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Price Regulation and Parallel Imports of Pharmaceuticals

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Abstract

This paper studies the effects of price regulation and parallel imports in the on-patent pharmaceutical market. In a theory model where the producer price is subject to bargaining between the brand-name producer and a distributor, we show that the effects of stricter price regulation crucially depend on whether the producer faces competition from parallel imports. While parallel imports improve the bargaining position of the distributor, price regulation counteracts this effect and may even be pro.table for the producer. We test the implications of our model on a unique dataset with information on sales and prices at both producer and retail level for 165 substances over four years (2004-7). We show that stricter price regulation reduces competition from parallel imports, and has no (strictly negative) effect on producer profits in the presence (absence) of parallel imports. Our results suggest that price regulation might improve static efficiency without being harmful for dynamic e¢ ciency in the presence of parallel imports.

JEL-Code: I110, I180, L130, L510, L650.

Keywords: pharmaceutical market, price regulation, parallel imports.

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1 Introduction

Price regulation and parallel trade are essential features of pharmaceutical markets in Europe. Almost every European country use price control to curb the growth in pharmaceutical expenditures.[1] Parallel trade is generally encouraged in the EU through the principle of free movements of goods, which implies that pharmaceuticals can be legally traded without the consent from the original producer across national borders. In the US, price regulation and parallel imports (particularly from Canada) have been discussed as policy measures to better control increasing medical expenditures, but are so far not implemented due to concerns for innovation incentives.[2]

From an economic perspective, price regulation and parallel trade are controversial in pharmaceutical markets. On the one hand, these policy instruments may improve static efficiency. Price regulation curbs the market power of pharmaceutical companies and forces prices closer to marginal production costs. Parallel trade stimulates (intra-brand) competition in the importing (high-price) country, and induces price convergency across high- and low-income countries. On the other hand, price regulation and parallel trade are likely to be harmful for dynamic efficiency. Price regulation directly cuts pharmaceutical prices below profit-maximising levels, whereas parallel trade limits the scope for international price discrimination, reducing pharmaceutical companies' profits and thus incentives for innovation.[3]

There exists several papers that study either price regulation or parallel trade in pharmaceutical markets, but the literature on the interaction and joint impact of these policy instruments is very limited. Our paper contributes to filling this gap in the literature by studying the effects of price cap regulation on market outcomes depending on the presence of parallel import. Based on the discussion above, we expect price regulation and parallel trade to have negative effects on prices and profits, and that the combination of these two policy instruments are particularly bad for pharmaceutical companies. In this paper, we show that these conjectures are actually false, and that the interaction between price regulation and parallel imports significantly changes the expected effects. In particular, we show that stricter price regulation can be beneficial to

[1] See Carone et al. (2012) for a recent overview of pharmaceutical market regulation in the EU.

[2] See, for instance, Vernon and Golec (2008) for a presentation of the US debate and a comprehensive literature review on this topic.

[3] Danzon (1997) provides an excellent presentation and discussion of the efficiency arguments related to regulation in pharmaceutical markets.

pharmaceutical firms in the presence of parallel imports, though it is clearly negative in absence of parallel imports.

Our paper consists of both a theory and an empirical part. In the theory part, we consider a patent-protected brand-name drug that is sold in a domestic (high-price) country and a foreign (low-price) country. In the domestic country, the brand-name producer negotiates the producer price with a monopoly distributor that may or may not have access to a parallel-imported version from the foreign country. The distributor sets the retail prices on the original and parallel-imported drug versions in the domestic country subject to price cap regulation. We show that, in absence of parallel imports, stricter price cap regulation reduces the bargained producer price and the profits of both the producer and distributor. However, in presence of parallel imports, the effects of stricter price cap regulation are ambiguous and depend on relative bargaining power.

The reason for the different results is that competition from parallel imports changes the pricing incentives of both the producer and the distributor. If the producer pushes for higher prices, the distributor will shift demand towards the parallel-imported drug by reducing its retail price. This implies that the producer price is constrained not only by relative bargaining power, but also by the producer's incentive to restrain competition from parallel importers. Thus, the presence of parallel import shifts market power from the upstream to the downstream part of the industry. However, stricter price cap regulation weakens competition from parallel importers, shifting market power back towards the upstream part of the industry. The producer can take advantage of this and obtain a higher producer price and profits if relative bargaining power is sufficiently strong.

In the empirical part, we estimate the effects of price cap regulation on sales, prices, profits and expenditures in therapeutic markets depending on the existence of parallel imports. The empirical analysis exploits exogenous variation in the price caps over time for different substances to identify causal effects on the dependent variables. We make use of a unique administrative data set covering all prescription-bound sales in Norway with monthly information on prices and volumes per product at both producer and retail level. The data set also includes information about the retail price cap levels and whether the drug is original or parallel-imported. Our sample consists of 165 on-patent substances and covers a four-year period from 2004 to 2007.

Using a regression model with product fixed effects, we find, as expected, that a reduction in the price cap weakens competition from parallel imports, resulting in higher market shares to the original product. A stricter price cap also reduces producer prices, but the effect is much weaker when the original producer faces competition from parallel imports, as predicted by our theoretical analysis. The effect on producer profit is clearly negative in absence of parallel import. However, in presence of parallel imports, a stricter price cap has no effect on producer profits. This is consistent with our theoretical results that suggest that price cap regulation is less harmful (and may potentially be beneficial) to the original producers when facing competition from parallel importers. Finally, we find that stricter price cap regulation reduces total expenditures, with the effect being stronger for substances with parallel imports than for substances without parallel imports. These results suggest that price regulation is less harmful to dynamic efficiency when original producers face competition from parallel importers, and that price regulation and parallel trade are policy complements rather than policy substitutes.

Our paper contributes to, and bridges, the two strands of literature on the effects of (i) parallel trade and (ii) price regulation of pharmaceuticals. To the best of our knowledge, this paper is the first to study price regulation and parallel imports in conjunction, taking explicitly into account the vertical structure of the pharmaceutical industry. The literature on *parallel trade of pharmaceuticals* consists of papers that are mainly concerned with the effects on prices, innovation and welfare. Ganslandt and Maskus (2004) study the effects of parallel trade using Swedish data, and find that competition from parallel imports reduced prices by 12-19 percent.[4] Using data from 30 countries, Kyle (2010) examines the effect of both potential and actual entry of parallel imports on prices of original drugs. She also finds that parallel import reduces prices, but the effects are weaker than those reported by Ganslandt and Maskus (2004). On the contrary, Kanavos and Costa-Font (2005) estimate the effect of the market share of parallel imports on price competition, but do not find statistically significant effects.

Even if parallel trade leads to lower prices, the welfare implications are far from clear-cut. Jelovac and Borday (2005) analyse the (static) welfare effects of parallel imports of pharmaceuticals using a theory model where a monopoly producer sells a drug in two countries. They find

[4] Granlund and Köksal (2011) find that the Swedish mandatory substitution reform caused 15-17 percent fall in prices on drugs facing competition from parallel imports.

that permitting parallel imports improves welfare if countries only differ in patients' utility of drug treatment, while it reduces welfare if countries only differ in insurance coverage.[5] While the static welfare effects of parallel trade may be positive, a main concern is that it reduces the monopoly rent of the patent holder and may therefore have adverse effects on innovation. However, Grossman and Lai (2008) offer a theoretical argument to the contrary. In a North-South model with innovation in the North and price regulation in the South, they show that allowing for parallel trade may in fact increase innovation incentives under optimal price regulation. The key to this insight is that regulators will optimally set different prices depending on whether or not parallel trade is allowed.[6]

Our paper differs from the above-mentioned papers in two important aspects. First, neither of these studies take explicitly into account the vertical structure of the pharmaceutical industry when assessing the effects of parallel trade; more specifically, how parallel trade affects the relative bargaining position of a distributor vis-á-vis the patent-holding producer. Second, while the above-mentioned studies are concerned about the effects of parallel trade *per se*, we focus instead on how the presence of parallel trade affects the impact of price regulation.

Regarding studies on the impact of *price regulation of pharmaceuticals*, several papers find that such regulation is detrimental to innovation incentives (see, e.g., Giaccotto et al., 2005; Vernon, 2005; Golec and Vernon, 2006; Kyle, 2007). Another strand focuses on the impact of price regulation on competition, pricing and expenditures in the off-patent market. For example, Danzon and Chao (2000) argue that price regulation in pharmaceutical markets tends to drive out competition and present empirical evidence in support of this claim. Furthermore, recent papers by Brekke et al. (2009, 2011) show that the use of reference pricing may be more effective than price cap regulation in reducing pharmaceutical prices and expenditures.[7] We contribute to this particular strand of the literature by analysing how the presence of parallel trade affects the impact of price cap regulation.

[5] There is also a more general literature on the welfare effects of allowing parallel imports (or, more generally, uniform pricing versus third degree price discrimination). In a seminal paper Malueg and Schwartz (1994) show that the welfare effects are generally ambiguous. Later contributions have considered extensions such as endogenous quality (Valletti and Szymanski, 2006) and strategic policy choices (Roy and Saggi, 2012).

[6] A related mechanism is present in the analysis by Pecorino (2002), who discusses whether the US should allow for parallel imports of prescription drugs from Canada.

[7] See also Brekke et al. (2013) for the effect of pharmacy margins on sales of brand-names and generics, and on prices and expenditures.

The rest of the paper is organised as follows. In Section 2 we describe the Norwegian pharmaceutical market. In Section 3 we develop our theory model and derive predictions for the empirical analysis. In Section 4 we present our data and descriptive statics of the main variables. In Section 5 we describe our empirical strategy, report the main results, and conduct robustness checks. In Section 6 we discuss potential endogeneity issues in our empirical analysis. Section 7 concludes the paper.

2 The Norwegian pharmaceutical market

Total sales of pharmaceuticals in Norway exceeded 20 billion Norwegian crowns (NOK) in 2013, where about 70 percent of the sales being patent-protected drugs.[8] In the European Economic Area, which Norway is a part of, pharmaceuticals can be legally traded due to the EU principles of free movement of goods. Obstruction of parallel trade by firms or national governments are generally not allowed and would be subject to EU litigation. However, parallel traders need a marketing licence to import drugs to Norway, and have to relable and repack the products with Norwegian text according to patient safety regulations. Parallel traders usually also rebrand the product by replacing the company name of the original producer with their own company name. The market share of parallel imports relative to the total pharmaceutical market in Norway is fairly small (3.6 percent in 2013), but considerably larger for the patent-protected market segment, as we will show in Section 4.

In Norway, price cap regulation applies to prescription drugs at retail level and is based on international reference pricing.[9] The price cap for a given drug is computed as the average of the three lowest prices in the following nine reference countries; Austria, Belgium, Denmark, Finland, Germany, Ireland, the Netherlands, Sweden, and UK. The computation is based on original drug prices at wholesale (pharmacy purchasing) level in the reference countries. The price cap at retail level is derived by adding a regulated mark-up that pharmacies can charge, which is partly a fixed fee and a (degressive) percentage add-on.[10] The retail price cap applies

[8] See the Facts and Figures 2014 report at the webpage of LMI; www.lmi.no. 1 Euro is about 9 NOK, 1 US dollar is about 7 NOK, and 1 British pound is about 11 NOK.

[9] For details, see the Norwegian Medicines Agency's website www.legemiddelverket.no.

[10] In 2013 the regulated mark-up was 22 NOK plus 7% up to 200 NOK and 4% above 200 NOK. For a drug priced at 300 NOK, the maximum mark-up is then 40 NOK, implying a retail price cap at 340 NOK.

to all drug versions, including parallel-imported (and generic) drugs.

The price caps are revised annually by the regulator (Norwegian Medicines Agency), and will change according to the price development in the reference countries. In August/September, the regulator ranks the substances according to sales in the previous year. The price cap revisions are then ordered according to this ranking, starting with the most selling drugs first.[11] In the empirical analysis, we exploit these revisions to identify the effects of stricter (or more lenient) price cap regulation.

While retail (and wholesale) prices are subject to price cap regulation, producer prices are not regulated but determined by negotiations between producers and distributors. In the off-patent market segment, the original producers face competition from generic drug producers, which limits their bargaining power vis-á-vis the distributors. However, in the on-patent market segment, the competitive threat for the original producers is competition from parallel importers, which is exactly what we study in this paper.

At downstream level, the Norwegian market is dominated by three wholesalers (Alliance Healthcare, NMD Grossisthandel, and Apokjeden Distribusjon) who distribute all pharmaceuticals that are sold on the market. The three wholesalers own most (85 percent) of the pharmacies. Table 1 describes the market structure of the downstream part of the industry in Norway.

[Table 1 about here]

We see that Apokjeden Distribusjon who owns pharmacies in the Apotek 1 chain was the largest wholesaler with 37.4 percent of the pharmacies on the Norwegian market in 2007. The second largest was NMD Distribusjon with Vitusapotek pharmacies and the franchise chain Ditt Apotek, covering 32 percent of the pharmacies on the market. The third largest wholesaler was Alliance Healthcare with the Boots/Alliance pharmacies, having 22.3 percent of the pharmacies on the market. In addition, there are public hospital pharmacies (Sykehusapotek) and a few independent pharmacies, who both receive the drugs from one of the three wholesalers.[12]

The wholesalers are required to store and deliver all pharmaceuticals demanded by patients

[11] For the exact details of the price cap revisions, see www.legemiddelverket.no.

[12] In 2007, the public hospital pharmacies had a contract with NMD Distribusjon, whereas the independent pharmacies was served by Alliance Healthcare.

(prescribed by doctors), implying that exclusivity contracts are not feasible in practice. Moreover, producers cannot sell directly to (independent) pharmacies, but need to reach an agreement with the wholesalers. Finally, the wholesalers are required to report the gross and net transacted producer prices to the government, and are not allowed to include side-payments in their contracts with the producers.[13]

Individuals in Norway are insured against medical expenditures by compulsory social insurance collected through general taxation. The national health insurance covers prescription drugs treating illnesses that last for some time (non-acute) and are sufficiently severe (non-trivial). For non-reimbursable prescription drugs, patients have to pay the full price out-of-pocket. For the reimbursable drugs, patients pay 38 percent of the price of the drug, but only up to certain expenditure caps per script and per year. If the pharmaceutical expenditures exceed these amounts, there is 100 percent insurance coverage.

3 Theoretical model

Consider a patent-protected drug that is sold in two countries, "domestic" and "foreign", by the original brand-name producer. The producer prices in the two countries are w and v, respectively. In the domestic country the drug is distributed by a monopoly distributor and the producer price, w, is a result of bargaining between the producer and the distributor.[14] We consider the case where $w > v$ in equilibrium, implying that there is scope for arbitrage which is assumed to be exploited by parallel-trading firms. For simplicity, we assume that the market for parallel-traded drugs is perfectly competitive. Abstracting from transportation costs, this implies that the domestic distributor can import parallel-traded drugs at a price v. This price is taken to be exogenous, reflecting the assumption that the domestic market is small relative to the foreign market so that domestic price changes have a negligible effect on foreign prices. Domestic retail prices for the original and the parallel-traded drugs are given by p_0 and p_1, respectively.

[13] Initially, the reason for this regulation was that the government based the (internal) reference price for substances with generic competition on the producer prices. However, this reference pricing scheme is abolished, but the regulation is preserved for monitoring and planning purposes of the health authority.

[14] In the theoretical model, we do not distinguish between wholesalers and pharmacies. This corresponds well with the Norwegian market where 85 percent of pharmacies are vertically integrated with wholesalers.

In the domestic market there is a continuum of consumers demanding the brand-name drug. The consumers differ in their willingness-to-pay (θ) for the drug treatment, where $\theta \sim U[0,1]$. The utility of a consumer with valuation θ is given by

$$U = \begin{cases} \theta - \alpha p_0 & \text{if buying the original drug} \\ \gamma\theta - \alpha p_1 & \text{if buying a parallel-imported drug} \end{cases}, \tag{1}$$

where $\alpha \in (0,1)$ is the coinsurance rate. The residual share $(1-\alpha)$ of the price is covered by medical insurance. The parameter $\gamma \in (0,1)$ reflects our assumption that consumers attach a higher value to the original brand-name product than to the parallel-imported product.[15] The difference in consumer valuation captures the reputation effect related to company name. The parallel importer usually repackages and rebrands the products replacing the original producers' company name with its own company name. Such rebranding is a way to create product differentiation and thereby relax competition with the original producer. Since the original brand name is presumably more familiar to most consumers than those of parallel importers, it is reasonable to assume that the type of product differentiation created by rebranding is vertical product differentiation, where reputation or brand-recognition effects imply that the willingness-to-pay is generally higher for the original brand-name version of the drug. This assumption is also supported by the observed price patterns, where parallel-imported drugs are generally priced lower than the original version of the drug.[16,17]

In an equilibrium where both product types are sold, consumers with high (low) willingness-to-pay demand the original (parallel-imported) drug. The consumer who is indifferent between buying the original and the parallel-imported drug is characterised by

$$\theta_0 = \frac{\alpha(p_0 - p_1)}{1-\gamma}, \tag{2}$$

while the consumer who is indifferent between buying the parallel-imported drug and refrain

[15] In order to ensure the existence of an equilibrium with positive sales of both product types when parallel imports are allowed, we make the assumption $p_0 > \frac{v}{\gamma}$.

[16] See Section 4 for descriptive statistics.

[17] Notice also that the assumption that product differentiation is vertical is not critical to the results derived in this section. Similar results can also be derived in a model of horizontal product differentiation. Further details are available upon request.

from drug consumption is characterised by

$$\theta_1 = \frac{\alpha p_1}{\gamma}. \tag{3}$$

Demand for, respectively, the original and parallel-imported drugs, are therefore given by

$$y_0 = \int_{\theta_0}^{1} ds = 1 - \theta_0, \tag{4}$$

$$y_1 = \int_{\theta_1}^{\theta_0} ds = \theta_0 - \theta_1. \tag{5}$$

The profit of the original brand-name producer is given by

$$\pi_0 = (w - c)\, y_0 + (v - c)\, y_1, \tag{6}$$

where $c \in (0, v)$ is the marginal cost of producing the drug. The first term is the profit from direct sales in the domestic country, whereas the second term is the profit from sales to parallel traders. For simplicity, and without loss of generality, we ignore the residual profits from direct sales in the foreign country, which are independent of the parallel trade and the pricing decisions in the domestic market.

Finally, the profit of the domestic distributor is given by

$$\pi_D = (p_0 - w)\, y_0 + (p_1 - v)\, y_1. \tag{7}$$

We consider the following two-stage game:

Stage 1 The domestic distributor and the original producer bargain over the producer price w.

Stage 2 The domestic distributor chooses retail prices and drug consumption takes place.

We assume that domestic retail prices are subject to price cap regulation, and consider the case where, in equilibrium, the price cap binds for the original product. Given our demand assumptions, an equilibrium where both product types are sold must necessarily have a retail price for the parallel-imported drug below the price cap.

3.1 Benchmark: No parallel trade

As a benchmark for comparison, we briefly consider the case where parallel imports of patented drugs are either prohibited or unprofitable (because the producer price difference between the countries is too small). In this case, domestic demand for the original drug is given by

$$\widetilde{y}_0 = 1 - \alpha p_0. \tag{8}$$

The profits of the brand-name producer and the distributor are, respectively, given by

$$\widetilde{\pi}_0 = (\widetilde{w} - c)\,\widetilde{y}_0, \tag{9}$$

$$\widetilde{\pi}_D = (p_0 - \widetilde{w})\,\widetilde{y}_0, \tag{10}$$

where $\widetilde{w}$ is the bargained producer price in the absence of parallel imports.

Assuming Nash bargaining between the producer and the distributor, the producer price is given by

$$\widetilde{w} = \arg\max \widetilde{\Omega} := \beta \ln \widetilde{\pi}_D + (1-\beta) \ln \widetilde{\pi}_0, \tag{11}$$

where $\beta \in (0,1)$ is the relative bargaining strength of the distributor. If the price cap (p_0) binds, the equilibrium producer price is given by

$$\widetilde{w} = (1-\beta)\,p_0 + \beta c. \tag{12}$$

A binding price cap then implies[18]

$$p_0 < \frac{1+\alpha c}{2\alpha}. \tag{13}$$

Producer and distributor profits are, respectively, given by

$$\widetilde{\pi}_0 = (1-\beta)\,(p_0 - c)\,(1 - \alpha p_0)\,, \tag{14}$$

$$\widetilde{\pi}_D = \beta\,(p_0 - c)\,(1 - \alpha p_0)\,, \tag{15}$$

[18] The right-hand side of the inequality is simply the monopoly price the distributor would charge in absence of price cap regulation.

whereas total expenditures are exogenously determined by the price cap, and given by

$$\widetilde{T} := p_0 \widetilde{y}_0 = p_0 \left(1 - \alpha p_0\right). \tag{16}$$

The effects of price cap regulation on producer profits and total expenditures are relatively straightforward:

$$\frac{\partial \widetilde{\pi}_0}{\partial p_0} = \left(1 - \beta\right)\left(1 - \alpha\left(2p_0 - c\right)\right) > 0 \quad if \quad p_0 < \frac{1 + \alpha c}{2\alpha}, \tag{17}$$

$$\frac{\partial \widetilde{T}}{\partial p_0} = 1 - 2\alpha p_0 \gtrless 0. \tag{18}$$

Stricter price cap regulation unambiguously reduces both producer and distributor profits.[19] Although a lower retail price leads to higher sales, the producer price is bargained downwards. As long as the price cap binds, the reduction in producer prices more than outweighs the increase in sales, leading to lower producer profits. The more bargaining power the distributor has, the larger is the negative effect of stricter price cap regulation on producer profits.

The effect of price cap regulation on total expenditures is *a priori* ambiguous, though, since a lower retail price leads to increased drug consumption. Therefore, the effect on expenditures depends on the price elasticity of drug demand. If the price cap is sufficiently low to begin with, stricter price cap regulation will always reduce total expenditures.

3.2 Parallel imports

Suppose now that the original brand-name producer faces competition from parallel importers. Since parallel-imported drugs are (by assumption) vertically differentiated from the original drug, it is profitable for the distributor to price these drugs below the regulated price cap.[20] Substituting from (2)-(5) into (7) and maximising π_D with respect to p_1, the profit-maximising

[19] Obviously, a lower price cap reduces also distributor profits given that the price cap is binding:

$$\frac{\partial \widetilde{\pi}_D}{\partial p_0} = \beta\left(1 - \alpha\left(2p_0 - c\right)\right) > 0 \quad if \quad p_0 < \frac{1 + \alpha c}{2\alpha}.$$

[20] We consider the case where it is profitable for the distributor to sell both the original and parallel-imported drugs. This requires that parallel-imported drugs are priced lower than the original drug.

retail price of parallel-imported drugs is given by

$$p_1(p_0, w) = \gamma p_0 - \frac{1}{2}(\gamma w - v). \tag{19}$$

As expected, a lower price cap (which determines the price of the original drug) reduces the optimal retail price charged for parallel-imported drugs. Notice also that a higher producer price for the original drug will have the same effect. If the distributor obtains a lower profit margin on the original drug, the profit-maximising response is to steer demand towards parallel-imported drugs by lowering their price.

With a retail price given by (19), sales for the two drug versions are given by

$$y_0(p_0, w) = 1 - \alpha p_0 - \frac{\alpha(\gamma w - v)}{2(1-\gamma)}, \tag{20}$$

$$y_1(w) = \frac{\alpha(\gamma w - v)}{2\gamma(1-\gamma)}. \tag{21}$$

Notice that, with a binding price cap for the original drug, the original producer price affects sales of the two drug versions through the distributor's pricing of the parallel-imported drugs. A higher original producer price reduces the distributor's profit margin on original drug sales. The distributor will optimally respond by lowering the retail price of the parallel-imported drugs, which reduces (increases) the sales of the original (parallel-imported) drugs. Notice that an interior solution with positive sales of both product types requires $\frac{v}{\gamma} < w < p_0$.

At the first stage of the game, when the players anticipate that retail prices will be given by p_0 and $p_1(p_0, w)$, the bargained producer price for the original drug is given by

$$w^* = \arg\max \Omega := \beta \ln(\pi_D - \overline{\pi}_D) + (1-\beta)\ln \pi_0, \tag{22}$$

where $\overline{\pi}_D = (p_0 - v)\left(1 - \frac{\alpha p_0}{\gamma}\right)$ is the distributor's profit from the sales of parallel-imported drugs in the case of a bargaining conflict with the original producer.[21] On general form, the first-order condition for an interior solution to this bargaining problem, i.e., $w^* \in \left(\frac{v}{\gamma}, p_0\right)$, is

[21] We assume that, in case of a bargaining conflict, the distributor optimally adjusts the price of parallel-imported drugs to $p_1 = p_0$, which implies that demand for such drugs is $1 - \frac{\alpha p_0}{\gamma}$.

given by

$$\frac{\partial \Omega}{\partial w} = \frac{\beta}{\pi_D - \overline{\pi}_D} \frac{\partial \pi_D}{\partial w} + \frac{1-\beta}{\pi_0} \frac{\partial \pi_0}{\partial w} = 0, \tag{23}$$

where

$$\frac{\partial \pi_D}{\partial w} = -y_0 \left(p_0, w\right) < 0, \tag{24}$$

$$\frac{\partial \pi_0}{\partial w} = y_0 \left(p_0, w\right) - \alpha \left(\frac{\left(\gamma w - v\right) + \left(1-\gamma\right) c}{2\left(1-\gamma\right)} \right) > 0. \tag{25}$$

If the distributor has all the bargaining power, $\beta \to 1$, the outcome is a corner solution where $w \to c$ and no scope for profitable parallel imports. In the other extreme case, if the original producer has all the bargaining power, $\beta \to 0$, the outcome is, depending on the level of p_0, either a corner solution with $w \to p_0$ or an interior solution with $w < p_0$.[22]

It is not feasible to obtain an explicit interior solution for w^*. However, we can use (23) to examine the comparative statics properties of the interior solution. We are foremostly interested in how the bargained producer price is affected by price cap regulation:

Proposition 1 *Let the equilibrium producer price, w^*, be an interior solution to the Nash bargaining game between the original producer and the distributor. Stricter price cap regulation will then reduce (increase) the equilibrium producer price if the relative bargaining power of the distributor is sufficiently high (low).*

Proof. In Appendix. ■

A reduction in the price cap leads, all else equal, to higher sales of the original drug. Contrary to the case of no parallel imports, this has two counteracting effects on the interior solution to the bargaining problem between the distributor and the producer. For the distributor, an increase in sales of the original drug means that the profit loss of a higher producer price becomes larger (i.e., $|\partial \pi_D / \partial w|$ increases), which, all else equal, reduces w^*. For the original producer, on the other hand, higher sales increase the profit gain of a higher producer price (i.e., $\partial \pi_0 / \partial w$ increases), which, all else equal, increases w^*. Thus, the overall effect of a lower price cap on the bargained producer price depends on the relative bargaining power of the distributor and the

[22] If $\beta = 0$, the equilibrium producer price is given by

$$w = \min \left\{ p_0, \frac{v}{\gamma} + \frac{2\left(1-\gamma\right)\left(1-\alpha p_0\right) - \alpha c \left(1-\gamma\right)}{2\alpha\gamma} \right\}.$$

producer. If the bargaining power of the distributor (producer) is sufficiently strong, the former (latter) effect dominates and a price cap reduction will be followed by a reduction (increase) in the producer price.

It is worth emphasising how the producer's incentives in the bargaining game change when facing competition from parallel importers. Without parallel imports, the producer would like to obtain a price as close to the price cap as possible, and the bargained price is only constrained by the relative bargaining power of the two parties. Thus, a lower price cap would always lead to a lower bargained producer price (see Eq. (12)). However, with competition from parallel importers, the distributor responds to a higher producer price by reducing the retail price of parallel-imported drugs in order to steer demand away from the original drug version. This reduces the producer's profit gain of a higher producer price, i.e., $\partial\pi_0/\partial w$ is smaller in the presence of parallel imports. In fact, unless the price cap is very low, the producer prefers to charge a producer price at a level below the price cap in order to stifle the distributor's incentives to steer demand towards parallel-imported drugs. Consequently, in an interior solution, the bargained producer price is constrained not only by the players' relative bargaining power, but also by the producer's incentives to restrain competition from parallel importers. This affects qualitatively the relationship between the price cap and the producer's incentives in the bargaining game. All else equal, a lower price cap boosts the sales of the original drug at the expense of parallel-imported drugs. This makes it less urgent for the producer to keep the producer price low in order to meet competition from parallel-importers. Consequently, the producer, if he has sufficient bargaining power, obtains a higher producer price.

Put differently, competition from parallel importers shifts market power from the upstream to the downstream part of the industry, improving the relative bargaining position of the distributor vis-à-vis the producer. However, stricter price cap regulation weakens competition from parallel importers, shifting market power back towards the upstream part of the industry. The producer can take advantage of this and obtain a higher producer price, if his relative bargaining power is sufficiently strong.

Having established the relationship between the price cap and the bargained producer price of the original drug, we can proceed to assess the equilibrium effects of price cap regulation on the sales of the two product types and on the profits of the original brand-name producer:

Proposition 2 *(i) If $\partial w^*/\partial p_0 > 0$, stricter price cap regulation leads to higher sales of the original drug, lower sales of the parallel-imported drugs, whereas the effect on the profits of the original producer is ambiguous.*

(ii) If $\partial w^*/\partial p_0 < 0$, stricter price cap regulation leads to higher sales of both drug versions and higher profits for the original producer.

Proof. In Appendix. ■

Regardless of how the bargained producer price responds to a change in the binding price cap, stricter price cap regulation leads to higher sales of the original drug, which is quite intuitive. If there is a positive relationship between the price cap and the producer price, the increased sale of the original drug due to stricter price cap regulation comes at the expense of parallel-imported drug sales. Again, this is quite intuitive. In this case, stricter price cap regulation has an ambiguous effect on the profits of the producer. Sales in the domestic market increases (although part of this sales increase replaces foreign sales to parallel importers), but this is counteracted by a lower producer price in the domestic market.

However, if a lower price cap leads to a higher original producer price, stricter price regulation will, perhaps counterintuitively, increase the sales of both product types. From (21) we see that, for a given original producer price w, and when the distributor sets p_1 optimally, the demand for parallel-imported drugs does not depend directly on the price cap. The distributor will optimally adjust the price of parallel-imported drugs to any changes in the binding price cap, in a way that makes the demand for parallel-imported drugs insensitive to the *level* of the price cap.[23] Stricter price cap regulation then only affects parallel-imported drug sales through changes in the original producer price. More specifically, if a lower price cap leads to a higher producer price, the corresponding reduction in distributor profit margins on sales of the original drug gives the distributor a strong incentive to steer demand towards parallel-imported drugs. The distributor will therefore reduce p_1 to an extent where demand for parallel-imported drugs increases.

In the latter case, where $\partial w^*/\partial p_0 < 0$, the producer unambiguously benefits from stricter price cap regulation. A lower price cap leads to a sales increase to the domestic market, both directly to the domestic distributor and indirectly via higher demand from parallel importers. On top of that, the profit margin on direct sales to the domestic market increases.

[23] This particular feature results from the linearity assumptions of the model.

In the presence of competition from parallel importers, total drug expenditures in the domestic market are given by

$$T := p_0 y_0 + p_1 y_1. \tag{26}$$

The effect of price cap regulation on total expenditures is then given by

$$\frac{\partial T}{\partial p_0} = y_0 + p_0 \frac{\partial y_0}{\partial p_0} + \frac{\partial p_1}{\partial p_0} y_1 + p_1 \frac{\partial y_1}{\partial p_0} \lesseqgtr 0 \tag{27}$$

As in the benchmark case of no parallel imports, the effect of stricter price cap regulation on total drug expenditures is *a priori* ambiguous. However, there are now more sub-effects to consider, and the strength of the previous sub-effects are likely to be different.

The sum of the first and second terms in (27) is the effect on original drug expenditures. As in the benchmark case, a lower price cap leads to increased sales of the original drug, making the effect on expenditures ambiguous. The sum of the third and fourth terms is the effect on expenditures of parallel-imported drugs. Since the distributor responds to a price cap reduction by reducing the retail price of parallel-imported drugs, the third term is positive. The sign of the fourth term depends on the sign of $\partial w^*/\partial p_0$. If $\partial w^*/\partial p_0 > 0$, stricter price cap regulation leads to a reduction in the sales of parallel-imported drugs. On the other hand, if $\partial w^*/\partial p_0 < 0$, stricter price cap regulation leads to an increase in demand for both product types, which reduces the scope for an overall reduction in drug expenditures.

However, even if the demand for parallel-imported drugs falls as a result of a lower price cap, it is by no means certain that the presence of parallel imports makes price regulation a more effective instrument for curtailing drug expenditures. The reason is that the net demand loss for parallel-imported drugs is caused by consumers who switch to the original drug, which has become relatively cheaper as a result of a lower price cap. Thus, even if stricter price cap regulation leads to lower prices for both product types, total demand increases *and* a larger share of demand is directed towards the most expensive drug.

3.3 Discussion and empirical predictions

Although we cannot say anything conclusive about whether and how the effectiveness of price regulation as an instrument to control drug expenditures is determined by the presence of parallel

imports, the results reported in Proposition 2 clearly suggest that stricter price cap regulation might be less harmful for the producer in markets with parallel imports. Obviously, allowing for parallel imports will reduce the profits of the producer. However, *given that parallel imports are allowed*, the original producer will likely be less harmed by price cap regulation and might even benefit from it.

This has some potentially interesting implications for the optimal use of price cap regulation as a policy instrument. A standard concern about price regulation in on-patent drug markets is that, although it might improve static efficiency by reducing total drug expenditures, it will also reduce the patent-holder's return on its investment in drug innovation and therefore reduce dynamic efficiency. Our analysis suggests that the dynamic efficiency concern of using (relatively strict) price cap regulation should be less of a worry in markets where parallel imports are allowed. In such markets, it might actually be the case that stricter price cap regulation leads to both lower expenditures and higher profits for the brand-name producer.

If stricter price regulation improves both static and dynamic efficiency in markets with parallel imports, the policy implication that follows is that allowing parallel imports of on-patent drugs should optimally be complemented by relatively strict price regulation. The negative effects of the former policy (in terms of dynamic efficiency) may be counteracted by stricter price cap regulation, shifting rents from the downstream to the upstream part of the industry – from distributors to producers. From a dynamic efficiency perspective, the optimal policy package should allocate as much of the total industry rents as possible to the upstream part of the industry. Under certain conditions, as we have seen, price cap regulation has precisely this effect in markets where the producer faces competition from parallel importers. Thus, our analysis suggests that both policies – allowing parallel imports and enforcing a relatively strict price regulation – might be part of the optimal policy package, making these instruments policy complements rather than policy substitutes.

Based on our theoretical analysis, we make the following empirical predictions that will be tested econometrically:

(i) In markets with parallel imports, a reduction in the price cap leads to an increase in both sales and market share of the original drug.

(ii) In markets without parallel imports, a lower price cap reduces both the producer price and the profits of the brand-name producer, whereas in markets with parallel imports both these effects are ambiguous.

We will also test the effect of stricter price cap regulation on total drug expenditures, although our theoretical analysis does not allow us to make any clear-cut predictions besides the effect being theoretically ambiguous.

4 Data and descriptive statistics

For the empirical analysis, we have obtained register data from the Norwegian Institute of Public Health. Our data are extracted from two different databases; the Prescription database and the Wholesale database. The Prescription database contains information about all prescription bound sales at retail (pharmacy) level in Norway from 2004 and onwards. From this database, we have monthly data on retail prices and sales volumes for original and parallel-imported drugs over a four-year period (2004–2007). Prices and volumes are in defined daily doses (DDD) per pack sold by the pharmacies. The data also include the price caps for each product, as well as detailed information about product name, manufacturer, marketing firm, launch date, pack size, strength, presentation form (e.g., tablet, capsule, injection), etc. From the Wholesale database, we have monthly information about prices (per DDD) at producer (ex-manufacturer) level for each pack purchased by the wholesalers. As explained in Section 2, these data are available due governmental regulation, and are net transacted prices. We merge the data from these two databases using the pack identity, which gives us prices at both retail and producer level for original and parallel-imported drugs.

We define our sample by excluding substances where the brand-name product has competition from generic versions, yielding a sample of 165 substances.[24] Table 2 presents descriptive statistics for our sample separately for the 110 substances without parallel import and the 55 substances with parallel import during the sample period.

[Table 2 about here]

[24] A complete list of the substances in our sample can be provided upon request.

A first observation is that the average prices for parallel-imported drugs are lower than the average prices for original brand-name drugs at both producer and retail level. This is partly because of different pricing at pack level, but also because parallel traders tend to enter the market with a smaller product sample than the original producer. We see from the table that brand-name producers offer 313 different packs whereas parallel traders offer 186 different packs. Moreover, the average pack size is larger for parallel traders (52 DDDs) than for brand-name producers (41 DDDs). Since the price per DDD is usually lower for larger packs, this is likely to explain parts of the price differences. This also explains why the price caps are on average lower for parallel-imported products than for original brand-name products.[25]

A second observation is that the producer prices are substantially lower than the retail prices. This holds for both original and parallel-imported drugs. The price differences imply that distributors have a fairly large product margin, which indicates bargaining power at the downstream level. Finally, as can be seen from the table, parallel traders have fairly high sales. For the 55 substances with parallel imports, the market share of parallel imported drugs is on average 17 percent.

In Table A1 in the Appendix, we report prices for each of the 55 substances with parallel import. These figures show the same pattern for almost every substance. Notice that the price cap binds for a large number of the original drugs, whereas parallel-imported drugs tend to be priced slightly lower than the price cap. Thus, the descriptive statistics seem to fit the assumptions of our theoretical model reasonably well.

In the empirical analysis, we exploit variation within substances (or products) to investigate the effect of the price cap on our dependent variables. It is therefore important with sufficient variation in the price cap variable. One way to display the within variation is simply to graph the price cap over time for each substance. As our sample consist of 165 substances, we only show this variation for the six largest (in sales value) substances with and without parallel import; see Figure 1 and 2 below.

[Figure 1 and 2 about here]

[25] As described in Section 2, the price cap is common to all products (brand-name and parallel-imported drugs), but varies according to pack size, strength and presentation form.

The figures show that there is substantial variation in the price caps over time. As explained in Section 2, these changes are due to price cap revisions by the regulator, and reflect price development in the nine reference countries.[26] This creates considerable variation in the price caps over time. An alternative way to investigate the within variation is to decompose the standard deviation into between and within components, which is reported in Table 3 below.

[Table 3 about here]

The table shows substantial within variation in the price cap variable.

5 Empirical method and results

When testing the main predictions from our theoretical analysis, we estimate the following fixed effect model:

$$y_{it} = \alpha + \beta P_{it} + \gamma_i + \delta_t + \varepsilon_{it}, \tag{28}$$

where i denotes product (substance or pack) and t denotes time period. The dependent variable y_{it} is either market shares, sales (DDD), producer prices, profits or total expenditures; P_{it} is the price cap; γ_i is a product fixed effect; δ_t is a period fixed effect; and ε_{it} is a mean-zero error term. Since our variables are typically not normally distributed, we use the natural logarithm of all variables (except for market shares), which implies that we estimate elasticities.

The product fixed effect (γ_i) captures time-invariant, unobserved (and observed) factors that affect our dependent variables. This could be product characteristics such as the share of brand-loyal consumers and physicians, type of patients (age, gender), type of disease (chronic or acute), type of product (tablet, capsule, injection), etc. The period fixed effect (δ_t) captures time trends in our dependent variables that are common across products.

We estimate the effects of price cap regulation on different samples. First, we run the regression on the full sample of 165 substances. This means that we include the substances

[26] The price cap revisions are conducted annually by the regulator (Norwegian Medicines Agency). Substances subject to price cap regulation are first ranked according to their sales in the previous year. The regulator will then compute the revised price caps for the higher selling substances first. Thus, the frequency of revisions may be less (more) than a year for drugs that increase (reduce) their sales across years. The exact details of the price cap revisions can be found on the regulator's website www.legemiddelverket.no.

that potentially could have parallel import, but *de facto* do not have parallel import. Second, we run the regressions separately for the 110 substances with no parallel imports and the 55 substances where we observe parallel imports. This enables us to measure the different effects that variation in price cap levels have on the original brand-names depending on whether or not there is competition from parallel imports.

5.1 Market shares and sales

When estimating the effects of price regulation on market shares of original and parallel-imported products, we use information at substance level since parallel-imported drugs in many cases differ from original drugs in pack size, presentation form, etc.

[Table 4 about here]

As can be seen from Table 4, we find significant effects of price cap regulation on markets shares. For the 55 substances with parallel imports, a 10 percent reduction in the price cap results in almost five percent increase (reduction) in the market share of the original (parallel-imported) drug.[27] Thus, stricter price cap regulation tends to drive out competition from parallel-imported drugs.

We also estimate the effect of changes in the price caps on the total sales (measured in DDDs) of original and parallel-imported drugs. In this regression, we use information at the pack (not substance) level to exploit the variation in our data.

[Table 5 about here]

Table 5 shows that the effect of price cap regulation on the sales of original drugs varies substantially according to whether or not they have competition from parallel imports. For all 165 substances, our results show an elasticity of -0.48. When splitting the sample into substances with and without parallel imports, we see that the effect of a change in the price cap on the sales of original drugs is much stronger in the presence of parallel imports (-0.86 vs. -0.35). This is consistent with our theoretical results, where a lower price cap (in markets with parallel import)

[27] In a linear-log model, the expected change in Y of a 1 percent increase in X is approximately $\widehat{\beta}/100$.

not only expands the market, but also shifts sales from parallel-imported drugs to original drugs.

5.2 Producer prices and profits

We expect the effects of price cap regulation on producer prices and profits to depend crucially on whether there is parallel import, as stated in our second prediction. We first test the effect of price cap regulation on producer prices of both original and parallel-imported drugs.

[Table 6 about here]

Table 6 shows that for all 165 substance a 10 percent reduction in the price cap leads to on average 12.7 percent reduction in the producer price.[28] Consistent with our second prediction, we find that the effect of price cap regulation is weaker for substances with parallel import. However, the effect is positive, with an elasticity of 1.08, suggesting a relatively high bargaining power of the distributor in the presence of parallel imports. As expected, the effect of price cap regulation on the price of the parallel importer is negative, but weaker than for the original drug.

When testing the effect of price cap regulation on the firms' profits, we use sales revenues per product as a proxy. For original drugs, this should be a good proxy of profits, since the cost of producing the drugs is likely to be constant over time. The correlation between sales revenues and profits is probably weaker for parallel importers, since their profits depend on foreign prices.

[Table 7 about here]

Table 7 shows, as expected, that a stricter price cap is harmful for the brand-name producer in markets without parallel imports. However, in markets with parallel imports, we find a non-significant effect of price cap regulation on producer profits. This is consistent with our second prediction. In markets with parallel imports, price regulation has a strong, positive effect on the brand-name producers' sales, but a weaker, negative effect on prices. The result in Table 7 shows that the these opposing effects offset each other. The effect on the profits (sales revenues)

[28] The reason that the elasicity can exceed one is that the producer price is much lower than the price cap enforced at retail (pharmacy) level. Table 1 shows that the average price cap is 71.78 NOK, while the average producer price of locally sourced drug is 49.8 NOK.

of the parallel importer is as expected positive. A 10 percent reduction in the price cap results in a 28 percent reduction in profits due to reduction in sales and prices.

5.3 Total expenditures

In the final regression, we estimate the effect of price regulation on total expenditures. We measure total expenditures at pharmacy level per substance. Total expenditures are simply the price per DDD times the sales volumes in DDDs for all products with the same substance. In absence of parallel import, a lower price cap directly reduces the pharmacy price of the brand-name product, but sales volumes (DDDs) increase, as shown in Table 4. In presence of parallel import, a lower price cap also shifts market shares from lower priced parallel-imported drugs to higher priced original drugs. Thus, the net effect of lower price regulation on total expenditures is ambiguous and may depend on whether or not the substance has competition from parallel-imported drugs, as explained in the theory section.

[Table 8 about here]

We see from Table 8 that a lower price cap reduces total expenditures. For all 165 substances a 10 percent cut in the price cap leads to almost 6 percent reduction in total expenditures. Thus, the price effect dominates the sales effect. This is as expected since demand for prescription drugs is fairly price inelastic. We also see that price regulation is more effective in reducing expenditures for substances with parallel imports.

5.4 Robustness check

We have performed two different robustness checks to the results from our main empirical strategy. First, we have used an alternative estimation strategy, where we estimate the effects of price cap regulation on the whole sample in a single regression including a term where we interact the price cap with a dummy variable indicating whether the product is subject to parallel import or not. Thus, we estimate the following fixed-effects model:

$$y_{it} = \alpha + \beta_1 P_{it} + \beta_2 D_i * P_{it} + \gamma_i + \delta_t + \varepsilon_{it}, \tag{29}$$

where D_i takes the value 1 if product i is subject to parallel import and takes the value 0 otherwise.

The results from these regressions, which are shown in Table A2 in the Appendix, are largely similar to the ones presented above. A lower price cap leads to higher sales of the brand-name product, and significantly more so in markets with parallel import. A lower price cap also leads to lower producer price and lower profits, but both these effects are significantly smaller in markets with parallel imports. While the effect of price cap regulation on profits is negative for all products, most of this negative profit effect vanishes when products face competition from parallel importers (a 10% reduction in the price cap leads to a 10% reduction in profits on products without parallel import, while the corresponding profit reduction for products with parallel import is only 2%). Finally, a lower price cap reduces total expenditures for all products, but significantly more so for products subject to parallel import competition.

Second, we have also applied an alternative (and stricter) criterion for selecting substances which are subject to parallel trade. In our main empirical analysis, we have classified a substance as having parallel import if parallel imports are observed in at least one period. A more stringent classification would be to require parallel imports in every period. If we use this criterion, the number of substances with parallel imports reduce from 55 to 15. The results from the fixed effects model with this alternative way to split the sample are presented in Table A3 in the Appendix. We see that the results are very similar, with two exceptions. First, the negative effect of a stricter price cap on brand-name sales is quantitatively much stronger (with a coefficient of -1.477 compared to -0.860 in the main model). Second, and quite interestingly, stricter price cap regulation has now a significantly positive effect on the profits of the original producer (a 10% reduction in the price cap leads to a 3.6% increase in profits).

6 Endogeneity issues

An unfortunate feature of our data is that we do not observe foreign drug prices. As a result, we have explicitly (in the theory model) and implicitly (in the empirical analysis) assumed that foreign producer prices are exogenous. However, we cannot rule out the possibility that variation in the price cap in Norway might be correlated with variation in those foreign producer

prices that determine the profitability of parallel trade to Norway, and therefore generate biased estimates. There are potentially two different sources of such a correlation.

One possibility is that changes in foreign producer prices might affect the price cap in Norway. The foreign prices that directly affect the Norwegian price cap are the prices in nine reference countries listed in Section 2. A change in one of the three lowest prices for a particular drug in these countries will automatically lead to an adjustment of the Norwegian price cap for this drug. However, there is little or no parallel import to Norway from these countries, for two reasons. First, since the price cap is set as the average of the three lowest prices in the reference countries, the scope for parallel export from these countries to Norway is by definition almost non-existing. In addition, these countries are typically high-price countries.[29] Thus, we believe that any potential effect of changes in the parallel-importers' purchasing prices on the Norwegian price cap is, at most, indirect and weak.

Another possibility is that changes in the Norwegian price cap give the original producer an incentive to set different prices in other countries, in order to affect parallel trade flows. This is a key mechanism in the theoretical model by Grossman and Lai (2008). While such an effect is certainly theoretically plausible, we believe that in practice it will be close to negligible in our study. Since Norway is a small country and only constitutes a small share of the total parallel-trade market in Europe, we find it quite unlikely that price cap adjustments in Norway will have a significant impact on price setting in typical parallel-exporting countries like Spain or Italy.

In addition to the potential endogeneity of foreign producer prices, the presence (or not) of parallel imports for a particular substance is also endogenous. This would have been a bigger worry if our aim was to estimate the effect of parallel imports *per se*, rather the effect of price cap regulation in markets with and without parallel imports. Still, a potential worry is that there might be two different reasons for an absence of parallel import: (i) entry of parallel importers might be blockaded, because the producer price difference between the countries for a particular substance is too small, or (ii) entry might be strategically deterred by the producer. In the latter case, the producer accepts a domestic producer price that is just low enough

[29] Kanavos and Costa-Font (2005) report that Greece, Spain, Italy, Portugal, and France are the main parallel-exporting countries within the EU, and report findings that parallel export accounted for about 20% of the Greek pharmaceutical market.

to make parallel trade unprofitable. The predictions from our theoretical model are based on a comparison of an interior-solution equilibrium with parallel imports and an equilibrium where the possibility of parallel imports does not exist. Thus, in our empirical strategy to test the predictions derived from our theoretical model, we implicitly assume that the absence of parallel trade is explained by blockaded entry. This is also consistent with our theoretical model, where it is fairly straightforward to show that strategic entry deterrence is never an equilibrium outcome.[30] Based on this model, one way to interpret the two samples (with and without parallel imports) is that the relative bargaining power of original producers vary across different substances: for some substances, the relative bargaining power $(1-\beta)$ is sufficiently high to make parallel imports profitable (where $w > \frac{v}{\gamma}$) while for other substances β is so high that entry is blockaded (implying $w < \frac{v}{\gamma}$).

One way to reduce potential endogeneity problems related to the fact that price cap changes might affect entry, is to adopt stricter criteria when selecting the markets where original producers face competition from parallel traders. If we require such markets to have parallel imports present in every single period, we can be more confident that the price cap variation over time in these markets take place within an interval that is relatively far from the entry/exit threshold. This is precisely what we have done as a robustness check to the main analysis and, as explained in Section 5.4, the results are quite similar. If anything, one can argue that the estimates from the more selected sample give a stronger confirmation of the theoretical predictions, since the relationship between the price cap and the original producer's profits is significantly negative.

7 Concluding remarks

In this paper we have shown that the effect of price cap regulation crucially depends on the presence of parallel imports. Assuming Nash-bargaining between an original producer and a monopoly distributor, we derive the following empirical predictions: (i) in markets with parallel imports, a reduction in the price cap leads to an increase in both sales and market share of

[30] Strategic entry deterrence implies that the original producer accepts a producer price $w = \frac{v}{\gamma}$, which makes it (just) unprofitable for the distributor to sell both drug versions. However, it is easily shown that the original producer's profits are monotonically increasing in w around $w = \frac{v}{\gamma}$. Thus, if the producer has sufficient bargaining power to enforce a producer price that makes parallel trade profitable (i.e., $w > \frac{v}{\gamma}$), voluntarily accepting a price which deters entry of parallel traders is never a profitable strategy.

the original drug; (ii) in markets without parallel imports, a lower price cap reduces both the producer price and the profits of the brand-name producer, whereas in markets with parallel imports both these effects are ambiguous. We also show that the effect of stricter price cap regulation on total drug expenditures is theoretically ambiguous.

The predictions are tested econometrically using data from Norway on monthly sales and prices for 165 substances in the period 2004-7. Consistent with our first prediction, we find that stricter price cap regulation drives out parallel imports resulting in higher market shares and sales of the original brand-name product. Consistent with our second prediction, we find that stricter price cap regulation reduces producer prices and profits to the brand-name producer, but the effect is weaker for substances with parallel imports. In fact, a lower price cap has no significant effect on the original producers' profits for substances with parallel imports. Finally, we find that stricter price cap regulation reduces total expenditures, and that the effect is stronger for substances with parallel imports.

Price cap regulation is a policy instrument to promote static efficiency in pharmaceutical markets by forcing prices closer to marginal production costs and reducing pharmaceutical expenditures. Our study shows that the existence of parallel imports makes price cap regulation more effective in promoting static efficiency. Thus, parallel imports and price regulation are policy complements, though stricter price cap regulation reduces the scope for parallel imports. More surprisingly, our results show that price cap regulation is less harmful to (and might even promote) dynamic efficiency in markets with parallel imports, as the effect on the original producers' profits of a lower price cap is less negative and might even be positive when there is competition from parallel import. However, this result needs to be interpreted with caution, since we do not explicitly model the R&D process or empirically test the impact of price regulation on measures of innovation. Clearly, a full welfare analysis of price cap regulation and parallel import is beyond the scope of our study and therefore left to future research.

Appendix

Proof of Proposition 1

Assuming an interior solution of (22), and applying the implicit function theorem, we have

$$sign\left(\frac{\partial w^*}{\partial p_0}\right) = sign\left(\frac{\partial^2 \Omega}{\partial p_0 \partial w}\right), \tag{A1}$$

where

$$\frac{\partial^2 \Omega}{\partial p_0 \partial w} = \beta\left(\frac{\frac{\partial^2 \pi_D}{\partial w \partial p_0}\left(\pi_D - \overline{\pi}_D\right) - \frac{\partial \pi_D}{\partial w}\frac{\partial\left(\pi_D - \overline{\pi}_D\right)}{\partial p_0}}{\left(\pi_D - \overline{\pi}_D\right)^2}\right) + (1-\beta)\left(\frac{\frac{\partial^2 \pi_0}{\partial w \partial p_0}\pi_0 - \frac{\partial \pi_0}{\partial w}\frac{\partial \pi_0}{\partial p_0}}{\pi_0^2}\right). \tag{A2}$$

Substituting the equilibrium value of p_1 from (19), and the demand functions, (20)-(21), into the profit functions of the distributor and the original producer, yields

$$\pi_D\left(p_0, w\right) = \frac{4\gamma\left(1-\gamma\right)\left(p_0 - w\right)\left(1 - \alpha p_0\right) + \alpha\left(\gamma w - v\right)^2}{4\gamma\left(1-\gamma\right)} \tag{A3}$$

and

$$\pi_0\left(p_0, w\right) = \left(w - c\right)\left(1 - \alpha p_0\right) - \frac{\alpha\left(\gamma w - v\right)\left(\gamma w - v + \left(1-\gamma\right)c\right)}{2\gamma\left(1-\gamma\right)}. \tag{A4}$$

Recall that the disagreement payoff of the distributor is given by

$$\overline{\pi}_D\left(p_0\right) = \left(p_0 - v\right)\left(1 - \frac{\alpha p_0}{\gamma}\right). \tag{A5}$$

From (A3) we derive

$$\frac{\partial^2 \pi_D}{\partial w \partial p_0} = \alpha > 0, \tag{A6}$$

and

$$\frac{\partial \pi_D}{\partial w} = -y_0 < 0, \tag{A7}$$

and from (A3) and (A5) we derive

$$\frac{\partial\left(\pi_D - \overline{\pi}_D\right)}{\partial p_0} = \alpha\frac{\left(w\gamma - v\right) + 2p_0\left(1-\gamma\right)}{\gamma} > 0. \tag{A8}$$

Thus, the first term in (A2) is unambiguously positive. Using (A4) we derive

$$\frac{\partial^2 \pi_0}{\partial w \partial p_0}\pi_0 - \frac{\partial \pi_0}{\partial w}\frac{\partial \pi_0}{\partial p_0} = -\frac{\alpha^2\left(\gamma^2(w-c)^2 - (v-c)(v-\gamma c)\right)}{2\gamma(1-\gamma)} < 0. \tag{A9}$$

The negative sign of (A9) is established by noticing that the numerator is monotonically increasing in w. Inserting the lowest value of w that is compatible with an equilibrium where both product types have positive sales, $w = v/\gamma$, the numerator reduces to $\alpha^2 c(1-\gamma)(v-c\gamma) > 0$. Thus, the expression in (A9), and therefore the second term in (A2), is unambiguously negative for any $w \in \left(\frac{v}{\gamma}, p_0\right)$. Since (A2) consists of the sum of a positive and a negative term, it follows, by continuity, that $\frac{\partial^2 \Omega}{\partial p_0 \partial w} > (<)\, 0$ if β is sufficiently large (small). Consequently, $\frac{\partial w^*}{\partial p_0} > (<)\, 0$ if β is sufficiently large (small). *Q.E.D.*

Proof of Proposition 2

From (20)-(21), the effects of the price cap on sales are given by

$$\frac{\partial y_0}{\partial p_0} = -\alpha\left(1 + \frac{\gamma}{2(1-\gamma)}\frac{\partial w^*}{\partial p_0}\right) \tag{A10}$$

and

$$\frac{\partial y_1}{\partial p_0} = \frac{\alpha}{2(1-\gamma)}\frac{\partial w^*}{\partial p_0}. \tag{A11}$$

The sign of (A11) is unambiguously positive (negative) if $\partial w^*/\partial p_0 > (<)\, 0$. The sign of (A10) is unambiguously negative if $\partial w^*/\partial p_0 > 0$, whereas it is *a priori* ambiguous if $\partial w^*/\partial p_0 < 0$. From the proof of Proposition 1 we know that $\partial w^*/\partial p_0$ is "more negative" the lower is β. For the limit case of $\beta \to 0$ we can solve explicitly for w^* and find an explicit expression for $\partial y_0/\partial p_0$, given by

$$\left.\frac{\partial y_0}{\partial p_0}\right|_{\beta=0} = -\frac{\alpha}{2} < 0. \tag{A12}$$

Thus, the direct effect of a price cap reduction on the sales of the original drug always dominates the indirect effect via the bargained producer price, establishing a negative relationship between y_0 and p_0 regardless of the sign of $\partial w^*/\partial p_0$.

The effect of the price cap on the profit of the original brand-name producer is

$$\frac{\partial \pi_0}{\partial p_0} = \frac{\partial w^*}{\partial p_0} y_0 + (w^* - c) \frac{\partial y_0}{\partial p_0} + (v - c) \frac{\partial y_1}{\partial p_0}. \tag{A13}$$

If $\partial w^*/\partial p_0 > 0$, the first and last terms in (A13) are both positive, whereas the second term is negative, implying that the sign of the total effect is ambiguous. However, if $\partial w^*/\partial p_0 < 0$, all three terms are negative, giving an unambiguously negative total effect. *Q.E.D.*

Descriptive statistics: Substances with parallel imports

[Table A1 here]

Alternative estimation strategy

[Table A2 here]

Alternative market selection criteria

[Table A3 here]

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Figures and tables

Figure 1. Variation in the price caps for the six largest (in sales value) substances without parallel imports.

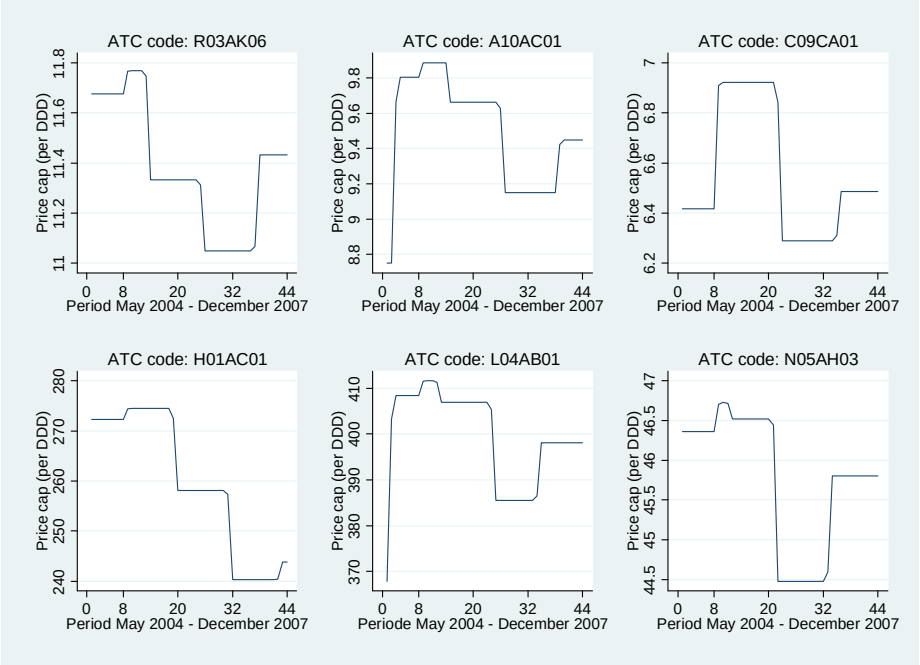

Figure 2. Variation in the price caps for the six largest (in sales value) substances with parallel imports.

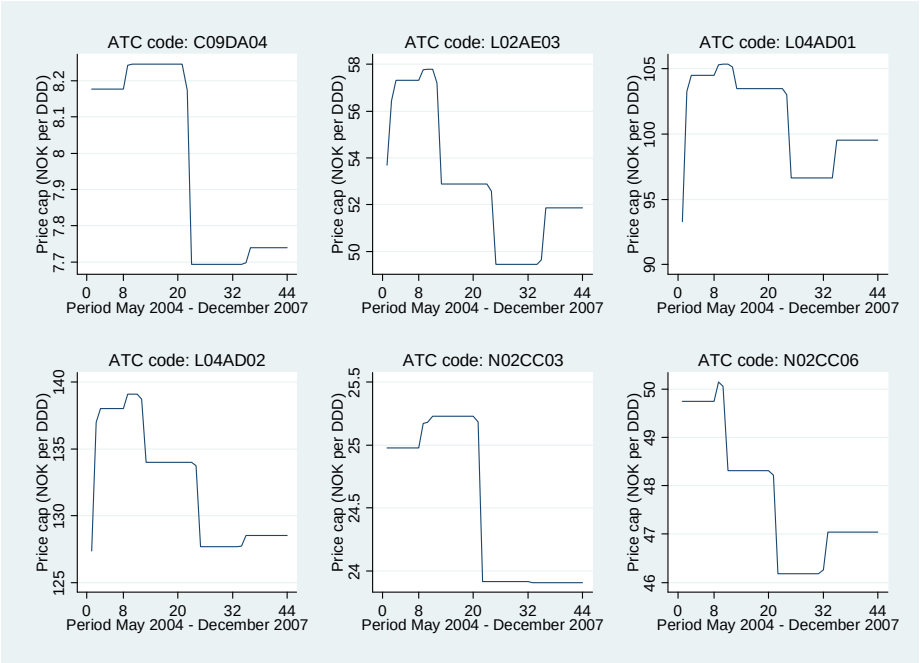

Table 1. Distribution of pharmacies according to ownership and chain, 2007

Pharmacy chain	Wholesaler	Vertical relation	Number of pharmacies	Market share (no. of pharmacies)
Boots/Alliance apotek	Alliance Healthcare	Integrated	137	22.3
Apotek 1	Apokjeden	Integrated	229	37.4
Vitusapotek	NMD	Integrated	152	24.8
Sykehusapotek	NMD	Contract	33	5.4
Ditt apotek	NMD	Franchise	44	7.2
Independent	Alliance Healthcare	Contract	18	2.9
Total			613	100.0

Table 2. Average prices, sales and market shares (standard deviations)

	Brand Name without parallel import	Brand Name with parallel import	*Parallel import*
Price Cap	71.78 (210.68)	53.43 (69.28)	42.14 (45.75)
Retail Price	71.62 (210.39)	53.34 (69.24)	41.61 (45.18)
Producer Price	49.84 (153.40)	36.45 (49.12)	26.36 (29.13)
Sales (in 1000 ddd)	108.90 (630.67)	116.32 (897.31)	56.66 (143.56)
Number observations	20 197	11 345	3610
Number Packages	548	313	186
Number ATC-groups	110	55	55

Table 3. Comparing overall and within variation in the Price Cap Variable

	The total sample		Six largest substances without parallel import		Six largest substances with parallel import	
	Mean	Standard deviation	Mean	Standard deviation	Mean	Standard deviation
Overall	62.81	165.48	115.39	117.45	69.41	41.51
Between		162.79		124.05		43.50
Within		14.11		6.02		3.33

Table 4. Effect of Price Cap Regulation on Market Shares of Brand-Name drugs, fixed effect models (robust standard errors)

Dependent variable: Brand-name market share	All products	Products with parallel import
Log P_{it}	-0.178***	-0.491***
	(0.012)	(0.034)
Constant term	1.473***	2.354***
	(0.037)	(0.107)
Period fixed effect	Yes	Yes
ATC fixed effect	Yes	Yes
R-squared	0.032	0.088
Number ATC	165	55
Number observations	7038	2372

Table 5. Effect of Price Cap on Sales (DDD), fixed effect models (robust standard errors)

		Brand-name		Parallel Import
Dependent variable: Log Sales (DDD)	All products	Products without parallel import	Products with parallel import	All PI products
Log P_{it}	-0.483***	-0.349***	-0.860***	2.178***
	(0.066)	(0.078)	(0.131)	(0.0.402)
Constant term	10.832***	10.251***	12.420***	2.829**
	(0.204)	(0.228)	(0.432)	(1.258)
Period fixed effect	Yes	Yes	Yes	Yes
Pack fixed effect	Yes	Yes	Yes	Yes
R-squared	0.044	0.037	0.061	0.103
Number ATC	165	110	55	55
Number packs	861	548	313	186
Number observations	31542	20197	11345	3610

Table 6. Effect of Price Cap on Producer Prices, fixed effect models (robust standard errors)

		Brand-name		Parallel Import
Dependent variable: Log Producer Price	All products	Products without parallel import	Products with parallel import	All products
Log P_{it}	1.265***	1.338***	1.078***	0.622***
	(0.005)	(0.007)	(0.009)	(0.018)
Constant term	-1.286***	-1.496***	-0.738***	0.711***
	(0.017)	(0.021)	(0.030)	(0.055)
Period fixed effect	Yes	Yes	Yes	Yes
Pack fixed effect	Yes	Yes	Yes	Yes
R-squared	0.665	0.667	0.679	0.048
Number ATC	165	110	55	55
Number packs	861	548	313	186
Number observations	31542	20197	11345	3610

Table 7. Effect of Price Cap on Profit, fixed effect models (robust standard errors)

		Brand-name		Parallel Import
Dependent variable: Log Profit	All products	Products without parallel import	Products with parallel import	
Log P_{it}	0.782***	0.989***	0.218	2.800***
	(0.067)	(0.078)	(0.132)	(0.398)
Constant term	-1.966***	-2.758***	1.570***	-7.974***
	(0.205)	(0.230)	(0.507)	(1.248)
Period fixed effect	Yes	Yes	Yes	Yes
Pack fixed effect	Yes	Yes	Yes	Yes
R-squared	0.040	0.038	0.049	0.119
Number ATC	165	110	55	55
Number packs	861	548	313	186
Number observations	31542	20197	11345	3610

Table 8. Effect of Price Cap Regulation on Total Expenditures, fixed effect models (robust standard errors)

Dependent variable: Log total expenditures	All products	Products without parallel import	Products with parallel import
Log P_{it}	0.596***	0.527***	0.697***
	(0.057)	(0.077)	(0.080)
Constant term	1.497***	1.523***	1.524
	(0.171)	(0.227)	(0.251)
Period fixed effect	Yes	Yes	Yes
ATC fixed effect	Yes	Yes	Yes
R-squared	0.140	0.124	0.199
Number ATC	165	110	55
Number observations	7038	4666	2372

Table A1. Descriptive statistics, substances with parallel import

Substance	Retail Price Brand-Name	Producer Price Brand-Name	Price Cap Brand-Name	Retail Price Parallel-Import	Producer Price Parallel-Import	Price Cap Parallel-Import	Periods with Parallel-Import
A02BC05	19.06 (16.17)	12.54 (11.62)	19.12 (16.37)	13.87 (3.15)	9.23 (2.10)	13.98 (3.19)	44
A07AA02	34.80 (0.11)	21.76 (0.01)	34.80 (0.11)	33.53 (1.52)	13.43 (2.75)	34.73 (0.25)	44
A07EA06	56.40 (15.27)	39.09 (10.41)	56.42 (15.28)	45.32 (9.03)	29.46 (5.32)	45.56 (9.05)	21
A08AA10	18.06 (3.67)	12.11 (3.01)	18.07 (3.65)	16.68 (3.62)	10.14 (2.29)	16.92 (3.56)	10
A08AB01	23.08 (0.58)	15.78 (0.41)	23.08 (0.58)	23.08 (0.05)	14.91 (0.01)	23.23 (0.00)	5
A08AX01	30.64 (0.45)	21.51 (0.23)	30.64 (0.45)	30.80 (0.02)	20.79 (0.01)	31.08 (0.00)	6
B01AC07	5.15 (0.38)	2.62 (0.31)	5.18 (0.42)	5.25 (0.41)	2.38 (0.24)	5.36 (0.45)	44
C09CA04	6.86 (1.51)	4.47 (0.91)	6.86 (1.51)	5.86 (1.21)	3.92 (0.70)	5.86 (1.21)	29
C09CA06	6.35 (3.05)	4.03 (1.79)	6.35 (3.05)	4.83 (1.20)	3.16 (0.74)	4.85 (1.20)	17
C09CA07	6.93 (2.55)	4.25 (1.33)	6.93 (2.55)	5.20 (1.32)	2.50 (0.83)	5.26 (1.32)	25
C09DA01	9.04 (1.62)	6.09 (1.12)	9.04 (1.62)	9.87 (0.18)	5.87 (0.01)	9.89 (0.16)	21
C09DA03	8.85 (1.06)	5.92 (0.69)	8.86 (1.06)	9.06 (0.23)	5.54 (0.07)	9.17 (0.20)	8
C09DA04	10.06 (1.58)	6.60 (1.12)	10.07 (1.57)	8.98 (1.18)	5.79 (0.84)	8.99 (1.19)	44
C10AA04	6.27 (2.21)	4.23 (1.52)	6.27 (2.21)	4.79 (1.20)	2.59 (0.34)	4.81 (1.21)	19
C10AX06	34.53 (1.18)	21.33 (2.14)	34.55 (1.19)	33.39 (0.58)	22.22 (0.00)	33.57 (0.10)	15
G03DA04	41.49 (5.23)	28.74 (3.91)	41.49 (5.23)	36.52 (0.18)	23.67 (0.00)	37.58 (0.10)	15
Substance	Retail	Producer	Price Cap	Retail	Producer	Price Cap	Periods

	Price Brand-Name	Price Brand-Name	Brand-Name	Price Parallel-Import	Price Parallel-Import	Parallel-Import	with Parallel-Import
G04CB01	9.91 (2.24)	6.07 (2.54)	10.27 (1.84)	10.80 (1.58)	6.92 (1.01)	10.88 (1.52)	44
G04CB02	11.01 (1.09)	6.98 (0.69)	11.01 (1.08)	11.01 (0.53)	6.53 (0.03)	11.04 (0.48)	23
H01AC01	233.50 (16.03)	168.10 (11.19)	233.57 (16.04)	225.04 (6.44)	148.25 (3.52)	228.83 (6.44)	18
H01CA02	37.55 (0.12)	25.85 (0.07)	37.55 (0.12)	37.37 (0.13)	26.32 (0.24)	37.37 (0.13)	9
J05AB11	168.41 (9.61)	108.20 (8.29)	169.38 (9.62)	170.82 (6.93)	111.11 (4.88)	171.35 (6.82)	31
L02AE03	51.25 (3.62)	36.62 (2.57)	51.28 (3.63)	51.67 (3.49)	35.56 (2.09)	52.12 (3.43)	44
L02BG03	39.33 (2.13)	27.92 (1.34)	39.36 (2.12)	38.48 (1.96)	27.45 (1.67)	38.92 (2.02)	34
L04AD01	104.68 (14.98)	68.27 (13.75)	104.76 (14.97)	107.66 (8.38)	64.29 (10.00)	109.95 (8.46)	44
L04AD02	145.76 (32.47)	102.79 (21.82)	145.78 (32.46)	124.28 (10.52)	84.53 (8.21)	125.42 (10.48)	44
N02CC03	49.57 (9.66)	31.89 (4.70)	49.62 (9.69)	44.45 (13.24)	28.12 (7.73)	44.72 (13.13)	44
N02CC05	56.74 (3.42)	34.26 (2.38)	56.75 (3.40)	52.16 (0.80)	30.69 (0.14)	53.25 (0.96)	19
N02CC06	65.79 (22.92)	42.67 (14.76)	65.84 (22.95)	46.75 (1.28)	31.36 (0.90)	47.38 (1.29)	44
N03AE01	8.23 (3.14)	3.63 (1.23)	8.23 (3.14)	7.76 (3.13)	3.26 (0.14)	7.86 (3.12)	44
N03AX14	39.45 (3.65)	27.40 (1.87)	39.46 (3.65)	37.52 (0.74)	26.46 (0.14)	37.79 (0.85)	4
N03AX16	33.76 (10.41)	21.85 (5.85)	33.76 (10.40)	18.67 (0.91)	12.76 (0.46)	18.73 (0.92)	21
N04BA02	31.19 (76.90)	20.79 (56.42)	31.21 (76.92)	8.28 (1.87)	4.74 (1.09)	8.38 (1.89)	44
N04BA03	68.09 (31.25)	44.06 (20.52)	68.12 (31.26)	66.19 (30.21)	40.36 (16.53)	66.36 (30.12)	21
N04BC05	67.89 (11.51)	41.47 (3.85)	67.89 (11.52)	58.91 (0.26)	35.00 (0.00)	58.91 (0.26)	7
N05AE04	62.54 (73.21)	43.13 (46.11)	62.54 (73.21)	49.00 (12.40)	31.57 (8.80)	49.43 (13.00)	28
N05AH03	48.25 (9.90)	33.46 (5.25)	48.25 (9.90)	41.67 (1.16)	27.85 (3.74)	42.62 (0.67)	44
N05AH04	56.92 (21.90)	36.71 (14.51)	58.73 (21.50)	39.18 (1.08)	26.69 (0.33)	39.28 (0.95)	16
N05AX12	72.59 (36.24)	51.04 (25.18)	72.59 (36.24)	50.86 (11.72)	34.89 (8.06)	51.42 (11.88)	2
N06AA06	12.78 (6.28)	6.06 (3.53)	13.06 (6.06)	7.33 (0.80)	3.31 (0.79)	7.91 (0.75)	44
N06AB10	7.77 (1.31)	4.94 (0.61)	7.79 (1.31)	6.27 (0.07)	3.89 (0.15)	6.37 (0.02)	18
N06AX16	13.90 (3.43)	8.63 (1.47)	14.30 (3.04)	12.59 (0.24)	8.35 (0.01)	12.76 (0.01)	13
N06BA09	138.16 (80.35)	92.37 (53.15)	138.38 (80.48)	124.84 (75.88)	85.19 (51.60)	126.20 (76.54)	10
N06DA02	35.38 (10.27)	25.02 (7.41)	35.42 (10.27)	33.96 (9.99)	22.08 (6.90)	34.13 (10.02)	40
Substance	Retail	Producer	Price Cap	Retail	Producer	Price Cap	Periods

	Price Brand-Name	Price Brand-Name	Brand-Name	Price Parallel-Import	Price Parallel-Import	Parallel-Import	with Parallel-Import
N06DA03	48.83 (24.45)	33.68 (16.66)	48.88 (24.50)	85.41 (0.22)	52.50 (0.00)	85.98 (0.07)	23
N07BC01	50.91 (12.24)	25.20 (3.27)	51.01 (12.19)	39.50 (0.89)	23.57 (0.38)	40.05 (1.24)	5
R01AC02	8.53 (0.45)	5.16 (0.32)	8.53 (0.45)	8.96 (0.45)	5.04 (0.38)	9.14 (0.51)	37
R01AD05	3.11 (0.95)	1.80 (0.37)	3.11 (0.95)	2.35 (0.19)	1.33 (0.12)	2.39 (0.19)	44
R01AD09	4.12 (0.29)	2.45 (0.09)	4.13 (0.29)	4.36 (0.07)	1.30 (0.00)	4.36 (0.07)	7
R03AC03	7.53 (5.50)	4.57 (3.47)	7.53 (5.50)	2.84 (0.06)	1.24 (0.09)	2.88 (0.06)	36
R03AK06	16.07 (3.67)	10.91 (2.62)	16.09 (3.67)	15.31 (0.39)	10.17 (0.41)	15.78 (0.00)	4
R03AK07	17.45 (0.73)	12.07 (0.50)	17.45 (0.73)	18.07 (0.51)	12.47 (0.39)	18.11 (0.51)	27
R03BB01	5.01 (1.55)	2.88 (1.13)	5.01 (1.55)	3.11 (0.47)	1.79 (0.46)	3.41 (0.46)	19
R06AX27	5.49 (1.43)	2.76 (0.49)	5.49 (1.43)	4.02 (0.33)	2.44 (0.06)	4.03 (0.33)	21
S01EE01	7.75 (0.48)	4.97 (0.17)	7.75 (0.48)	7.49 (0.03)	4.87 (0.02)	7.63 (0.03)	9
V03AE02	91.86 (4.51)	65.25 (2.46)	91.87 (4.52)	91.64 (4.66)	62.23 (1.49)	92.07 (4.60)	34

Table A2. Effects of Price Cap Regulation; fixed effects models with interaction term

Dependent variable	Brand-name sales (DDD)	Producer prices	Profits	Total expenditures
Log P_{it}	-0.316***	1.334***	1.018***	0.575***
	(0.078)	(0.006)	(0.078)	(0.057)
Log P_{it}* D_i	-0.563***	-0.235***	-0.798***	0.106***
	(0.138)	(0.011)	(0.139)	(0.031)
Constant term	10.990***	-1.220***	-1.743***	1.447***
	(0.207)	(0.017)	(0.208)	(0.171)
Period fixed effect	Yes	Yes	Yes	Yes
Pack fixed effect	Yes	Yes	Yes	No
ATC fixed effect	No	No	No	Yes
R-squared	0.044	0.669	0.041	0.141
Number ATC	165	165	165	165
Number packs	861	861	861	-
Number observations	31542	31542	31542	7038

Table A3. Effects of Price Cap Regulation; products with parallel imports in all periods. Fixed effect models (robust standard errors)

Dependent variable	Brand-name market share	Brand-name sales (DDD)	Producer prices	Profits	Total expenditures
Log P_{it}	-0.399***	-1.477***	1.115***	-0.362**	0.646***
	(0.047)	(0.186)	(0.014)	(0.184)	(0.041)
Constant term	1.929***	14.367***	-0.822***	2.032***	1.955***
	(0.150)	(0.590)	(0.044)	(0.584)	(0.131)
Period fixed effect	Yes	Yes	Yes	Yes	Yes
ATC fixed effect	Yes	No	No	No	Yes
Pack fixed effect	No	Yes	Yes	Yes	No
R-squared	0.136	0.091	0.731	0.074	0.588
Number ATC	15	15	15	15	15
Number packs	-	85	85	85	-
Number observations	660	3183	3183	3183	660