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Excessive Pricing of Pharmaceuticals

What are the drivers leading to excessive pricing in the Norwegian pharmaceutical market?

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Master thesis in Business Analysis and Performance Management

NORWEGIAN SCHOOL OF ECONOMICS

Executive summary

Millions of people depend on drugs in their everyday life to improve their life quality or even survive. Recently there has been an increase in the number of cases where prices of patented and generic pharmaceuticals skyrocket, which has led to an increased demand for further regulations. Therefore, our master thesis seeks to answer the following research question:

What are the drivers leading to excessive pricing in the Norwegian pharmaceutical market?

From economic theory, three main hypotheses for drivers are developed; shortages, falling demand or abuse of market power. If market power is a prominent driver, this may be used as an argument for increased intervention in the Norwegian pharmaceutical market.

The study is based on a comprehensive dataset from 2010-2020, covering 2,857 drugs. We apply a logistic regression model to estimate the effect various variables have on the probability of a price increase for a drug. The model rejects the hypothesis of falling demand being a driver at a 25% significance level. Further, it provides indications that market power may be a driver, as a higher market concentration is estimated to have a statistically significant positive effect on the probability of a price increase. We also find that monopolists have higher price increases compared to drugs with competition. This difference is statistically significant.

Additionally, five case studies are performed. For three of the case studies, monopolists threaten to withdraw their product from the Norwegian market if their application for higher prices is rejected. It may seem like the pharmaceutical companies manage to abuse their market power against the regulatory authorities. For the two remaining cases, the prices are revised by the Norwegian authorities and increased according to international reference prices. However, the reference prices vary considerably across the comparable countries. Finally, a difference-in-differences approach estimates that the increase in pharmaceutical expenditures the first year after a price increase accumulate to 257 million NOK.

Based on our findings, we suggest more intervention, but recognize that a cost-benefit assessment is necessary. We argue that although wrongful intervention may be more costly per case, the probability of this mistake is low due to the high degree of market power observed. We argue that the process for increasing prices should be stricter and that the reference price practice should be supplemented by a qualitative evaluation. Additionally, one should strive to facilitate competition by further reducing entry barriers.

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1. Introduction

Imagine that your life could suddenly be at risk due to circumstances outside of your control. Luckily, a magic wand exists that will save your life if it is used quickly enough. It is reasonable to assume that your willingness to pay for this magic wand is quite high, right? Millions of people suffer from severe allergies, and risk anaphylaxis in the case of an allergic reaction. This scenario is their reality. A sting from a bee or particles from particular foods may be enough to put their lives at risk, and an EpiPen could be lifesaving (Atlanta Allergy & Asthma, 2021). In the US alone, 3.6 million are prescribed an EpiPen each year. From 2009 to 2016, the price for an EpiPen in the US was increased stepwise from $103.5 to $608.61, an increase of 488%. The manufacturing cost of an EpiPen was estimated to be under $10 per package, and even though it was not under patent protection, no alternative was available (Miyashiro, 2017). This price may seem unreasonable compared to the costs, but for the 3.6 million people whose life could be saved by the EpiPen, it would be though to refrain from buying one due to the increased price. After all, their life is at stake.

The phenomenon of a dominant firm charging prices that are considered excessive relative to appropriate benchmarks and in a way deemed to be unfair is called excessive pricing (Gilo, 2021). The EpiPen is just one example of a pharmaceutical whose price has skyrocketed, and there are several more. According to the OECD Secretariat (2018), there has been a recent increase in the calls for intervention against high pharmaceutical prices and increased competition enforcement to tackle excessive pricing in the industry.

In 2020, Norwegians consumed pharmaceuticals worth an average of 5,690 NOK per person, accumulating to a total value of roughly 30.6 billion NOK nationwide (Soldal, 2021). This is a large amount of money, and if several cases like the EpiPen case in the US were to appear in Norway, the costs for society would be enormous. However, all pharmaceuticals in Norway are regulated through maximum prices (Statens legemiddelverk, 2019), which might make it more difficult to practice excessive pricing. Still, we see that several pharmaceuticals increase their prices by at least 50% in Norway as well, also after patent expiration. Therefore, we are going to explore the following research question:

What are the drivers leading to excessive pricing in the Norwegian pharmaceutical market?

The research question will be explored by combing economic theory, a dataset with sales data for several pharmaceuticals and case studies. The study will be performed on the basis of three hypotheses as to why prices have been increased; falling demand, shortages, or abuse of market power. If demand is falling, this would lead to reduced sales volumes and the fixed costs per unit would increase. Higher fixed costs per unit would reduce profitability which could warrant a price increase. We distinguish between shortages in input factors and production capacity. If there is a shortage in input factors, the price for labor or raw materials is likely to increase, which could warrant a price increase for the pharmaceutical. If a shortage is due to limited production capacity, the quantity supplied does not meet the quantity demanded, which could warrant a price increase according to economic theory. Lastly, if a pharmaceutical company obtains sufficient market power, they may be able to increase prices excessively without losing demand or being outcompeted by competitors. This type of price increases stems from a market failure, and the price increase would not be warranted as it is taking advantage of the consumers. If market power is found to be a leading driver of excessive pricing in the Norwegian pharmaceutical market, it may be cause for increased regulation and intervention.

The thesis will be structured as the following. First, a literature review will be presented, followed by a comprehensive theoretical framework for competition. As the pharmaceutical market has its peculiarities, we will explain the institutional background and its implications on the market mechanics. The dataset is then presented, before the methodology for the analysis is laid out. A thorough analysis of the price increases is then performed, before discussing whether the findings can be raised as an argument for increased regulation and intervention in the Norwegian pharmaceutical market.

2. Literature review

When a patent expires, producers of generic drugs may enter the market based on the formula for the original preparation. Generic drugs are "synonymous preparations", meaning drugs with the same active substance, pharmaceutical form and strength (Helse Nord RHF, Helse Midt-Norge RHF, Helse Vest RHF & Helse Sør-Øst RHF, 2018). This causes the market to switch from a monopoly to a market with potential competition. Economic theory predicts that entrance from competitors will cause the price to converge towards the marginal cost.

However, recently there has been an increase in the number of excessive pricing cases in the pharmaceutical industry, both within patented and generic drugs. This has led to several studies and reports being written on the topic. Most of the articles explore whether excessive pricing is happening and what the appropriate regulatory measures, if any, are. We split this section into two segments. The first segment presents literature regarding the phenomenon of excessive pricing in generics, before studies looking into the drivers of excessive pricing are presented.

2.1 Excessive pricing of generic pharmaceuticals

An important issue in determining excessive pricing is to figure out if a price is "too high". This has been the topic for several papers, and most are based around the EU case of United Brands where excessive pricing is defined as the price having "no reasonable relation to the economic value of the product supplied". Further, it is mentioned that a price can be unfair in itself, or when compared to competing products (European Court reports 1978 p. 207).

In response to recent competition enforcement actions taken against excessive pricing in the pharmaceutical industry, OECD launched a discussion on the topic of competition law within pharmaceuticals. The OECD Secretariat (2018) prepared a background note on the topic. It acknowledges that there is an increasing amount of excessive pricing cases, both for pharmaceuticals with and without patent protection. Further, arguments both for and against intervention are presented. The risk of making the wrong decision for a case is split into wrongful intervention, a type I error, and not intervening when necessary, a type II error. It is argued that the cost of type I-error intervention is higher than for a type II error, since removing incentives for R&D may reduce life quality and life expectancy, which is considered more

costly than increased expenditures. Finally, it is discussed if, and if so how, the government should intervene against exploitative excessive pricing in both the case of therapeutic and inter-brand competition. Therapeutic competition is defined as drugs with different active substances aiming to heal the same conditions. Inter-brand competition appears when generic alternatives with the same active substance enter the market.

During the discussion, Kyle (2018) presents a view that intervention against excessive pricing in pharmaceuticals should be considered differently in the innovative and generic market segment. It is argued that there is a stronger argument for intervention in the case of generics, as the dominant position is likely not attained through quality or innovation. However, an argument is made that more efficient regulatory processes and higher prices signaling an attractive market, could be more efficient than intervention.

Calcagno, Chapsal and White (2019) argue that the structure of pharmaceutical markets makes it difficult to assess whether a price is excessive and whether a firm has a dominant position, as suggested in the United Brands case. Firstly, they argue that it is difficult to determine the relevant substitutes for a drug and thus hard to assess whether a position is dominant. Secondly, they argue that it is tough to determine a benchmark price to compare with, due to heavy and differing regulation cross-borders as well as renegotiation of drug prices over time. Finally, to assess if excess profit is being made, costs must be distributed across the drug portfolio. The authors argue that this is tough, as costs are shared across both successful and unsuccessful drugs and the profitability of a drug will vary with the treatment population and local regulations. Due to these complications in determining excessive pricing in the pharmaceutical industry, the high economic cost of unnecessary intervention, and a mature pharmaceutical regulatory system in Europe, the authors argue that intervention against excessive pricing of pharmaceuticals should be done with great caution.

Abbott (2016) discusses whether patent protection should be a justification for excessive pricing. In the discussion, it is touched upon the fact that generics in the US on average are priced 75% lower than the original drug. Abbott emphasizes that competition authorities tend to prefer to address excessive pricing by trying to “fix the market”, i.e., by facilitating healthy competition. However, it is argued that due to heavy regulations, the pharmaceutical market bears little resemblance to a freely competitive market.

After the 1984 Waxman-Hatch Act was enacted in the US, allowing entry of generic drugs when branded drugs' patents expire, several articles studied the effect generic competition had on the branded drug's price. Contrary to what was to be expected, two early studies found that the branded drug prices rose after generics entered the market (Frank & Salkever, 1992; Grabowski & John, 1992). This phenomenon was named the "Generic Competition Paradox" by Scherer (1993). However, not all studies found this to be the case, as Caves, Whinston and Hurwitz (1991) found that the price was reduced, but by a negligible amount. After these findings were published, new articles sought to explain the paradox. A wide range of articles, e.g., Frank and Salkever (1997), Grabowski and Vernon (1996), and Kamien and Zang (1999), argued that the pharmaceutical market can be separated into a brand-loyal segment which is price insensitive and a price-sensitive segment which would explain the original producer's price increase. Differences in insurance coverage have also been raised as an explanation (Ferrara & Kong, 2008). However, more recent studies are less supportive of the paradox. Lakdawalla, Philipson and Wang (2006) found that generic competition generally had no effect on branded drugs' prices. Further, several studies have found that branded drugs' prices decline with generic entry (Saha & Xu, 2021; Caves, Whinston, & Hurwitz, 1991; FTC, 2011; Wiggins & Maness, 2004). It is still worth mentioning that there are newer studies also supporting the generic competition paradox, e.g., Vandoros and Kanavos (2013), where an increase in branded drugs' prices post generic entry in regulated European markets is found.

2.2 Why generic pharmaceutical prices suddenly hike

Collins and McCaskill (2016) published a report on behalf of the US Senate Special Committee on Aging, documenting and investigating five cases of sudden price spikes in off-patent prescription drugs. It found that in all cases, the prices were increased suddenly after the companies under investigation acquired off-patented drugs. Central elements in the business models of the acquirers were to find a drug that had the sole supply, was considered the gold standard treatment, had a small market with closed distribution and where they could perform price gouging. The report argues that the acquiring companies took advantage of the patients, taxpayers and the US health care system.

Graber (2017) asks the question of whether sudden price hikes in the US pharmaceutical industry are caused by inherent problems in the regulatory regime or due to natural deviations

in the market. 14 off-patent drugs which have had price increases of more than 200% between 2013 and 2017 are selected for further investigation of the competitive landscape. The cases are classified according to whether the increase is due to natural deviations in the market, e.g., cost or demand shocks, or due to business tactics, i.e., exploiting vulnerabilities in the market. Four types of events leading up to the price hikes are identified; acquisitions, shortages, reduced competition and consolidations. For eight of the cases, the pharmaceutical was acquired before the price increase and there were no or few viable alternatives on the market, which could indicate exploitation of a weak market. For four of the cases, there was a shortage leading up to the price hike and this indicates that the price increased due to natural market behavior. Graber argues that cases with acquisitions and subsequent steep price increases shows exploitation of the customers. Our study would differ from Graber's, as it is done for the Norwegian market which has a different regulatory regime, e.g., with maximum prices for pharmaceuticals. Our analysis is also based on a greater selection of 2,857 pharmaceuticals over a longer period, as our dataset contains data for 11 years. Additionally, we are able to estimate an aggregated logistic regression model which may unveil more general results compared to individual case studies.

First (2019) also presents three cases of steep price increases of pharmaceuticals post-acquisition and uses this as an argument for greater antitrust intervention in the US pharmaceutical market. An argument is raised that there are high barriers to entry in pharmaceutical markets, which would tackle the conventional expectation that new generics will enter a market and contribute to reduce excessive pricing.

Finally, it is found worthwhile to review a paper by Hauschultz and Munk-Nielsen (2020), in which price cycles in the Danish pharmaceutical markets are studied. When a price cycle ends, the drug prices are frequently more than doubled. In order to determine whether the price cycles occur due to strategic interactions, demand shocks or cost shocks, the cycles are compared to the ones observed in the Swedish market. The authors do not find the two markets to have matching price cycles. Therefore, it is concluded that the cycles are a feature of competition rather than being driven by either demand shocks or cost shocks.

3. Theoretical framework

In this section, a theoretical framework which could explain different mechanisms driving excessive pricing will be presented. We will give a broad presentation of competition theory and begin by presenting the characteristics and market equilibrium in a market with perfect competition. As most markets are not perfectly competitive, we will continue by elaborating on common barriers to entry and other sources of market power. Both characteristics and market equilibriums in monopolies and oligopolies will then be presented. Finally, we present a way to measure market concentration, the Herfindahl-Hirschman Index.

3.1 Perfect Competition

3.1.1 Four conditions for perfect competition

Perfectly competitive markets have several characteristics. We will present the four most important conditions but note that the list is not exhaustive. First, there must be a large number of small, independent buyers and sellers present in the market. This means that no single entity can influence the market equilibrium on its own and they are all price takers. Hence, any firm can change its behavior without affecting the market equilibrium. Second, there must be homogenous products. This implies that customers view the products as perfect substitutes and do not care who the producer is. Third, there must be free entry and exit. This means that anyone must be able to enter or leave the market without any barriers. Finally, perfect information about prices and quantities must be freely available and all decision makers are assumed to be rational. This ensures that no seller can overcharge a buyer, and no customer will pay a price above the perceived value of a product (Goolsbee, Levitt, & Syverson, 2016, p. 21; Pepall, Antonioni, & Rashid, 2016; Greenlaw & Taylor, 2017).

3.1.2 Market equilibrium under perfect competition

The market equilibrium can be defined as the "point at which the quantity demanded by consumers exactly equals the quantity supplied by producers*"* (Goolsbee, Levitt, & Syverson, 2016, p. 21). The equilibrium price is therefore "the only price at which quantity supplied equals quantity demanded" (Goolsbee, Levitt, & Syverson, 2016, p. 21). We will here assume that all firms' objective is to maximize profits. Profits are considered after all costs are

subtracted, including capital and opportunity costs. Since firms in perfectly competitive markets are price takers, they take the market price as given and cannot influence it by changing their behavior. Therefore, firms only need to decide which quantity to produce. The following derivation is from chapter 7 and 8 in the book *Microeconomics* by Goolsbee, Levitt and Syverson (2016).

The marginal cost is the addition to total cost TC of producing one more unit of output Q:

$$MC = \frac{\Delta TC}{\Delta Q}$$

The marginal revenue is the addition to total revenue TR from selling one more unit of output:

$$MR = \frac{\Delta TR}{\Delta Q}$$

Under perfect competition, marginal revenue is equal to the market price for the good. The reason is that the firms' behavior will not influence the price in any way, and the price does not vary with a single producer's produced quantity. The firm will therefore produce the quantity at which $MR = MC$. If it produces at a point where $MR > MC$, it could earn more profit by increasing the quantity produced. Likewise, if it produces at a point where $MR < MC$, it is producing the last units at a loss since the additional units add more costs than revenues to the firm. Since marginal revenue corresponds with price for price takers, a firm under perfect competition will maximize profits by setting:

$$MR = P = MC$$

This equilibrium with price P^* and quantity Q^* is illustrated in the figure below.

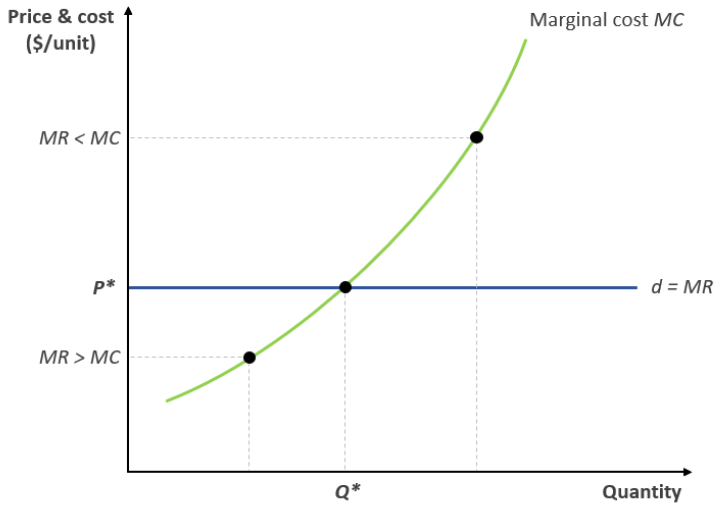

Figure 1: Equilibrium in perfect competition

We see that the demand curve for a given firm is horizontal, since quantity demanded does not vary with the firm's price. The steepness of the MC curve increases, indicating that marginal costs rise with output for larger volumes. Marginal costs might decrease in the beginning, e.g., because of complications in production with the first units or because workers become more specialized in their tasks. Later, marginal costs might increase due to capacity constraints, resources that become more expensive with increased use or coordination complications (Goolsbee, Levitt, & Syverson, 2016, pp. 248-323).

In the short run, a firm will decide to produce as long as the price is at least as high as its short-run average variable cost AVC, even though the price might not cover its short-run average total costs ATC which also includes fixed costs. These fixed costs are unrelated to the production and therefore irrelevant for the short-term decision. If the firm can earn additional profits from operating as opposed to shutting down, because the price exceeds AVC, it should do so in the short run. If the price is lower than AVC, the firm loses money for each unit it produces and should shut down the production. Therefore, when $P < AVC$, quantity produced is zero.

This is illustrated in the figure below, where we see that the short-run supply curve starts at the price equal to the lowest AVC.

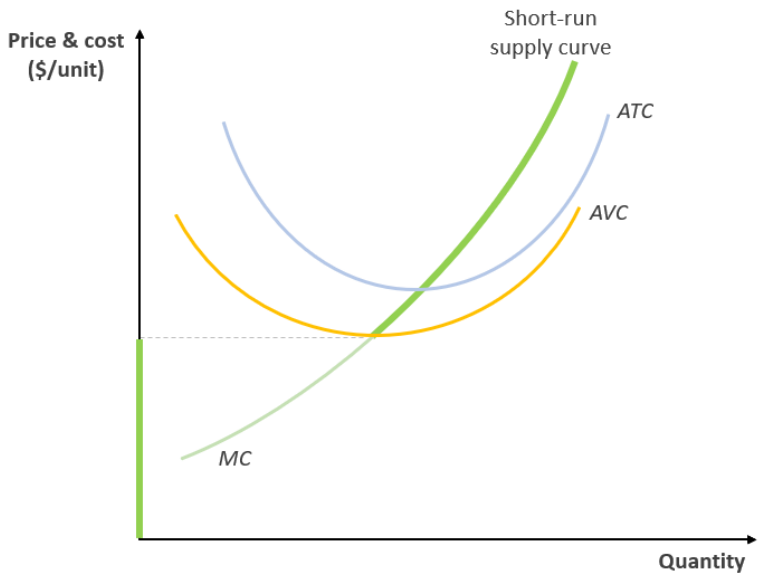

Figure 2: A firm's short-run cost curves

The ATC and AVC curves are U-shaped and exceed MC in the beginning but are lower than MC for larger quantities. The reason is that when the additional cost of producing one more unit is lower than the average cost per unit, the average cost per unit falls if we increase production by one unit. This will continue until $MC = ATC$ or $MC = AVC$, where the curves intersect. Beyond this point, the additional cost of producing an extra unit is higher than the average cost of the previous units, and the average cost thus increases. Therefore, the marginal cost curve intersects the average cost curves at their minimum (Goolsbee, Levitt, & Syverson, 2016, pp. 248-323).

However, this is not a stable equilibrium in the long run, since most firms have fixed costs they need to cover. In the long run, selling at a price that only covers the short-run variable costs will incur a loss equal to the fixed costs. As production can be shut down completely, the fixed costs can be viewed as variable in the long run. Therefore, we have $ATC = AVC$ in a long-term perspective. These fixed costs must be accounted for, and a firm will produce where the price is equal to its long-run marginal costs LMC. This is illustrated below.

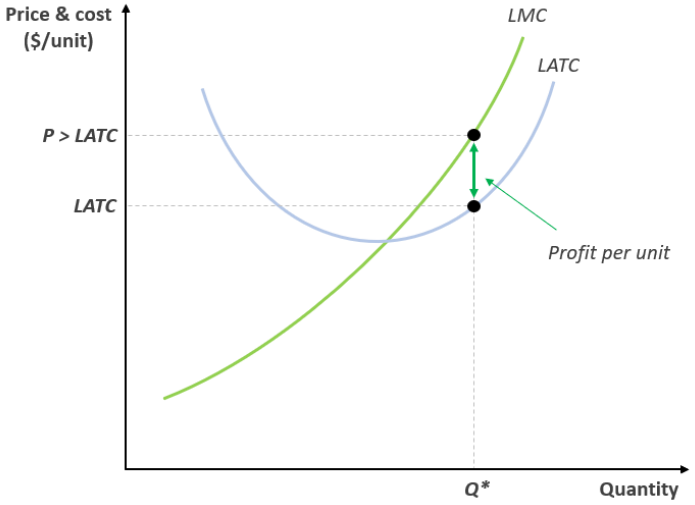

Figure 3: A firm's long-run cost curves

If firms are making profits at this price, as in the figure above, more firms will enter the market due to the attractiveness of earning profits. This will increase the quantity supplied, leading to a lower price. As long as the incumbent firms are making a profit, new competitors will enter. This will go on until the price is equal to the minimum long-run average total costs $LATC^*$. At this price, there are no profits in the market and no more firms have incentives to enter. Similarly, if the price is below the $LATC$, some firms are making losses and will therefore exit the market. This will usually be the firms with the highest costs. The exit will reduce the accumulated quantity supplied, which increases the price until it is equal to $LATC^*$ and no firms make losses. Hence, the long-run equilibrium under perfect competition is:

$$P = LMC = LATC^*$$

This is illustrated below.

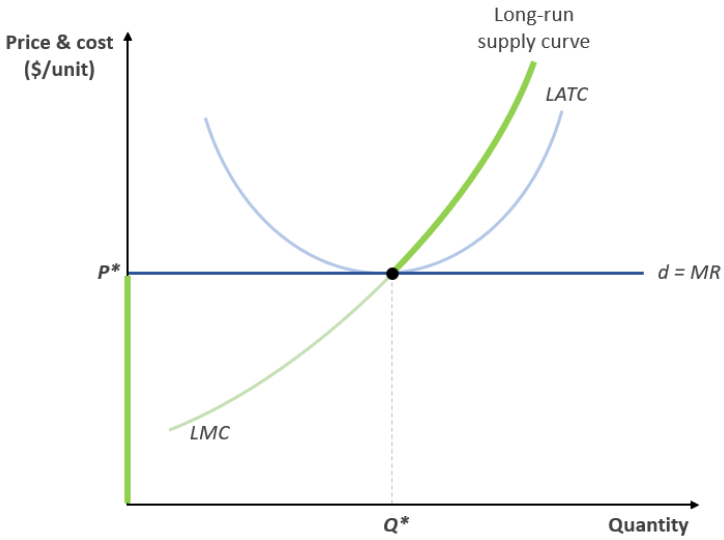

Figure 4: The long-run equilibrium in perfect competition

We see that the industry demand curve is horizontal and intersects at the point where the $P = LATC^*$. For a given firm, the supply curve is the part of LMC that is above $LATC$. For prices below this point, the firm will exit the market in the long run (Goolsbee, Levitt, & Syverson, 2016, pp. 248-323).

However, perfectly competitive markets rarely exist in the real world. Usually, products are differentiated to a certain degree, either directly or indirectly, and there are at least some barriers to entry (Goolsbee, Levitt, & Syverson, 2016, p. 323).

We will now take a closer look at markets where there is some extent of market power.

3.2 Market power

3.2.1 Barriers to entry

Barriers to entry can be defined as "factors that prevent entry into markets with large producer surpluses" (Goolsbee, Levitt, & Syverson, 2016, p. 332). Unlike in markets with perfect competition, where profits will attract new entry until $P = MC$, barriers to entry make it difficult for new competitors to enter the market. Thus, firms are effectively allowed to set a price above marginal cost without the risk of losing all their customers to a competitor (Goolsbee, Levitt, & Syverson, 2016, p. 332).

We will now explain some of the most common barriers to entry.

Irreversible investments are investments related to entering a market, that the company cannot recuperate if it were to decide to leave the market, e.g., physical investments, intangibles or learning effects. These are sunk costs that existing firms do not need to consider when they set their price. On the other hand, these must be taken into account by firms considering to enter a market. Potential entrants may fear that existing firms with sunk investment costs will respond with an aggressive price war if they enter the market. This reduces the entrant's expected profits post-entry, which makes entry less profitable and riskier. The higher the irreversible investments are, the higher the profits post-entry need to be. This is why irreversible investments are the most fundamental entry barrier (Lien, Knudsen, & Baardsen, 2017, pp. 103-105).

Regulations are an important barrier to entry in certain markets, e.g., required quality and production standards, licenses required to produce or patents giving exclusive production rights. In markets with high R&D costs and low marginal costs, such as the pharmaceutical industry, patents are given to producers to ensure that companies have incentives to invest in R&D, since they will be able to recuperate the costs through a temporary monopoly situation afterwards (Goolsbee, Levitt, & Syverson, 2016, p. 336).

Economies of scale is when the total average cost per unit decreases when the volume increases due to lower fixed costs per unit. As all markets are of limited size, a new entrant's sales volume must be obtained either by capturing market shares from incumbents or by increasing the total demand. This might make it difficult to reach a volume which allows for a competitive $LATC$ compared to the established players, making entry less profitable. Likewise, economies of scope is when the average cost per unit decreases when the number of different products produced increases. These costs are usually related to resources that benefit all the products, such as brand name, distribution channels and production and logistics facilities. The additional costs of producing a new variant are significantly lower for the incumbent that already has other products, than for a new entrant (Lien, Knudsen, & Baardsen, 2017, pp. 105-106).

High switching costs involves that a customer must give up something in order to switch to a competing product. This tends to generate market power for the established firm, creating a barrier to entry. This could be related to loyalty programs, customers being locked into contracts, cross-product compatibilities or customer know-how. Searching costs is a specific

type of switching costs. If it is time-consuming or difficult to gather information about alternative products, the customer has lower incentives to switch.

We mentioned previously that products must be completely homogenous for a market to be perfectly competitive. However, most products in the real world are differentiated in some way, and hence product differentiation is another barrier to entry. Products may either be differentiated directly, through the product's functionalities and appearance, or indirectly, e.g., through a strong brand name, physical location, or excellent customer service. Some customers will have a particular preference for one firm's product and therefore be willing to pay a premium for it. This variation in willingness to pay allows the preferred firms to set their price above competitors' price without losing all their customers to the competitors. Potential entrants are then prevented from entering the market and capturing market shares by simply offering a lower price than the incumbent (Goolsbee, Levitt, & Syverson, 2016, pp. 334-335).

In summary, barriers to entry are irreversible investments, regulations, economies of scale, economies of scope, high switching costs and product differentiation. These are important reasons why markets are rarely perfectly competitive, and we will now look at the market equilibrium under different situations with market power.

3.2.2 Situations with market power

We found previously that the market equilibrium in perfectly competitive markets is given where $P = MC$. The reason is that the firms are price takers. Firms with market power, on the other hand, are not price takers since their behavior has an impact on the market. We will now derive the market equilibria in different markets where at least one player has market power.

Monopoly

A monopoly is a market where one supplier serves the entire market and hence has significant market power. We will now derive the equilibrium for monopoly markets, and the following derivation is from chapter 9 in the book *Microeconomics* (Goolsbee, Levitt, & Syverson, 2016). For companies with market power, there is a relationship between the quantity supplied and price. Since monopolists have the entire market to themselves, they face a downward-sloping demand curve. If a firm wants to sell more, it will have to reduce the price, and if it wants to set a higher price, it will have to give up some quantity. We assume that price discrimination is not possible, so if the monopolist wants to sell an additional unit, it will have

to reduce the price not only for this unit, but for all the other units it sells as well. The marginal revenue for a monopolist is therefore not equal to the price but must also contain the lost revenue from the previous units. This can be expressed as:

$$MR = P + \left(\frac{\Delta P}{\Delta Q}\right) Q$$

Here, P is the new price set to sell the additional unit, while Q is the quantity before adding the extra unit. Note that $\frac{\Delta P}{\Delta Q} < 0$ since selling an extra unit implies reducing the price. Therefore, the marginal revenue equals the price earned for the extra unit, less the revenues lost from the price reduction on all the previous units. For a linear inverse demand curve of the form $P = a - bQ$, where a, the vertical intercept of the demand curve, and b are constants, $\frac{\Delta P}{\Delta Q} = -b$. We can use these expressions to derive the marginal revenue as:

$$MR = a - 2bQ$$

Thus, the marginal revenue curve has the same intercept as the inverse demand curve but is twice as steep. Just like under perfect competition, the market equilibrium under monopoly is given where $MR = MC$. However, since the marginal revenue for a monopolist is lower than the price, the firm will not produce where $P = MC$. This would imply setting a low price for all their units to sell a high quantity. Instead, a monopolist will restrict its quantity to keep prices higher (Goolsbee, Levitt, & Syverson, 2016, pp. 331-366).

This is illustrated in the figure below.

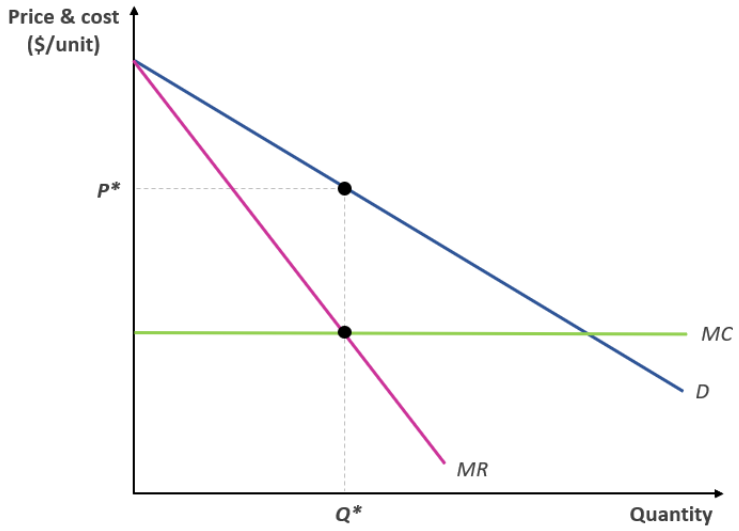

Figure 5: A monopolist's equilibrium

However, few firms are able to retain a natural monopolist position over time. In most cases, the high profitability will attract new entrants into the market or national competition authorities will intervene to facilitate competition (Goolsbee, Levitt, & Syverson, 2016, pp. 360-361). It is therefore more common to see oligopolies where the markets are split between a few firms with market power. Competition can be depicted as either Bertrand, where firms compete by choosing their price, or Cournot, where firms compete by choosing their volume (Sørgard, 2017, p. 53). As Bertrand is the most relevant for the pharmaceutical market, we will focus on Bertrand competition.

Bertrand competition

The following derivation is from chapter 4 in the book *Konkurransestrategi* (Sørgard, 2017). Under Bertrand competition, price is the strategic variable. The firms compete by setting their price simultaneously based on what price they expect the competitors to set. The market equilibrium under Bertrand competition varies significantly depending on whether the products are homogenous or differentiated.

Bertrand competition with homogenous products

We assume a market with two firms selling identical products. The total demand in the market is a function of price given by $D(P)$. Both firms have a constant marginal cost c. P_i denotes the price for firm i, where $i = 1, 2$.

Since the products are homogenous, the consumers will buy from the seller with the lowest price. If they set the same price, we assume that each firm gets half of the demand for the given price. For now, we also assume that none of the firms have fixed operating costs that would cease if the firm decided not to produce. Under the prerequisite that each firm alone could meet the entire demand, firm i's profit π_i is given as follows under the three potential outcomes:

$\pi_i = 0$	if	$P_i > P_j$
$\pi_i = \frac{(P_i - c)D(P_i)}{2}$	if	$P_i = P_j$
$\pi_i = (P_i - c)D(P_i)$	if	$P_i < P_j$

We can apply this to find the Nash equilibrium, defined as the equilibrium in which none of the firms will regret their own choice of strategy when they observe their competitor's choice of strategy (Sørgard, 2017, p. 19). A strategy can be defined as a set of instructions indicating which action a player should choose in any given situation, where a player can be understood as a firm (Sørgard, 2017, p. 17). In the first outcome, firm i sets a price above the marginal cost and above firm j's price. It does not earn any profits, since firm j captures the entire market due to its lower price. If firm i sets its price equal to firm j's price, as in the second situation, it gets half the market. However, if it slightly undercuts firm j's price, it will capture the entire market and can double its profits (Sørgard, 2017, pp. 53-55).

If firm i captures the entire market, firm j will regret its choice since it ends up with zero profits but could have captured the entire market by slightly undercutting firm i's price. Hence, as long as price is above marginal cost, a firm will always regret its action when observing what the competitor does. Therefore, any price above marginal cost cannot be a Nash equilibrium. The Nash equilibrium under Bertrand competition is therefore equal to the equilibrium under perfect competition, where $P_i^* = P_j^* = c$. Given that they have the same marginal cost, they will both set the price equal to marginal cost and supply half the market each. None of the firms have incentives to reduce the price further, since the price then will be below marginal cost and it will incur a loss (Sørgard, 2017, pp. 53-55). This is called The Bertrand Paradox, implying that even though the market is very concentrated, the competition

is so fierce that all the profits are eliminated, leaving the firms with zero profits (Brekke, 2020A).

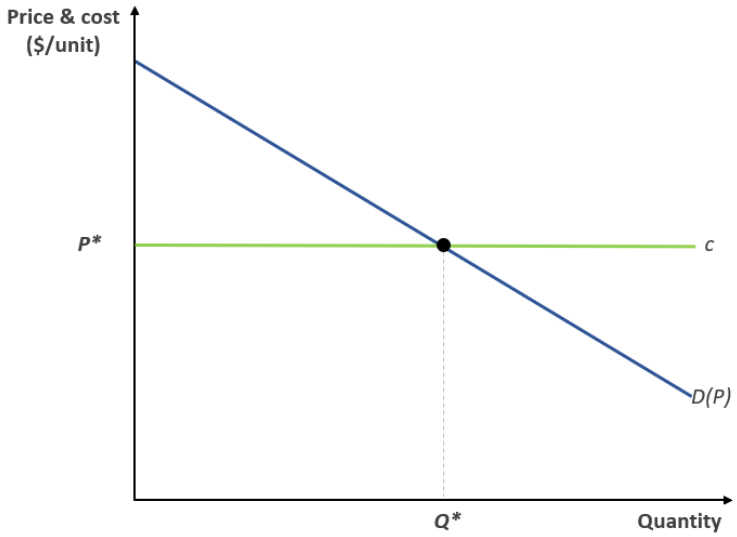

Figure 6: The Bertrand Paradox

We now assume that the firms have different marginal costs, where $c_i < c_j$, meaning that firm i has a lower marginal cost. In this case, both firms setting a price equal to their marginal cost is no longer a Nash equilibrium. In that case, firm i would set $P_i = c_i$, capture the entire market and both would earn zero profits. However, firm i could set its price somewhere between its own and firm j's marginal cost. In that case, it would not be profitable for firm j to undercut, so firm i would be left with the whole market and still earn a profit margin for each unit. The Nash equilibrium under Bertrand competition with homogenous products but different marginal costs is therefore given by:

$$P_j^* = c_j$$

$$P_i^* = c_j - \varepsilon$$

Where ε is a small, positive number. Firm i will gain profits approximately equal to $(c_j - c_i)D(c_j)$. This is illustrated as the green shaded area in the figure below (Sørgard, 2017, pp. 55-57).

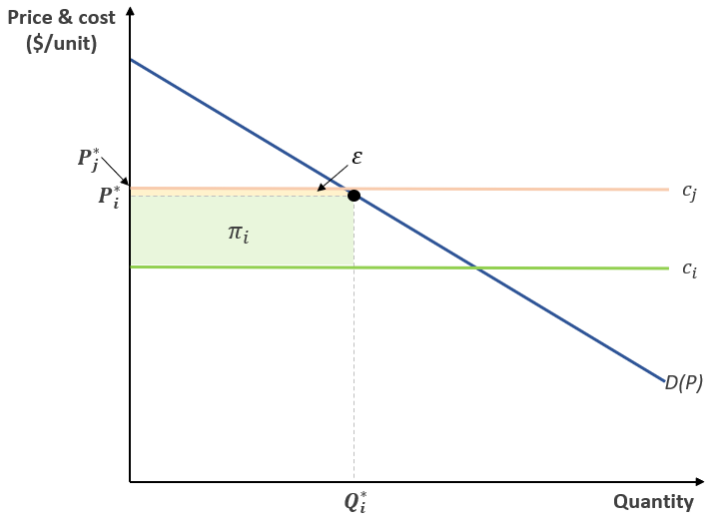

Figure 7: Equilibrium in Bertrand competition with different marginal costs

We now assume that the firms have avoidable fixed operating costs. Setting the price equal to marginal cost could then not be a Nash equilibrium, because the firms would be left with no contribution margin to cover the fixed costs. The two firms can save fixed costs by shutting down production without reducing their contribution margin, as it is already equal to zero. We presume that both firms have fixed operating costs F and marginal costs c. The price must exceed the marginal cost in order to cover the fixed costs, and we assume that the contribution margin exactly covers the fixed costs. This can be denoted as:

$$(P_i - c)\frac{D(P_i)}{2} = F$$

$$\frac{P_i D(P_i)}{2} = F + \frac{cD(P_i)}{2} \rightarrow P_i = \frac{2F}{D(P_i)} + c$$

This is still no Nash equilibrium, since both firms have incentives to slightly undercut the other and capture the entire market, which would double the contribution margin and give profits equal to F. The two Nash equilibria are therefore given by:

$$P_i^* = c + \frac{F}{D(P_i^*)} \text{ and } P_j^* = c + \frac{F}{D(P_j^*)} + \varepsilon$$

$$P_i^* = c + \frac{F}{D(P_j^*)} + \varepsilon \text{ and } P_j^* = c + \frac{F}{D(P_i^*)}$$

The firm with the lowest price will capture the entire market and earn zero profits. It would lose half the market if it increased the price marginally, while the firm with the highest price would experience a loss if it undercut the rival. Hence, none of the firms will regret their decision when they observe their rival's choice (Chaudhuri, 1996; Sørgard, 2017, pp. 53-57).

This is illustrated below.

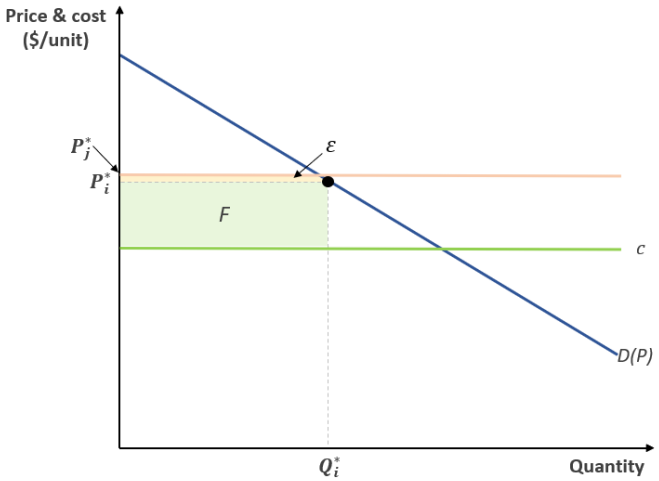

Figure 8: Equilibrium in Bertrand competition with avoidable fixed costs

There are three ways firms may be able to coordinate so both can stay in the market and avoid the Bertrand paradox. First, if the products are differentiated, consumers might prefer one product, and therefore not base their choice solely on price. Second, if there are capacity restraints, the firm with the lowest price might not be able to serve the entire market, and there might be demand remaining for other firms. Third, if the firms compete repeatedly, the fear of aggressive response might dampen the competition (Sørgard, 2017, p. 57).

We will here focus on the first and look at the equilibrium under Bertrand competition with differentiated products.

Bertrand competition with differentiated products

With differentiated products, some consumers will have a preferred product if they have the same price. This allows a producer to set the price higher than the rival's product without losing all demand. The demand function for firm i can be written as follows:

$$Q_i = A - bP_i + kP_j$$

$$\text{where } 0 < k < b, \qquad i, j = 1,2 \qquad \text{and} \qquad i \neq j$$

The parameter A is a measure of the market size, where a greater A represents a higher demand. The condition $0 < k < b$ indicates that a change in the firm's own price has a greater impact than a corresponding change in the rival's price. With firm i's marginal cost c_i and fixed cost F_i, firm i's profit is given by:

$$\pi_i = (P_i - c_i)\big(A - bP_i + kP_j\big) - F_i$$

In order to find the Nash equilibrium, we need to understand what price firm i will choose for a given price set by firm j. This is called the firm's reaction function or best response function, but it is important to note that the steps are hypothetical and that the firms actually set their price simultaneously. Firm i will choose its price so that the firm's marginal profit equals zero, which can be used to find its reaction function:

$$\frac{\partial \pi_i}{\partial P_i} = A + kP_i + bc_i - 2bP_i = 0$$

We solve the equation for P_i:

$$P_i = \frac{A + kP_j + bc_i}{2b} \equiv R_i(P_j)$$

This is firm i's reaction function, R_i, as a function of firm j's price, P_j, and exogenous parameters. The Nash equilibrium is given where both firms' expectations about the rival's choice are consistent with the rival's choice. We find the equilibrium by solving the reaction function simultaneously by replacing P_j in firm i's reaction function with firm j's reaction function:

$$P_j = R_j(P_i) = \frac{A + kP_i + bc_j}{2b}$$

$$P_i = R_i\big(P_j\big) = \frac{A + k\left(\frac{A + kP_i + bc_j}{2b}\right) + bc_i}{2b}$$

We solve for P_i to find firm i's optimal price:

$$P_i^* = \frac{2b(A + bc_i) + k(A + bc_j)}{(2b + k)(2b - k)}$$

Firm j's optimal price is found the same way, and if the firms have the same marginal cost $c_i = c_j = c$, the Nash equilibrium for Bertrand competition with differentiated products is given by:

$$P_i^* = P_j^* = \frac{A + bc}{2b - k}$$

This is illustrated in the figure below, where the graphs show the firms' reaction functions as functions of the rival's price, and the intersection shows the equilibrium.

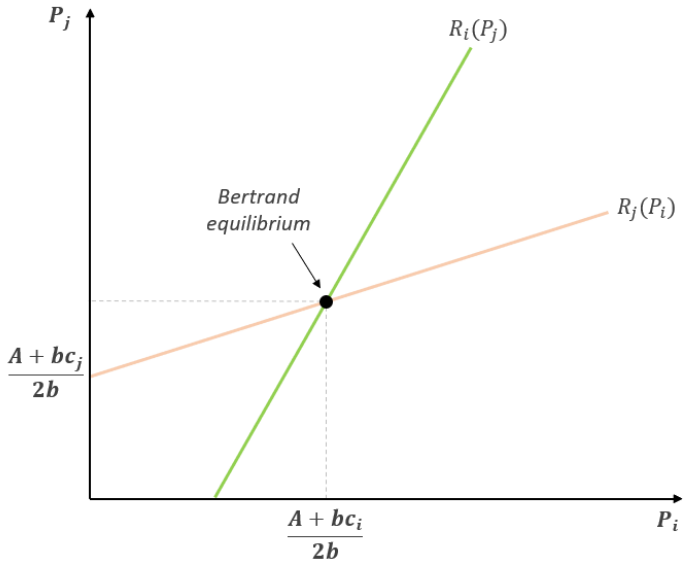

Figure 9: Equilibrium in Bertrand competition with differentiated products

The intersection is found by setting the rival's price equal to zero in one's own reaction function. By deriving firm i's reaction function with respect to P_j, we find the slope of the reaction curve:

$$\frac{dP_i}{dP_j} = \frac{k}{2b} > 0$$

The slope is positive, implying that the higher price firm j chooses, the higher price firm i will choose. We can therefore say that the action variables are strategic complements. However, the price increase in one's own price is lower than the increase in the rival's price. The reason for this is that firm i wants to use its lower price as a competitive advantage (Sørgard, 2017, pp. 57-60).

3.2.3 Market concentration

A market's concentration is affected by the number of firms in the market and their relative market shares. A highly concentrated market might indicate that the competition is low and that there are high barriers to entry which prevents other firms from challenging the incumbents. This entails a concern that firms with a high degree of market power might take advantage of their position and exploit consumers with few or no alternative suppliers and little bargaining power. National competition authorities therefore observe market concentration in various markets and take this into consideration when assessing mergers and acquisitions (Brekke, 2020B).

The Herfindahl-Hirschman Index

A common market concentration measure is the Herfindahl-Hirschman Index (HHI). This is given by the following formula:

$$HHI = \sum_{i=1}^{n} (m_i)^2$$

Where m_i is firm i's market share, given by $m_i = \frac{q_i}{Q} * 100$. The index accumulates the square of all the market's firms' market shares, returning a number between 0 and 10,000. The concentration can be classified into the four following categories (Brekke, 2020B; US Department of Justice, 2018):

$HHI \leq 1\,500$	Competitive market
$1\,500 < HHI < 2\,500$	Moderately concentrated market
$HHI \geq 2\,500$	Highly concentrated market
$HHI = 10\,000$	Monopoly

3.3 How may economic theory explain excessive pricing?

Based on the theory presented in this section, we have derived three main hypotheses about drivers leading to excessive pricing in the Norwegian pharmaceutical market; shortages, falling demand and market power.

Our first hypothesis is that the price increases are driven by shortages in input factors or production capacity. A shortage in input factors such as raw material or labor would increase the factor prices if the demand for an input factor exceeds the supply, assuming that the prices are a function of supply and demand. We know that all firms must consider costs when setting their prices. For operation to be profitable, the price must be equal to or higher than the costs. Increased costs would therefore require a higher price for a pharmaceutical's profitability to remain unchanged. Alternatively, if the demand for a pharmaceutical exceeds supply, e.g., due to limited production capacity, the prices may be driven up similarly. We refer to this as a shortage in production capacity, which could also induce increased prices. However, shortage issues would normally be temporary and if the price is kept high, leaving the incumbents with high profits, new entrants should be expected.

A second hypothesis is that the prices are increased due to falling demand for the pharmaceuticals. Economic theory tells us that for operation to be profitable in the long run, the firm must also cover its fixed costs. These are covered through the product's contribution margin, multiplied by the number of products sold. If the sales volume falls, e.g., due to a reduction in demand, the contribution margin per product must be higher. This can be done by reducing the variable costs or by increasing the price. Therefore, a possibility is that the firms have experienced falling demand for their pharmaceuticals, giving higher fixed costs per unit, and have increased the prices accordingly for profitability to remain constant.

Our final hypothesis is that the price increases are driven by market power. We mentioned previously that if firms have market power, they may be able to set a price above marginal cost. The next chapter explains thoroughly that the pharmaceutical industry is characterized by high barriers to entry, which makes it probable that the producers have some extent of market power. Given that many pharmaceuticals are necessity goods, which makes consumers relatively inelastic to price changes, opportunistic firms may take advantage of their position to increase their prices and potentially revenues.

We will now explain characteristics of pharmaceutical markets, before presenting the dataset and methodology that will be applied to further test our hypotheses.

4. Institutional background

Pharmaceutical markets are severely distinct from perfectly competitive markets and are therefore often highly regulated (The OECD Secretariat, 2018). The Norwegian Ministry of Health and Care services have three main objectives on the pharmaceutical area. Firstly, the population shall have access to secure and effective drugs independent of their ability to pay. Secondly, pharmaceuticals shall be used correctly, both professionally and economically. Thirdly, the price of pharmaceuticals shall be as low as possible (Helse- og omsorgsdepartementet, 2005). In this section we will present characteristics of the pharmaceutical industry that influence the fundamental market mechanisms significantly and induce government intervention. When analyzing the market, it is useful to distinguish between considerations on the demand and supply side of the market.

4.1 Demand-side considerations

From the demand side, pharmaceutical markets can be divided into three categories. Firstly, there are non-reimbursed or over-the-counter medicines for which the consumer pays the full price. These can be either prescription or non-prescription drugs. Secondly, there are reimbursed prescription medicines. These are medicines for which the consumer will get all or parts of the expense reimbursed through public or private health insurance. Thirdly, there are pharmaceuticals purchased by hospitals (The OECD Secretariat, 2018).

Above all, it should be recognized that many medicines are necessity goods which patients depend on in order to treat health conditions, improve life quality, live longer or even survive. Therefore, most consumers are less price sensitive and have a higher willingness to pay for medicines compared to other products. In such cases, an increase in price will give a relatively small reduction in demand. This could be taken advantage of by opportunistic firms (The OECD Secretariat, 2018).

The second category, reimbursed prescription medicines, is especially interesting. A key characteristic that makes the pharmaceutical industry unique, is the fact that the consumer, payer, and decision maker are separated roles, potentially with different interests and incentives (The OECD Secretariat, 2018). Laat (2002) depicts the phenomenon well: “Who

consumes, neither chooses nor pays; who pays, neither consumes nor chooses; who chooses, neither pays nor consumes".

Some drugs are considered merit goods that should be available to all. Therefore, supply cannot be left completely to the market. Rather, reimbursement plans are implemented in order to ensure access for everyone. In the case of public health insurance and reimbursements from the state, these costs are ultimately borne by taxpayers. Since the expenses are partly or fully covered by a third party, the consumer who purchases the medicines will usually be less price sensitive. A consumer might pick a medicine based on the effect and side effects of the drug, how easy it is to access and how it is taken, rather than price. However, since most patients have insufficient knowledge on this area, they depend on doctors to make the treatment decisions. Likewise, the doctors are not responsible for the financing either and might not take the costs fully into account when prescribing drugs. They might have incentives to prescribe the drugs they are most familiar with and spend less time updating themselves on prices. This could allow producers to raise their prices without expecting demand to fall by too much. This is especially the case when there are limited therapeutic alternatives, which is common for patented products (The OECD Secretariat, 2018).

Due to these challenges, the market for reimbursed medicines receives significant attention from competition authorities and health regulation. Public and private health insurers apply various mechanisms to align the individuals' interests and incorporate cost-effectiveness in each role's incentives. Several mechanisms can be used to increase price responsiveness for the different players (The OECD Secretariat, 2018).

For consumers, this can be done through co-payments. In such a system, patients must partially cover the expense themselves. Alternatively, reimbursement schemes can incentivize consumers to choose cheaper drugs, e.g., if the consumer pays a lower deductible when accepting a generic alternative, or if the reimbursement amount is capped at the cheapest alternative's price (OECD, 2014). In the last few years, the Norwegian authorities have decentralized the financing responsibility for several pharmaceuticals to place the responsibility closer to where the prescription and treatment decisions are made (Finansdepartementet, 2021).

For physicians, one solution is to prescribe by substance name rather than brand name, either voluntary or mandatory. One might also implement financial incentives for prescribing

generics rather than original versions, or couple financial incentives with pharmaceutical budgets or benchmarking of prescribing patterns. For pharmacists, generic or low-cost drugs may be offered as a substitute for the original product, either voluntary or mandatory. Alternatively, one can impose regulations on the pharmacist's margins, for example by applying regressive margins that encourage sale of cheaper medicines or delinking the margins from the sales value (OECD, 2014). In Norway, pharmaceuticals' prices are regulated through maximum prices, which we will return to in the supply-side considerations section below.

As for insurers, options include bulk-buying, tenders to purchase drugs directly from the manufacturer or formularies and discounts for drugs flagged as "preferred drugs" (Apotekforeningen, 2017). In Norway, the entity called Sykehusinnkjøp HF is responsible for procurement on behalf of the regional health trusts. Due to quantity discounts and tenders, annual savings on procured pharmaceuticals from 2016-2019 have been estimated to be 2-6 billion NOK (Finansdepartementet, 2021).

Non-reimbursed medicines are regulated to a smaller extent since the patient's and physician's choices do not affect the government's costs. Furthermore, the fact that they are not reimbursed usually means that they are not essential. Alternatively, it could mean that competition and basic market mechanisms will naturally ensure a reasonable price. However, high switching costs or price insensitive physicians might prevent the expected market mechanisms from functioning. High switching costs may be present if patients fear the side effects from alternative drugs, or when the patient needs medication continuously and it is time-consuming to find and obtain prescriptions for alternative drugs. Likewise, doctors might not be aware of the differences in price between the original drug and generics or might not have incentives to prescribe the cheapest alternative. Therefore, excessive pricing might also be a problem in the market for non-reimbursed medicines (The OECD Secretariat, 2018).

4.2 Supply-side considerations

The competition in the pharmaceutical industry is usually divided into three categories: therapeutic, intra-brand and inter-brand. Therapeutic competition is characterized by high R&D expenses and occurs when firms develop new, patented and innovative therapies that are better than the existing ones. Intra-brand competition is the competition between a patented product and parallel imports of the same product from cheaper markets, into a market with

higher prices. The packaging might be different, but the medicine itself is the same (Statens legemiddelverk, 2017). Inter-brand competition occurs when other firms enter the market with generics after the patent for the original drug is expired. The generic version is a different product from a different manufacturer, but it contains the same active substance and has the same treatment effect as the original drug (The OECD Secretariat, 2018).

When a generic competitor enters the market, it may set a price close to the marginal cost. This would put pressure on the original firm to reduce their price. According to studies performed in the US and the EU, the first generic entrant typically sets a price that is 20-30% lower than the price of the original drug, while subsequent entrants set prices that are about 80% lower (OECD, 2009). When this is the case, the need for price regulation is dampened since the increased competition leads to reduced prices through market mechanisms. Many jurisdictions therefore attempt to incentivize generic competition through policies that simplify the approval process for generic drugs (The OECD Secretariat, 2018).

4.2.1 Patents to ensure innovation and R&D investments

Pharmaceutical markets with therapeutic competition are among the economic sectors with the highest R&D intensity (Galindo-Rueda & Verger, 2016). R&D in the pharmaceutical industry is a long, expensive and risky process, e.g., in order to be approved in Norway, a drug must have a documented effect and it must be documented that the drug does not have harmful effects that are disproportionate to the expected effect (Helse Nord RHF, Helse Midt-Norge RHF, Helse Vest RHF & Helse Sør-Øst RHF, 2018). The following statement summarizes the cost structure well: “The first pill can cost more than USD 1 billion while the second costs only a dime” (The OECD Secretariat, 2018, p. 22). The marginal cost of producing a pill once it is developed is minimal, but the development process requires significant time and money (The OECD Secretariat, 2018). It takes about 15 years and 10-20 billion NOK to develop a drug (The OECD Secretariat, 2018; LMI, 2018). Additionally, approximately 90% of new drugs entering clinical trials fail, and the costs related to these failed projects must also be recovered. Therefore, firms depend on intellectual property (IP) protection, e.g., patents that allow them to be the sole provider of the drug for a given period of time, so their limited number of successful drugs can provide sufficient returns on their total R&D investments (LMI, 2018; The OECD Secretariat, 2018). Studies show that 75% of pharmaceutical firms’

profits come from only 10% of all drugs. For some major firms, 70-80% of the total pharmaceutical sales come from their top three products (OECD, 2000).

In the absence of patents in a functioning market, other firms would enter with similar products, based on the R&D process that the originator has already spent significant time and money on (Collins & McCaskill, 2016). The competition would bring market prices closer to the marginal cost, and the originator would not be able to recoup its investments. Therefore, the patent system shall ensure financial incentives to invest in novel and useful R&D (U.S. Patent and Trademark Office & Economics & Statistics Administration, 2016).

In Norway, firms can apply for patents for five types of inventions within the pharmaceutical industry (Patentstyret, 2018). Patents can be granted for substances, manufacturing methods for a substance and new formulations such as pills or capsules. Patents can also be granted for medical preparations where medical utilization areas for existing substances are invented, or when new medical utilization areas, i.e., new indications, are found for known preparations (Statens legemiddelverk, 2016B).

A patent grants a firm exclusive rights to utilize the invention, e.g., to be the sole provider of its invented product, for a given period of time. Usually, they are given the maximum time of 20 years. The effective patent time for pharmaceuticals, i.e., the time the product is on the market and patented so that originators earn profits to recoup R&D costs, is usually significantly shorter than for other patented products. The reason is that pharmaceuticals must pass long and complex clinical trials before they receive marketing authorization and can be sold. Firms can therefore apply for prolonged protection of pharmaceuticals for up to five years, this is called a Supplementary Protection Certificate (Patentstyret, 2018).

Firms in the pharmaceutical industry frequently obtain dominant positions due to the strong role of IP protection. These positions are usually not challenged before firms with generics enter the market. Two sources of bargaining power might help buyers negotiate and obtain better prices. First, a customers' bargaining power tends to be high if they purchase a significant volume. Therefore, national health care systems and large insurance companies might have high bargaining power due to their high volumes. However, the other factor that gives customers bargaining power is "their ability to walk away from the deal, completely or in part" (The OECD Secretariat, 2018, p. 22). In order to negotiate on price, buyers must have credible alternatives, e.g., other drugs or treatments. In pharmaceutical markets, unless not

getting treatment is an alternative, there must be therapeutic alternatives for customers to have bargaining power. In many markets, therapeutic alternatives are not available, which induces a need for price regulation in order to protect buyers from being abused (The OECD Secretariat, 2018).

4.2.2 Price regulation

A drug's entry price might be determined through several methods. With no price regulations, there would be free pricing. However, as mentioned earlier, many drugs are merit goods and may be critical for patients to survive or will improve life quality significantly. Therefore, many countries consider price regulation to be necessary, especially when there is little or no competition. Price regulation could be done by restricting rate-of-return, reference pricing, cost-plus pricing, clinical and cost-effectiveness pricing, maximum price thresholds and other value-based methods (The OECD Secretariat, 2018).

One method to determine prices is to apply internal or external reference pricing. Internal reference pricing is done by comparing a product's price to the price of other drugs in the same therapeutic class within the same market. External or international reference pricing is done by comparing a product's price in one country to the price of the same product in other markets. A market is usually defined as a country in this context. The method is simple, but it entails some challenges. For example, there might not be products available for comparison, and the method does not consider the value a product brings to society. Furthermore, reference pricing incentivizes firms to set high initial prices to keep reference prices high, and they dampen price competition within pharmaceutical categories (The OECD Secretariat, 2018).

Other approaches involve more complex pricing methods. One method is to use rate-of-return regulations where prices are calculated based on the opportunity cost of similar investments in terms of size and risk. Alternatively, value-based pricing methods such as comparative-effectiveness can be used. With this approach, prices are based on the superior effectiveness of a new drug compared to existing alternatives or setting a maximum price for drugs based on ex-ante and ex-post evaluations of the value of medicines. Even though these methods may be more in line with economic theory, the complexity of these approaches makes them difficult to apply. For example, it might be challenging to objectively define the value or effectiveness of a drug. Second, there might be methodological and ethical challenges, for example regarding how to determine the appropriate price based on the value that is derived.

Additionally, estimates or evidence of a drug's value or effectiveness might not be available at the time when the reimbursement decision must be made (The OECD Secretariat, 2018).

In Norway, all prescription drugs for humans with marketing authorization receive a maximum price set by The Norwegian Medicines Agency, Statens legemiddelverk (SLV), before they can enter the market (Statens legemiddelverk, 2019). The maximum price applies to all drugs within an interchangeable group. For drugs to be in the same interchangeable group, they must contain an equal amount of the same substance (same ATC code) with the same strength, have the same formulation and the same package size +/- 20% (Statens legemiddelverk, 2021C). Drugs that do not require prescription and drugs without marketing authorization are not regulated with maximum prices (Statens legemiddelverk, 2018A). SLV first sets the maximum purchase price that the wholesalers can charge the pharmacies (maximum AIP). This is usually done through international reference pricing where the AIP is set equal to the average of the three lowest market prices of the drug in the available of in nine comparable countries. The nine countries are: Sweden, Finland, Denmark, Germany, Great Britain, The Netherlands, Austria, Belgium and Ireland (Apotekforeningen, 2017).

For SLV to determine the maximum sales price for a drug (maximum AUP), a percentage markup, a fixed sum per package, VAT and potentially additional markups are added to the maximum AIP. The maximum prices are revised by SLV regularly and published publicly on SLV's webpage. SLV revises the maximum price of the most common substances annually to ensure that the prices reflect the price development in Europe and the current exchange rates (Apotekforeningen, 2017). The producers may also request revisions of a given drug by writing an application where they aim to justify a new maximum price (Statens legemiddelverk, 2019).

When a drug gets inter-brand competition and SLV considers the drugs to be interchangeable, a step-price system is usually introduced. The step-price system shall ensure that the price of previously patented drugs with a high price is reduced stepwise when generics are introduced. The step price is introduced when the original preparation has stable competition from at least one generic drug in Norway. The step price is set in three steps similar to the ones for maximum prices. First, a step-price AIP is set as a percentage of the maximum AIP when the substance receives competition from generic alternatives. Then, a markup for the pharmacies and VAT is added, which gives the step-price AUP (Apotekforeningen, 2017). The AIP is cut

in two to three steps with a certain percentage each time, based on the size of the revenues from the pharmaceutical (Statens legemiddelverk, 2018B).

Even though the step price is the cap for social security reimbursement, a drug may have a maximum price that exceeds the step price. If drugs are sold at a price higher than the step price, it is usually because either the patient or the doctor reserves the patient against interchange. The pharmacies are obligated to provide at least one drug at the step price within each interchangeable group. For these drugs, the pharmacies shall give the customer the option to substitute the prescribed drug for a drug offered at step price. Social security and patients in Norway are estimated to save about two billion NOK annually due this system (Statens legemiddelverk, 2018B).

Several characteristics distinguish pharmaceutical industry from markets with perfect competition and prevent market mechanisms from functioning according to economic theory. The fact that pharmaceuticals are necessity goods with low price elasticity, and that the consumer, payer and decision maker are separated roles with different incentives, induce strong regulations such as the maximum price regulations in Norway. Patent regulation is essential due to the high R&D intensity, but also constitutes a significant barrier to entry, together with high switching costs, and irreversible investments in the case of therapeutic competition. Therefore, there is reason to believe that behavior in pharmaceutical markets is significantly different from what economic theory predicts.

5. Data

The three datasets that will be used in the analysis have been provided by Farmalogg. Farmalogg is responsible for operating the common article number register that is established by the Norwegian Pharmacy Association and the three largest pharmaceutical wholesalers in Norway (Farmalogg, 2014). The first dataset consists of historical maximum AIPs, maximum AUPs and step prices from January 2010 to December 2020, which are updated every 15 days. The second consists of monthly sales data over the same period, while the last dataset includes technical information about the drugs. A drug is included in the data when at least one of the drugs with the same ATC code has had an increase in their maximum AIP of more than 50%. The total number of pharmaceuticals in the dataset is 2,857.

To allow for merging of the datasets, the price data and sales data must have the same granularity. Therefore, the price data's granularity is reduced to be monthly, with a month's prices defined as the valid prices as of the first day of the month. Further, there are some months in 2020 where a product has multiple sales rows. These are merged into a single row as they occur when data is stored across multiple data warehouses. When merging the datasets, months where either only price or sales data is available were excluded. If only the price data is available, there were no sales in the period and the data is therefore excluded. If only the sales data is available, manual inspection shows that this is associated with returns and the data is therefore excluded. Finally, all months where there is registered less than one package sold are excluded, as they are likely to be either errors or returns. With these criteria, the final dataset consists of 152,852 monthly observations, reduced from 158,430 rows of monthly sales data and 407,373 rows of biweekly price data.

The final transformation that was done in the dataset with technical information about the pharmaceuticals. For the variables "Producer", "Pharmaceutical form" and "Strength", it is ensured that the data is consistent, e.g., GlaxoSmithKline and GlaxoSmithKline AS are ensured to both be GlaxoSmithKline, and 1g and 1000mg are both registered as 1g.

5.1 Variable generation

Several variables have been generated from the dataset to test our hypotheses. For the calculation of market-based variables, a market is defined as drugs with the same ATC code,

pharmaceutical form and strength. Unlike the definition of interchangeable groups, this definition does not account for variation in package sizes, as it may create overlapping markets.

Below is a table defining the variables that have been added.

Variable name	Definition
Actual AUP	Revenue including VAT divided by number of packages sold
% change in maximum AIP	Percentage change in maximum AIP compared to the previous period with sales data
Months away from price increase	Number of months until the month of the price increase
# of players	Number of unique producers in a market
DDD market share[1]	DDDs sold by the producer divided by DDDs sold in the market
Herfindahl-Hirschman Index (HHI)	Sum of the squared market shares in a given market

Table 1: Variables generated

Two dummy variables were also generated in order to sort the data by different criteria. These are defined below.

[1] DDD stands for Defined Daily Dose and is used as a cross-pharmaceutical measurement of volume

Dummy variable		Definition
Period with price increase	1	Month with % change in maximum AIP > 50%
	0	Month with % change in maximum AIP < 50%
Constant monopolies leading up to the price increase	1	Only one player in the market during all periods leading up to the increase
	0	At least one period with competition leading up to the increase

Table 2: Dummy variables generated

Additionally, indexes for the number of packages sold, DDD market share, actual AUP and HHI have been added to allow comparison of the development in these variables for the pharmaceuticals leading up to and after the price increase. The index values are calculated by the following formula:

$$Index = \frac{Value\ current\ month}{Index\ base} \cdot 100$$

The index base is the average of the three months one year before the price increase. If data is not available for this period, data from the first available months after this is used. The indexes can be interpreted as the percentage change in the variable compared to the index base level.

Finally, dummies have been added to indicate whether the drug had an increase in the actual price, was subject to falling demand leading up to the increase or experienced reduced competition leading up to the increase. An increase in the actual price is defined as having at least one period after the increase where the actual AUP was higher than the previous maximum AUP. Falling demand is defined as an average decrease in the number of packages sold of at least 10% during the three final months leading up to the price increase compared to the index base. Falling competition is defined as a reduction in the mode of competitors from the first to the second half of the last twelve months before the increase.

5.2 Descriptive statistics

The dataset includes 449 cases of pharmaceuticals increasing their maximum AIP by at least 50%. However, not all these cases share the same characteristics. In some cases, the actual price is never increased and some of the pharmaceuticals have constant monopolies. Finally, some of the cases have falling demand and/or falling competition. These characteristics are shown in the table below.

Cases with an increase in maximum AIP of >50%: 449
Cases with an increase in actual AUP: 390
Cases without constant monopoly: 189
Cases with falling demand: 53
Cases with falling competition: 13

Table 3: Count of cases

To better understand the development in key variables leading up to a price increase, descriptive statistics for the pharmaceuticals with an actual price increase are presented. The statistics are presented as of the first full month with an increased maximum AIP. The number of observations for HHI and market shares are lower, as some drugs do not have a corresponding DDD, which is used to calculate these measures. In the table below, “Index” is abbreviated to “Idx.”, and “Players” shows the total number of players in the defined market.

Descriptive statistics: Month of increase in maximum AIP

Statistic	N	Mean	St. Dev.	Min	25th pctl	Median	75th pctl	Max
Idx. Packages	390	431.9	3,777.8	0.02	67.3	95.5	118.2	66,040.0
Idx. Market share	333	327.7	3,914.2	0.03	100.0	100.0	100.0	71,436.6
Idx. Actual AUP	390	174.0	126.5	18.6	130.6	147.0	180.4	1,626.7
Idx. HHI	333	103.1	12.9	56.3	100.0	100.0	100.0	189.2
True HHI	333	8,863.5	2,041.7	2,995.4	8,122.5	10,000.0	10,000.0	10,000.0
Players	390	1.6	1.1	1	1	1	2	5

Table 4: Descriptive statistics of all cases with actual AUP increase

The data includes some extreme outliers which we observe by comparing the mean to the median, and the minimum and maximum values. This should be accounted for when performing trend analyses and potentially in regressions to avoid bias driven by extreme observations.

"Indexed packages" is centered around the 95-index mark, which shows that the majority of the drugs experience a slight drop in demand right after the price increase. The median drop in demand is 4.5%. Most of the pharmaceuticals keep their market share, which is reflected through the median of 100 and the 25^{th} and 75^{th} percentile in the indexed market share. This is expected, as the median number of players is also 1, representing monopolies. However, we see from the minimum and maximum values that there are some pharmaceuticals with large relative movements in market shares.

The median increase in actual AUP is 47%. When taking the quartiles into consideration, we see that in most cases, the price for consumers is increased by 30-80%. We also note that the minimum value, representing a decrease in actual AUP of more than 80%, is still considered an actual price increase, because the actual price increase has not yet happened during the first full month with new maximum prices.

Several of the markets are monopolies, which affects both the indexed and actual HHI. It is worth mentioning that the variation within the indexed HHI is less extreme than the other indexes, which indicates that HHI is a quite stable measure. All the markets are rather concentrated, and we observe that even the minimum value of 2,995 for the true HHI is categorized as a highly concentrated market.

Due to the high share of monopolies in the previous table, which we suspect includes some patented pharmaceuticals, we present descriptive statistics excluding constant monopolies in the table below.

Descriptive statistics: Month of increase in maximum AIP

Statistic	N	Mean	St. Dev.	Min	25th pctl	Median	75th pctl	Max
Idx. Packages	189	507.9	4,806.0	0.02	50.0	97.0	124.4	66,040.0
Idx. Market share	163	565.1	5,593.5	0.03	88.9	100.0	105.9	71,436.6
Idx. Actual AUP	189	158.2	70.6	18.6	125.9	145.0	171.9	780.9
Idx. HHI	163	106.2	17.9	56.3	100.0	100.0	111.2	189.2
True HHI	163	7,678.1	2,402.8	2,995.4	5,465.8	8,119.1	10,000.0	10,000.0
Players	189	2.3	1.3	1	1	2	3	5

Table 5: Descriptive statistics of all cases with actual AUP increase and no constant monopolies

Even after excluding the cases with constant monopolies, at least 25% of the cases have a monopoly position at the time of the price increase. For the indexed variables, the descriptive statistics are generally similar to the results we saw when including the constant monopolies above.

We also find it worthwhile to depict to what extent the pharmaceutical companies use the whole interval provided by their maximum price. It seems unintuitive that companies would apply for increased maximum prices, get approval and not price their products accordingly. Below is a histogram displaying the distribution of cases across their actual AUP divided by maximum AUP in the first full month with new maximum prices.

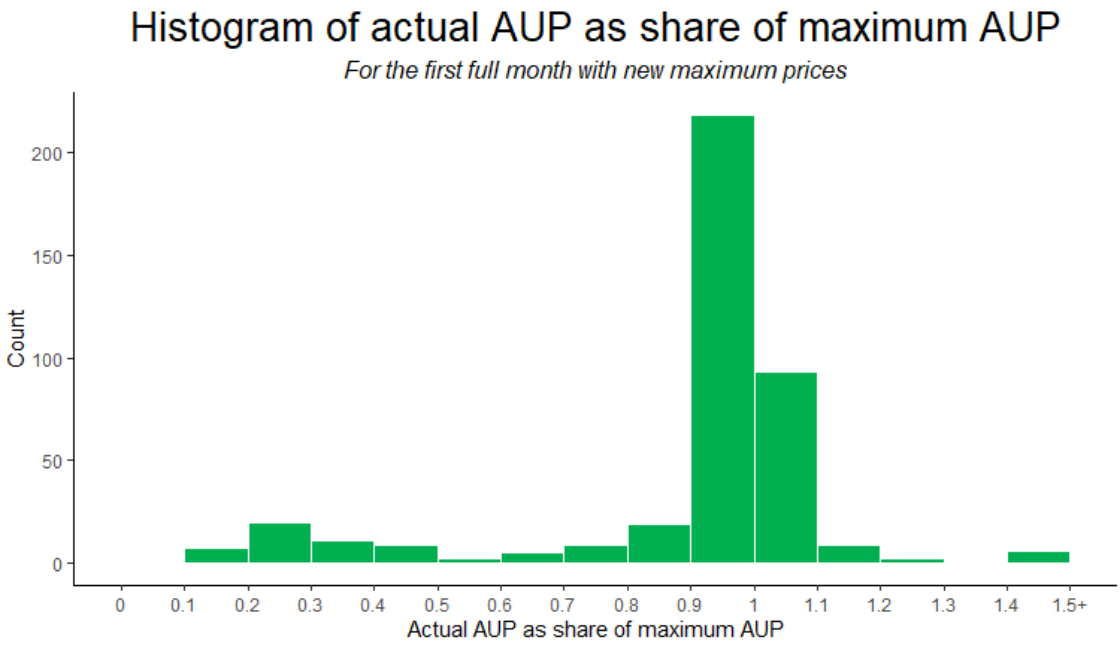

Figure 10: Histogram showing actual AUP as share of maximum AUP

The histogram shows that most drugs are centered around 1, implying that actual AUP is close to maximum AUP. However, some producers price their products significantly below their new price cap. It is unclear why this would be chosen as a strategy, but it is possible that there was no application process in these cases and that they were rather initiated by SLV in relation to SLV's annual price revisions. In this case, producers may not always be interested in an increased maximum price, as this could reduce the sales volume. There are also some drugs with actual prices above their maximum prices. This is due to the revenue including additional services, e.g., injecting vaccines or fees for repackaging. It is natural to expect such extra fees to be rather stable, as they are normally required for usage of the drug. Manual inspection has revealed that all drugs with a ratio above 2.0 are liquids for injection or infusion, which are typically used at hospitals and require significant additional service.

6. Methodology

In this section, we will present the methodology applied to analyze the dataset. The results can then be interpreted and give a better understanding of potential drivers of excessive pricing in the Norwegian pharmaceutical industry. We begin by explaining how logistic regression can be applied to estimate the probability of a price increase. Thereafter, we present a difference-in-differences approach to estimate the increase in pharmaceutical expenses caused by increased prices.

6.1 The Logistic Regression Model

Logistic regression is a suitable approach to estimate the probability that the maximum price for a given product is increased in a given time period. The approach is well suited for binary dependent variables where we are interested in the probability of one of two outcomes rather than the numerical values in the outcomes, which are arbitrary (Menard, 1995, p. 9).

The logistic regression model estimates values between 0 and 1, as negative probabilities and probabilities above 1 do not make sense (Menard, 1995, pp. 7-13). This binary dependent variable differentiates logistic regressions from ordinary least square (OLS). The potential outcomes of the dependent variable can be defined as follows:

$$Y_{i,t} = \begin{cases} 1 \text{ if the maximum price is increased} \\ 0 \text{ if the maximum price is not increased} \end{cases}$$

For product i at time t.

Since one of the two outcomes must occur, we know that $P(Y_{i,t} = 0) = 1 - P(Y_{i,t} = 1)$. Logistic models avoid predicting values below 0 or above 1 by replacing the probability with the odds. The odds that $Y_{i,t} = 1$ is defined as the ratio of the probability that $Y_{i,t} = 1$ to the probability that $Y_{i,t} \neq 1$:

$$Odds(Y_{i,t} = 1) = \frac{P(Y_{i,t} = 1)}{1 - P(Y_{i,t} = 1)}$$

The odds have no maximum value but is still restricted to 0. In order to lessen both restrictions, the natural logarithm of the odds is applied. This is called the logit of $Y_{i,t}$ and can vary from negative to positive infinity while ensuring a probability between 0 and 1. The equation for the relationship between the dependent variable $Y_{i,t}$ and our independent variables is written as:

$$logit(Y_{i,t}) = \alpha + \beta_1 X_1 + \beta_2 X_2 + \cdots + \beta_k X_k$$

Where, in a linear regression function, the parameter α represents the intercept, i.e., the value of $Y_{i,t}$ when X is zero, and β are parameters that represent the change in $Y_{i,t}$ associated with a one-unit increase in X (Menard, 1995, p. 1). The expression above can be converted back to the odds through exponentiation if we calculate $Odds(Y_{i,t} = 1) = e^{logit(Y_{i,t})}$. This gives us the following equation:

$$Odds(Y_{i,t} = 1) = e^{\ln[Odds(Y=1)]} = e^{\alpha+\beta_1 X_1+\beta_2 X_2+\ldots+\beta_k X_k}$$

A one-unit change in X then multiplies the odds by e^{β}. We can apply this to convert the odds back to the probability that $Y_{i,t} = 1$, since we know that $P(Y_{i,t} = 1) = \frac{Odds(Y_{i,t}=1)}{1+Odds(Y_{i,t}=1)}$. Therefore, the probability of $Y_{i,t} = 1$ is given by:

$$P(Y_{i,t} = 1) = \frac{e^{\alpha+\beta_1 X_1+\beta_2 X_2+\ldots+\beta_k X_k}}{1 + e^{\alpha+\beta_1 X_1+\beta_2 X_2+\ldots+\beta_k X_k}}$$

The logistic regression model applies maximum likelihood techniques that search for and identify the best set of parameters to maximize the log-likelihood function. This is done through an iterative process of estimation, testing, revising and re-estimation. The process continues to improve the solution until it converges, i.e., until the change in the likelihood function from one step in the process to another is negligible. The log-likelihood function indicates how likely it is to obtain the observed values of $Y_{i,t}$ given the values of our independent variables and parameters.

6.1.1 Evaluating the logistic regression model

The estimated logistic regression model can be evaluated across three dimensions. First, we study summary statistics to measure how well the overall model works and how much of the

variance is explained in the model. Second, tests are conducted to evaluate the statistical significance of the coefficients of the independent variables. Lastly, we study various regression diagnostics to examine whether the assumptions behind the model seem to hold.

Summary statistics

While sum of squares and the *F*-statistic are used to measure the goodness-of-fit for linear regression models, log-likelihood (LL) is used to select parameters and evaluate the overall model for logistic regression models (Menard, 1995, pp. 17-21). Statistical packages usually present it multiplied by -2 as -2LL, because it then has approximately a χ^2, chi-square, distribution. Since the LL is negative, the -2LL statistic is positive. A low value of -2LL indicates better prediction of the dependent variable. The intercept-only -2LL, denoted D_0, corresponds to the total sum of squares (SST) in linear regression analysis. The -2LL that includes the independent variables, hereby denoted D_M, is equal to the error sum of squares (SSE) in linear regression analysis. D_M indicates how poorly a model fits with all of the dependent variables in the equation. Finally, we can define the difference between them as the model chi-square; $G_M = D_0 - D_M$. This is analogous to the regression sum of squares (SSR) and the multivariate *F* test for linear regression. We treat G_M as a chi-square statistic to test the null hypothesis that $\beta_1 = \beta_2 = \ldots = \beta_k = 0$ for our logistic regression model. With a statistically significant G_M we can reject the null hypothesis and conclude that information about the independent variables give us better predictions of $P(Y_{i,t} = 1)$ than without the independent variables.

R^2 is called the coefficient of determination and indicates how much of the variance that is explained in the model (Menard, 1995, pp. 19-23). In linear regression analysis, R^2 is defined as $\frac{SSR}{SST}$. We can apply this and the versions of -2LL mentioned above to find the corresponding coefficient of determination for logistic regression analysis, where $R_L^2 = \frac{G_M}{D_0} = \frac{G_M}{G_M + D_M}$ (Hosmer & Lemeshow, 1989, p. 148). R_L^2 explains the "proportional reduction in χ^2" or the "proportional reduction in the absolute value of the log-likelihood measure" (Menard, 1995, p. 22). It indicates how much the badness-of-fit D_0 chi-square statistic is reduced when we include the independent variables. R_L^2 varies between 0, where $G_M = 0$ and $D_M = D_0$, and the independent variables do not reduce the badness-of-fit at all, and 1, where $G_M = -2LL$ and $D_M = 0$, and the model predicts the dependent variable perfectly. Alternatively, one may apply

the McFadden Pseudo R^2 (Hu, Shao, & Palta, 2006). This is defined as $R^2_{McF} = 1 - \frac{\ln(L_M)}{\ln(L_0)}$. L_M is here the likelihood for the model being estimated, while L_0 is the value of the likelihood function for a model with no predictors, corresponding to SSR. Like R^2_L, the R^2_{McF} indicates the proportional reduction in the error variance and varies between 0 and 1, where a higher R^2_{McF} indicates better predictive power.

Statistical significance testing of the coefficients

We apply the likelihood ratio test to evaluate the extent to which the contribution of an independent variable to the explanation of a dependent variable is statistically significant (Hill, Griffiths, & Lim, 2012, pp. 595-599). We calculate the model with and without the variable (Menard, 1995, pp. 38-39). The test statistic is given as G_M with the variable, minus G_M without the variable. The result can be called G_1 when we test X_1, G_2 for X_2 and G_k for X_k. It has a chi-square distribution, and the degrees of freedom (df) are given as the df with the variable minus the df without the variable.

Regression diagnostics

The last part of evaluating the logistic regression model consists of verifying whether the assumptions behind the model hold (Menard, 1995, pp. 58-79). If the assumptions are violated, there may be problems related to biased coefficients, inefficient estimates or invalid statistical inferences. Biased coefficients means that the coefficients systematically tend to be too high or too low, too far from or too close to zero compared to the real values. Inefficient estimates implies that the coefficients tend to have relatively large standard errors, which makes it more difficult to reject the null hypothesis. Invalid statistical inference occurs when the calculated statistical significance is inaccurate. Furthermore, extreme observations may cause problems if they influence the estimated parameters disproportionally. Such cases are called outliers if a variable has unusually high or low values or if two or more variables have an unusual combination. If they influence the coefficient estimates disproportionally, they are called influential cases.

Specification Error

The most important assumption is that the model is specified correctly (Menard, 1995, pp. 58-79). This implies that the functional form of the model must be correct, and that the model includes all relevant independent variables and does not contain any irrelevant independent variables. A model that is not specified correctly may lead to biased coefficients that are

systematically over- or underestimated. The logistic regression model may be incorrect in its functional form if $logit(Y)$ is equal to a nonlinear combination of the independent variable, or if the independent variables are not additive, but multiplicative or interactive. Usually, misspecification is not a problem if we apply logistic regression instead of another S-shaped function, but it is likely to be a problem if we apply a linear regression model on a binary dependent variable.

Collinearity

Collinearity problems occur when independent variables are correlated with each other (Menard, 1995, pp. 58-79). If an independent variable is a perfect linear combination of the other independent variables, we have perfect collinearity. Some correlation is usually expected and not a problem (Menard, 1995, pp. 58-79). However, one should be concerned about variables with a correlation above 0.8, and a correlation above 0.9 almost certainly gives coefficients that are not significant, even if the coefficients are large. Collinearity may also give unreasonably high coefficients. Collinearity between independent variables can easily be checked in a correlation matrix. The problem with high collinearity is that there is no good solution to it. Removing the variables may result in omitted variable bias, and the best approach may be to be aware of it and careful with drawing conclusions about individual predictors and focus on the combined effects of the variables.

Analysis of Residuals

In logistic regression, analysis of residuals is mainly used to identify cases where the model works poorly or cases that exert more than their share of influence on the estimated parameters in the model (Menard, 1995, pp. 58-79). The residual reflects the difference between the observed and predicted probability. It is given as $e_j = P(Y_j = 1) - \hat{P}(Y_j = 1)$, where $\hat{P}(Y_j = 1)$ is the estimated probability that $Y_j = 1$ for a given case j in the model. We standardize residuals in logistic regression by adjusting them for their standard errors, since the error variance is a function of the conditional mean. The Pearson residual, also known as the standardized or chi residual, is the difference between the observed and estimated probabilities divided by the binomial standard deviation of the estimated probability. It is written as:

$$r_j = z_j = \chi_j = \frac{P(Y_j = 1) - \hat{P}(Y_j = 1)}{\sqrt{\hat{P}(Y_j = 1)[1 - \hat{P}(Y_j = 1)]}}$$

For large samples, the standardized residual z_j should be normally distributed with a mean of 0 and a standard deviation of 0. A model that fits observation j poorly, will result in large absolute values of z_j. Alternatively, one may study the logit residual e_j which may be expressed as:

$$l_j = \frac{P(Y_j = 1) - \hat{P}(Y_j = 1)}{\hat{P}(Y_j = 1)[1 - \hat{P}(Y_j = 1)]}$$

Nonnormality of Residuals

In logistic regression, the residuals are assumed to have a binomial distribution, which approaches a normal distribution for large samples (Menard, 1995, pp. 58-79). Unlike linear regression, however, where a nonnormal distribution in small samples causes problems regarding the statistical inference, this is not necessarily a problem in logistic regression. The standardized or deviance residuals can also be used to identify cases for which the model fits poorly and cases that influence the estimates disproportionately much.

Detecting and Dealing With Influential Cases

We can identify cases with a large influence on the parameters through high values of the leverage statistic h_i (Menard, 1995, pp. 58-79). In linear regression, the leverage statistic is given as $\hat{Y}_j = h_{1j}Y_1 + h_{2j}Y_2 + \ldots + h_{nj}Y_n = \sum_i h_{ij}Y_i$. The expression gives the predicted value of Y for a case j as a function of the observed values of Y for case j and all other cases. Each coefficient h_{ij} explains the influence that the observed variable Y_i has on the predicted value $\hat{Y}_j$.

The leverage statistic works similarly in logistic regression (Menard, 1995, pp. 58-79). It is equal to 0 if there is no influence, and equal to 1 if it fully determines the model parameters. With k independent variables or df associated with G_M, the h_i values sum up to $k + 1$ and the mean value of h_i, $\frac{\sum h_i}{N}$, is equal to $\frac{k+1}{N}$. Cases with h_i values greater than $\frac{k+1}{N}$ can be considered influential cases.

Another option is to examine the change in the Pearson χ^2 statistic or in the D_M that follows from removing the case (Menard, 1995, pp. 58-79). In the Pearson χ^2, the change from removing case j is given as $\Delta\chi_j^2 = \frac{z_j^2}{1-h_j}$. In the D_M, the change is given as $\Delta D_j = d_j^2 - \frac{z_j^2 h_j}{1-h_j} =$

$d_j^2 - h_j(\Delta\chi_j^2)$, where d_j is the deviance residual. ΔD_j and $\Delta\chi_j^2$ have a chi-square distribution. Their square roots are approximately normally distributed, and if $\sqrt{\Delta D_j}$ or $\sqrt{\Delta\chi_j^2}$ is less than -2 or greater than 2, it is an indication of poor fit and should be checked more closely. The quantity $\frac{x_j^2 h_j}{1-h_j}$ is itself an indicator of the change that follows from deleting a variable, found as Cook's distance.

Outliers and Residual Plots

We mentioned that cases with a $\sqrt{\Delta D_j}$ less than -2 or greater than 2 should be examined further (Menard, 1995, pp. 58-79). Graphical approaches such as detecting outliers from a plot is also useful and may be easier as it is more visual. When the previously mentioned measures indicate a poor fit, we can look at how G_M and R_L^2 would be impacted if we deleted the outliers. However, outliers should not necessarily be deleted only because they fit poorly, and the model would be improved without them. Instead, the observations should be checked, and if the findings seem plausible, they should probably be retained. Nonetheless, it could be useful to include new variables in the model that may explain why the rare outliers exist.

6.1.2 Adjusting for Fixed Effects

In panel data, like our dataset, we have data about several products over several time periods (Hopland, 2018). The variables can be divided into three categories; variables that differ between products but are constant over time, variables that change with time but are equal for the products, and variables that differ both between products and over time. Likewise, the error term can be decomposed into the same three categories. As we are not interested in variation that only varies between products but is constant over time, such as regulations and how common the diseases are, we want to eliminate this bias. This can be done in statistical programs by using a Fixed Effects estimator, which removes the individual specific error-term component.

6.2 Difference-in-Differences

We will now study how a difference-in-differences (DD) approach can be used to estimate the financing expenditures caused by increased prices on pharmaceuticals. This can be done by studying the change in product revenues before and after a price increase. Since the revenues

including VAT reflect the money spent on a drug, higher revenues would mean higher expenditures for consumers and taxpayers.

When comparing the revenues for a drug before and after the price increase, the explicit change does not necessarily reflect the causal effect of the price increase (Hill, Griffiths, & Lim, 2012, pp. 282-286). One cannot simply compare the revenues before and after the price increase since there may be underlying time trends that would have increased the revenues regardless of the price increase. Likewise, one cannot just compare drugs with a price increase to drugs without a price increase either, since there probably existed differences between the two groups before the price increase as well. The DD approach is a common tool to find the causal effect of a treatment, in this case a price increase, by adjusting for time trends and individual-specific trends. The approach is especially common when analyzing natural experiments, called quasi-experiments.

We use data from before and after the treatment to compare the differences between the treatment group, drugs that experience a price increase, and the control group, drugs that do not experience a price increase, before and after treatment (Hill, Griffiths, & Lim, 2012, pp. 282-286). This allows us to adjust for underlying trends and hence find the causal effect. This is illustrated graphically in the figure below.

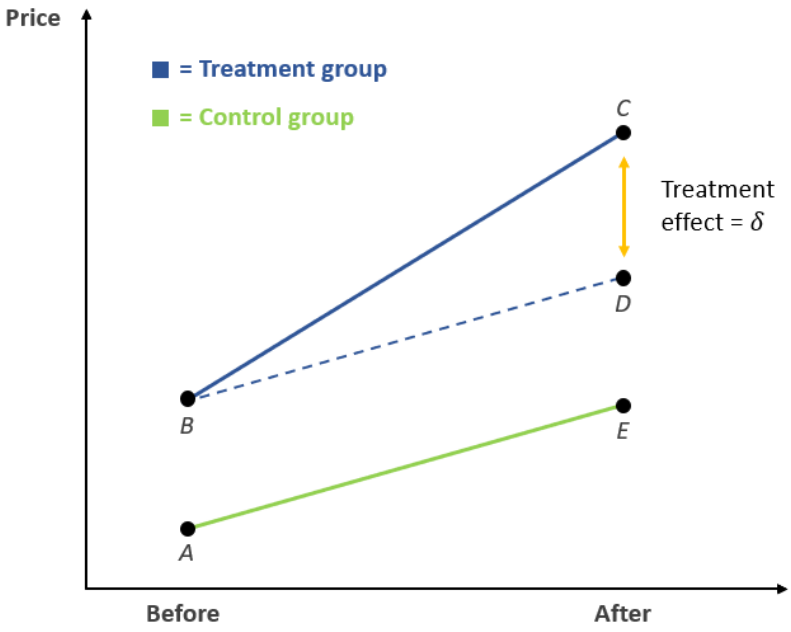

Figure 11: Difference-in-Differences visualization

The general increase we see from B to D and from A to E can be interpreted as an underlying time trend that does not follow from the treatment, such as inflation. The price difference between D and E was already present before the treatment, and must therefore not be included when calculating the causal effect of a treatment by looking at the difference between the control group and the treatment group. The causal effect must be considered as the additional increase we observe in the treatment group compared to the control group; the distance between C and D.

We apply this to find the DD estimator which represents the causal effect:

$$\hat{\delta} = \left(\hat{C} - \hat{E}\right) - \left(\hat{B} - \hat{A}\right)$$

This can be rewritten as:

$$\hat{\delta} = \left(\bar{y}_{Treatment,After} - \bar{y}_{Control,After}\right) - \left(\bar{y}_{Treatment,Before} - \bar{y}_{Control,Before}\right)$$

"Treatment" is a binary dummy variable defined as follows:

$$Treatment = \begin{cases} 1 \text{ if the product experiences a price increase} \\ 0 \text{ if the product does not experience a price increase} \end{cases}$$

"After" is a binary dummy variable defined like this:

$$After = \begin{cases} 1 \text{ if we study a period after the price increase} \\ 0 \text{ if we study a period before the price increase} \end{cases}$$

The estimator $\hat{\delta}$ can be found as the coefficient to the interaction term between "Treatment" and "After" in the DD regression function, which is given by:

$$y_{i,t} = \beta_1 + \beta_2 \cdot Treatment_i + \beta_3 \cdot After_t + \delta(Treatment_i \cdot After_t) + e_{i,t}$$

If product i is in the treatment group, $Treatment_i = 1$ and the coefficient β_2 tells us how much this increases the dependent variable $y_{i,t}$ which represents the revenues. If the period t we study is after the price increase, $After_t = 1$, and β_3 tells us how much this increases the revenues. If both the dummy variables are equal to 1, we study a product after its price has increased, and the coefficient δ tells us how much the revenues change because of this. The

error term $e_{i,t}$ captures the rest of the variation in the model that is not explained by the independent variables.

The regression function can be explained in the following way:

$E(y_{i,t})$	Treatment	After	Category	Point in figure
$\boldsymbol{\beta_1}$	0	0	Control, Before	A
$\boldsymbol{\beta_1 + \beta_2}$	1	0	Treatment, Before	B
$\boldsymbol{\beta_1 + \beta_3}$	0	1	Control, After	E
$\boldsymbol{\beta_1 + \beta_2 + \beta_3 + \delta}$	1	1	Treatment, After	C

Table 6: Difference-in-Differences regression function

This can be summarized in the table below:

Group/period	Before	After	After – Before
Control	β_1	$\beta_1 + \beta_3$	β_3
Treatment	$\beta_1 + \beta_2$	$\beta_1 + \beta_2 + \beta_3 + \delta$	$\beta_3 + \delta$
Treatment - Control	β_2	$\beta_2 + \delta$	δ

Table 7: Difference-in-Differences interpretation of coefficients

A challenge with DD can be to find suitable control groups which actually have the same underlying trend and will be affected equally by macro effects, so that all control variables are held constant (Hill, Griffiths, & Lim, 2012, pp. 282-286). One should therefore confirm that the groups have common trends in advance of the treatment, as illustrated in figure 11. This implies that even though the groups have different price levels, the change moves in the same direction and they move more or less similarly. If the groups do not have common trends, there is a concern that the results are driven by spurious correlations and that there is no real causality between the dependent and independent variable (Hopland & Ullmann, 2019). A placebo test can be conducted to check for parallel trends. This is done by adding a false treatment variable in the model to pretend that the treatment finds place before it actually does. If a significant effect is found for the false treatment variable, the concern for spurious correlations is enhanced.

With the theoretical framework and our methodology presented, analyses will be carried out to identify key drivers of excessive pricing of pharmaceuticals. Firstly, a trend analysis of key variables will be presented, followed by a logistic regression model. Then, an analysis will be performed to further explain the relationship between market power and excessive pricing, before case studies are presented to depict case-specific factors. Finally, a difference-in-differences model is used to estimate the increase in pharmaceutical expenses caused by increased prices.

7. Analysis

We will now apply the presented methodology to analyze various aspects of excessive pricing in our dataset. Based on our theoretical framework, we derived three hypotheses about drivers leading to excessive pricing in the Norwegian pharmaceutical market; shortages, falling demand and market power. These will now be tested based on the variables presented in the data section.

This chapter has five sections. First, trend analyses will be conducted to study how different variables develop before and after the price increase. A logistic regression model is then applied to examine which drivers seem to be statistically significant for excessive pricing. Further analyses are performed to study whether market power also seems to influence the size of a price increase, not just the probability of its occurrence. Five case studies are then conducted to better understand the process behind some of the larger price increases, before a difference-in-differences approach is used to estimate the accumulated increase in pharmaceutical expenditures caused by price increases.

7.1 Trend analysis

As a first step, it is useful to examine the development in the number of packages sold, DDD market share, HHI and actual AUP in both the year before and after the price increase. This will allow us to better understand the typical development for key variables in relation to a price increase. The main source for this analysis will be graphs displaying mean indexed variables. In order to reduce the skewness from outliers, a trim of 10% has been applied to all means. The trim removes the top and bottom 10% outliers. In the graphs, the horizontal blue line marks index 100, i.e., no change in the variable, and the vertical line marks the first full month with the new maximum prices. The indexes should be interpreted as the specific month's value relative to the index base, e.g., an index of 120 represents that the value is 20% higher than the index base.

The graphs are split into cases with and without falling demand and competition leading up to the price increase, as we expect different trends in these group. Further, the graphs exclude drugs defined as having constant monopoly in order to avoid drugs that are under patent and prevent these from driving the trends in market share and HHI.

7.1.1 Packages sold

We argue that the number of packages sold is a good proxy for demand, as it is present for all the drugs in the dataset and does not contain endogenous price effects, like other variables such as revenues would.

One reason for an increased price could be a reduction in demand, since the lower sales volume would increase the fixed costs per package and reduce the profitability if the price is unchanged. However, we note that only 53 out of 189 cases are defined as having a falling demand by our criteria. In the graph below, the data is split into the cases with and without falling demand.

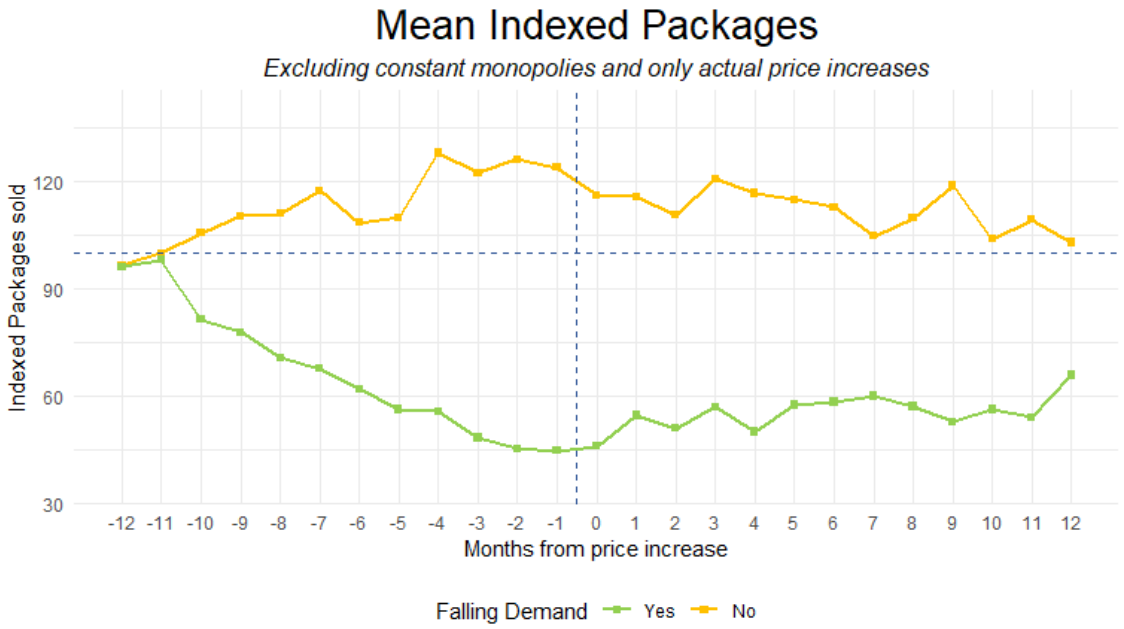

Figure 12: Mean indexed packages categorized by falling demand

The green graph shows us that when demand falls, the reduction is considerable with an average of around 55% at the time of the price increase. Particularly notable is the increase in demand after the price has been raised. This is contrary to what would be predicted by economic theory, where a price increase is expected to cause demand to fall further. The fact that demand increases after the price increase may indicate that the falling volume is caused by shortages, rather than falling demand. In such a case it is natural that the volume recovers after a period of time, when the shortage has passed.

When calculating the average difference between indexed packages for the last month before the increase and the average index in the twelve months after the increase for the cases with

falling demand, we find an average increase equal to 20% of the index base. When performing a Wilcoxon paired test, the null hypothesis of equal populations is discarded at 0.1% significance level. This test is used as the data does not follow a normal distribution.

For the group without falling demand, the number of packages sold falls immediately when the price increases. The reduction is roughly 10-15% and may be considered a small reduction given that AIP has been increased by at least 50%. This supports the hypothesis that demand for pharmaceuticals is relatively inelastic to price. When we look at the period as a whole, the trend seems rather stable, and it seems inconclusive whether the demand actually drops after the price is increased or if these are just natural deviations. However, there is a statistically significant reduction in the sales volume when performing a Wilcoxon paired test at 0.1% significance level. The average reduction is equal to about 20% of the index base.

If we rather divide the data into the cases with and without falling competition, the pattern is similar for both groups, as shown in the graph below.

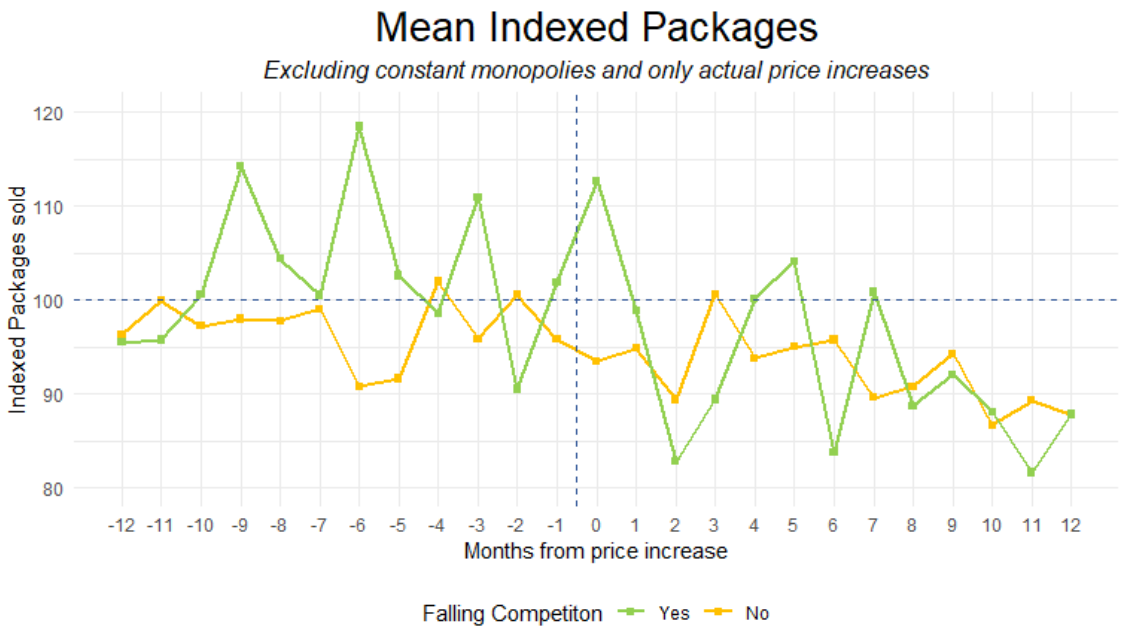

Figure 13: Mean indexed packages categorized by falling competition

We note that the number of cases with falling competition is merely 13 and that the graph therefore is based on a very limited number of datapoints. However, the graphs show that, although fluctuating, both groups have a rather stable demand before the increase which turns into a negative trend after the price increase. This negative trend is consistent with economic

theory. However, when the data is split in this way, neither of the groups have a statistically significant reduction, even at a 25% significance level.

Overall, the response to the price increase for the drugs without falling demand is consistent with what you would expect from economic theory. However, the fall in demand is not as large as one could expect when increasing the price by at least 50%. This indicates that demand is insensitive to price changes, which could be abused by firms with market power to hike their prices without experiencing a large reduction in volume. All else equal, a 50% increase in price combined with a 15% reduction in quantity, increases the profits. Still, unobserved variables such as costs must be considered if one were to conclude that profits have increased.

For the group with falling demand leading up to the price increase, it is unintuitive that they should experience increased demand after the price is increased. However, several hypotheses could explain this. There may have been a temporary shortage, which would allow the producer to return to previous volumes after the shortage has passed. This cannot be observed from the information in our dataset. There may also have been a reduction in the competition as a result of the falling demand, leaving the incumbent with market power and an ability to increase their price. However, this is not very likely, as we would then have expected to observe a similar pattern among the cases with falling competition.

7.1.2 DDD Market Share

The next variable to be studied is the DDD market share. Economic theory suggests that, assuming no similar price increase from all other players in the market and no market power, the market share will be reduced when the price is increased. Therefore, we would expect to observe a negative effect on the DDD market share following an increase, unless the producer has market power. If producers have market power, they may be able to increase their price without suffering a notable loss of market share.

In the graph below, the development in indexed DDD market share is depicted for pharmaceuticals with and without falling demand.

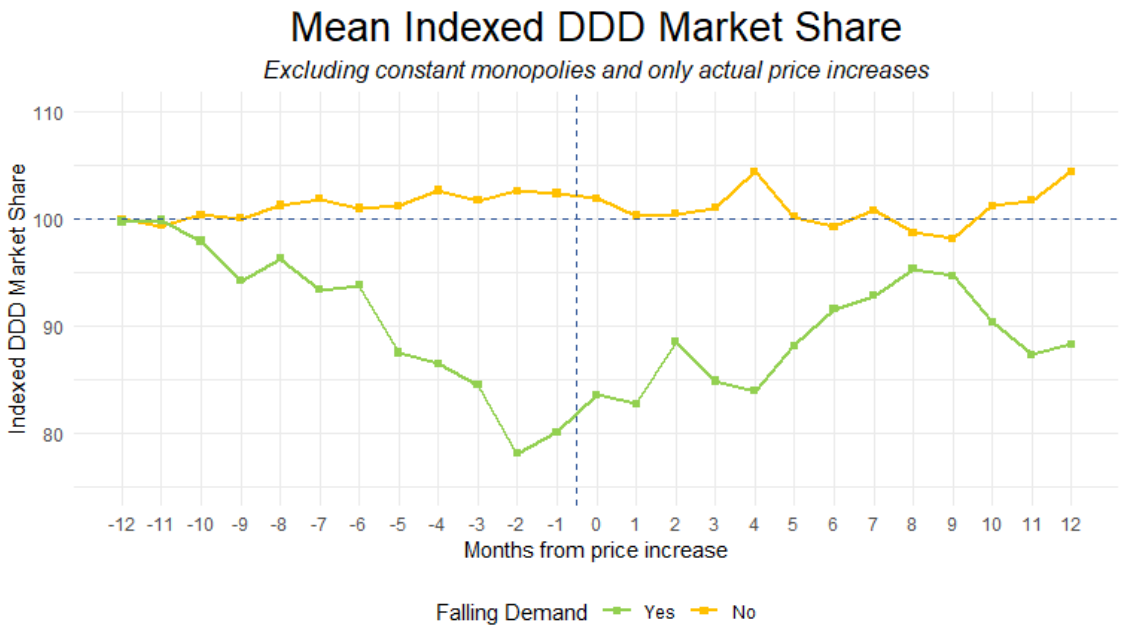

Figure 14: Mean indexed DDD market share categorized by falling demand

The first thing to note is that the group without falling demand has a very stable DDD market share throughout the whole period. The price increase seems to have minimal to no effect on the market shares, which could indicate market power. Alternatively, it could indicate that other players in the market have increased their prices similarly. What is more interesting, is that the cases with falling demand have a clear negative trend leading up to the increase, which reverts after the price is increased. The average pharmaceutical loses approximately one fifth of their market share and reverts to a total loss of a little more than one tenth by the end of this period. This may serve as further evidence that the demand drop could be caused by shortages. If the production returns to normal after a while, it would allow for increased volumes and increased market share. If input factor shortages are assumed to be global and hence affect all firms similarly, market shares would remain stable. This points towards a hypothesis that the potential shortages here are related to production capacity. However, input factor shortages could also affect products individually due to different suppliers and contracts. Another explanation for this development could be that players exit the market due to the falling demand, but if this was the general case, we would expect both the market share to surpass the 100-mark on the index and more cases with falling competition, which with our definition only accumulates to 13 cases. It is also worth mentioning that the trend shifts immediately after the last full month with the old price. When we perform a Wilcoxon paired test, we find

that the market share increases with a significance level of 1%, and an average index increase of 17.

In the graph below, the cases are split by whether the producers experience falling competition or not.

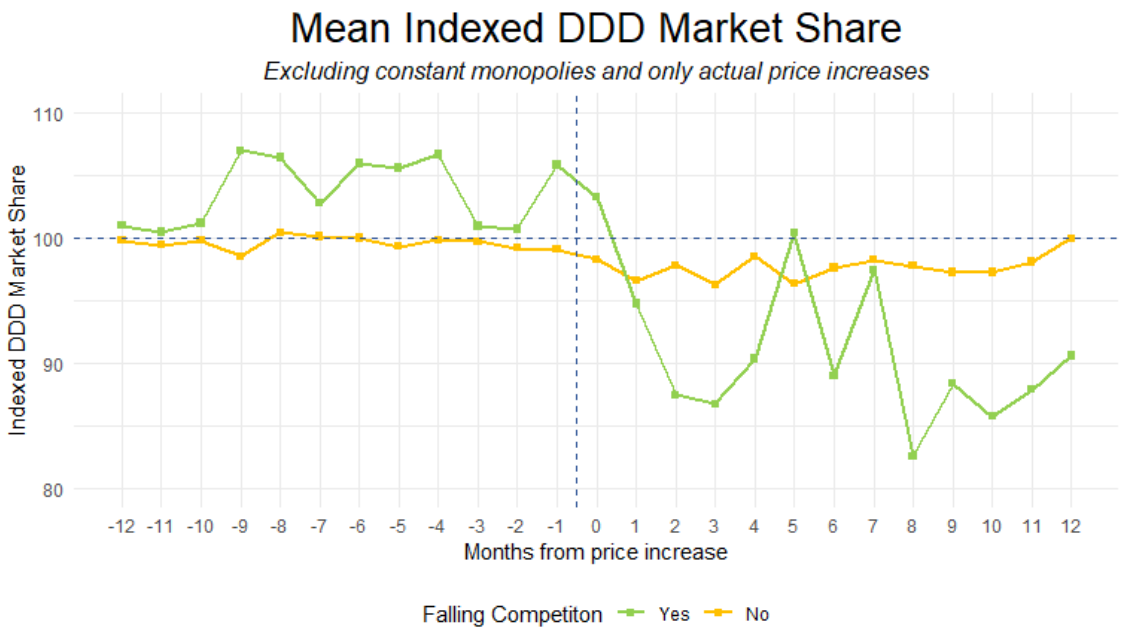

Figure 15: Mean indexed DDD market share categorized by falling competition

The reduced market share in cases with falling competition is quite surprising, as one would expect the market share to increase when the number of competitors in the markets falls. However, there may be strategic choices that lead the drugs in question to increase the price to take a premium position in the market. Alternatively, competitors that left the market may have had a small market share. It is also worthwhile to repeat that the number of cases with falling competition is very low, and we can therefore not conclude that the drop is statistically significant at a 10% level. The development in market share after the price increase for the group without falling competition, or rather lack thereof, is an indication that there may be abuse of market power.

7.1.3 Herfindahl-Hirschman Index

The Herfindahl-Hirschman Index indicates how concentrated a market is. When a market is highly concentrated, at least one of the players has market power. Therefore, we find it worthwhile to examine the development in HHI leading up to the price increase. If the trend

shows an increase in HHI, this may point towards the players gaining market power and that this may the reason for the price increase.

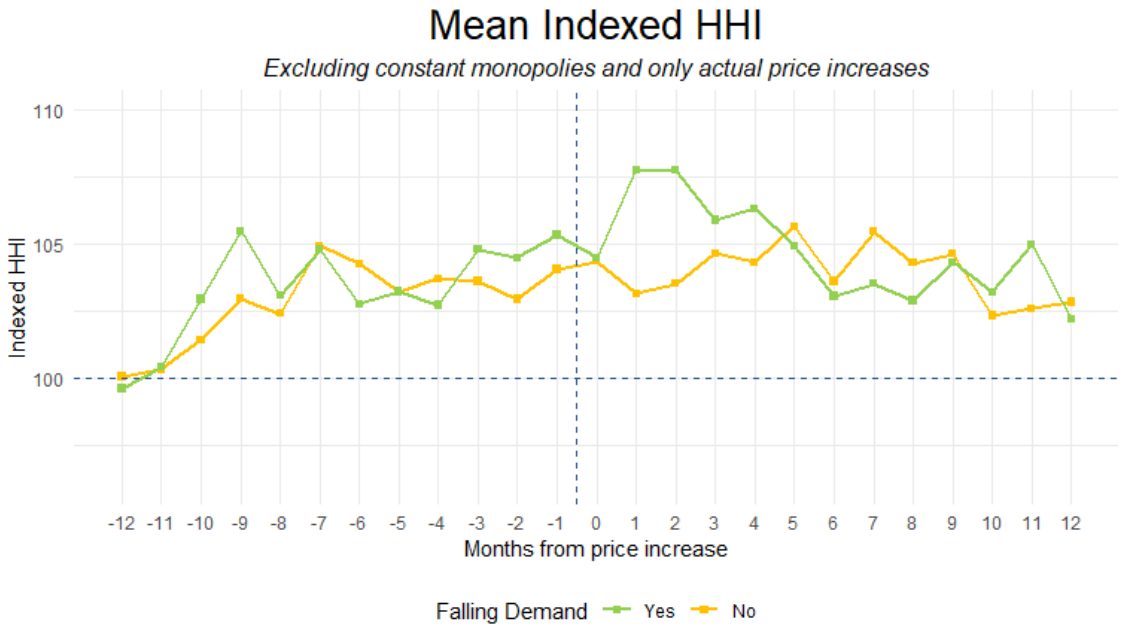

Figure 16: Mean indexed HHI categorized by falling demand

When we look at the graph for the drugs with and without falling demand, there is a clear positive trend in HHI leading up to the price increase. However, the increase is not very extreme, as the average HHI increases by 5% compared to the index base. While a 5% increase is not too drastic, it is worth noting from the descriptive statistics that the average HHI in the dataset is roughly 7,500. Therefore, the average increase in absolute terms of roughly 375 may be more notable. The average HHI stays quite stable after the increase. As depicted in the graph below, the trend is quite similar for the cases with falling competition.

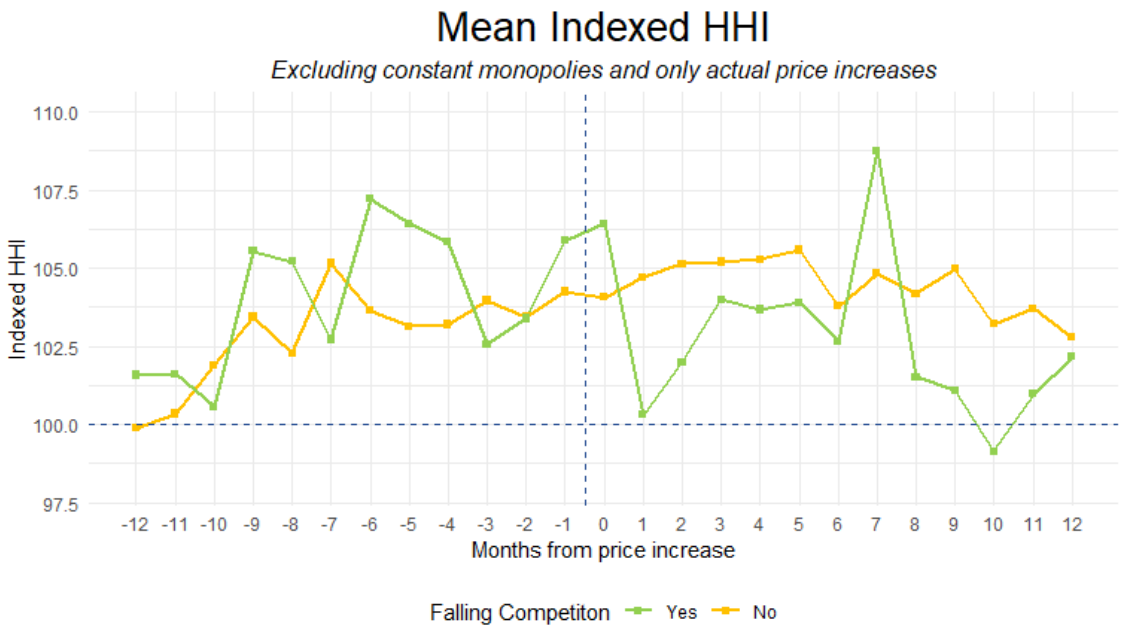

Figure 17: Mean indexed HHI categorized by falling competition

The development in HHI seems to be rather stable with a small increase before the price increase. What may be of greater interest, which will be analyzed later, is whether a high HHI value in absolute terms is a driver of excessive pricing. However, the trend analysis gives evidence that there may be limited opportunism related to the market concentration, i.e., although there is a relation between price increases and increased market concentration, we question whether the increase in HHI is large enough to be abused to achieve excessive pricing.

7.1.4 Actual AUP

As a final trend analysis, the development in actual AUP will be analyzed. The actual AUP shows which price the pharmaceuticals are sold for to consumers. If a firm reduces its price after obtaining an increased maximum AUP, it may indicate an unsuccessful high-price strategy where the firm had less market power than first believed, or that the need for an increased price was temporary, e.g., due to shortages. By depicting the development in actual AUP, we can also better understand the size of the price increases that the customers experience.

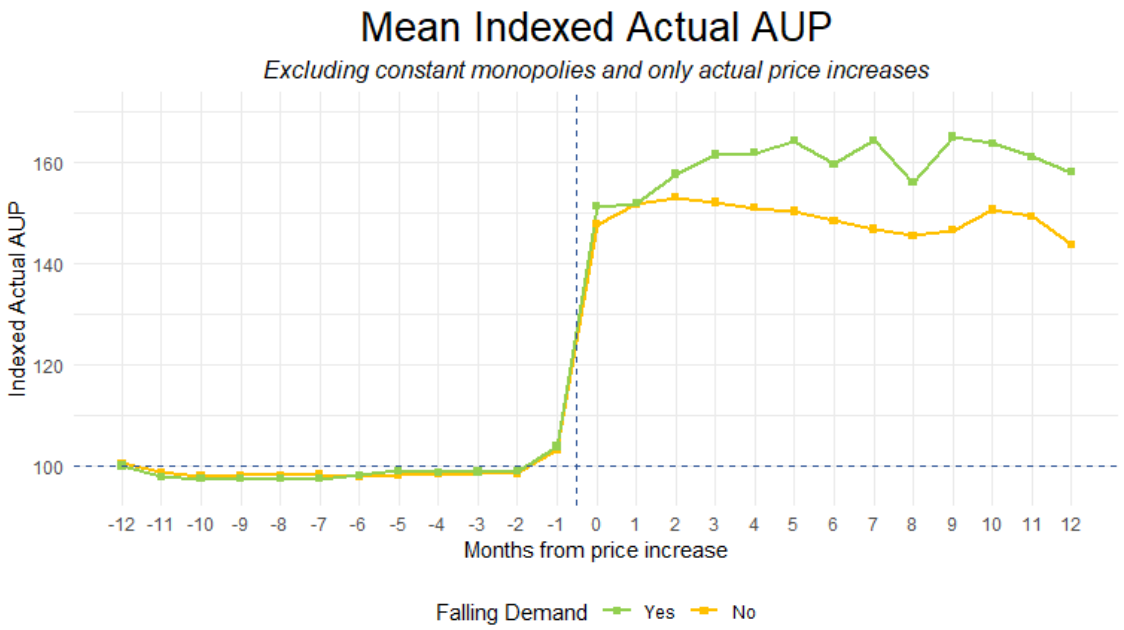

Figure 18: Mean indexed actual AUP categorized by falling demand

When we split the cases by whether demand is falling, we can observe that the average increase in actual AUP is higher for the cases with falling demand. Whereas the mean is an increase of roughly 50% for the cases without falling demand, it is roughly 60% for the cases with falling demand. Several arguments can be made for why the increase is higher when demand is falling. Firstly, with falling volumes, the fixed costs per unit increases and this may simply be sufficient for explaining the larger price hikes. Secondly, if the falling demand occurred because of shortages, there may have been costly adjustments to the production process that must be recovered, or raw material prices may have increased.

It is also worth mentioning that for both groups there seems to be a negative trend in the actual AUP during the final months in the graph. This may indicate that some of the producers are too aggressive in their pricing and must reduce the price to maintain their current sales volume. However, this did not seem to be the problem when we analyzed the sales volume for cases with falling demand. Hence, it may also be an indication of new entries due to high profitability. This would be consistent with economic theory and with the fact that the process of introducing a new generic drug in Norway is relatively long.

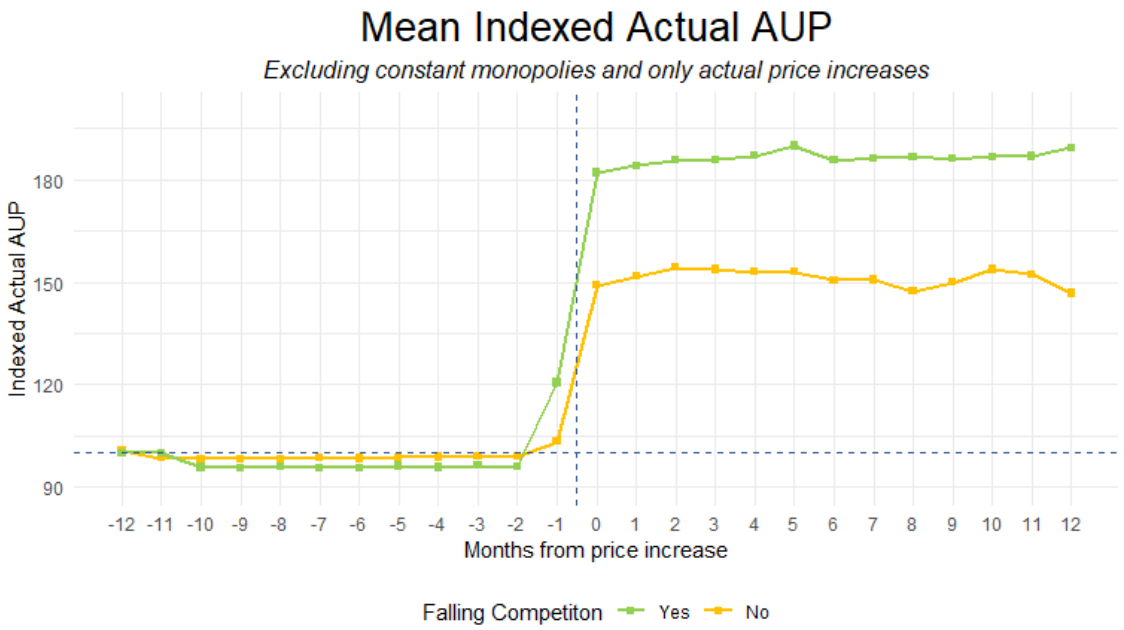

Figure 19: Mean indexed actual AUP categorized by falling competition

When the cases with falling competition are separated from the rest, we can see that they have a significantly higher average increase in price, reaching almost a 100% increase. A natural explanation for this would be that the producers are abusing the increased market power they have obtained after the number of competitors has been reduced. However, it is also possible that the competitors have left the market due to low profitability, which could make the large increase necessary to achieve sufficient profitability.

For the change in actual AUP, there are several unobserved variables making it difficult to conclude. First and foremost, we do not have access to the variable costs for the pharmaceuticals over time, which could be an explanatory variable for the size of the price increase. Similarly, we lack data about the fixed costs, which could help explain why the average increase is higher for the group with falling demand. However, there is little indication that firms reverse their price increases due to unsuccessful high-price strategies.

While the trend analysis does not give any clear answers to what the reasons for excessive pricing of pharmaceuticals are, it allows for some reflection around our hypotheses. Firstly, we have identified indications that market power is a driver of increased prices. This would be consistent with economic theory, which states that sufficient market power would be expected to lead to higher prices. Therefore, it is worthwhile to further test whether there seem to be indications of market power leading up to the price increase. Secondly, there are

indications that some increases may be driven by shortages. This is also a plausible explanation, at least in the short run, which is consistent both with economic theory and with findings in the US. Thirdly, there are clearly cases of falling demand, where the demand does not resurge to its previous levels, which may also warrant a price increase. The potential causes will now be analyzed further to examine whether they seem to be significant drivers of excessive pricing.

7.2 Logistic regression

To explore whether different variables have a statistically significant impact on the probability of a price increase, a logistic regression model will be applied. Robustness tests are then conducted to examine how robust the results are to changes in our assumptions.

7.2.1 The model

The logistic regression model shows the relationship between explanatory variables and a dependent binary variable. The results will reveal which variables have a statistically significant impact on the probability of increasing the maximum AIP by at least 50%. In addition to the drugs that do experience an increase in their maximum AIP, all other drugs with the same active substance are included for the same period. Further, fixed effects are added on an active substance level for each period. This is done to control for deviations within drugs with the same active substance, e.g., seasonal variation or if a new and better active substance has replaced the old one. As some active substances have several periods with increases, the time variable is also controlled for.

For all the drugs included in the regressions, an index base is made for packages, market share, HHI and competitors for all relevant time periods. To explore the changes in these variables leading up to the price increase, the average of the last three months before the price increase is divided by the index base and multiplied by 100 to make a trend index. For the variable “Change in competitors”, the change is defined as the difference in mode during the two periods. These trend indexes allow the model to reveal trends in the data that occur in the time period leading up to the price increase. Finally, a dummy is added which is equal to 1 if the drug’s maximum AIP is different from the highest maximum AIP within this interchangeable group with the same package size during the last month before an increase happens. This

variable is added as in such cases, the producer can simply ask for their maximum AIP to be increased as a higher maximum AIP has already been approved for this group of drugs.

This leaves us with cross-sectional data for which the results of the logit regression are shown in the table below. By using R's method for detecting influential cases, "influence.measure()", four influential observations were removed. Using the procedure laid out in the methodology chapter, we can reject the null hypothesis that all coefficients are equal to zero at a 0.1% significance level. It is also worth noting that we have corrected for asymptotic bias in the results through a post-estimation routine that applies the analytical bias correction derived by Fernández-Val (2009).

Variable	Coefficient	e^{β}	St. Dev.	P-value	Sign.
Change in packages	-0.0001	1.00006	0.0001	0.5332	
Change in competitors	-0.0222	0.53817	0.0095	0.0191	*
Change in market share	0.0003	1.00034	0.0002	0.0666	.
Change in HHI	-0.0153	0.98847	0.0092	0.0976	.
log2 (Market share)	0.0367	1.03508	0.0481	0.4463	
log2 (HHI)	2.0110	7.16106	0.4235	0.0000	***
Players in market	0.1611	1.13714	0.1775	0.3641	
Not highest AIP	1.1370	3.18040	0.4284	0.0080	**

Significance codes: 0.001 '***', 0.01 '**', 0.05 '*', 0.1 '.'

Table 8: Logit model

The logistic regression model estimates how each of the independent variables affect the probability that the maximum AIP of a given drug will be increased by at least 50%. The binary variable $Y_{i,t}$ is equal to 1 if the drug has experienced an increased maximum AIP and 0 if not. Our logit regression model has a pseudo R^2 of 53.9%, which means that the explanatory variables explain more than half of the variation in $Y_{i,t}$.

The estimated coefficients mostly have the expected signs. However, the coefficient for change in HHI indicates that an increasing HHI reduces the probability of increasing maximum prices. The coefficient is statistically significant at a 10% level. This is surprising, as an increasing HHI represents a more concentrated market and increasing market power for at least one player. It is unclear to us why this would lead to a lower probability of increasing the price, but it is worth noting that a higher HHI in absolute terms leads to a higher probability

of increasing the price. Additionally, a higher absolute number of players in the market indicates an increased probability of increasing the price in our dataset. This is unexpected and not consistent with economic theory. However, the coefficient is not statistically significant even at a 25% level, and it is seemingly caused by multicollinearity with HHI, which we will return to when testing the robustness of the model.

The remaining estimated coefficient signs are consistent with our hypotheses. The model indicates that an increase in demand gives a lower probability of increasing prices. However, the coefficient is not statistically significant at a 25% level. Further, we find that a reduction in the number of competitors increases the probability of increasing the price, which would be an indication of increased market power. Increasing market shares also increase the probability, which similarly indicates increased market power. While a change in market share is statistically significant at a 10% level, a change in competitors is significant at a 5% level. For the absolute variables, both a higher market share and HHI increases the probability of a price increase. Both variables indicate a high degree of market power. It is worth noting that the coefficient for market share is not statistically significant even at a 25% level. This is not too surprising, considering that all drugs within a market are allowed to make use of the same maximum price. However, the coefficient for HHI is strongly significant. Finally, the probability of a price increase is higher if there is another drug within the interchangeable group with a higher maximum AIP. This is expected, as the process is much more lenient, and the new maximum prices are already approved.

We will now focus on the coefficients that are significant at a 10% level, interpreting these as to how a change in these variables affect the predicted odds. To interpret logit coefficients, they should exponentiated, i.e., $e^{Coefficient}$. This gives the odds ratio for a one-unit increase in the explanatory variables, i.e., which factor the odds, before increasing the variable, should be multiplied by if the explanatory variable increases by one unit. For the second base logarithm of absolute HHI, the exponentiated coefficient is 7.16, which means that if HHI is doubled, the odds should be multiplied by 7.16. The model predicts that the absolute value of HHI is highly relevant for the probability of a price increase, which is to be expected from economic theory. Similarly, if the drug has a maximum AIP below the interchangeable group's highest AIP, the model suggests that the odds would increase by a factor of 3.18. This shows a drastic increase in the predicted odds if the producer can increase their AIP without going through a time- and resource-consuming application process.

For the variables measuring change, the change in competitors is rather straight forward to interpret. If the number of competitors increases by one, the odds are reduced by a factor of 0.538 or a decrease of 46.2%. This shows that changes in the number of competitors is an important indicator for price increases. For the change in market share and HHI, it is important to keep in mind that the variables are indexes. This means that a one-unit increase represents an absolute increase equal to 1% of the index base, i.e., the average value across the three months one year before the increase. For HHI, an increase equal to 1% of the index base reduces the odds with a factor of 0.988, i.e., a 1.2% reduction in the odds. To put this into perspective, if we rather look at a 10% increase in HHI during the period, which would be an increase in the variable "Change in HHI" of 10, we expect a reduction in the odds with a factor of 0.886, or just above 11,4%[2]. For an increase in market share equal to 1% of the index base, the model predicts an increase in the odds by a factor of merely 1.00034 or 0.034%. By doing the same exercise as with HHI, a 10% increase in market share during the period is predicted to increase the odds by a factor 1.0034. In the fitted model, a change in HHI affects the probability severely more than a change in market share. However, we note that neither the coefficient "Change in HHI" nor "Change in market share" are significant at a 5% level.

The findings from the logistic regression analysis are consistent with our hypothesis that market power is an important driver of excessive pricing. It also rejects the hypothesis that the price increases are driven by falling demand, as the coefficient for the variable "Change in packages" is far from significant. It also highlights that an explanation for price increases could be that the producer changes their maximum prices to be in line with competitors after previously having lower maximum prices. However, it can be debated whether this is really excessive pricing, as it would merely be to change the price to match competitors. On the other hand, the producer would have contributed to keep prices low if it had kept its lower maximum prices. If the producer is the last one without the higher maximum price, the consumers' ability to buy a cheaper product would disappear when the last producer follows the competitors' price increase and excessive pricing would be a greater problem.

7.2.2 Robustness

Since the trend variables have been defined manually and not by the model, it is important to examine how robust the results are to changes in our assumptions. The trend variables have

[2] Found by calculating the one-unit increase factor by the power of 10

been constructed in such a way that they should indicate the trend leading up to the change, with the expectation that most pharmaceutical companies will respond to changes in the market rapidly. As the average processing time for applications to change maximum prices is 1.5 months, the trend should be noticeable during the last three full months with the old maximum prices (Statens legemiddelverk, 2021B). It is also expected that the trend is rather recent as we assume that the players respond quickly and opportunistically, and we therefore calculate the trend base no further back than one year. In order to test the robustness, we will now change some of these assumptions and discuss the changes that occur in the logistic regression model. The full results from the regressions are presented in the appendix.

Until now, we have assumed that the players respond to changes in the market rather quickly. An alternative hypothesis could be that the producers want to observe the change over a longer period to ensure that the change is permanent, before taking any strategic actions. Therefore, we now change the numerator to the average of the sixth to fourth last months before the price increase rather than the three last months. If the assumption that the pharmaceutical companies respond to market changes quickly is true, we would expect the variables measuring change to have reduced significance as this is further away from the month of the price increase. What is observed is that all these variables, except “Change in competitors”, are insignificant at a 10% level. “Change in competitors” has a reduced significance but is still significant at a 5% level. This is rather consistent with the expectations, as it shows that the firms are opportunistic regarding a fluctuating market share. As for the change in competitors, it may be explained by the producers wanting to ensure that the competitor has made a final decision to exit the market before adjusting their price. It is not unusual to observe that players sporadically have months without sales in the dataset, which does not necessarily mean that they have exited the market. Overall, the findings seem to be robust in terms of the companies showing opportunistic behavior.

Further, it is assumed that the price increases are based on recent trends. In order to test this assumption, the original change variables are recalculated with the base extending back to a maximum of two years rather than one year. As it is expected that the development during this extended period is unsystematic, the change should introduce more noise to the model. Therefore, we expect the model to return insignificant coefficients for the “Change” variables. When running the model, none of these variables are significant at a 10% level. This is

consistent with expectations and indicates that the trends are recent and therefore may be viewed as being related to the price increases.

Finally, a correlation matrix is printed to check for collinearity in the model.

Correlation matrix of all explanatory variables

	CP	CMS	CHHI	CC	HHI	MS	C	NHA
CP	1.000							
CMS	0.097	1.000						
CHHI	-0.005	-0.008	1.000					
CC	-0.005	-0.029	-0.318	1.000				
HHI	0.001	-0.017	0.019	-0.096	1.000			
MS	0.011	-0.110	-0.166	**-0.660**	0.258	1.000		
C	-0.002	0.042	0.171	0.137	**-0.695**	-0.533	1.000	
NHA	-0.009	-0.005	0.025	0.011	-0.123	-0.121	0.099	1.000

CP: Change in packages, CMS: Change in market share, CHHI: Change in HHI, CC: Change in competitors, HHI: log(HHI), MS: log(Market share), C: Competitors, NHA: Not highest AUP

Table 9: Correlation matrix of all explanatory variables

As depicted in the table above, none of the correlations are above the threshold of 0.8 from the methodology chapter. However, the correlation between market share and change in competitors and between HHI and number of players can be said to be high. Combining this with the unexpected results for number of players in our model, we find it worthwhile to estimate the model without absolute HHI, since this variable is a function of the number of players and their market share and could therefore create bias.

Variable	Coefficient	e^{β}	St. Dev.	P-value	Sign.
Change in packages	0.0000	1.00000	0.0000	0.5390	
Change in competitors	-0.4372	0.64584	0.3656	0.2366	
Change in market share	0.0004	1.00040	0.0002	0.0408	*
Change in HHI	0.0015	1.00150	0.0086	0.8570	
log2 (Market share)	0.0186	1.01878	0.0503	0.7114	
Players in market	-0.4826	0.61718	0.1322	0.0003	***
Not highest AIP	0.8209	2.2725	0.4153	0.4807	*

Significance codes: 0.001 '***', 0.01 '**', 0.05 '*', 0.1 '.'

Table 10: Logit model without HHI

In the table above, the results from the logistic regression model without HHI are printed. When excluding HHI, "Players in the market" comes out as a highly significant coefficient and indicates that a higher number of players reduces the chance of a price increase. This indicates that the unexpected results in our original model are driven by the correlation between HHI and number of players in the market. It may also indicate that market power is more dependent on the concentration in the market than the number of players in the market, e.g., a player in a market with five competitors holding a 90% market share may be said to have more market power than a player in a market with three competitors holding a 33% market share each.

For the correlation between market share and change in competitors, excluding either variable gives no different interpretation of the effects or statistical significance.

7.3 Does market power affect the size of price increases?

Several indications of market power being a key driver of excessive pricing are found through the analysis. A natural next step would be to explore whether market power also influences the magnitude of the price increase, i.e., does market power lead to more aggressive excessive pricing? The threshold that has been used to define excessive pricing has been an increase of maximum AIP of at least 50%, but there is clearly a difference between an increase of 50% and 200%. Therefore, some analyses will be performed to explore the relationship between the actual price increase and market power. We argue that the actual increase is more relevant

to explore as opposed to the increase in maximum prices, as the actual price charged reflects the actual impact from the new maximum prices.

In the graph below, boxplots are generated to depict the relationship between the actual price increases and the number of players in the market. The boxes represent the interquartile ranges, with the thick horizontal line representing the median. The lines stretching above and below the boxes show either the maximum and minimum values, or the end of the relevant quartile plus 1.5 of the interquartile range. The y-axis has been limited to 500. Six observations are omitted due to this criterion. Five of them are monopolies with indexed prices of ~500, ~700, ~1,600, ~1,700 and ~2,700, while one is in a duopoly with an index price of ~800.

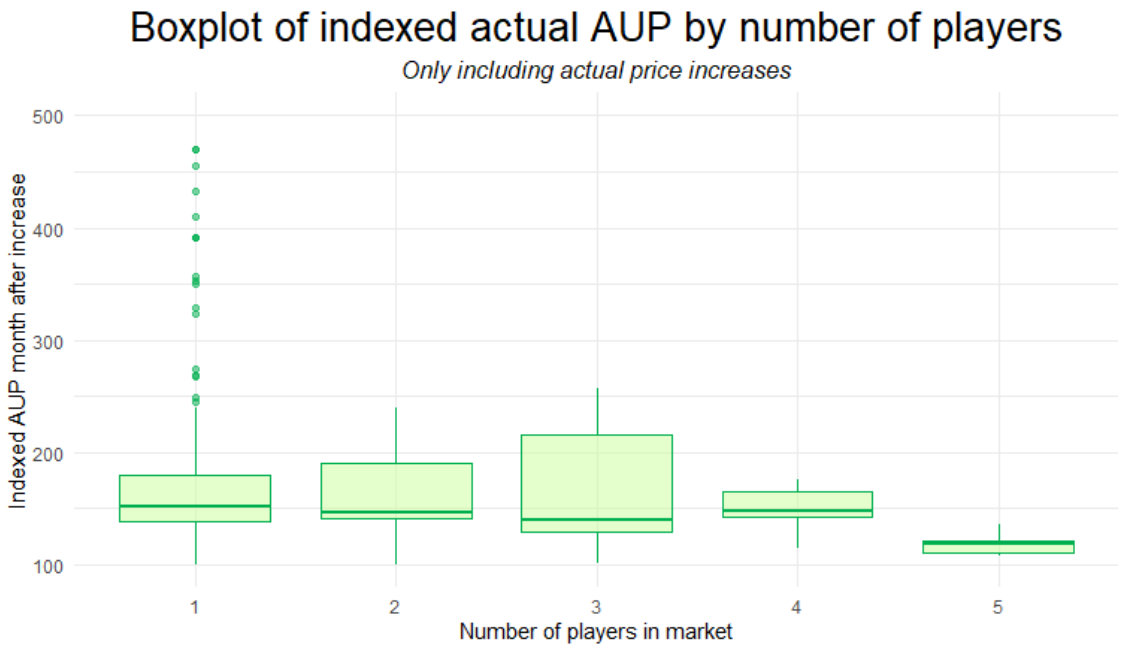

Figure 20: Boxplot of indexed actual AUP by number of players in the market

From the graph we can see that the median values for the groups with one to four players are very similar, with the third quartile being somewhat different between the groups. In markets with five players, the price increases are visually lower, which would be consistent with economic theory as these markets are expected to be more competitive. Except for the one case mentioned earlier, all outliers are within monopoly markets. This would be an indication that market power is associated with higher price increases and more severe excessive pricing.

It is worthwhile to also look at the distribution of the price increases across the different groups. This is depicted in the violin chart below.

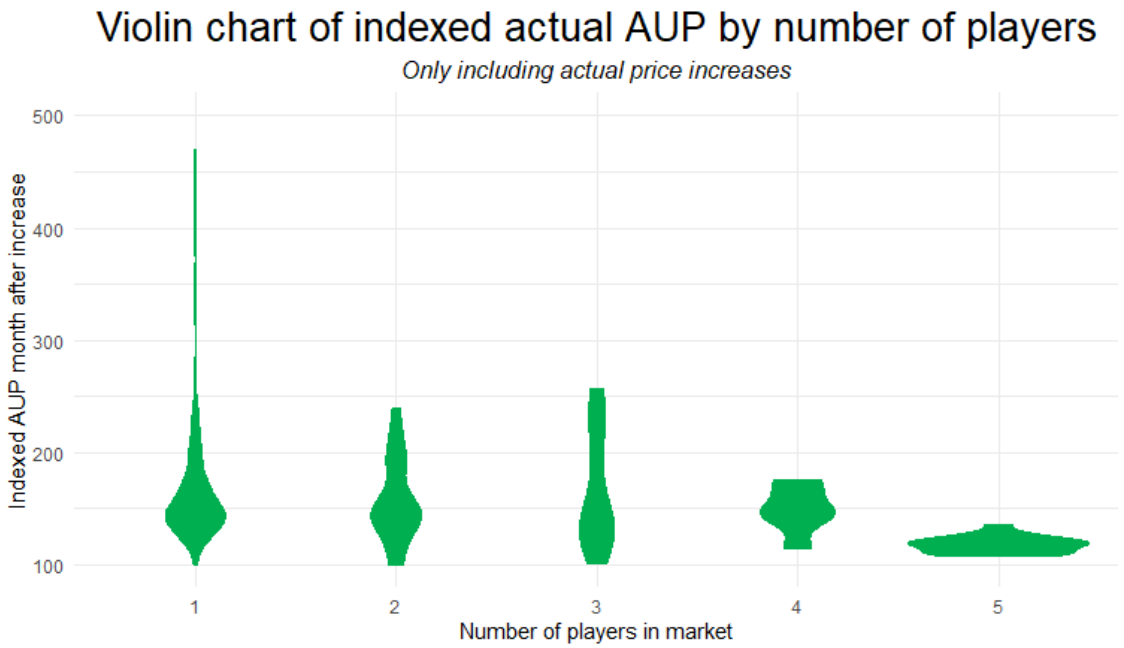

Figure 21: Violin chart of indexed actual AUP by number of players in the market

This graph further supports the observations from the boxplot, as the widest points are at similar levels across the markets with one to four competitors, while it is lower for the group with five competitors.

A Wilcoxon rank sum test is performed to test if there is a statistically significant difference between the price increases in monopolies and markets with competition. The test shows that monopolies have larger price increases with a p-value of 0.02%. The median increase in monopolies is 52%, while it is 43% in markets with competition, and the difference is statistically significant.

Furthermore, we plot the indexed actual AUP during the first full month with new maximum prices across the HHI in a scatter plot to explore the relationship between actual prices and market concentration.

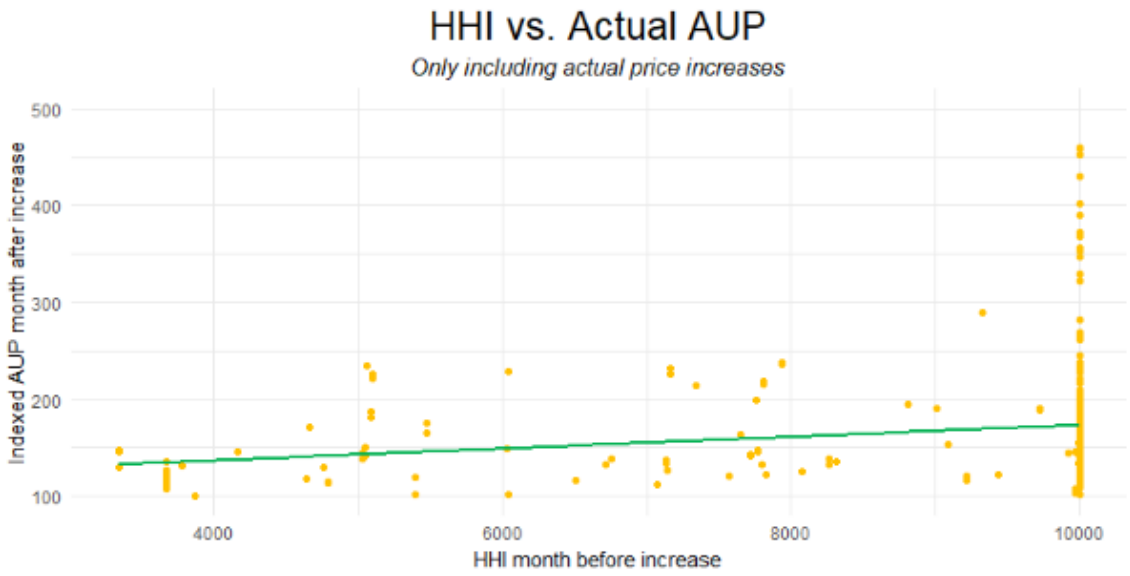

Figure 22: Scatterplot of HHI and actual AUP

Unsurprisingly, the highest values are located at the 10,000 mark which represents monopoly markets. This is expected after seeing that the highest price increases are present in monopoly markets. The trend line shows a positive relationship between higher HHI and higher price increases, but it is likely to be heavily influenced by the large number of cases in monopoly markets. However, an argument can be raised that there are more cases of large price increases when the HHI is high. If this is the case, it further indicates that higher market power leads to more severe excessive pricing.

7.4 Case studies

In addition to the analysis conducted on an aggregated basis, five observations of relatively high price increases have been selected for closer case studies. This may bring a more qualitative aspect to the analysis and give a more thorough understanding of the reason for the price increases. Although one cannot know to what extent they are representative for the other observations, they do provide examples of how and why these prices are increased. We will first study two cases based on SLV's annual revision of maximum prices and their international reference pricing practice. Secondly, we study three cases where the firms have contacted SLV and requested a price increase. Due to confidentiality, the names and producers of the pharmaceuticals are here anonymized.

7.4.1 Cases based on reference pricing

The first two cases are examples of SLV's regular price revisions where SLV takes initiative to the price increases (Statens legemiddelverk, 2015D; Statens legemiddelverk, 2015C; Statens legemiddelverk, 2016C). We mentioned earlier that SLV revises the maximum price of the most common active substances annually (Apotekforeningen, 2017). In these cases, SLV contacts the producers and refers to the Norwegian regulations on pharmaceuticals, requesting price information about certain drugs in the nine countries used as a reference for calculating the maximum AIP (Statens legemiddelverk, 2015D; Statens legemiddelverk, 2015C). SLV informs that the information will then be used to re-evaluate the maximum AIPs for the given preparations.

Case 1

The first observation selected for a case study is drug A, which had an increase in the maximum AIP of 180% in December 2015, from 1,349.22 NOK to 3,777.42 NOK. This is illustrated in the figure below.

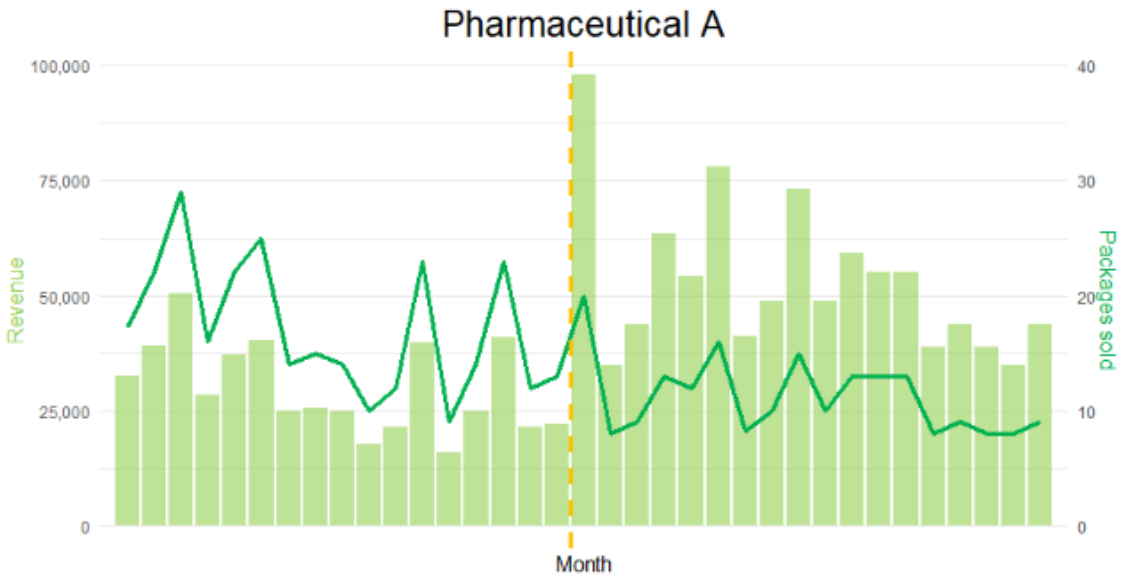

Figure 23: Development of revenue and packages sold for pharmaceutical A

The price increase is depicted as the orange dotted line. The light green columns represent the revenues in NOK each month before and after the price increase, and their values can be found on the y-axis to the left. The dark green line represents the number of packages sold in the months before and after the increase, with the values on the y-axis on the right side.

There are in total three producers of products within the same interchangeable group the years before and after the price increase. However, one competitor has many months without sales starting the month before the price increase, which could indicate that it was struggling. One may therefore question whether this competitor has any true market power, or if the market can be said to be close to a duopoly. The sales volume of drug A is also 54% lower in this period compared to the average of the years before. Although fluctuating, both the revenues and the number of packages sold also seem to fall in the months before the increase.

In December 2015, the first month where the price increase takes effect, the revenues skyrocket due to a combination of the price, which is 180% higher, and a relatively high sales volume. However, the number of packages sold falls further in the months after the price increase. This could be a continuation of the already existing negative trend in demand, for example indicating that the disease is less common or that the treatment is being replaced by other treatments, i.e., subject to therapeutic competition. Alternatively, it could be a reaction to the price increase, indicating that customers are price sensitive and either refrain from buying the drug or choose cheaper alternatives within the same interchangeable group. For example, our data shows that in February 2016, 280 packages of an interchangeable product with the same package size were sold at the step-price AUP of 670 NOK. Meanwhile, only nine packages were sold of pharmaceutical A, at an AUP of 4,882 NOK. Regardless of the falling demand, the total revenues seem to stabilize at a higher level than before the price increase, although they are somewhat reduced from the high levels that we observe in the first month after the increase. A study of the case documents between SLV and producer A regarding the price increase may give a better understanding of the process behind the increase.

Process description

In the case of pharmaceutical A, the product is only marketed in two other countries when SLV requests price information (Statens legemiddelverk, 2015D; Statens legemiddelverk, 2015C). Adjusted for volume and local currency, the reference prices give an average price per package of 3,913.13 NOK. This is based on a per-package price of 1,609.09 NOK in the Netherlands and 6,217.40 NOK in Germany, reflecting an extreme price difference between the countries used for comparison. Nevertheless, the calculated price per package is overwritten in this case. The reason is that a stronger version of the drug has seven countries available for comparison, where the three cheapest calculate to an average price of 3,777.42 NOK per package. This price is therefore set for drug A as well. The reason specified is that

"a lower strength cannot be more expensive than a higher strength per unit, cf. SLV's guidelines regarding the relationship between different strengths of a given pharmaceutical".

Case 2

The second case had an increase in maximum AIP of 167% in January 2017, from 372.77 to 994.34 NOK per package. This is illustrated below.

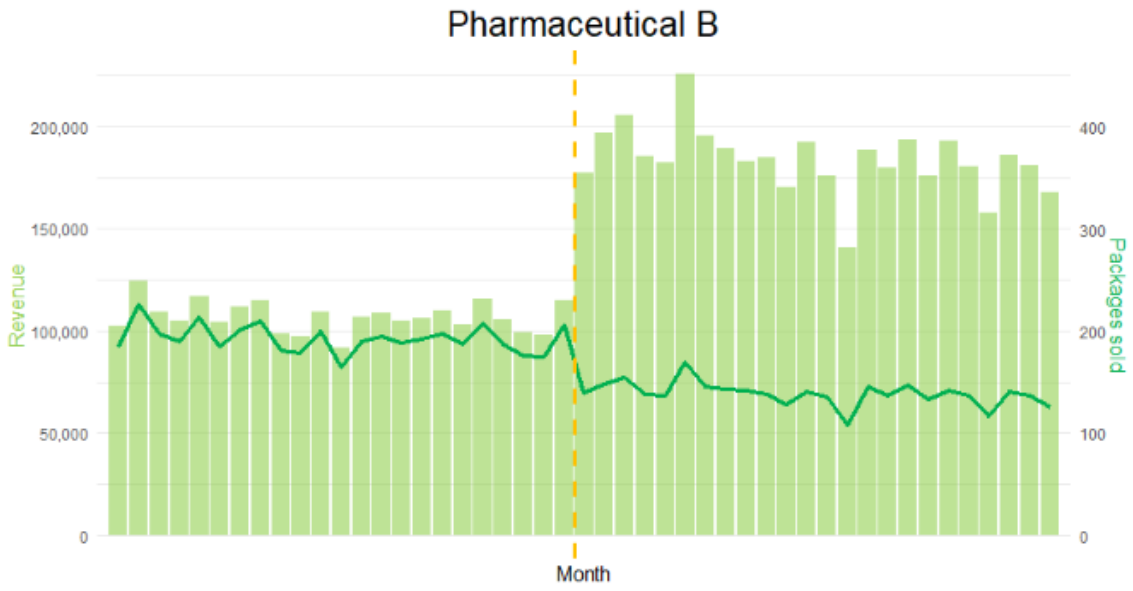

Figure 24: Development of revenue and packages sold for pharmaceutical B

The market consists of two players both before and after the price increase. Despite a very slight reduction in sales volume before the price increase, the revenues seem to be rather stable. The increased price gives a reduction in demand, and the sales volume seems to stabilize at a new, lower level. Nevertheless, the revenues jump significantly right after the increase and are close to doubled in some periods. They are slightly reduced throughout the year but stabilize at a much higher level than before the increase.

Process description

Also in this case, only two countries are available for comparison at the time when SLV requests price information. Adjusted for currency and package size, a price of 565 NOK in Sweden and 1,424 NOK in Denmark give the new average AIP of 994.34 NOK per package in Norway (Statens legemiddelverk, 2016A). We note that there is a significant difference of 859 NOK per package between the reference prices in this case as well, supporting our previous observation that the adopted AIP may vary substantially depending on how many and which countries are available for comparison. Both Sweden and Denmark practice tenders

where producers compete through price bids, which is done monthly in Sweden and every fourteen days in Denmark (Hauschultz & Munk-Nielsen, 2020). This may cause the reference prices to be quite high occasionally, and they may not be representative for the countries' prices through a year.

Further discussion

Although reference pricing is meant to prevent excessive pricing, we question to what extent the practice may be abused. In both cases, the available reference prices affect the average substantially due to the considerable gap between them. If the price had not been overwritten in case 1, e.g., because the stronger version had not been marketed in Norway or because reference prices for the stronger version had not been available, the revenues for drug A would vary critically with the reference prices available. This is what happens in case 2.

One may therefore wonder whether it would be a possible and considered alternative for producers to pull their products from low-price countries temporarily for high reference prices to remain in order to increase maximum AIPs significantly. According to SLV, this would be complicated in practice and is therefore unlikely (Statens legemiddelverk, 2021A). SLV verifies the reference prices reported by the producers and includes products registered as "temporarily expired" in the calculations. The product would hence have to be formally removed from the market at the time of verification, which is unknown by the producer. The firm would also have to go through the process of reapplying for a market authorization to re-enter these markets, which further complicates the process. However, SLV points out that new entrants could choose to strategically enter the Norwegian market first, which is a more probable strategy. In that case, no reference prices would be available, and it could be easier to obtain their desired price.

Additionally, there may be local conditions suggesting that some countries should have a higher price, such as shortages, limited demand or particular costs in a given country. Such reasons should probably not justify a higher price for the same product in other countries where the local condition is not present. SLV points out that if there are shortages in raw materials, these are usually global shortages which would affect all countries equally (Statens legemiddelverk, 2021A). Otherwise, they inform that reference prices may be excluded from the calculation if they seem to be unreasonably low, but that reference prices are not excluded the same way if they seem to be unreasonably high. They also inform that reference prices are

not controlled for individual factors such as local conditions, as there is a trade-off between high prices and resources spent on price regulation. Our impression is therefore that although the intention with the reference pricing practice is good, there may be a need for qualitative and discretionary considerations to supplement the practice and prevent abuse, which is not done today due to cost-benefit evaluations.

7.4.2 Cases where monopolists threaten to remove product

While it seems unlikely that the price increases initiated by SLV's annual revision are driven by market power, there are other cases that may seem more speculative. We will now study three cases where the producers contact SLV and apply for a price increase. A closer look at the application processes may help us understand whether the increased revenues can be justified, e.g., for the producers to survive in the market, or if they are simply a transition from consumer surplus to producer surplus.

Case 3

The first observation we will study within this category is pharmaceutical C, which had an increase in the maximum AIP of 527%, from 59.83 NOK to 375 NOK per package in October 2015. The price was further increased to 750 NOK in September 2018, resulting in a total price increase of 1,154% from 2015 to 2018. This is illustrated below.

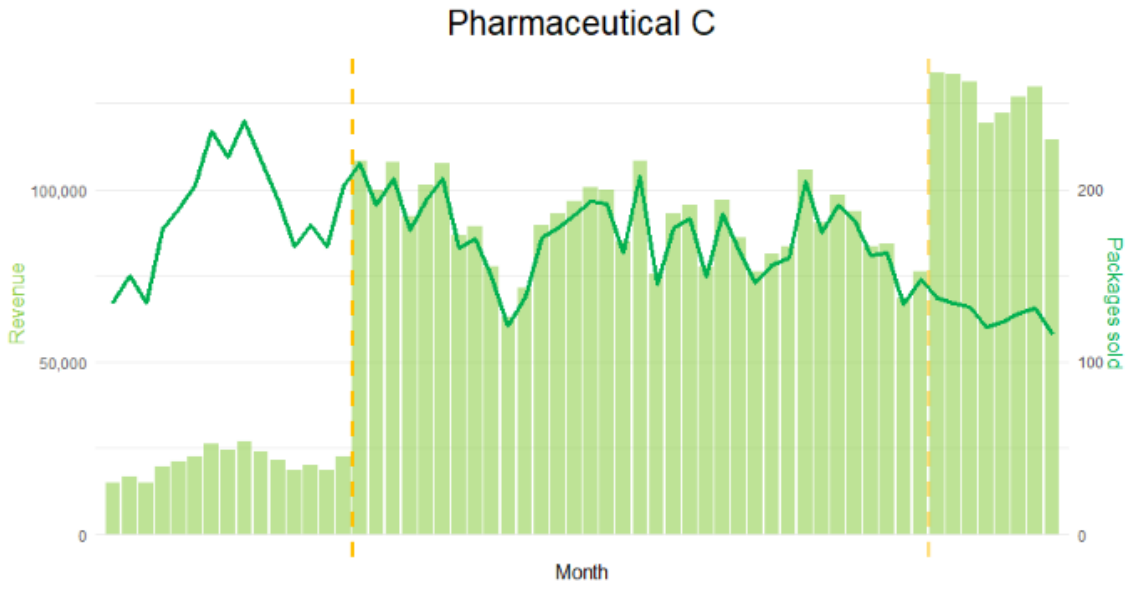

Figure 25: Development of revenue and packages sold for pharmaceutical C

The case is a monopoly market, with producer C being the only provider of the drug in Norway. The number of packages sold is almost doubled in the year before the first price increase, then falls for a few months before it rises again the month before the price increase. After this, the demand seems to have a slight downward-sloping trend but is not much lower than the level in the first months of the figure. The revenues, on the other hand, rise significantly and are more than four times as high after the increase. Naturally, the revenues follow the development in demand and are therefore somewhat reduced when demand falls, but they remain considerably higher and three times as high as the levels before the price increase.

The revenues spike even higher after the second price increase in 2018 and remain at that level for the rest of the period for which we have data. The number of packages sold falls slightly but is still not much lower than what it is in the first months of the figure, and it stays at this level for the rest of the period for which we have data. This may indicate that the consumers are insensitive to price changes for drug C, and that they must accept the price increases as there are no other suppliers in the market. Unfortunately, we do not have case documents regarding the second price increase, but a study of the case documents regarding the increase in December 2015 may give a better understanding of the situation.

Process description

In this case, producer C is the one to contact SLV, taking initiative to the price increase (Statens legemiddelverk, 2015F; Statens legemiddelverk, 2015A; Statens legemiddelverk, 2015E; Statens legemiddelverk, 2015B). It explains that the production of drug C is being outsourced from a factory in Norway to another European country, and that the pharmaceutical is produced in a very small scale for the Norwegian market. It is argued that producer C believes it is important to keep preparations on the market where they are the only provider, including pharmaceutical forms with low sales volumes. They further argue that the price of the drug has not been increased since 2009, and thereby request an increase in the maximum price to 375 NOK per package in order to be able to keep the product on the market.

SLV requests information about production costs for drug C and price information for the original preparation, as drug C is a generic drug, to base the evaluation on this information. Interestingly, this information does not seem to affect the decision regarding the price increase. In the answer, producer C clarifies that it has had great focus on reducing the number of

production sites and consequently reducing product lines with low sales volumes to small markets. They specify that they have already decided to withdraw 43 product lines from Norway. They further argue that the product has a low wholesale price and risks being removed from the market. Lastly, it is informed that the original preparation is only available in Belgium, with a price of 2.15 EUR. Adjusting for size, if this price were to be used as a reference for drug B, it would indicate a price around 2.69 EUR, far below the adopted price of 375 NOK. After receiving this information, SLV approves to increase maximum AIP of pharmaceutical B to the originally requested price of 375 NOK per package.

Further discussion

This process raises several questions. On one hand, it may be a good argument that it is desirable to keep the product on the market, as it is preferable to provide consumers with alternatives and to have various strengths and pharmaceutical forms for different use and users (Statens legemiddelverk, 2021B). This is of particular interest when the pharmaceutical's indication is for children, who can be said to be especially vulnerable (Statens legemiddelverk, 2021A). This is the case for drug C. SLV explains that they also have their own independent doctors who can be consulted to evaluate how critical the availability of certain pharmaceuticals is (Statens legemiddelverk, 2021A). Therefore, approving a price increase could probably be justified if this is the only way it can be profitable for a producer to keep a product on the market. The argument that moving production from Norway to another country increases shipping costs may also justify a price increase to some extent.

However, with conflicting interests it is difficult to know to what extent it is true that the product is not profitable and may be removed from the market if the price is not increased. It is therefore questionable that information about the production costs, even though it is requested, is never presented, and hence never considered when setting the increased price. We mentioned earlier that the pharmaceutical industry is characterized by high fixed costs which are difficult to distribute to the products. This could be a reason why cost calculations have limited value and credibility, but may also seem contradictory, as one cannot know whether a product is profitable without information about its costs. According to SLV, cost calculations are also hard to verify, and they explain that there is a trade-off between high prices and the time and money spent on the application processes. Additionally, there seems to be no link between the price of the original preparation, which could be used as a reference price, and the new approved price for product C. SLV comments that this information also has

limited value, as the producer of the original preparation may have different production costs that are not representative for firm C. SLV further explains that one must consider when the price was last increased, and that long periods without changes in the maximum prices could justify higher price increases. However, we do question if six years can justify an increase of 527%, or nine years an increase of 1,154%.

In this case, it is difficult to evaluate whether the price increase can be justified. Therefore, there is a chance that producer C takes advantage of its position as a monopolist and the threat to remove drug C from the market as a mean to obtain its preferred price with no further explanation.

Case 4 and 5

The last two cases belong to the same producer, a monopolist that applied for a price increase in December 2012. We will now study the price increases individually before we take a closer look at the process behind.

Case 4

The price of pharmaceutical D increased from 80.10 to 459.11 NOK per package in July 2013, a price increase of 473%. This is depicted in the figure below.

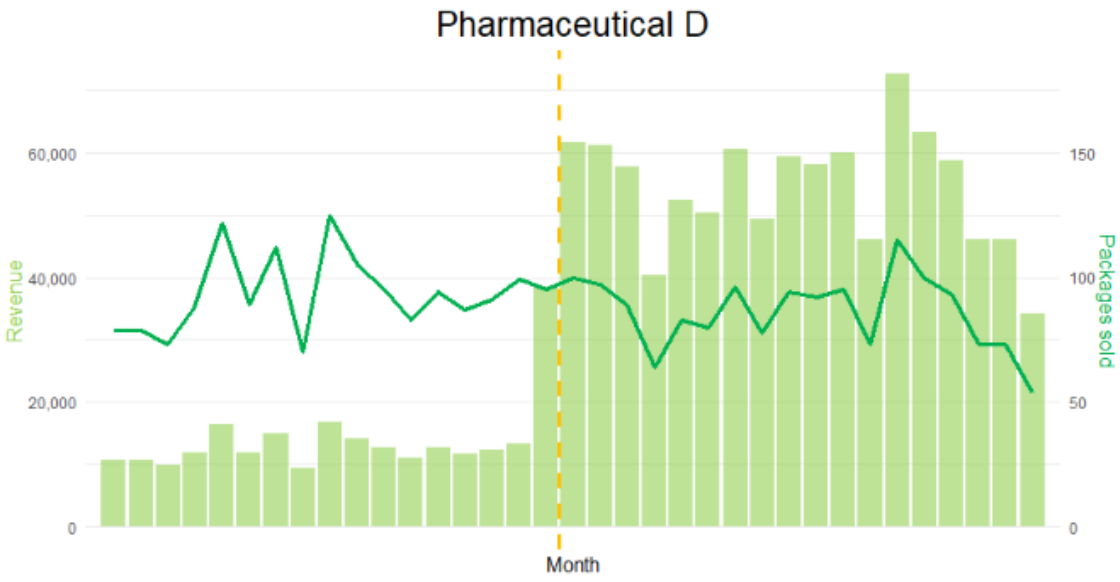

Figure 26: Development of revenue and packages sold for pharmaceutical D

In this case, demand is actually increasing in the last months leading up to the price increase. It falls right after the increase but bounces back rather quickly, before it experiences a steep

reduction and ends up at a level below the level it was at before the price increase. Revenues, on the other hand, are almost six times as high right after the price increase. Although they vary and are somewhat reduced with time, they stay at a much higher level than they were before. Note that the revenues look like they spike already in the last month before the price increase, which is because the price was increased during this month. The orange dotted line represents the first full month with the increased price.

Case 5

In our last case, the maximum AIP was increased from 108.73 to 551.15 NOK per package in July 2013, an increase of 407%. This is illustrated below.

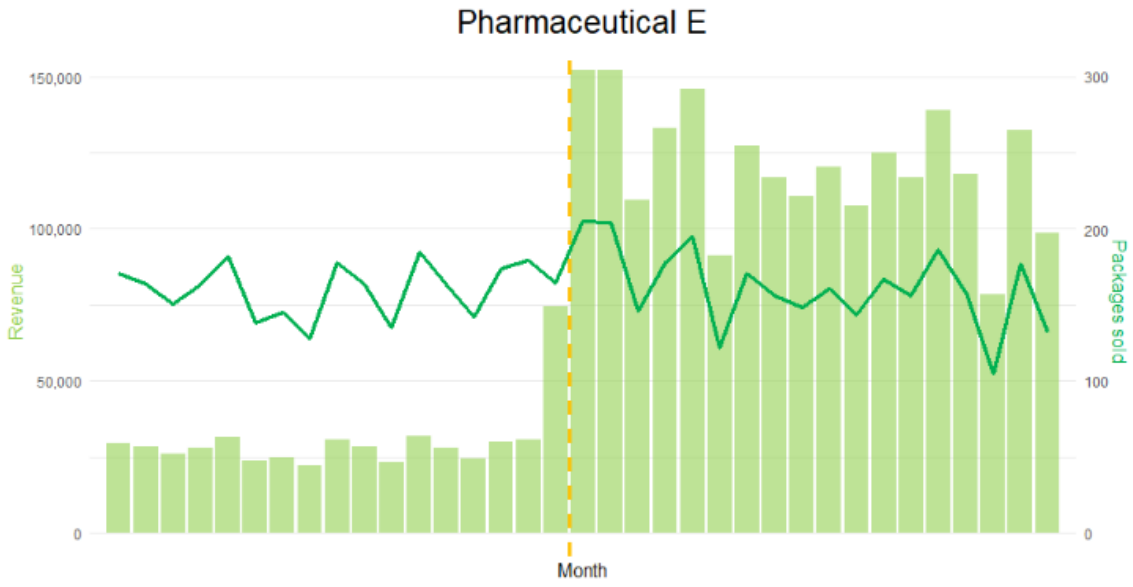

Figure 27: Development of revenue and packages sold for pharmaceutical E

Demand is relatively stable before the price increase, although fluctuating. It also seems to be quite stable around the same level after the increase, but with a minor negative trend. This indicates that demand for pharmaceutical E is relatively price inelastic. Similar to the previous case, the revenues are almost six times as large after the price increase. In the period after the price increase, they have a minor negative trend, but remain much higher than before the price increase. As with case 4, the price was increased during the last month before the orange dotted line, which represents the first full month with the increased price.

Process description for case 4 and 5

The process behind the price increase in case 4 and 5 is interesting. The producer obtained a monopoly position in October 2012 and contacts SLV to request increased prices two months

later (Statens legemiddelverk, 2021E). They argue that the products are not profitable and that they will be removed from the market if the prices are not increased. The firm further states that they are in the process of increasing their prices all over Europe, and that the reference prices in some other countries "are not there yet", but that this is only a question of time. For this reason, they ask to be exempt from the reference pricing practice.

In their reply, SLV states that reference pricing is the main practice, but that certain circumstances may permit a maximum AIP higher than the calculated AIP from reference pricing. They list the two conditions that must be met for an exception to be made. Firstly, there must be a large risk that the pharmaceutical is no longer available on the market if the reference price-based AIP is adopted. Secondly, the access to pharmaceuticals that are cost efficient and valuable to society must be affected negatively if the pharmaceutical is removed. Lastly, they explain that if these conditions are met, SLV will consider making an exception and set a discretionary price, and request documentation of the production costs as a basis for their evaluation.

The producer responds by emphasizing that the reference countries who have not increased the price face a serious risk of losing the products. They argue that after acquiring the factory and production lines from another firm three years ago, they have adjusted the production process to ensure compliance, quality etc., which has led to increased production costs. The firm states that it is essential to have a uniform price level in Europe and refers to countries that have recently accepted increased prices. Further, the producer argues that the pharmaceuticals are used to treat serious diseases and attaches documents with comprehensive descriptions of the drugs and their impact. The firm also attaches the application sent to another European country including further explanations of which patients may be affected and how. Lastly, the firm repeats that it will consider removing the pharmaceuticals from the market if the prices are not increased and mentions that removal will have negative consequences due to the extensive use of the drugs and the long clinical experience with them.

A few months later, the firm sends calculations of the production costs for the pharmaceuticals (Statens legemiddelverk, 2021D). They comment that it is important to have homogenous prices across countries to prevent parallel trade within the EU, explaining that patients in countries with low prices could be left without pharmaceutical alternatives due to parallel export. Further, it is argued that Norway's individual requirements regarding packaging and

labelling obligates the firm to adjust the packaging and produce in small quantities especially for Norway. This increases production and packaging costs further, which already constitute a great share of the costs. After this, SLV accepts the increased maximum AIPs that were originally requested.

Further discussion

Some questions about this process can be raised as well. First and foremost, it is noteworthy that the firm requests a price increase two months after obtaining a monopoly situation. The argument that production costs have increased after they bought the production lines from another firm, which they did a few years earlier, may therefore seem questionable. Additionally, the request in the introduction to make an exception from the reference pricing practice proposed with the argument that it is necessary to have homogenous prices across Europe seems like a request for special treatment, as this argument should apply equally to all pharmaceuticals. Pursuing similar price levels across countries to protect consumers in low-price countries against parallel export could be a reasonable argument. However, one may question why this should be considered in this particular case when there are numerous examples of pharmaceuticals with widely different price levels across countries. If all drugs were to have the same price levels across all countries, the reference pricing practice would be a paradox in itself.

Production in small quantities and specialized packaging for Norway could justify a price increase. On the other hand, we find it difficult to understand why this problem should have arisen and necessitate an increased price now, given that sales volume has been stable and the requirements for packaging in Norway have remained unchanged. Unlike the producer in case 3, this firm does provide a calculation of the production costs, which indicates that the requested price does have a link to the estimated costs. However, we note that the calculated production costs slightly exceed the requested maximum price for one of the products. This could imply that the calculations are rough estimates, which would make sense as we know that it is challenging to distribute costs to products within the pharmaceutical industry. Alternatively, it could be a consequence of the firm’s desire to have homogenous prices across countries with different production costs, where the overall consideration leads to a slight deficit for one product, but a surplus for the other.

As with case 3, it seems like the interest in keeping products on the market and the fear of losing them trump potential excessive prices, considering the limited resources that can be spent on price regulation. It is difficult to know for sure whether the price increases reflect abuse of market power or a necessary measure to ensure that market presence is profitable. In the end, two very different versions of the same story can be presented; the producer that acquires a competitor and must adjust production and revise prices for all products that are no longer profitable, or the firm that becomes a monopolist and takes advantage of its market power to increase its prices significantly in all countries.

7.5 Impact on the drug expenditures from excessive pricing

The analyses above have studied how potential drivers affect the probability of a price increase and the process behind some price increases. Additionally, it may be interesting to estimate the size of the impact such increases have on pharmaceutical expenses, which affects the consumers, insurance companies and taxpayers who pay for the drugs.

A difference-in-differences analysis is performed to estimate the increase in pharmaceutical expenditures caused by increased prices. Drug revenues including VAT are used as the dependent variable, since these represent the price paid by the customers. The regression model then estimates how much the revenues increase from the year before the price increase to the year after for drugs that do experience a price increase. It adjusts for time trends and individual-specific trends by comparing the difference to the control group; pharmaceuticals with the same active substance whose prices have not increased. We apply the same fixed effects as in the logistic regression model. The regression results are depicted below.

Variable	Coefficient	St. Dev.	P-value	Sign.
After Dummy	-8,877.7	9,192.7	0.3342	
Treatment Dummy	-62,228.6	4,975.8	0.0000	***
DD Dummy	47,659.4	21,165.6	0.0243	*

Significance codes: 0.001 '***', 0.01 '**', 0.05 '*', 0.1 '.'

Table 11: DD regression

The DD coefficient indicates that on average, monthly revenues increase with 47,659.4 NOK when the price of a drug increases. This is significant at a 5% significance level. However, the

high standard error of 21,165.6 NOK tells us that the variation between the observations is high. This is expected as the absolute revenues from different drugs will deviate due to natural reasons. The coefficient is therefore not a representative mean for the effect of a price increase of an individual pharmaceutical. Instead, we can multiply the mean with 12 months and the total number of price increases, 449, to find the accumulated impact for the first year after the increased prices. This calculation gives an accumulated increase in pharmaceutical revenues and hence expenses of almost 257 million NOK in a year. Naturally, the impact this has on each individual consumer depends on how the increased expenses are distributed between individuals. However, some already vulnerable patients may be victims of very high price increases. A significant part of this amount is also reimbursed by the government, but this is still money that could be spent differently, and which is covered by taxpayers.

However, the number must be interpreted with carefulness. The coefficient is based on an average of the last twelve months before and the first twelve months after the price increase. We therefore multiply by 12 since these months have had an impact on the estimate. However, the price increases have occurred at different times over 11 years and we do not know for how long the high prices remain after the first year. The estimate should therefore not be used to estimate the accumulated loss over several years.

Furthermore, the DD estimate presumes a suitable control group with common trends to ensure that the groups would respond similarly to external shocks. A placebo test which simulates treatment six months before the actual price increase is conducted to examine whether this assumption is met. The DD coefficient in the placebo test is negative at -12,610.5 and is not significant at a 10% significance level[3]. These findings support our assumption of common trends and indicates that the model is robust.

[3] The results from the placebo regression are presented in the appendix

8. Discussion

In this section, we will apply our findings to discuss to what extent intervention against excessive pricing with pharmaceuticals is appropriate. In order to discuss this, one must understand the costs of wrongful intervention or lacking necessary intervention. It is important to note that costs should be considered as the total costs including, e.g., loss of flexibility, freedom to choose between drugs, loss of life quality and ethical concerns. When the costs are outlined, the probability of making a type I and type II error should be considered.

We shortly explained the difference between type I and type II errors previously. A type II error occurs when competition authorities fail to intervene to regulate a price that is actually excessive (Calcagno, Chapsal, & White, 2019). This may cause higher prices on pharmaceuticals and create allocative inefficiency (The OECD Secretariat, 2018).

Type I errors, on the other hand, may have serious consequences (The OECD Secretariat, 2018). A type I error is when competition authorities mistakenly intervene when the market would have self-corrected without intervention. Intervention may reduce prices in the short run, but if the price is not excessive, it also prevents firms from recouping their investment costs (Calcagno, Chapsal, & White, 2019). This will lead to low investments and innovation and will reduce other firms' incentives to enter the market, creating dynamic inefficiency. Research has found that a 1% increase in pharmaceutical revenues leads to an increase in the annual number of new pharmaceuticals approved for use of about 3% (Goldman, et al., 2008). Likewise, if strict regulation causes producers to remove their pharmaceuticals from the market because they are not profitable, unavailability of the drug may reduce patients' wealth significantly. Many drugs are critical for patients to treat their diseases and improve life quality, sometimes even survive. Since the pharmaceutical industry is exceptional in its function of improving life quality and increasing life expectancy, competition authorities should be careful when intervening to regulate prices in pharmaceutical markets (Calcagno, Chapsal, & White, 2019).

On the other hand, our data shows that excessive pricing is happening for several pharmaceuticals which are not under patent protection. In this case, the argument stating that type I errors could lead to reduced investments if R&D-costs are not recouped is weak due to two main reasons. The first is that the investments should have been recouped already as the

drug has been in the market for a long time already. Further, the original developer of the active substance may have exited the market. If so, the market would be dominated by generic products, and these producers have minimal R&D-costs to recoup. Therefore, the costs of type I errors may be limited to the risk of the drugs exiting the Norwegian market due to low profitability, since there is a low risk of reducing the R&D investments in the sector. It is important to note that there is reason to believe that not all drugs would exit the market in this case, but some probably would. If so, the question would rather be if the cost from the drugs exiting the market exceeds the cost from allocating inefficiencies stemming from excessive pricing. We quantified the excess cost for the drugs in our dataset to a total of 257 million NOK for the first year after a price increase. However, some of the price increases are likely to stem from increased costs or diminishing sales volumes and should therefore not be considered as allocation inefficiencies. To put the number into perspective, the Norwegian Ministry of Finance (2014) considers the value of a statistical life to be 30 million NOK in 2012 currency. If a drug is withdrawn from the market, both lives and life quality could be lost as a direct consequence. Additionally, there may be ethical concerns that should be considered if the rejection of an application for increased prices leads to withdrawal of the drug.

Our analyses have shown that market power has a strong presence within the cases of excessive pricing. This may be used as an argument that there is a rather low risk of the drugs being withdrawn from the market if the application for a price increase is rejected. If so, it would reduce the cost of a type I error. Given that the drug generates a profit with the original price, a rational producer should not withdraw the drug from the market given a rejected price increase. However, strategic interactions may make this profitable if it would cause authorities to change their decision on future price applications. If a precedence for allowing previously rejected price increases in the case of withdrawal occurs, a lot of bargaining power may be transferred from the authorities to the producers.

The fact that market power is highly present in our dataset also makes it plausible that the probability of making a type II error is higher than making a type I error. This follows from our analysis showing that HHI and falling competition are strong indicators of excessive pricing, which might indicate that the cases are driven by market power. However, there are several unobserved variables in our analysis with variable costs probably being the most important one. Further, we do not have insight into how many cases are rejected and why they

are rejected. Therefore, it might be more difficult to determine which error type is more probable by merely using our findings and data.

According to the OECD Secretariat (2018), four conditions must be met for competition enforcement against excessive pricing to be justified. Firstly, the firm suspected of excessive pricing must have significant market power, close to a monopoly position, so it is likely that it has sufficient market power to set excessive prices. Additionally, the more market power a firm has, the less likely is it that market mechanisms will work correctly. Secondly, there must be significant barriers to entry which prevent the market from self-correcting. Without barriers to entry, high prices and profit margins would be temporary until other firms see potential for profit and enter the market. Thirdly, governments should not intervene when this might affect R&D negatively and where the risk and cost of type I errors are high. Lastly, for competition enforcement against excessive pricing to be justified, other types of regulatory intervention must be considered not to be an alternative.

For the first condition, our analysis shows that significant market power is generally present in the markets where excessive pricing occurs. This would certainly be the case in the monopoly situations, where we also find the most extreme cases. The high degree of market power should be a strong argument for further intervention. Further, high barriers to entry are present in the pharmaceutical market. Even though the investments associated with introducing a generic drug to the market are severely lower than for the original development, receiving a market authorization still requires several tests. Additionally, the process is time consuming, which makes the time to market high. Finally, doctors will normally prescribe the drug they are most familiar with, and while pharmacies are obliged to suggest the cheaper interchangeable drug, not all consumers are willing to change to the cheaper version. In sum, this constitutes significant barriers to entry which further testaments the need for intervention.

The next condition returns to our previous discussion regarding whether intervention would negatively affect R&D. We argue that R&D would be mostly unaffected, as the patent protection has expired for many of the drugs and since the player with market power is not necessarily the original developer. The R&D costs should then have been recouped already, and we would expect intervention to have limited effect on R&D. The final condition is that other types of regulatory intervention are found to be insufficient. Our analysis does not give answers to this, but we can propose some alternative suggestions for intervention. It is

important to keep in mind that the Norwegian pharmaceutical market is already quite regulated compared to other countries due to maximum prices, but our analysis shows clear indications that some producers still manage to abuse their market power to set excessive prices.

A natural first step would be to impose stricter requirements for increasing maximum prices. As we have seen in the case of pharmaceutical A and B, the international reference prices may vary a lot, especially when the drug is present in few countries. Therefore, the referencing could be changed to omit some reference prices in cases where a subjective evaluation suggest that they are not representative. This would make the reference pricing practice more robust against potential attempts to manipulate the system. Further, the case study of pharmaceutical C revealed that even though requested, cost calculations were not required when applying for increased maximum prices. Requiring such calculations to be presented could also make it tougher to abuse market power to raise prices. However, adding such requirements would make the process more costly for both the regulatory body and the pharmaceutical companies, and it is difficult to validate cost calculations. It is also likely to extend the average processing time. These are clear disadvantages which must be considered against the potential gain from detecting cases of excessive pricing.

Another possibility would be to make changes that affect the barriers to entry, effectively facilitating increased competition in the market. This may be a more suitable approach to handle situations like the case for pharmaceutical D and E, where cost calculations have been attached and reference pricing shall not be used, but a firm threatens to withdraw the drug from the market. Several measures could be taken to simplify the process for generic entry. One possibility would be through international cooperation, where the generics are approved for multiple countries by a single, common authorization. For example, generics that are allowed in the nine reference countries could be allowed to skip the authorization process in Norway. Such an approach has the advantage of being simple and effectively reducing the barriers to entry, but it involves risks as the drugs would then not be approved by the Norwegian authorities themselves.

The RAND Corporation (2008) estimated the potential effects of two types of drug price regulation in the US. The first type was price controls, where the consumer price is the same, but the producer revenues are reduced. The second type of regulation was reduced co-payments, where the producer revenues are the same, but the consumer co-payments are

reduced. Compared to a baseline estimate of the status quo, they estimated the effects of the regulations on three aspects: consumer drug and health care spending, life expectancy, and the net effect as a monetized value of life expectancy minus medical and drug spending. They found that reducing co-payments without affecting pharmaceutical revenues have a higher probability of benefitting current and future generations of consumers. However, it should be mentioned that the estimations do not seem to take into account the potential incentive effects that might follow from reduced co-payments where consumers may become less price sensitive, which may increase relative spending on pharmaceuticals (The OECD Secretariat, 2018).

It is worthwhile to compare our findings to Graber's (2017), as she studied the US market which does not have a similar regulatory regime with maximum prices. This could therefore be used as a proxy-benchmark to the successfulness of the Norwegian regulations. Like our study, Graber finds market power to be an important driver for excessive pricing, with eleven of fourteen cases being tied to either reduced competition, consolidations or recent acquisitions. However, what is noticeable is that the relative price increases in the US market are more extreme with nine of the fourteen cases increasing the price by over 1,000%. In our dataset, there are only three cases of this magnitude. Graber also collected cases from a five year-period, while our study is based on data collected over eleven years. This may indicate that while the Norwegian regulations may open for producers exploiting their market power, they does avoid the most extreme cases and it may be argued that it to some extent works as intended. Even though the Norwegian cases are less extreme, our findings still indicate that market power is being abused at the expense of consumers and taxpayers.

As to markets with therapeutic competition, there is broad agreement that competition enforcement against excessive pricing is unsuitable due to the risk of impeding innovation (The OECD Secretariat, 2018). It is argued that such a product has market power due to its IP protection, and that the high price is supposed to be a reward for risky investment. However, it has recently been argued that one should not exclude IP cases from excessive pricing intervention completely. Some argue that competition enforcement cannot reduce market entry from potential competitors since entry is not possible in the first place. Furthermore, they argue that demand-side pressure tends to be weak, so supply and demand do not set competitive prices correctly. To minimize the impact that intervention may have on innovation and investment, one might apply calculations of the probabilities of product success in

advance. However, methodologies to perform such calculations are very data intensive and highly advanced, and sector regulators may be better suited than competition agencies to take on this responsibility.

Our discussion raises arguments in favor of stricter price regulation in the Norwegian pharmaceutical market. Although the consequences of a type I error can be considered significantly more severe, we argue that the probability of a type I error seems low, as our analyses indicate that market power is a driver of excessive pricing. Further, the cost of such errors may be limited, as R&D costs are assumed to already be recouped for several of the drugs. However, we note that stricter price regulation will increase the time and costs spent on regulations, which must be considered.

9. Conclusion

There have been several cases of excessive pricing in other countries, where powerful producers have taken advantage of price insensitive customers, drug prices have skyrocketed, and pharmaceutical expenditures have increased accordingly. The OECD Secretariat (2018) claims that there has been a recent increase in the calls for intervention against high prices of pharmaceuticals, and the number of enforcement cases tackling excessive pricing of pharmaceuticals. Our study is based on three hypotheses for drivers leading to price increases; falling demand, shortages or abuse of market power. If market power is a leading driver of excessive pricing in the Norwegian pharmaceutical market, it may be cause for increased regulation and intervention. Therefore, this master thesis is an attempt to answer the following question:

What are the drivers leading to excessive pricing in the Norwegian pharmaceutical market?

Initially, competition theory with a focus on perfectly competitive markets and markets with Bertrand competition was presented broadly, which gives an understanding of the behavior we might expect from economic theory. This is followed by an introduction to the Herfindahl-Hirschman Index which measures how concentrated a market is on a scale from 0-10,000.

The pharmaceutical industry is characterized by many factors that distinguishes it from other markets and prevents market mechanisms from functioning as expected according to economic theory. The demand side is characterized by price insensitive customers with a relatively high willingness to pay, and the phenomenon where the consumer, payer and decision maker are separated roles, potentially with conflicting interests and incentives. The supply side is characterized by patents to compensate for a high R&D intensity where the development process is long, expensive and risky. In Norway, maximum price regulations are used to protect consumers in a market with high entry barriers and dominant firms. These characteristics induce a need for a closer study of the industry to examine whether consumers may be abused by firms with market power.

Studies were performed based on a dataset of 2,857 drugs where one or more of the drugs in a given market have had an increase in maximum AIP of at least 50% from 2010-2020. It includes information such as the drugs' maximum prices, actual prices and sales volumes.

Several trend analyses were conducted to study the development in the number of packages sold, the DDD market share, HHI and actual AUP before and after the price increase. The cases were also split by whether they experience falling demand or falling competition before the price increase. The findings were many and ambiguous, but they strengthened our three hypotheses; there are indications that both market power and shortages seem to be drivers leading to price increases, in addition to cases where falling demand seems to be the cause.

A logistic regression model was applied to examine whether the drivers seem to be statistically significant for excessive pricing. The model estimated how the probability of a price increase for a given drug in a given period was affected by sales volume, market share, HHI, players in the market and whether a competitor had a higher maximum price. The hypothesis that price increases are driven by falling demand was rejected, since the effect was not significant at a 25% level. Market power seems to be a significant driver, where a higher HHI increases the probability of a price increase, with a strongly significant effect.

Further analyses were performed to study whether market power also seems to influence the size of a price increase, not just the probability of its occurrence. The findings show that there is a statistically significant difference in the median increase, which is 52% for monopolies and 43% in markets with competition. The findings also show a positive relationship between HHI and the size of the price increases.

Five case studies were conducted to understand the process behind some of the price increases better. Pharmaceutical A and B had price increases initiated by SLV, and the new prices were based on reference prices from the same drugs in other countries. We do however question whether this practice may be abused if the producer strategically enters the Norwegian market first, in which case there will be no reference prices available. Additionally, we suggest adding a qualitative aspect to the practice that assesses whether the reference prices are representative or if they may be driven by local conditions that are not relevant in Norway.

Pharmaceutical C, D and E belonged to monopolists that threatened to remove the drugs from the market if the price was not increased. The price of pharmaceutical C was therefore increased by 1,154% in total over three years. We question why producer C obtained the price it asked for with no link to the requested pricing information about the original preparation and without presenting requested information about production costs. The monopolist of pharmaceutical D and E, on the other hand, did provide cost calculations. However, it seems

suspicious that the producer applied for the price increases two months after becoming a monopolist. It is also interesting that the firm requests an exemption from the reference pricing practice. The arguments, that its prices must be increased in the reference countries as well, and that prices should be equal across Europe to protect patients in low-price countries from parallel export, would make the reference pricing practice a paradox in itself.

A difference-in-differences approach estimated an accumulated increase in pharmaceutical expenditures caused by price increases of 257 million NOK for the first year after the price increase. This may be a significant increase for some already vulnerable patients, and the share covered by the government and ultimately taxpayers is money that could have been spent differently.

The question of whether intervention against excessive pricing is appropriate is a question of finding the balance between committing type I errors, intervening when the price is actually correct or the market would have corrected it itself, and type II errors, failing to intervene when the price is actually excessive. If government intervention causes producers to remove their pharmaceuticals from the market or reduces firms' incentives to invest in R&D to develop new drugs, this unavailability will reduce the patients' wealth, life quality and potentially life expectancy. However, although type I errors may be more expensive individually, we argue that the accumulated cost of committing them is lower compared to type II errors given the low probability of committing them. The reasons are that producers should already have recouped their investment costs during the IP protection period, and that many markets are dominated by generic producers who do not have such high R&D costs to recoup. We argue that the process for increasing maximum prices should be stricter and that the reference price practice should be supplemented by a qualitative evaluation to assess whether the reference prices are suitable for comparison. This would increase the time and money spent on assessing price increases, so an analysis of the trade-offs would be necessary. Additionally, facilitating competition by reducing entry barriers, e.g., through international cooperation, could reduce prices without regulating them directly.

Some topics are left for further research. Our approach to calculating the total cost for the Norwegian society from excessive pricing of pharmaceuticals was rather simple and could be done much more comprehensively. We also suggest that future research may explore what factors affect the size of the prices increases by using econometric models. Finally, to better

understand the relative probability of committing a type I and type II error, research could be done based on a combination of our dataset and data on rejected applications. Such research could also analyze the firms' response to a rejected application, in order to see how credible their threats of exiting the market are.

We hope this master thesis provides valuable insight into the drivers of excessive pricing in the Norwegian pharmaceutical industry and that it may contribute to prevent exploitation of vulnerable patients. After all, their life is at stake.

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Appendix: Supplementary tables

Variable	Coefficient	St. Dev.	P-value	Sign.
Change in packages	0.0002	0.0003	0.3520	
Change in competitors	-0.9596	0.4200	0.0223	*
Change in market share	0.0001	0.0007	0.8401	
Change in HHI	-0.1433	0.0090	0.1136	
log2 (Market share)	0.0188	0.0503	0.7092	
log2 (HHI)	2.0119	0.4389	0.0000	***
Players in market	0.1788	0.1852	0.3343	
Not highest AIP	1.0780	0.4500	0.0166	*

Significance codes: 0.001 '***', 0.01 '**', 0.05 '*', 0.1 '.'

Appendix table 1: Logit with trends up until six to four months before increase

Variable	Coefficient	St. Dev.	P-value	Sign.
Change in packages	0.0001	0.0001	0.2560	
Change in competitors	0.0509	0.3149	0.1059	
Change in market share	-0.0000	0.0000	0.6336	
Change in HHI	-0.0076	0.0073	0.2987	
log2 (Market share)	-0.0068	0.0478	0.8868	
log2 (HHI)	2.5730	0.5424	0.0000	***
Players in market	0.2636	0.2068	0.2025	
Not highest AIP	1.0860	0.4524	0.0164	*

Significance codes: 0.001 '***', 0.01 '**', 0.05 '*', 0.1 '.'

Appendix table 2: Logit with trends starting two years before increase

Variable	Coefficient	St. Dev.	P-value	Sign.
After Dummy	8,574.4	3,792.2	0.0238	*
Treatment Dummy	-19,778.5	4,846.8	0.0000	***
Diff-in-Diff Dummy	-12,610.5	8,954.6	0.1591	

Significance codes: 0.001 '***', 0.01 '**', 0.05 '*', 0.1 '.'

Appendix table 3: Placebo test DD regression