	.007 (.040)	-.013 (.015)	-.036 (.023)	.014 (.029)	.000 (.020)	.022 (.018)
Interaction period 9	.009 (.039)	-.010 (.014)	-.034 (.023)	.017 (.029)	.003 (.019)	.025 (.018)
Interaction period 10	.009 (.039)	-.010 (.014)	-.034 (.023)	.020 (.029)	.006 (.019)	.028 (.018)
Interaction period 11	.056 (.056)	.037 (.040)	.013 (.043)	.002 (.032)	-.011 (.025)	.011 (.024)
Interaction period 12	.049 (.049)	-.029 (.032)	.006 (.036)	.007 (.031)	-.007 (.023)	.015 (.021)
Interaction period 13	.019 (.039)	-	-.024 (.025)	.014 (.030)	-	.022 (.019)
Interaction period 14	.045 (.041)	.026 (.023)	-.002 (.030)	.020 (.029)	.006 (.020)	.029 (.020)
Interaction period 15	.043 (.040)	.024 (.022)	-.000 (.029)	.015 (.030)	.001 (.021)	.024 (.020)
Interaction period 16	.065 (.044)	.045 (.027)	.021 (.032)	.028 (.034)	.014 (.027)	036 (.026)
Interaction period 17	.024 (.039)	.005 (.022)	-.020 (.030)	.038 (.032)	.024 (.024)	.047* (.023)
Interaction period 18	.026 (.038)	.007 (.020)	-.017 (.029)	.040 (.030)	.026 (.022)	.049* (.021)
Interaction period 19	.015 (.036)	-.005 (.020)	-.028 (.029)	.046 (.032)	.032 (.024)	.055* (.024)
Interaction period 20	-.014 (.038)	-.033 (.024)	-.057 (.031)	.030 (.035)	.016 (.028)	.039 (.027)
Interaction period 21	-.029 (.039)	-.048 (.026)	-.072* (.033)	.028 (.034)	.014 (.027)	.037 (.026)
Interaction period 22	-.033 (.039)	-.052 (.030)	-.076* (.037)	.010 (.035)	-.003 (.028)	.019 (.028)
Interaction period 23	-.019 (.037)	-.038 (.025)	-.062 (.034)	.013 (.034)	-.001 (.027)	.022 (.026)
Interaction period 24	-.033 (.037)	-.043 (.025)	-.076* (.034)	.010 (.034)	-.004 (.027)	.019 (.026)
Interaction period 25	-.035 (.043)	-.054 (.035)	-.078 (.042)	.012 (.039)	-.002 (.034)	.021 (.033)
Interaction period 26	-	-.019 (.039)	-.043 (.045)	-	-.014 (.030)	.009 (.029)
Ln price cap	.707** (.058)	.707** (.058)	.707** (.058)	.604** (.047)	.605** (.047)	.604** (.047)
Herfindahl-index/100	-.001 (.001)	-.001 (.001)	-.001 (.001)	.000 (.000)	.000 (.000)	.000 (.000)
Period dummies	Yes	Yes	Yes	Yes	Yes	Yes
Joint insignificance of interactions (Prob>F)	.818	.763	.214	.619	.887	.097
Number of observations	965	965	965	1397	1397	1397
Number of products	47	47	47	65	65	65
R-squared	.53	.53	.53	.50	.50	.50

*: significant at the 5% level. **: significant at the 1% level.

Table 4. Testing for pre- and post-reform differences in price trends for drugs in the comparison group. Fixed effect results with robust standard errors.

	(1)
Reform dummy	-.007 (.023)
Ln price cap	.778** (.019)
Herfindahl-index/100	.003 (.007)
Constant	.294** (.074)
Period dummies	Yes
Number of observations	1016
Number of products	24
R-squared	.69

**: significant at the 1% level.

Table 5. Price effects of reference pricing. Fixed effect results with robust standard errors.

	(1)	(2)	(3)	(4)	(5)	(6)
Products subject to reference pricing	-.242**	-.189**	-.070**	-.079**	-.080**	-.076**
	(.015)	(.019)	(.017)	(.018)	(.018)	(.020)
Branded products subject to reference pricing		-.110**	-.109**	-.109**	-.109**	-.107**
		(.026)	(.021)	(.021)	(.021)	(.021)
Ln price cap			.739**	.737**	.737**	.736**
			(.019)	(.019)	(.019)	(.019)
Therapeutic competitors* reference period				-.022**	-.064**	-.063**
				(.008)	(.017)	(.017)
Branded therapeutic competitors* reference period					.061**	.060**
					(.016)	(.016)
Herfindahl-index/100						.002
						(.002)
Constant	1.738**	1.733**	.391**	.393**	.396**	.446**
	(.019)	(.019)	(.035)	(.035)	(.035)	(.051)
Period dummies	Yes	Yes	Yes	Yes	Yes	Yes
Number of observations	2765	2765	2765	2765	2765	2765
Number of products	69	69	69	69	69	69
R-squared	.36	.37	.68	.68	.69	.69

**: significant at the 1% level.

Figure 1. Average prices of drugs subject to reference pricing, their therapeutic competitors and the "others" group.

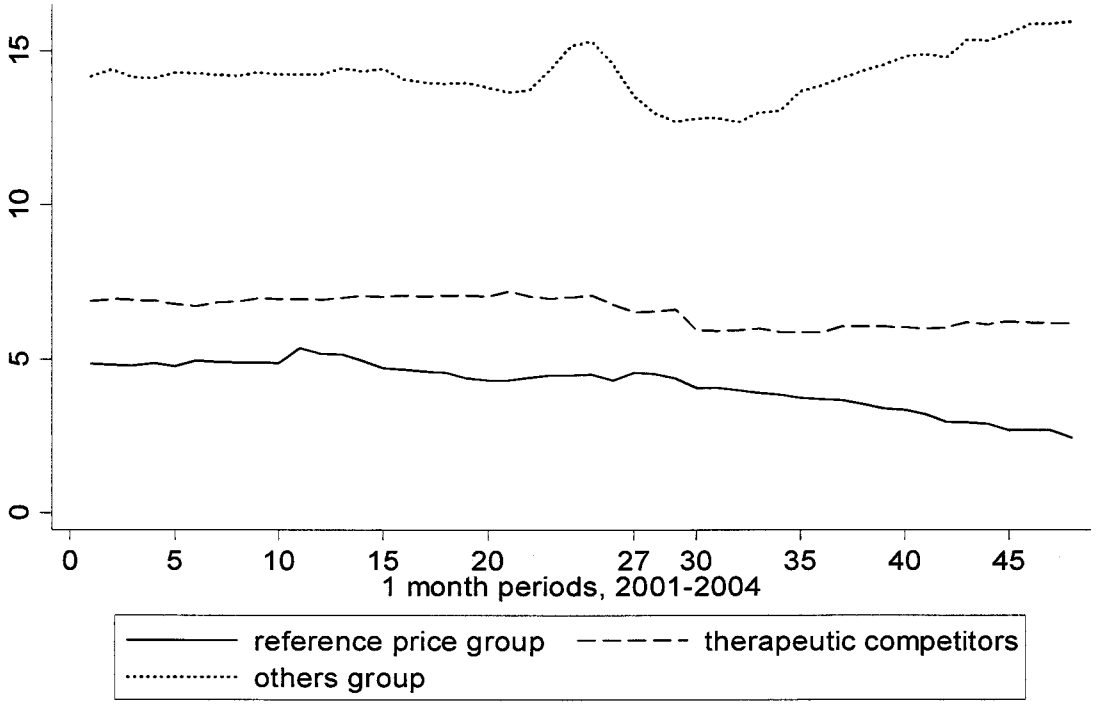

Figure 2. Average prices of brand-names and generics in the reference pricing group.

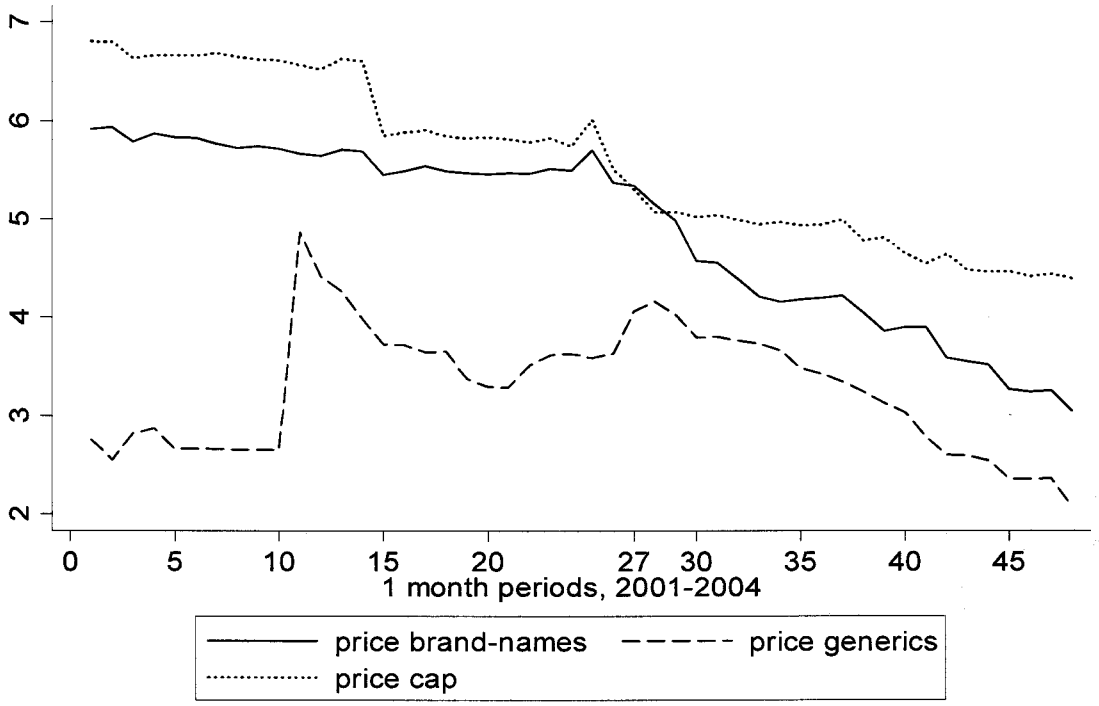

Figure 3. Average prices of brand-names and generics in the therapeutic competitor group.

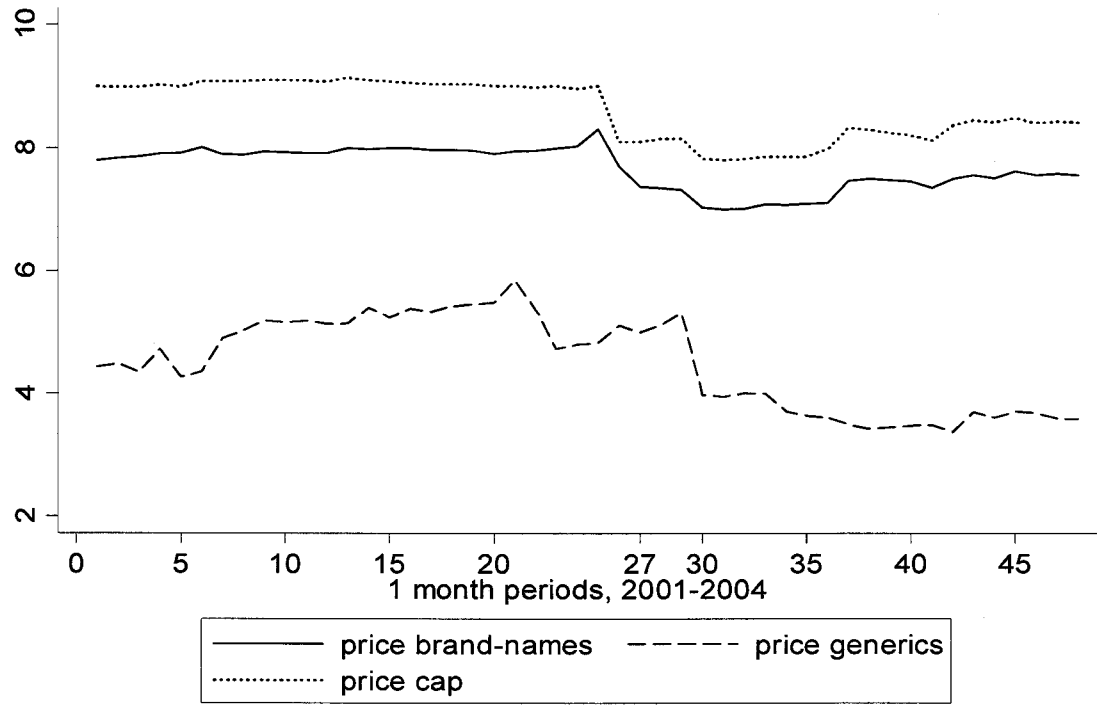

Figure 4. Average prices of brand-names and generics in the "others" group.

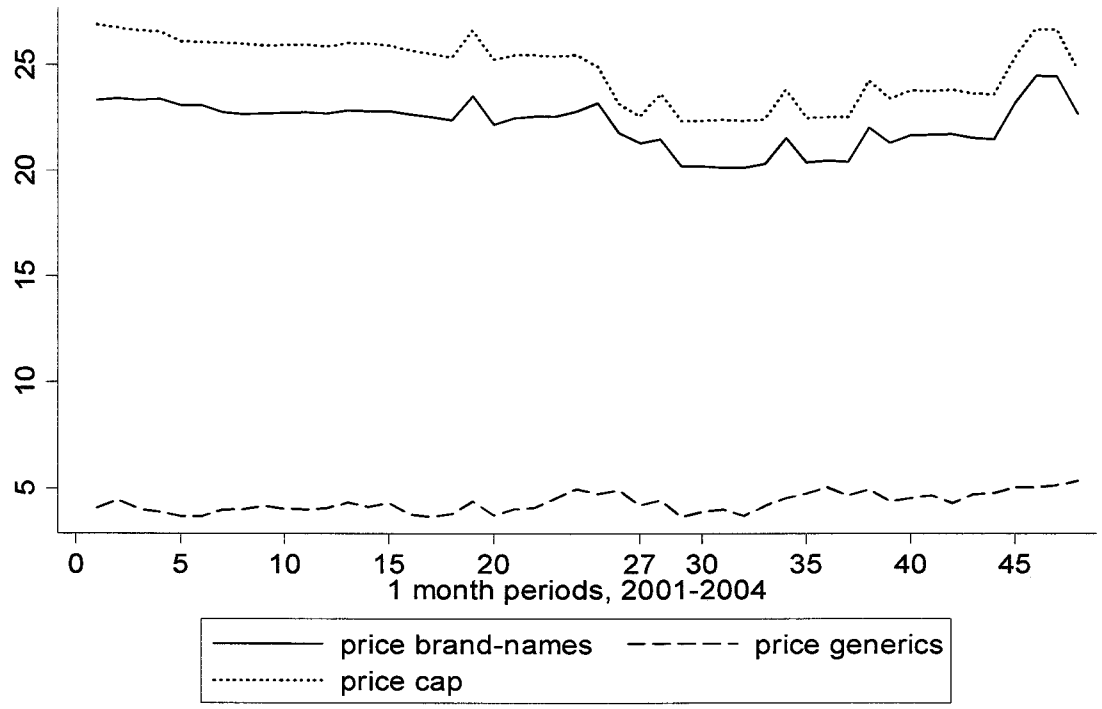

Figure A1. Average prices of brand-names and generics in the reference pricing group when excluding generics with entry in the sample period.