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Prosjektet har mottatt midler fra det alminnelige prisreguleringsfondet.

Price Hikes of Older Drugs*

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Abstract

Price hikes of older off-patent drugs have become a frequent phenonomen. Despite free entry in such markets, policy makers and competition authorities have devoted increasing attention to these hikes. In this paper we study the relationship between price hikes and market structure and the consequences for market outcomes by exploiting a unique dataset that covers the univers of prescription drug sales in Norway from 2011 to 2020. From this dataset we extract monthly product-level data for all substances where at least one drug got a price hike. First, we find that price hikes are more likely in concentrated markets with fewer competitors controlling for several other factors. Second, using a difference-in-difference design, we find that a price hike results in higher prices and profits over longer periods without inducing entry or shifts in market shares. Since total expenditures also increase, the hikes imply an efficiency loss in the post-patent period.

Keywords: Market power; excessive pricing; pharmaceuticals
JEL code: L13; L41; L65

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1 Introduction

Large price hikes on older drugs have become a frequent phenomenon in many pharmaceutical markets.[1] For these drugs the patent term of the original brand-name drug has expired and generic drug producers have entered and captured market shares or even taken over the market. In off-patent drug markets we expect price hikes to be corrected by standard market mechanisms such as loss of market shares to lower priced drug versions or entry of new drug producers. Indeed, competition from generic drugs is generally perceived by policy makers to be a key instrument in reducing prices and expenditures to the benefit of patients and insurers in the post-patent period.[2]

Despite free entry and generic drug competition, the large price hikes on older drugs have gained increasing attention by policy makers and competition authorities across the world. In the US, the perhaps most famous example is Daraprim, an old drug for parasitic infections, where the company Turing Pharmaceuticals increased prices from \$13.50 to \$750 a pill overnight in 2015.[3] This was only one of several examples, which led to public hearings before the US Senate.[4] Another very recent example is the largest price-fixing case in US history, which involved a large number of generic drug producers that hiked the prices of a range of drugs with several 1000 percent.[5] The court decision resulted in large criminal fines to the companies, but also forced divestitures of drugs that were part of the collu-

[1] See, for instance, the recent report from the EU Commission (2024) for competition cases. See also Berndt et al. (2017) on the development of competition and prices of generic drugs in the US.

[2] This is to a large extent supported by the economic literature; see, e.g., Berndt et al. (2017) and Lakdawalla (2018).

[3] This company was run by the former CEO Martin Shkreli who became a symbol for the price gauging of old drugs in the US. See, e.g., the article in the New York Times;
https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html

[4] A company called Valeant increased the price of two old heart drugs (Isuprel and Nitropress) with several 1000 percent. Reodelis Therapeutics, after it acquired an old tuberculosis drug called Seromycin, hiked the price of a month's supply to \$10,800 from \$500. See article in the National Public Radio
https://www.npr.org/sections/health-shots/2019/12/31/792617538/a-decade-marked-by-outrage-over-drug-prices

[5] See, e.g., the article in the New York times;
https://www.nytimes.com/2019/05/11/health/teva-price-fixing-lawsuit.html)

sion.[6] The recent law passed by the Biden administration allowing Medicare to negotiate prices on drugs illustrates the concern for market power and inflating prices of not just new innovative drugs but also older drugs.

In Europe drug prices are to a larger extent subject to regulation, which in principle should limit the scope for drug producers to hike prices. However, anecdotal evidence show that this is not necessarily the case. In a recent report, the EU Commission (2024) refers to several antitrust cases related to price hikes by pharmaceutical companies that exploited market power or colluded. One example is the Commission's case against the pharmaceutical company Aspen, which hiked prices of six old (mostly blood) cancer drugs in a range of European countries.[7] By threatening to de-list or withdraw the drugs from national markets, the company was able to raise the prices with several hundred percent despite the presence of price regulation in most of the countries. The Commission claimed that Aspen had abused its dominant position by charging excessive prices. Aspen disagreed but offered in 2021 commitments to reduce prices and ensure delivery of the cancer drugs for up to ten years in the countries where prices had been hiked.[8]

These examples illustrate that price hikes of older drugs pose a key challenge in pharmaceutical markets. In the post-patent period, policy makers aim for lower prices, lower expenditures for patients and insurers, and thus better access to important medicines. A key instrument is free entry when the patent term expires and pro-competitive policies to stimulate competition from and between generic drug producers. However, the huge price hikes of many older drugs suggest that standard market mechanisms and current policies may not be sufficient to discipline market power or collusion in all off-patent drug markets. While the antitrust

[6] See, e.g., the press release by the US Department of Justice https://www.justice.gov/opa/pr/major-generic-drug-companies-pay-over-quarter-billion-dollars-resolve-price-fixing-charges

[7] The EU commission's decision is available at https://ec.europa.eu/competition/antitrust/cases/dec_docs/40394/40394_5350_5.pdf

[8] In the UK there have been several excessive pricing cases in pharmaceutical markets, see e.g., the CMA cases against Pfizer and Flynn or Advanz. In these cases, the companies took advantage of a loophole in the UK price regulation which applied only to branded drugs. By de-branding off-patent drugs and launching generic versions, the companies avoided price regulation and could freely set prices. This enabled hugh price hikes of several 1000 percent of a several old drugs. See, e.g., the CMA press release https://www.gov.uk/government/news/cma-decision-upheld-in-major-drug-price-abuse-case

cases offer detailed information on the price hikes by individual companies, systematic knowledge of this phenomenon across markets and drug therapies over time is very limited and our paper aims at filling this gap in the literature.[9]

In this paper we study the relationship between price hikes and market structure and the consequences of these hikes on market outcomes. We also investigate to what extent the market corrects a price hike by inducing entry by new drug producers or shifts of market shares towards substitutable drug therapies. To do so, we exploit a unique database covering the universe of prescription drugs sold to patients in Norway with detailed sales information at retail (pharmacy) level.[10] From this database, we compile a dataset covering all substances where at least one drug got a sudden and large price increase during the ten-year period from 2011 to 2020.[11] The data are at product (pack) level and contain detailed monthly information about sales (revenues and volumes) and product characteristics (substance, company, product name, branded or generic, administrative form, etc.). We define a market by the substitution group, which is the set of drugs that the patient can choose among when entering the pharmacy with a prescription.[12]

First, we investigate the relationship between market structure and price hikes. To do so, we use an approach that exploits the fact that price hikes occur at different dates during the ten-year period. In particular, we estimate at linear probability model using substance fixed effects to control for unobserved (and observed) heterogeneity across drug therapies. Moreover, we estimate the probability of a price hike to occur using only a short time window (from 3 to 9 months) prior to the event. Based on this approach, we find that a price hike is more likely to occur in markets with fewer competitors and higher concentration (measured by

[9] See Section 2 for a brief review of the existing literature.

[10] The database have information about sales of prescription drugs to hospitals as well, but these data were not made available to us due to business secrecy issues related to the rebates that drug companies offer to the hospital purchasing body. However, prices for the pharmacy sales of prescription drugs that we have in our data are real transaction prices at retail level and thus not list prices or regulated prices.

[11] We define a sudden and large price hike by a price increase of 50 percent or more of a given drug from one month to the next. This is a strict definition, but we use it to avoid including price changes that are due to regulatory revisions of the price cap, as will be explained in more detail later in the paper.

[12] The substitution groups are defined by the regulator and contain (branded and generic) drugs with the same substance, dosage strength, and usually also administrative form (e.g., tablets, capsules, injections, etc.).

the Herfindahl index). One less competitor increases the probability with almost 10 percentage points.

Second, we study the consequences of price hikes on market outcomes. To do so, we employ a difference-in-difference (DID) design, where similar drugs that did not experience a price hike are used as control. Using a four-year time window centered around the date of the price hike, we estimate both standard and dynamic DID models to capture both the average treatment effect and the evolvement of the effects relative to the date of the price hike. Including substance fixed effects, we find that a price hike results in a significant increase in retail prices and profits for the drug producers. The increase in profits are almost 60 percent. The dynamic DID models show that both the price and profit effects last for the whole (24 month) post period.

Third, we investigate whether the price hikes are counteracted by market forces such as entry or shift in market shares. To do so, we employ the same DID approach as described above. Estimating several models, both static and dynamic, we do not find any significant effects on market entry, market concentration or market shares. This indicate that drug producers rationally expected that a price hike could be profitably implemented. A natural conjecture is that the price hikes were implemented due to market power. While we do not observe the production costs, using only within-substance variation when measuring the effects should account for cost shifts as an alternative explanation to price hikes.

The rest of the paper is organised as follows. In Section 2 we relate our study to the existing literature. In Section 3 we describe the institutional setting of the Norwegian pharmaceutical market. In Section 4 we present our data and descriptive statistics. In Section 5 we describe the empirical model for estimating the likelihood of a price hike to occur and present the results of this analysis. In Section 6 we present the DID research design and our empirical strategy for identifying the consequences of price hikes. In Section 7 we present the results of the DID estimations and on the set of market outcomes.

2 Related literature

The literature on the economics of pharmaceutical markets is vast; see, e.g., Lakdawalla (2018) for an overview. A major part of this literature focuses on new medicines protected by patents, where a key issue is the trade-off between static and dynamic efficiency. The patent scheme stimulates innovation by allowing drug producers to charge high prices during the patent term, but the high prices pose a challenge for payer budgets and thus access for patients to new medicines.[13]

Our paper is concerned with market power and high drug prices, but focuses instead on older drugs where the patent term has expired and innovation incentives no longer are a concern. The vast majority of papers on off-patent markets are concerned with the competition from generic drugs. Some papers study the entry game between the incumbent brand-name producer and the entering generic drug producers.[14] Other papers study the dynamics of the competition between brand-name and generic drug producers given that entry has occurred.[15] Related to both these strands a set of papers that focus on pro-competitive policies for stimulating entry and competition from generic drugs in off-patent markets.[16]

While the above-mentioned literature tends to find that generic drug competition in general is beneficial to society, a recent strand of papers point at higher prices and more concentrated markets for off-patent drugs. Conti et al. (2018) study the new price gouging legislation in the US using data from generic drug markets from 2013 to 2014. They report price increases across all generic drug markets at 38 percent on average, and find that 28 percent of all generic products exceeded the 15 percent price increase threshold in the new legislation. Berndt et al. (2017) use data on generic drug markets in the US from 2004 to 2016 and show that the majority of markets are small in terms of market size and have become more concentrated due to lower entry and higher exit rates over the period. They find that most markets are served by two-three firms with a sizeable share of

[13] A strand of papers propose alternative pricing models to solve this dilemma; see, e.g., Lakdawalla and Sood (2009) and Brekke et al. (2022) for two-part pricing models for new medicines.

[14] See, e.g., Scott Morten (1999, 2000), Ellison and Ellison (2011), among others.

[15] See Caves et al. 1991; Grabowski and Vernon 1992; Frank and Salkever 1997; Grabowski et al. 2006; Knittel and Huckfeldt 2012; Branstetter et al. 2016, among others.

[16] See, e.g., Berndt et al. (2017), Lakdawalla (2018) for an overview. For reference pricing policies, see, e.g., Kortelainen et al. (2023), Brekke et al. (2009, 2011).

monopolies, which can explain that the observed price increases on generic drugs in the recent years. Ganapati and McKibbin (2021) show that US markups are largely driven by generic manufacturer market power rather than concentration at other levels of the supply chain.

There is also a growing literature on anti-competitive behavior in generic drug markets. A few recent papers have studied the largest price-fixing case in US history, which involved a large number of generic drug producers.[17] Clark et al. (2022) provide estimates of the causal price effects of the price-fixing cartel among generic drug producers. Using quarterly Medicaid data for the period 2011–2018 and a DID approach comparing the evolution of prices of allegedly collusive drugs with a group of competitive control drugs, they find that the collusion led to price increases of between 0 and 166% across the different markets. Cuddy (2020) provides estimates of the surplus to the generic drug cartel members using a structural model of retail drug procurement where generic drug producers submit bids to national pharmacies. She reports counterfactuals indicating that the collusive ring generated over $12 billion in surplus over 18 months, and points at the unprecedented backlog of generic drug applications at the FDA exacerbated the situation. Starc and Wollmann (2022) provide evidence that the price increases induced by the generic drug cartel encouraged entry from other generic drug producers, although with a lag due to FDA approval delays. They find that the cartel did not break down, as entry was accommodated with lower yet supra-competitive prices. Reduced form analysis shows that the price hikes lasted for longer periods. Estimating a structural model, they find that cartel profits would have been significantly higher in absence of entry, but shorter FDA approval delays would have had large gains to payers and patients.

Our paper contributes to this growing literature on market power and price increases in off-patent markets along several dimensions. First, we do not focus on a specific antitrust case, although our data cover (some of) Aspen's cancer drugs that the EU commission investigated for excessive pricing. Instead, we take a different and broader approach by compiling a dataset with a large number of

[17] See, e.g., the press release by the US Department of Justice https://www.justice.gov/opa/pr/major-generic-drug-companies-pay-over-quarter-billion-dollars-resolve-price-fixing-charges

price hikes, which is extracted from a database covering the universe of prescription drug sales to patients in Norway over a ten-year period from 2011 to 2020. This approach is closer to Conti et al. (2018) and also related to Berndt et al. (2017).

Second, we expand this literature by estimating the likelihood of price hikes to occur and the corresponding effects on market outcomes by using a DID approach. As in Berndt et al. (2017) we focus on the relationship between market structure and price increases, but we take a different approach by estimating a linear probability model with substance fixed effects using only a narrow time window prior to the hike. When estimating the effects of price hikes on market outcomes, we construct a control group of drugs that did not experience a price hikes, as in Clark et al. (2022). However, different from Clark et al. (2022) we do not focus specifically on an alleged price-fixing case, but applies the DID approach to all substances where at least one drug experienced a price hike from 2011 to 2020.

Third, we provide empirical results from a regulated European market, whereas the existing literature almost exclusively focuses on the US industry where prices are set in the market without regulatory constraints. There is a paper by Granlund and Rudholm (2024) that studies collusion in the generic drug market in Sweden. Applying a statistical method for estimating the probability of collusion, they find that a large number (64 percent) of the generic drug auctions had price patterns partly due to collusion. They estimate that moving from competition to collusion increases average prices by 65 percent. Our paper take a different approach by studying price hikes rather than collusive pricing patterns per se. The Norwegian market is also very different as prices of generic drugs are not set in auctions like in Sweden, but instead subject to price regulation, which will be explained in the next section.

3 The Norwegian pharmaceutical market

We conduct the analysis of price hikes using Norwegian data. In this section we provide a short description of the institutional setting. Norway has a mandatory National Health Insurance funded by general taxation that offers coverage for prescription drug expenditures. Inclusion of drugs in the public insurance scheme is decided by the Norwegian Medical Products Agency (NMPA). As a general rule

only medicines for long-term chronic (non-acute) conditions qualify for reimbursement. In addition, a drug is included only if the cost-efficiency ratio is above a certain level.[18]

The NMPA regulates also prices of prescription drugs. In Norway all prescription drugs are subject to price cap regulation, irrespective of whether they are covered by the public insurance scheme or not. The price caps are based on international reference pricing, where the cap for a given drug is set equal to the average of the three lowest prices in a basket of nine reference countries.[19] This defines the maximum wholesale (pharmacy purchasing) price. The maximum retail (pharmacy selling) price is derived by adding a maximum margin that pharmacies can add to the price cap at wholesale level. This margin is a combination of a fixed mark-up (in NOK) and a percentage mark-up based on the price cap at wholesale level.[20] The price caps are revised over time, where drugs with high sales revenues have an annual revision.

In addition, there is a reference pricing (called stepped price) scheme for drugs where the patent has expired and generic versions have entered the market. This scheme is intended to reduce prices and expenditures by providing a financial incentive for patients to switch from the (high priced) brand-name drug to (lower priced) generic drug versions. The reference price (stepped price) defines the maximum price that is subject for reimbursement in a given substitution group, i.e., branded and generic drugs with the same substance, dosage strength and administrative form (tablet, injection, etc.).

The reference price is set as a fixed percentage cut of the price of the original brand-name drug prior to entry of generic drugs. The cuts are gradually increased over time, which is why the scheme is called stepped price. Patients can demand a drug that is priced higher than the reference price, which is usually the case for branded drugs, but would then have to pay the full price difference between the

[18] See the NMPA webpage for more details:
https://www.dmp.no/en/public-funding-and-pricing-of-medicines

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

[20] Currently, the fixed mark-up is NOK 29 per pack and the percentage mark-up is 2% of the price cap at wholesale level (maximum pharmacy purchasing price). For addictive drugs there is an additional mark-up of NOK 19, and for drugs that need cooling 0,5% on the maximum pharmacy purchasing price.

price of the demanded drug and the reference (stepped) price.[21]

The pharmacies are obliged to propose generic substitution to patients that enter with a prescription of a brand-name drug and to inform them about the extra surcharge that applies if they refuse to substitute. They are also obliged to have at least one (generic) drug priced at the reference price in store. The reference pricing scheme applies also to drugs that do not qualify for reimbursement, where the stepped price effectively is a sort of price cap on (one of the) generic drugs.

For prescription drugs included in the public insurance scheme, there is demand-side cost sharing. In particular, patients have to pay a defined percentage (now 50 percent) of the price of the drug up to a maximum of NOK 520 per prescription. There is also an annual expenditure cap (now NOK 3165) on all sorts of copayments for health services and medicines. Once this cap is reached, there is 100 percent coverage for all additional expenditures covered by the public insurance scheme. Notably, the extra surcharges under reference (stepped) pricing when patients refuse to substitute to cheaper generic drug versions are not eligible for the expenditure caps. In this case, the patients would have to pay the full price difference out of pocket irrespective of whether or not the expenditure cap is reached.

Given the existence of price cap regulation in Norway, one might ask how drug producers are able to induce large and sudden price hikes. Price cap regulation aims at curbing firms' market power by limiting the ability to charge monopoly prices. However, the drug producers can ask the regulator (NMPA) for a higher price cap based on an individual assessment. The most common argument is that it is not profitable to sell the drug at the current price level due to drop in demand, higher costs, or lack of capacity. In many cases, the drug producers threatens to delist the drug or exit the market unless the price cap is increased. This was indeed what Aspen did in a large set of European countries, including also Norway, to hike the prices of the cancer drugs according to the EU commission's excessive pricing case, as described in the Introduction.

A key challenge for the regulators when assessing individual applications for adjusting the price caps is that production costs and capacity in most cases are

[21] To give an example, if the brand-name producers charges NOK 150 and the stepped price is set at NOK 100, the patient would have to pay NOK 50.

private information for the drug producers. This means that the regulators have to base their assessment on reported information from the drug producers, which is not directly observable and also hard to verify. Thus, it is difficult for regulators to assess whether the threat of delisting or exit from the market is due valid reason or exploitation of market power by the drug producer. From case handlers at the NMPA, we are told that applications for higher price caps are usually approved unless there are close substitutes (say, other generic drug versions or close therapeutic alternatives) available on the market.

4 Data and descriptive statistics

To investigate price hikes in the pharmaceutical market, we have compiled a dataset covering all substances where at least one drug had a large and sudden price increase during a ten-year period from 2011 to 2020. The dataset is extracted from a unique database covering the universe of prescription drugs sold to patients in Norway.[22] The data are delivered by Farmalogg, which is a company that administrates the database covering all drug sales through wholesalers and pharmacies on the Norwegian market.[23] The data contain detailed sales information at retail level for every drug sold to patients entering the pharmacy with a prescription from their doctor.

When compiling the dataset, we defined a price hike as a price increase of at least 50 percent from one month to the next of a given drug.[24] The reason for this strict definition is to ensure that we do not include price increases that are due standard regulatory revisions of the price caps, as described in the previous section. By using this definition of a price hike we ensure that the data include only price increases that are induced by the drug producers through individual requests for a higher price cap to avoid exit or delisting of the drug, as illustrated

[22] The data do not contain information about hospital drugs as this rebates and thus net prices are set in negotiations or competitive tenders and thus protected as business secrecy.

[23] Farmalogg is a company owned by the Norwegian Pharmacy Association. For more details, see https://www.farmalogg.no/en/.

[24] Exploitation of market power could be done by gradual increases in the prices over time, but the price cap scheme where price cap revisions are based on individual applications from the drug producers limits this possibility.

with the Aspen case referred to above. Obviously, the 50 percent threshold is arbitrary and implies that our sample does not cover the entire population of price hikes induced by the drug producers.[25]

The dataset provides detailed product-level information at monthly level over the ten-year period. Every pack has a unique code (product number). Attached to this code there is information about the ATC code[26], substance name, company (producer) name, product name, and whether the drug is a brand-name or generic version. The data contain also information about additional product characteristics, such as pack size, dosage strength, the defined daily dose (DDD), administrative form (tablet, capsule, injection, etc.), substitution group code[27], etc.

For each drug in the sample, we have monthly sales revenues and volumes at retail (pharmacy) level. Volumes are reported both in terms of number of packs and number of DDDs. By dividing the sales revenues by the sales volumes, we get the monthly (sales-weighted) average price per pack or per DDD for each drug version (pack). In the analysis we mainly use the average price per DDD as this variable is standardised across pack sizes and dosage strengths. We have also regulatory information, such as the price cap (maximum pharmacy selling price) and the reference (stepped) price (maximum reimbursement price).

We define the relevant (product) market by a substitution group. A substitution group is the set of drug variants that the regulator define as substitutable at the pharmacy level, i.e., the set of drugs that the patient can choose among when arriving the pharmacy with a prescription. The drugs in a substitution group have the same substance, and usually also the same dosage strength and administrative

[25] We asked the NMPA for records of individual applications for increases in the price caps covering the years 2011 to 2020. The NMPA responded that they did not have capacity to give us a full record and sent us only a few examples (including Aspen's application for higher price caps on the cancer drugs that were subject to the EU commission's excessive pricing case).

[26] ATC is an abbriviation of the Anatomical Therapeutic Chemical code, which is a unique code assigned to a medicine according to the organ or system it works on and how it works. This code scheme has five levels, where ATC5 defines a substance, i.e., a class of drugs which are therapeutically equivalent. Essentially, this covers all drug variants (dosage strenghts, pack sizes, administrative forms) of the original brand-name drug and generic drug versions.

[27] This is a code that defines which drugs that can be substituted at the pharmacy when a patient enters with a given prescription. Usually, this includes brand-name and generic drugs with the same dosage strength and administrative form.

form. This implies that patients can choose between the brand-name drug and various generic versions of this drug.[28] The price cap and the reference (stepped) price apply at substitution group level and are thus common to all drug versions that belong to the same substitution group.

Based on the product-level data, we compute a set of variables at the market (substitution group) level. By dividing the sales volumes of a given drug by the total sales volumes within a substitution group, we get the market share of each drug producer. We use these market shares to compute the Hirschman-Herfindahl index (HHI) as a measure of the degree of concentration for each market. A HHI of 10,000 reflects that there is only one drug producer in the substitution group, which allows us to capture (to some extent) the degree of market power. Since the data contain information about whether a drug is a generic or a brand-name, we can also compute the market share of generic drugs at the substitution group level. Finally, as a measure of competition, we also compute the number of drug producers in each substitution group, which complements the HHI in measuring the degree of competition.

Table 1. Descriptive statistics, substitution groups with or without price increase.

	Substitution groups with price increase		Substitution groups without price increase	
	Pre	Post	Pre	Post
AUP per DDD	15.24 (47.71)	30.10 (92.40)	27.09 (43.69)	29.21 (57.29)
DDD / 10,000	9.04 (24.93)	8.85 (24.62)	7.92 (36.58)	8.50 (33.44)
Revenue / 10,000	19.40 (39.47)	25.28 (53.93)	27.18 (77.94)	26.14 (67.89)
AUP per pack	250.30 (466.60)	349.82 (529.94)	420.18 (609.18)	392.66 (552.36)
Step price per pack	146.07 (156.68)	160.34 125.50)	363.98 (457.28)	336.06 (355.58)
Max AUP per pack	278.38 (365.54)	437.77 (618.49)	505.90 (745.89)	447.48 (626.29)
Herfindahl index	7067.5 (2430.6)	6957.8 (2474.5)	6783.9 (2139.0)	7214.7 (2225.5)
Producers	2.66 (1.47)	2.62 (1.57)	2.62 (1.26)	2.74 (1.40)
Market share generics	0.34	0.27	0.39	0.41
Monopoly	0.23	0.24	0.15	0.14
No generics	0.15	0.18	0.06	0.06
Observations	6,554	5,231	7,251	6,533
Substitution groups	99	97	110	106
ATC groups	60	59	32	31

Table 1 summarises the descriptive statistics of the variables, split by substitution groups (markets) that had a price hike some time during the ten-year period 2011 to 2020 and substitution groups that never had a price hike during this pe-

[28] To obtain a drug with a different dosage strength or administrative form, patients would need a new prescription from the doctor. The same applies of course for a similar drug with a different substance.

riod. Recall that the sample only consists of substances where at least one drug had a price hike of at least 50 percent from one month to the next. In total this amounts to 60 substances and 209 substitution groups, where 32 of the substances had at least one substitution group without a price hike during the period.[29]

From the table we see that the average retail (pharmacy selling) price per daily defined dose (AUP per DDD) almost doubles (from 15 to 30 NOK per DDD) for the substitution groups with a price hike from the pre-period to the post-period. The average retail price for the substitution groups without a price hike increases much more moderately from NOK 27 to 29. Similarly, for the average price per pack (AUP per pack) there is a fairly large increase for the drugs in the substitution groups with the price hike, but a decrease in prices in the substitution groups without the price hike.

Moreover, the average sales volumes are marginally decreasing (with 2.1 percent) for the substitution groups with a price hike, and slightly increasing (with 7.3 percent) for the substitution groups without price hike. Thus, it seems like the large price increases in the substitution groups with the price hikes do not result in similarly large reductions in sales volumes. This may be due to price inelastic demand for prescription drugs and limited substitution across substitution groups.

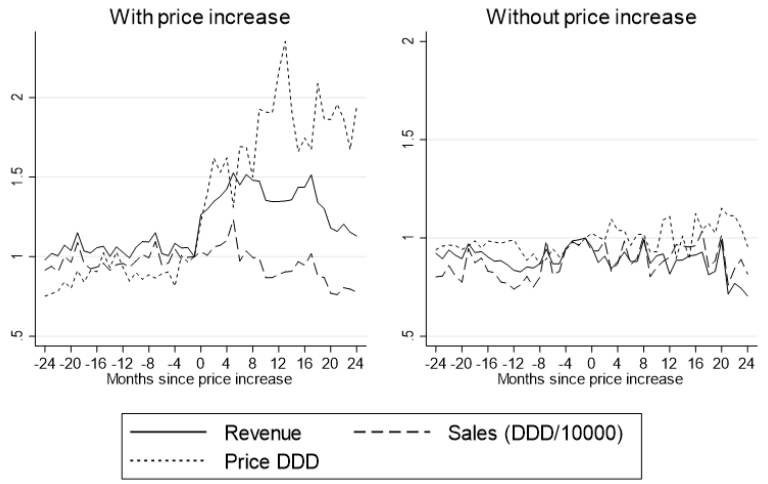
The price caps (Max AUP per pack) appear not to be binding for the average retail prices (AUP per pack). However, the price caps are usually binding for the brand-name drugs but not for the generic drugs, which tend to be priced lower. Thus, the average retail prices, which is are the sales weighted brand-name and generic prices, are necessarily lower than the price cap for a given substitution group.

The market concentration (measured by the HHI) in the substitution groups are generally high. The substitution groups with a price hike are more concentrated prior to the price hike, but less concentrated after the price hike. This could indicate that the price hike induces entry of new producers or loss of market shares to rivals in the substitution groups with a price hike. However, the average number of producers are actually weakly lower after the price hike in the substitution groups with a price hike, whereas the opposite is true for the substitution

[29] For the remaining 28 substances there are either one substitution group (which got a price hike) or several groups where all got a price hike during the period.

groups without a price hike. The same pattern is observed for the share of generic producers.

Figure 1: Changes in prices, volumes and revenues before and after a price hike



In Figure 1 we plot the development of average sales revenues, sales volumes (DDDs), and average retail dose prices (AUP per DDD) in a four year window split by substitution groups with a price hike (to the left) and without a price hike (to the right). The time window is centred around the month of the price hike (month 0), and the levels of the three variables are normalised to 1 at the month prior to the hike (month -1). Thus, the graphs changes over time in the three variables relative to the levels at the month prior to the price hike. Substitution groups without a price hike are matched with the substitution groups with a price hike with the same substance (ATC5 code), which means that the graphs are plotted for the same time interval for all substitution groups with the same substance.

The figure shows an immediate and a sharp increase in the average prices and sales revenues for the substitution groups with a price hike. The higher prices seem to last for the full two-year period after the hike was initiated. Sales revenues are also at a higher level during post-period, but seem to decline towards the end. This can be explained by a drop in sales volumes in the period after the price hike. For the substitution groups without a price hike, we observe a slight increase in sales volumes, but a fairly stable development in sales revenues and dose prices

until the last months where both variables seem to decline.

Figure 2. Changes in no. of rivals and concentration before and after a price hike

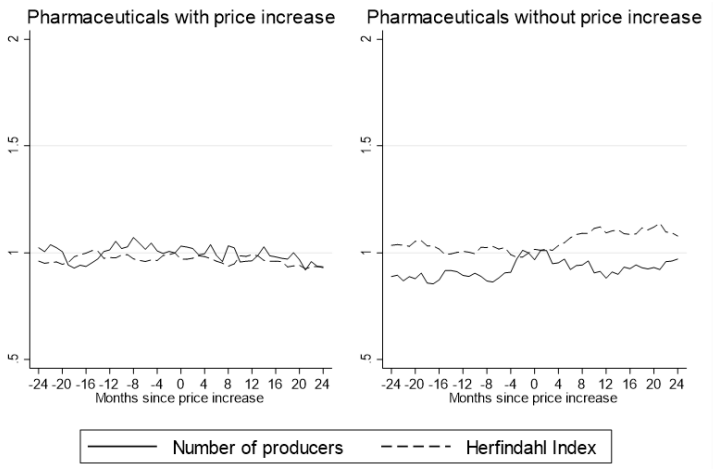


Figure 2 plots the development of the number of drug producers and market concentration (HHI) split by substitution groups with a price hike (to the left) and without a price hike (to the right) over four years centred around the month of the price hike (month 0). Levels are normalised to one in the month prior to the price hike (month -1), which means that the graphs represent relative changes, as in Figure 1. Substitution groups without a price hike are clustered at substance level, and thus plotted for the same months as the substitution groups with a price hike that have the same substance (ATC5 code).

For the substitution groups with a price hike, we see that market concentration (HHI) and the number of drug producers is fairly stable before and after the price hike. Thus, we observe no major changes in market structure on average prior to the price hike, but also not much entry occurring during the two years after the price hike took place. The same pattern is observed for the HHI, which suggests that the price hike did not induce entry or loss of market shares to rivals. For the substitution groups without a price hike, we see that the number of competitors declines and the HHI increases in the post period relative to the levels in the month prior to the hike to place for the substitution groups with the same substance.

5 The likelihood of a price hike

As a first empirical analysis we want to estimate whether market power can explain the likelihood of a price hike. To do so, we estimate a linear probability model where we predict a price hike to occur in a substitution group using a set of explanatory variables.

To capture market power we use to standard measures of competition, namely the number of rivals and the degree of market concentration (the HHI). Since these two measures are highly correlated, the regression models are estimated separately using either one as an explanatory variable. We expect that markets price hikes are more likely in markets with fewer rivals and higher concentration. The reason is that drug producers can more credibly threaten to withdraw the product from the market if there are few rival producers present. In this case the regulator would be more inclined to allow for an increase in the regulated prices to secure the drug to the patients.

Recall from the descriptive statistics (Table 1) that the average number of producers in a substitution group is 2.6. Furthermore, the average HHI is higher than 7000 points, which implies that market shares are not symmetrically split across drug producers, and that market structure is close to monopoly. Indeed, the share of monopoly markets in our sample are more than 20 percent on average for the substitution groups that experience a price hike.

When estimating the relationship between competition and the likelihood of a price hike, we control for a set of other factors, such as market size (measured by sales volume in DDDs) and the proportion of generic drugs in the substitution group. Small markets are more likely to be monopolised due to fixed costs of delivering the drug on the national markets. A higher proportion of generic drugs could imply fiercer competition than if there is a brand-name producer with a large market share in the substitution group.

In the linear probability model we include substance fixed effects to account for unobserved (and observed) heterogeneity that is time invariant and likely to affect the probability of a price hike. This might be factors like the type of disease, whether the disease is chronic or acute, the drug characteristics (treatment effects, side effects), patient population (elderly vs. young), etc. Thus, the probability of

a price hike is identified using only the within-substance variation, which means that we compare only substitution groups with and without price hikes that share the same substance. We also include year fixed effects to account for time trends common to all substances (and substitution groups) across years, such as changes to the regulatory regime or the reimbursement scheme. Recall that the data cover the years from 2011 to 2020. Finally, we estimate the linear probability models using different time windows ranging from 0 to 9 months prior to the price hike occurred.

Table 2. Market concentration and likelihood of price hikes

	Price increase	Price increase	Price increase	Price increase
Herfindahl index	0.0487***	-	-	-
	(0.0177)			
Prop. generics	-0.1515	-	-	-
	(0.1931)			
DDD	0.0001	-	-	-
	(0.0008)			
Herfindahl index in t-3	-	0.0483***	-	-
		(0.0175)		
Prop. Generics in t-3	-	-0.1689	-	-
		(0.1943)		
DDD in t-3	-	0.0008	-	-
		(0.0009)		
Herfindahl index in t-6	-	-	0.0367*	-
			(0.0204)	
Prop. Generics in t-6	-		-0.4284**	-
			(0.1941)	
DDD in t-6	-	-	0.0015	-
			(0.0011)	
Herfindahl index in t-9	-	-	-	0.0512***
				(0.0195)
Prop. Generics in t-9	-	-	-	-0.2486
				(0.1867)
DDD in t-9	-	-	-	0.0013
				(0.0010)
ATC groups	49	49	48	47
Substitution groups	195	194	190	188
Observations	614	591	556	542

Table 3. The number of rivals and likelihood of price hikes

	Price increase	Price increase	Price increase	Price increase
Producers	-0.0851***			
	(0.0330)			
Prop. generics	-0.1233			
	(0.2162)			
DDD	0.0001			
	(0.0002)			
Producers in t-3		-0.0913**	-	-
		(0.0394)		
Prop. Generics in t-3		-01686		
		(0.2061)		
DDD in t-3		0.0009	-	-
		(0.0009)		
Producers in t-6	-	-	-0.1162***	-
			(0.0430)	
Prop. Generics in t-6			-0.3564*	
			(0.1954)	
DDD in t-6	-	-	0.0019*	-
			(0.0011)	
Producers in t-9	-	-	-	-0.1030***
				(0.0353)
Prop. Generics in t-9				-0.3054*
				(0.1829)
DDD in t-9	-	-	-	0.0015
				(0.0010)
ATC groups	49	49	48	47
Substitution groups	195	194	190	188
Observations	614	591	556	542

***: significant at 1% level, **: significant at 5% level, *: significant at 10% level

Table 2 shows that an increase in the HHI with 1000 points increases the likelihood of a price hikes between 4.9 to 5.1 percentage points depending on which time window that is used. Similarly, Table 3 shows one more rival drug producer in the market reduces the probability of a price hike with between 9.2 to 13.6 percentage points depending on the time window of the estimation. We find no effects of market size (sales volumes in DDDs) or the proportion of generic drugs across substitution groups. All estimates are highly significant and thus measured with a high level of precision.

6 The effects of a price hike

In this section we want to estimate the effects of price hikes on market outcomes in the post hike period. To do so, we use a difference-in-difference (DID) research design, where the treatment group consists of drugs in markets (substitution groups) with a price hike and the control group consists of drugs in markets without any price hike. The effects of the price hike are identified by comparing the relative changes in the outcome variables in the treatment and control groups in the period

pre and post the date of the hike.

The validity of the control group relies on two key assumptions. First, the parallel trend assumption, which requires the drugs in the control group to have a similar pre-trend in the outcomes as the drugs in the treatment group prior to the event. In the next section we show that this assumption seems to hold for our analysis. Second, the drugs in the control group should not be affected by the price hikes of the drugs in the treatment group. In our setting this implies no demand shift across the substitution groups induced by the price hikes. In next section we report findings that show no significant demand effects on the drugs in the control group in the months after the price hikes occurred in the treatment group.

Since the price hikes are spread out over time during the years 2011 to 2020, we use a standard event-study design to estimate the DID models. In particular, we normalise the date (month) of the price hike to zero ($t = 0$), irrespective of the calender date, and estimate the DID model on a symmetric time window pre and post the month of the price hike. In the main model, we use a 24-month pre and post period, which implies in total a four year time window for each event. The results are robust to variations in the time window (see the Appendix).

We estimate first a standard DID model that measure the average treatment effect. This model can be specified as follows

$$y_{istm} = \gamma_s + \lambda_t + \sum_m \delta_m + \sum_{\tau s} \beta_{\tau s} Hike_{\tau s} + \varepsilon_{istm},$$

where the subscript i denotes the drug, s the market (substitution group), t the year, m the month, and τ the month in the year when the price hike occurred. Recall that we have data from 2011 to 2020 and estimate the DiD model using monthly information in a four-year time window centered around the date (month) when the price hike in a given market occurred.

The dependent variable y_{ist} is either the average retail (pharmacy selling) dose price (in NOK), the sales volume (in DDDs), the sales revenue (in NOK), or the average expenditure (per DDD) at a given market in a given month and year. All dependent variables are log-transformed.

$Hike_{\tau s}$ is a post-event dummy taking the value 1 for all periods after the

price hike occurred in a given market, and zero otherwise. Thus, $\beta_{\tau s}$ is our key coefficient of interest, which captures the equilibrium effects of the price hike using the development in outcomes of the drugs in the markets without a price hike as the counterfactual.

In the regressions we include substance fixed effects (γ_s) to control for unobserved (and observed) time-invariant heterogeneity. This includes characteristics of the patient population (e.g., age, gender, size), characteristics of the disease (e.g., chronic vs. acute, common vs. rare, severity), characteristics of the product (e.g., tablet, injection, treatment and side effects), and potentially also characteristics of the production (e.g., technology, ingredients, biological or chemical production), given that such market specific heterogeneity remain constant over time. The market fixed effects imply that the effects of the event (price hike) are estimated using only *within* market variation over time in our outcome variables.

To account for time trends and seasonal variation, the regressions include year dummies (λ_t) and month dummies (δ_m). The year fixed effects (λ_t) capture time trends that are common to all markets at the given year. Recall our data cover the period from 2011 to 2020, and that we estimate the DiD model using only a four-year time window centered around the month when the price hike occurred in a given market. By including year fixed effects, we are essentially estimating the effects of the price hikes conditional on the year that the event occurred for both the treatment and comparison groups. The month fixed effects (δ_m) are included to account for seasonal variation (in, say, demand for a given drug therapy). In the regressions we have in total 48 month dummies (24 months pre and post the event) for each market. Finally, ε_{st} is the error term.

6.1 Prices, volumes, and revenues

In Table 4 we report the results from the DID model on average retail (pharmacy selling) prices (per DDD), sales volumes (in DDDs), sales revenues (in NOK), and

expenditures (per DDD).

Table 4. The effects of price hikes on prices, volumes, and revenues

	ln(Revenue)	ln(DDD)	ln(AUP)
Price increase	0.5045***	0.2509***	0.2542***
	(0.0755)	(0.0768)	(0.0312)
Fixed effect:			
Substitution groups	Yes	Yes	Yes
Year	Yes	Yes	Yes
Month	Yes	Yes	Yes
ATC groups	60	60	60
Substitution groups	209	209	209
Observations	25,569	25,569	25,569

***: significant at 1% level, **: significant at 5% level, *: significant at 10% level. [1] AUP per DDD.

We see that markets where a price hike occurs has an increase of 25 percent in the retail (pharmacy selling) price on average. Despite the price increase, we find that the price hike is associated with an increase of 25 percent in sales volumes (DDDs). This is mainly due to a decline in sales volumes in the control group, as can be seen from Figure 1. In sum, the price and volume effects result in an increase of 50 percent in sales revenues, which shows that the price hikes are highly profitable for the drug producers. The flipside of the coin is that total expenditures for patients and third-parties are higher. Thus, the regulatory approval of higher price cap comes with a cost.

6.2 Does the market correct for price hikes?

A key question is whether the market corrects for the price hikes. Since patent protection is expired in these markets, we would expect that large price hikes would trigger entry and loss of market shares to rival firms and thus push prices downward. The descriptive statistics indicate that this does not happen (cf. Table 1 and Figure 1). In this section we test this more rigorously. In particular, we estimate the DID model specified in Equation (1) using the number of producers

and the HHI as outcome variables.

Table 5. The effect of a price hike on the number of rivals and market concentration

	Herfindahl index	Producers
Price increase > 50%	-0.4178*	-0.187
	(0.2315)	(0.113)
Fixed effect:		
Substitution group	Yes	Yes
Year	Yes	Yes
Month	Yes	Yes
ATC groups	60	60
Substitution groups	209	209
Observations	9,130	9,130

***: significant at 1% level, **: significant at 5% level, *: significant at 10% level

From Table 5 we see that the effect of a price hike on the number of drug producers is negative but insignificant. However, we find a negative effect on market concentration (HHI), which suggests that a price hike is associated with less concentrated markets. Given that the number of producers is constant, this means that market shares become more evenly distributed after the price hike. However, the effect is small in magnitude and imprecisely estimates, as it is significant only at the 10 percent level.

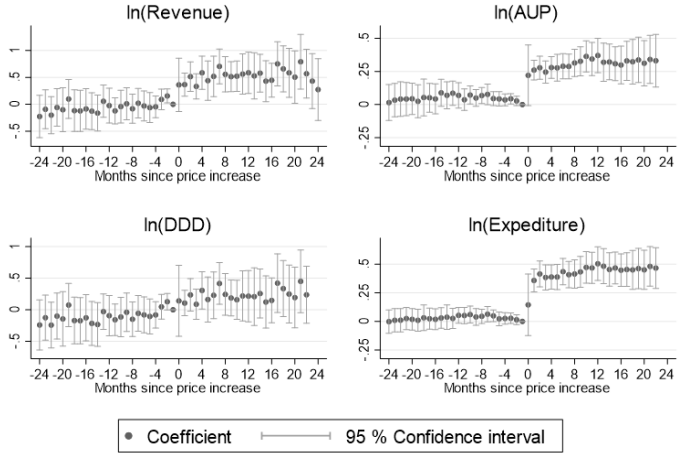
Thus, combined with the evidence on prices, volumes, and revenues, we find little evidence for standard market mechanisms correcting the price hikes induced by the drug producers. An explanation for this finding can be that entry barriers in these markets are sufficiently high, so that the incumbent drug producers are able to raise price without losing market shares. The entry decision of new drug producers is based on the expected profit relative to the fixed costs of entering the market.

6.3 Dynamic effects of price hikes on market outcomes

In this section we estimate a dynamic DID model using the same treatment and control groups as in the previous sections. The key difference is that we know estimate the effects on market outcomes month by month relative to the date of

the price hike. The results are reported in Figure 3 below.

Figure 3. Dynamic effects of price hikes on prices, volumes, revenues and expenditures



The figure show the DID point estimates and the confidence intervals. As a first observation, one can see that the parallel trend assumption appears to hold as there are no significant coefficients prior to the month of the price hike for the outcome variables of the treatment and control group, except for a few months for the sales volume (DDD) variable.

For the market outcomes, we see from the figure that the results are very similar to the ones from the static DID model reporting the average treatment effects (cf. Table 2). Indeed, the point estimates for the retail (pharmacy selling) price are around 25 percent and persistent over the two-year post period. Moreover, the point estimates for the sales revenues are around 50 percent and also persistent for the post period. However, the point estimates of the price hike on sales volumes are mostly insignificant and vary quite a bit. This differs from the static DID model measuring the average treatment effect. Finally, we find that the average expenditure per dose (DDD), which measures the cost to patients and payers, is highly significant, large in magnitude, and gradually increasing during the post period up to 50 percent. Thus, the results from the dynamic DID model support the results from the static DID model.

7 Concluding remarks

In this paper we have studied the more recent phenomenon of price hikes of older drugs in pharmaceutical markets, which has received increasing attention by policy makers and competition authorities despite no patent protection and free entry in such markets. To do so, we exploit a unique database covering the universe of prescription drug sales to patients in Norway. From this database we compile a dataset with monthly product-level data of all substances where at least one drug had a price hike during the ten-year period from 2011 to 2020. Using substitution groups as the relevant market, we split drugs into substitution groups with and without price hikes in the empirical analysis.

First, we estimate the likelihood for a price hike to occur using a linear probability model with substance fixed effects. The results show that both the number of rival firms and the degree of market concentration do have a significant impact, whereas market size and the share of generic drugs do not predict price hikes.

Second, we estimate the corresponding effects of a price hike on market outcomes using both a static and a dynamic DID approach. The results show that price hikes have a strong, positive and lasting effect on average prices, revenues and expenditures. Despite these effects on market outcomes, we do not find evidence for a price hike inducing more entry or loss of market shares.

Combined, these results indicate that price hikes are induced by firms that have market power and that the effects are detrimental for society as patients and insurers pay more for essential drugs. The results do also suggest that policy makers, regulators and competition authorities need to pay attention to drug markets where the patent term has expired. Indeed, policy makers and regulators should consider measures that lowers entry barriers, whereas competition authorities could potentially screen such markets for collusive practices or abuses of market power.

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