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The interaction effect of price-cap regulation and competition on price: an Indian case study.

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Abstract

Using data on the Indian pharmaceutical market, the effects of competition, regulation and the interaction effect of competition and regulation was investigated. The used data included data on prices, sales, and therapeutic purposes of multiple medicine sold in India. Submarkets were defined through therapeutic purposes and drug type to determine relative prices. The regression analyses show that high concentrated markets – nearing perfect competition – on average have a higher normalized price. This indicates that in these markets the price dispersion is high, this is especially the case in unregulated markets. Furthermore, regulation interacting with higher competition results in higher relative prices. This might be evidence that regulation hinders dynamic competition, but these results must be interpreted with care. As evidence also points to the possibility of regulation not being exogenous, and competition being related with higher normalized prices. The results provide evidence that regulation is associated with higher relative prices, this can be seen as evidence of price collusion or further supporting the claim that regulation is not exogenous.

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1. Introduction

In an effort to control ever rising healthcare expenditures, governments more often use direct or indirect price control regulations to lower medicine prices. Through these regulations they hope to lower their healthcare expenditure. Medicine expenses are for decision-makers an easy target to lower healthcare expenditures. Firstly, this is because they are directly cost-saving and not as politically sensitive as other cuts to healthcare (Mrazek, 2002). Secondly, the social debate on the profitability of healthcare conglomerates has further shifted the public opinion into the view that medicine prices should be regulated. Furthermore, low- and middle-income countries try to improve the availability of essential drugs using direct price controls.

Theoretical advantages of price-cap regulation over cost-based regulations are presented in the literature. But less attention is being payed to the combined effect of regulation and other factors, such as competition, on price. The focus of research was more on the impact of price regulation on the further development of new medicine and the intensity of research and development (Vernon, 2005). The interaction effect of regulation and competition on medicine prices is not as much researched, which is a shame due to the importance of this effect in measuring the opportunity cost of a policy. Researching this effect gives policy makers a more complete view on the indirect effect of regulation on price. This is especially crucial in a market such as the pharmaceutical -market due to its high investments in R&D and its heavy reliance on competition to maintain reasonable and social welfare optimal prices.

The pharmaceutical market is a difficult market to comprehend, a lot of different motives are at stake. And decision makers are often not the cost payers, which is the case in most regular markets. Puig-Junoy (2010) suggest other measures then price regulation to be taken. Her main argument which will be elaborated on further in section 2, is that price regulation, and price cap-regulation in specific, hinders generic dynamic price competition. Through this effect the price regulation results in a levelling of at a higher price than would occur in regulation. His results are based on a literature review of 16 different papers. Interesting to see is wether these finding hold in the case of India.

The main aim of this research will be to answer the following question: *What is the interaction effect of competition and regulation on the market retail price of medicine in India?* The expected answer of this question provided by the applicable theory is that, regulation can be seen as

a hinder to dynamic price competition, such as argued by Puig-Junoy (2010). Implying that the interaction effect of regulation and competition will be negative.

This research will try to bring a contribution to the understanding of the effects of regulation and competition. Trying to integrate the existing theoretical ideas of the effects of competition and regulation on price. Furthermore, this paper will try to shed a light on the possible reasons why competition and regulation interact in their specific manner.

To achieve this ambitious target. Firstly, I will discuss the theoretical framework in section 2. Theoretical Framework, giving a broad explanation of the existing theory. Secondly, in section 3. Data and Methodology the used data and methodology will be explained. Thirdly, the results of the research will be discussed, and limitations will be set in section 4. Results. Further discussion of the results and the conclusion will be formed in section 5. Discussion and conclusion. And the last section of this paper section 6. References will contain the references of the used literature.

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2. Theoretical Framework

2.1 Price-cap regulation in general.

Price regulation is one of many legislative actions a legislator can use to intervene in the marketplace, price regulation is often chosen by regulators to try and improve the public welfare. Public welfare is tried to be served by lowering the market prices and therefore to lower healthcare expenditure. The general idea of regulation trying to improve public welfare stems back to the ideas of Arthur Pigou in the early 19th century, his argumentation stated that an unregulated market leads to curtain market failures. These market failures entailed mainly market power problems such as monopoly power of a monopolistic firm. Pigou came to the conclusion that regulation may be necessary to ensure an efficient outcome. And that therefore legislators have to attempt to overcome these market failures to ensure public interest. Critical notes from later economists mainly focus on the question whether these price regulations actually improve public interest.

There are different forms of price regulation, the two most popular regulation methods are price-caps and rate-of-return regulation. Price-cap regulation has in the literature been presented as the better alternative of the two. The main argument supporting this claim is that firms operating under a rate-of-return price regulation have no direct incentive to lower their cost. Their profits are directly positively related to their cost, which leaves us with the paradox that higher costs are associated with higher profits. This results often in inefficiency. Under price-cap regulation there remains an incentive for firms to keep producing productively. There is even room for firms to compete on price in the market if it's lower than the capped price. The added benefit of this efficient producing is shared with the customer through the lower price due to the regulation (Averch & Johnson, 1962). But the main problem of price-cap regulation is that firms may pull out of a market if the regulated price is too low, or not even enter the market at all. Furthermore, a benefit of price cap regulation over rate of return regulation are the lower administrative costs accrued under price cap regulation compared to rate of return regulation. Prices are not subject to expensive commission reviews under price cap regulation, as is with rate of return regulation (Cabral & Riordan, 1989). An applied example of this theory is brought forward in the same study by Cabral & Riodan (1989) who find that AT&T prices across different states in the United States are on average between 7 and 10 percent lower in states applying a price cap regulation compared to rate of return regulation.

Next to the incentives improvement of the price-cap regulation over the rate of return regulation, there is also evidence that price-cap regulation leads to allocative efficiency. Bradley and Price (1988) found evidence for the argument that under the assumption of profit maximization,

firms operating under a price constraint through regulation will move over time to a price fitting the Ramsey Structure. Concluding that price-cap regulation over rate-of-return regulation not only promotes efficient production, but also efficient pricing.

Not only the actual implementation of price regulation has influence on the price, but also the perceived probability of the firms that such price regulation is introduced. For example, firms may lower their prices to prevent actual implementation of regulation at all (Glazer & McMillan, 1992). The literature suggests that price regulation in general is effective if there are market failures, but legislators always must incorporate the firm's perspective in their decision-making process to ensure an efficient outcome. And firms are still competing in markets rather than pulling out.

2.2 Effect of price regulation on price and availability in the pharmaceutical market.

Pharmaceutical markets are known for their specific characteristics. For example, their price inelastic demand, in combination with a high degree of supply-sided market power due to the patenting system and often costs being paid by insurance companies. These specific characteristics bring along that application of research from pharmaceutical markets in other markets may result in problems. But this supply sided market power often leads regulators into intervening in this market which also makes it necessary to research to ensure these policies are effective (Contoyannis, Hurley, Grootendorst, Jeon, & Tamblyn, 2005).

Regarding the pharmaceutical market, the literature does not give a definite answer to what the relationship is of price-cap regulation and price. In the short-term is seems logical that a price would go down with price regulation, otherwise there would be no incentive for the regulator to introduce a price-cap regulation, and firms are only allowed to set their price beneath the regulated price. But the question remains what happens to the price in the long run. A meta-analyses was done on the impact of price capping and regulation on the reimbursement rate on the price dynamics, this research showed evidence indicating that price-cap regulation leads to a higher price of generic medicine than would be present in the absence of this regulation (Puig-Junoy, 2010). But the literature is not one sided, there is contradicting evidence that although initially hurt, after seven-year consumers benefit as the unregulated price rises above the price-cap level. Concluding that the benefit to society is not from price-capping the already existing products but more the future products Essential in this research is the conclusion that pharmaceutical firms would optimally set launch prices 50% higher. Lastly the researchers identify a policy implementation problem, namely the dynamic distortion caused by the major differences in growth rates of the individual medicine

products. Together with the challenge of new formulas, new doses and new delivery systems to the enforcement of the price regulation (Abbott A. , 1995).

Next to the effect on price, there is also an effect on availability if price regulation is introduced. This effect has two sides firstly, the effect on the delay of the introduction of the regulated medicine, and secondly if research and development of future drugs is influenced by the price regulation. Regarding the effect of delay of the introduction of the regulated medicine firms may be afraid to immediately introduce a product in a price regulated market, due to parallel trade and external price referencing of consumers (Danzon, Wang, & Wang, 2005). The research and development expenditure of a firm is also expected to go down when it faces price regulation. There are two mechanisms which hinder the R&D expenditure. Firstly, the expected profit of the firm goes down when price regulation is introduced, and secondly there arises a cash-flow problem. This research also simulated a price regulation comparable to other non-US markets and found a reduction in R&D investment intensity in between 23% and 32% (Vernon, 2005). But important to realize that the effect on social welfare is not measured.

The trade-off between price and availability was best shown in a research considering the United States, by R.E. Santerre and J.A. Vernon (2006). This research showed that the price control regulation in the United States had resulted in a total consumer surplus gain of $472, but at the same time 198 different drugs were not introduced due to these same regulations. Other research suggests that the social benefit of these 198 not released drugs war outweigh this consumer surplus gain of the price regulation. Regarding the pharmaceutical firms their profit, research comparing 19 countries. Adopting new price regulation has been found to greatly reduce their profitability. Especially if the market before was largely unregulated, furthermore concluding that if price controlling policy remains active for a longer period, this stimulates the cost-reducing effect (Sood, de Vries, Gutierrez, Lakdawalla, & Goldman, 2009).

2.3 The effect of competition on price in the pharmaceutical market

The general idea is that competition lowers price, more competition suggests that firms have more incentive to invest in investments which lower the production costs, and due to the wider choice consumers often choose for the cheaper versions of comparable products.

Lexchin (2004) compared prices of brand-named drugs which acquired generic competition to those who lack generic competition and found that those who acquired generic competition did not lower the prices of the brand-named drugs. Even suggesting that the prices of brand-named medicine may even rise, to capture the higher segment of the market. A possible explanation is the

high brand-loyalty of consumers and the low price-elastic demand of consumers, who often do not pay the costs of these medicine. The brand loyalty of physicians may play a role in this (Grabowski, & Vernon, 1992).

2.4 The effect of price-cap regulation on competition.

Important to this research is the question what the interaction effect is of competition and price regulation on price. To get a total view on this effect it is also important to realize that regulation influences competition. Firms decide to enter based on a variety of elements, and price regulation certainly is one of them. A case study on the Norwegian implementation of a yardstick-based price cap regulation on generic medicine found that the price regulation succeeded into triggering a price competition. This research exposed that regulation is also indirectly aimed to lower the entry barriers for new competitors, which increased competition and reduced overall market power. They justify this counter-intuitive claim by arguing that without the price regulation, the 'branded' generic will apply a high pricing strategy which is able to maintain mainly through loyalty from physicians who do not have an economic incentive in picking a medicine for their patient
(Dalen, Strøm, & Haabeth, 2006). But on the other hand, the previously mentioned research by Puig-Junoy (2010) suggests the opposite, stating that regulation instead creates a barrier for dynamic competition. Creating a market with market failures and consumers not getting all the benefits possible. Again, the literature does not give a decisive answer to the question what price regulation does with competition, which makes this research only more interesting to receive a complete image on the interaction between regulation and competition.

Furthermore, price regulation can also be used by companies as a reference price. Research suggest that the price regulation imposed in Canada on generic medicine failed to lower the cost of generic drug prices. And came to the conclusion that the pharmaceutical market is in itself already competitive enough, and that price regulation in profitable markets only leads to firms' pricing at the regulated price (Anis, Guh, & Woolcott, 2003). Further research on the same policy implementation found that the spread of prices, so the difference between the highest and the lowest price, is smaller when competition and consequently the number of producers is high (Lexchin, 1993). In the case of India this spread is expected to even be higher due to it being a developing country. According to Wang (2006) a unique feature of pharmaceutical markets in developing countries is that they entail both high-quality global products and low-quality local product (Wang, 2006).

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Furthermore, regarding the relationship between regulation and competition. Danzon and Chao (2000) looked at product-level data of drug sales in seven countries. And stated that there is more competition in pharmaceutical markets which are less regulated. Meaning the stricter regulation there is imposed, the less price competition there is. Secondly arguing that imposing regulation higher the price of future medicine and lowers the R&D expenditure of firms active in the pharmaceutical market. Secondary research has further fueled the idea that market and price competition is stronger in less-regulated markets, also pointing to the questionable effect of regulation on price through diminishing generic competition (Simoens, 2012).

Opposing competition there is collusion, research has shown that firms try to evade price-cap regulation by colluding in the period prior to the introduction of the price regulation. There are many forms of collusion, the type focused on in this research was price fixing. Firms were able to collude because of the transparent process of implementing price control, and the time firms have before the price control is introduced. Firms coordinate their pricing strategies in the period before the regulation to ensure a higher price-cap price. This effect drastically undermines the effect of price regulation on price (Bhaskarabhatla, Chatterjee, Anurag, & Pennings, 2016).

2.5 Research Hypothesis

Especially Lexchin and Puig-Junoy bring forward compelling arguments supporting the claim that competition may be hindered by regulation. Computing from the previously discussed literature regarding competition under regulation is the following: I expect there to be a positive interaction effect between regulation and competition on the price. Meaning that the expected negative effect of competition on price is lowered in the cases were regulation is involved. And that the interaction effect of competition and regulation on price will be positive. The two main argument supporting this hypothesis are: Firstly, that regulation creates a barrier for dynamic price competition, such as argued by Puig-Junoy (2010). Secondly, collusion occurring in the market in the period prior to introduction of the price regulation also may hinder price competition in the period after price regulation (Bhaskarabhatla, Chatterjee, Anurag, & Pennings, 2016). Firm with an unspoken agreement to up the price in the phase before regulation, also might agree to not compete as hard on price after regulation. Part of this argument is based on the fact that firm have already colluded in some way, which make all parties more trustworthy.

General economic theory suggests that the variables competition and price regulation both should have a negative effect on the price. My hypothesis regarding these variables

follows the general economic theory: both competition and regulation as separate variables will have a negative effect on the price. Building on the argument provided by Lexchin (2006) that competition makes for a lower spread in prices. I suspect that markets may splinter due to price regulation, that due to the lack of competition due to the price regulation branded medicine will not indulge in price competition.

Furthermore, it is also possible that the results of this research will imply an opposing effect then the effect suggested above. This would be the case if the interaction effect was negative, implying that the expected negative effect of competition is even more negative in cases were regulation is set. A possible argument supporting this side is that a market is shocked up by a regulation, meaning that more companies actively seek to compete on price.

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3. Data and Methodology

3.1 Data

The All India Organization of Chemists and Druggists (the AIOCD), a powerful retail trade organization provided the data this research is based upon. Which contains monthly product-level data on the Indian pharmaceutical market from the period January 2011 until July 2016, and is therefore regarded as highly accurate. The dataset contains data on medicine prices, sales volumes, and therapeutic code to identify the therapeutic purpose of the drug, drug type and total number of pills/capsules in the pack. The price in the dataset is the price the retailer pays to the producer, using the price to retailer removes any influence on the side of the pharmacy to the price. India is a good sample to research the effect of medicine price regulation due to its size, and its recent introduction op price-cap regulation on pharmaceutical prices.

The National Pharmaceutical Price Authority (NPPA) is the agency concerned with price regulation on the Indian pharmaceutical market. This agency switched from a cost-based price regulation to a price-cap regulation in 2013. In this research for the regulated medicine I will only look at medicine that fall under the 2013 or 2015 regulations. In 2013 the NPA introduced two policy changes through the publication of "Compendium of Ceiling Prices of Essential Medicines" based on the provision of Drug Price Control Order (DPCO). Firstly, it applied price regulation on curtain formulations of specific medicine, secondly a market-based approach was used to determine a ceiling price. This market based approach means the following for deciding the ceiling price: "Under the market-based approach, the ceiling price of a scheduled drug is determined by first working out the simple average of price to retailer (PTR) in respect of all branded-generic and generic versions of that particular drug formulation having a market share of 1 percent and above, and then adding a notional retailer margin of 16 percent to it. The maximum retail price (MRP) for that particular drug formulation must not exceed the notified ceiling price plus applicable local taxes (NPPA, 2015)."

Due to the multiple moments of regulation introduction, this paper chose to focus only on the most important introduction. The introduction of the DPCO 2013 was the fist major introduction of price regulation after the 1995 DPCO introduction, and due to there being good data available on this 2013 DPCO introduction, this introduction will be highlighted. Meaning that data from the introduction of the DPCO 2015 will not be used. This results in the elimination of data with a value for *month* higher or equal then 52 (this corresponds to the 1st of April 2015, the moment the DPCO 2015 became active).

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Firstly, the data set is a multi-panel dataset which contains multiple variables for over a period of 51 months. This time variable is captured in the variable *month* which is 1 at January 2011, and 51 at March 2015. Secondly, the dataset contains data on medicine with different delivery techniques. These delivery techniques come with different dosage units and have different production costs. Due to the problem with comparing these different delivery methods, this research will only focus on capsules and tablets. These two delivery types are the most comparable, and the working formulation are in the same dosage units (namely milligrams) and have similar production costs. A justification for this data selection is a directive from the European union, namely European Union Directive 2004/27/EC. This directive states that tablets and capsules may be considered interchangeable. Next to the difference in delivery methods medicine still differ greatly from each other, and to throw them all on one big pile would be a failure in understanding these differences. The division of submarket I made was twofold: firstly, I divided based upon the therapeutic purpose of the medicine, and secondly, these therapeutic were divided per drug type. This division is justified by the idea that most products in these submarkets are actual competitors. So, for example a subgroup is "Azithromycin", an antibiotic often used to treat infections such as chlamydia (Gupta, et al. 1997). This submarket is the largest submarket with entails in total around 5.41 percent of the data entries, and 295 firm operating in this submarket. So, this subgroup was split into two submarkets, "Azithromycin - Tablet" and "Azithromycin – Capsule", as shown in table 2. In total 288 submarkets were created. After the exclusion still 369.049 data entries remained, see table 1. Each of these submarkets is given a unique number in the variable *submarkid* this is later used to check for fixed submarket specific effects.

Due to the use of the difference-in-difference methodology and the desire to research the effect of regulation. Only submarkets were chosen which at least had 1 product in them which had the value of *r_ever* of 1, around 45% of the products in the data set encounter regulation. This can be observed in table 4.

Table 1: Summary statostocs drug type.

Drug type	Frequency	Percent	Cum.
Capsule	34.722	9,41	9,41
Tablet	334.327	90,59	100
Total	**369.049**	**100,00**	**100,00**

Source: AIOCD data.

Table 2: Example subgroup and submarkets.

Subgroup	Capsule	Tablet	Total
Azithromucin | J1F1	277	19.867	20.144
Total	**277**	**19.867**	**20.144**

Source: AIOCD data.

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Moreover, the dataset contained a variety of different dosage strengths ranging from micrograms to kilograms to IU. To make a fair comparison I only looked at medicine which strength were defined in MG which was over 97% of the sample, as shown in table 3. Moreover, to compare the different dosage strengths within this measurement unit I used a standardization method to transform the *ptr_price* (price which the retailer pays to the producer) to a price per milligram of active substance. Formula 1 was used for this standardization. The result was captured by the variable *norm_p* for each month t, each submarket j. This standardization method was used because this made the comparison between the prices of medicine in different submarkets available. The use of this system of normalized prices of submarkets has its limitations, which will be discussed in section 4.3.

Furthermore, entries were excluded containing combination of medicine. The reasoning behind this data exclusion was that the attribution of the price to the amount of active substance which was problematic with combinations of substances. Also, medicine which were not formally registered as combinations, but whose strength variable possessed a value such as: “200/20 MG” were all left out. There was no certainty to say which strength was the right one, and for that reason they were left out. Still 369049 entries remained in the dataset.

$$Equation\ (1):\ norm\_p_{j,t} = \frac{ptr\_price_{i,t}}{Dosage\ strenth\ \times\ number\ of\ capsulles\ or\ tablets\ in\ pack}$$

$$Equation\ (2):\ relative\_p = \frac{norm\_p_{j,t}}{weighted\ average\ norm\_p_{j,t}\ in\ submarket\ j,\ \ at\ period\ t}$$

As said before, to analyze the interaction effect of competition under price regulation, it is essential to assess the differences between regulated and unregulated medicine. To do so we created a dummy variable *regulation* to shows if a product is ever subjected to price regulation. This variable is equal to 0 if it is not subject to price regulation and holds the value of 1 if the product is in one period of time price regulated by the provision instated by the DPCO.

To determine the degree of competition, the Herfindahl-Hirschman index was calculated for each individual market. This index measures the concentration in a market and is often used to determine the level of competitiveness in a market. This index ranges from 0 to 1, with 0 meaning a lot of small producers, and 1 identifying a monopolist (Rhoades, 1993). The calculation of this index started with using the sales volumes of each individual product to calculate the total sales volumes of each submarket. This total sales volume per submarket was used to determine the market share of each medicine i per submarket j per month t. The Herfindahl-Hirschman index captured in the variable *HH_index* is simply the sum of all squared market shares of each subgroup j. Graph 1 shows

the distribution of the HH_index, this shows that there are a lot of markets with a low concentration, meaning that in those markets competition is expected to be high. Notable in graph 1, and table 4 is that the distribution of the Herfindahl-Hirschman index is quite even, even though it looks like there are a lot of competitive markets. The nature of the Herfindahl-Hirschman index brings along that it quickly goes down. A second indicator for competition is the variable *nfirm_m* which gives the number of firms operating in the same submarket. In the dataset the value of this variable is between 2 and 295, meaning that in the market with the greatest number of firms there are 295 firms present.

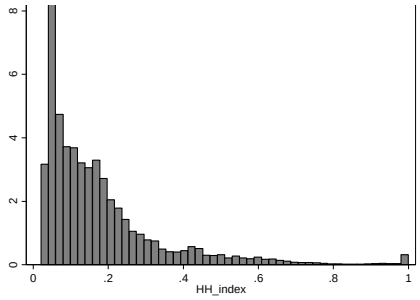
Lastly, the variable *submarkid* is a categorical variable which is used to identify to which submarket the data entry belongs, there is a unique code for each j submarket. The same is the case for the variable *firmid* which gives a unique value for each firm k, and is also categorical. More descriptive statistics on the used variables can be found Table 4.

Table 3: Strength unit distribution

Strength_Unit	Frequency	Percentage	Cum. Percentage
GM	40	0,01	0,01
IU	3955	1,06	1,06
MC	4703	1,25	1,31
MD	106	0,02	2,33
MG	369.049	97,67	100,00
Total	**377.853**	**26.097**	**26.457**

Source: AIOCD data.

Graph 1: distribution of HH_Index



Source: AIOCD data.

Table 4: descriptive statistics different variables.

Variable	Observations	Mean	Std. Deviation	Min.	Max.
R_ever	369.049	0,4508859	0,4975826	0	1
Npack	369.049	13,22952	49,15461	1	1200
Salesunits	369.049	46.485,58	338080,3	1	4.84e+07
Salesvalue	369.049	1.208.687	4.720.738	2	1.39e+08
nfirm_m	369.049	108,4401	87,97118	2	295
markteshare	369.049	0,0339774	0,1203496	6.98e-09	1
HH_Index	369.049	0,1760228	0,1605515	0.0007387	1
p_mg	369.049	1.104996	10,58195	1,54e-06	576.96
weigthed_pmg	369.049	0,0446351	1,277605	8,85e-19	95

Source: AIOCD data.

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3.2 Methods

To research the hypothesis that the interaction effect of price regulation and competition on price is negative, I will use a difference in difference regression method. Which is often used to evaluate healthcare policies. This method is useful to estimate the effects on relative prices between regulated and unregulated medicine. Difference in difference analysis is used to compare outcomes prior and after a policy introduction and looks at two groups. First of all the intervention group, this group is affected by the policy. And secondly, at the control group, this group is not affected by the policy. This method is chosen due to its structure being a quasi-experiment which in retrospect can be used to create an experiment like situation with a control and intervention group (McKinnon, Harper, Kaufman, & Bergevin, 2014).

The difference in difference methodology implies a three-way interaction effect. Firstly, a variable *regulation* will be used to determine whether the data entry is in the treatment group or not, this variable will hold the value of 1 in case it is in the treatment group and will hold 0 if it is in the control group. Secondly, a variable *treatment_moment* indicates whether the data is before or after the treatment took place, this is independent whether the data entry is in the treatment group or not. So all data after the 1st of June 2013 the variable *treatment_moment* will contain the value 1, and all the data from before this date will be 0. Lastly a variable for the Herfindahl-Hirschman index will be used, this variable will be introduced further below.

A limitation of the difference in difference method is that it depends on the assumption that the prices of the regulated medicine would have followed the same trend as the unregulated medicine if they would not have been regulated. The problem concerning this limitation lays in the fact that there is not an even comparison between two perfect homogeneous products. The group of regulated medicine is not the same group as the unregulated medicine. Due to the dataset being a collection of medicine, the medicine-specific effects are somewhat mitigated. And therefore, the results can still be useful to give insight into what effects have influence on price of medicine.

Using a linear regression, the difference in difference effect will be captured in the three-way interaction effect. An ordinary least square regression will be used to determine the effect of the interaction effect. I chose for an ordinary least square regression because under certain assumptions will the regression will result in a minimum variance mean-unbiased estimation. *rel_p* is the independent variable in this regression. Furthermore, when the distribution of the variable *rel_p* is

observed, there are some outlier variables visible. As seen in table 5, the highest 1% quantile start at a *rel_p* value of 53,20, these values can be considered outliers since they do not directly compete with the average product in the market. A *rel_p* value of 53 means that this product i in period t is 53 times as expensive as the average in submarket j. This spread may also be an indication that the markets are not properly defined.

The distribution and the different quantiles of the variable *rel_p* is displayed in table 5, important to note is that more than 95% of the distribution has a price which is higher than the average price in the market. From this distribution we can assume that a lot of small firms operate with a high pricing strategy, maybe only focusing on niche markets. But this distribution also enlightens us on a

potential problem, because how can one argue that a product 53 times the average price in the market is a real competitor in the same market. A limitation of this research is brought to light by this distribution, but this will be further discussed in the appropriate section. Important to note for the remaining research is that to limit the bias effect of these outliers, especially those in the highest 1 percent percentile, we chose to exclude the highest 1 percent of the results in our regression. So, any entry with a *norm-p* value of above 53.20352 was dropped. Only 1 percent of the observations was deleted, in total 4880 observations were deleted. Furthermore, an alternative regression was added as a robustness check, this robustness check will be further elaborated on in section 3.3.

Table 5: dispertion norm_p

Percentiles	*Norm_p*
1%	0.379859
5%	1.052478
10%	1.618632
25%	3.103472
50%	6.424036
75%	12.6583
95%	26.21768
99%	53.20352

Source: AIOCD data.

As shown in equation 3, the independent variable is *rel_p* (relative price) in month t, of medicine i, in submarket j and from firm k. This price will be estimated using the following independent variables. First of all, a dummy variable for price regulation, a competition variable, an interaction variable for competition and regulation and a time variable. The interaction variable using the difference in difference method will capture the interaction effect of competition and regulation.

$$Equation\ (3): rel\_p_{t,i,j,k} = \alpha + \beta_1 * HH\ \ Index_{i,j,t} + \beta_2 * regulation_{i,t} + \beta_3 * treatment\_moment + \beta_4 * HH_{Index_{i,j,t}} * regulation_i * treatment\_moment + \beta_4 * HH_{Index_{i,j,t}} * regulation_i + \beta_5 * HH_{Index_{i,j,t}} * treatment_{moment_t} + \beta_6 regulation_i * treatment\_moment + \beta_7\ firmid_{k,t} + \beta_8 * submarkid_{i,t} + \varepsilon$$

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The variable *firmid* captures the firm specific time irrelevant effect the firms have on the price. Branding of medicine is an important aspect in the pharmaceutical industry, these effects must be adjusted for. Physicians who prescribe these medicines may be loyal to brands, because they lack the economic incentive to switch (Dalen, Strøm, & Haabeth, 2006). The same holds for the submarket specific effects, which are accounted for by the variable *submarkid*. To justify the use of the categorical variables *firmid* and *submarkid* it is important that both variables have a grouped significance. With both regressions functions a joint significant F-test was preformed to check whether the parameters were pooled significant. The results of these test are reported in section 4.1 Results.

Important to realize is the nature of the Herfindahl-Hirschman index, which is the sum of the squares of the market shares. The index may be low for markets where a lot of competitors have a small market share. This skewedness may affect the results of the regression. Therefore, a second regression was completed to evaluate the effect with another indicator of competition, namely the variable *market share*. This variable simply showed the market share of product i in submarket j in period t.

3.3 Robustness checks

Firstly, to check for the robustness of the model concerning the use of the weighted relative price a second regression analyses will be used. This regression uses the median price in the submarket to determine the relative price. The difference in the method of calculating made it so that the bias created by a lot of small firms operating with a small market share with a high pricing strategy have a bigger influence on the relative price. Equation 4 and 5 were used to determine the independent variable of this new regression: *nw_rel_p,* which is not a weighted normalized relative price. This difference can be observed in equation 5, which just looks at the median price of all firms in the submarket, without using a form of market share to give weight to different prices. The main purpose of this robustness check will be to check if the directions and significance levels of all the variables remain the same as in the main regression analyses performed on equation 3. Equation 6 will be used to run the regression

$$Equation\ (4):\ nw\_norm\_p_{j,t} = \frac{ptr\_price_{i,t}}{Dosage\ strenth\ \times\ number\ of\ capsulles\ or\ tablets\ in\ pack}$$

$$Equation\ (5):\ nw\_rel\_p = \frac{nw\_norm\_p}{median\ nw\_norm\_p\ in\ submaket}$$

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$$Equation\ (6): nw\_rel\_p_{t,i,j,k} =$$
$$\alpha + \beta_1 * HH\ \ Index_{i,j,t} + \beta_2 * regulation_{\ i,t} + \beta_3 * treatment\_moment + \beta_4 * HH_{Index_{i,j,t}} *$$
$$regulation_{\ i} * treatment\_moment + \beta_4 * HH_{Index_{i,j,t}} * regulation_{\ i} + \beta_5 * HH_{Index_{i,j,t}} *$$
$$treatment_{moment_t} + \beta_6 regulation_{\ i} * treatment\_moment + \beta_7\ firmid_{\ k,t} + \beta_8 * submarkid_{i,t} + \varepsilon$$

Secondly, as mentioned in section data due to the nature of the Herfindahl-Hirschman, we also decided to use a different indicator for competition. Namely the variable *nfirm* which is a contiguous variable indicating the number of firms active in the specific submarket j. Equation 7 is the equation used for this regression analyses. Again, the same regression analyses as in equation 3 is preformed, and the differences between the two outputs will be investigated. This regression does know the data exclusion of the top 1 percentile, for the same reason as mentioned in the section methods.

$$Equation\ (7): rel\_p_{t,i,j,k} = \alpha + \beta_1 * nfirm_{j,t} + \beta_2 * regulation_{\ i,t} + \beta_3 * treatment\_moment +$$
$$\beta_4 * nfirm_{j,t} * regulation_{\ i} * treatment\_moment + \beta_4 * nfirm_{j,t} * regulation_{\ i} + \beta_5 * nfirm_{j,t} *$$
$$treatment_{moment_t} + \beta_6 regulation_{\ i} * treatment\_moment + \beta_7\ firmid_{\ k,t} + \beta_8 * submarkid_{i,t} + \varepsilon$$

`

4. Results

4.1 Results main regression analyses

The regression output of equation 3 can be viewed in table 6, the regression shows us some interesting and unexpected results. Using 369049 observations the main results show a negative and significant interaction effect of regulation and the Herfindahl-Hirschman index (β_4) on price. Furthermore, the variable Herfindahl-Hirschman index on itself is significant and negative, and the dummy variables regulation and *treatment_moment* are both significant and positive. The result of the T-test on the grouped significance of both the firm specific and submarket specific effect resulted in a significant result. These results and the appropriate interpretation will be discussed in greater detail below.

Regarding the negative and significant interaction effect between the dummy variables *treatment_moment, regulation* and the Herfindahl-Hirschman index. This indicates that a higher Herfindahl-Hirschman in combination with regulation results in a higher relative price. The Herfindahl-Hirschman of course is higher when a market is less concentrated, which is an indication of a lower level of competition. So, a lower level of competition in combination with the treatment effect of regulation results in a lower relative price. This interaction effect is significant at the 1% level. Therefore, the results of the interaction effect should be interpreted as follows: this regression analyses states that more competition in a submarket in combination with a regulated product results in a higher normalized price.

The most remarkable outcome of the regression output is the coefficient of the variable *HH_index*, this variable gives the value of the Herfindahl-Hirschman index. The coefficient with a value of around -10.9291, which is significant at the 1% level is unusual to say the least. This coefficient implies that a medicine which is unregulated (otherwise the interaction effect of regulation and the Herfindahl-Hirschman index would also play a role) with an Herfindahl-Hirschman index value of 1 – which implies a monopoly – will have a normalized price which is 12.26779 point lower than in a market with a Herfindahl-Hirschman index of 0 – implying perfect competition. This implies that a market with perfect competition has a much higher price than a market with zero competition. This finding goes against the general economic theory that competition is supposed to lower the price. But these results must also be analyzed with caution since no entries with a Herfindahl-Hirschman index of 1 were included.

Furthermore, the regression analyses regarding the interaction effect of the dummy variables *regulation* and *treatment_moment* indicates that there is a positive and statistically significant

relationship between the relative price and the incurred price regulation. The coefficient which can be seen in table 6 in the second column, has a value of 0.820512 and is significant at the 1% level (**β_7**). This relationship is remarkable, one would expect the relative price to be lower if regulation plays a role. But an important implication here is that for that to be the case regulation should be exogenous. Now it is possible that regulation exists because these products are priced high in the market, and due to this high pricing, the regulator decided to intervene in the market. Therefore it is difficult to conclude what relationship exists between regulation and the relative price.

The explanatory value of this regression is high, the regression knows a R^2 value of 0.6482. Meaning that around 60 percent of the variable variation is explained by the model displayed in equation 3.

As explained in the methodology section, the variables *firmid* and *submarkid* were included to check for fixed effects respectively of the firm and of the submarket. A pooled t-test was performed on these parameters, to check if these categorical variables were of significant effect. The results can be seen in table 6. In the third column the t-values of both tests can be observed. The *firmid* parameter was significant at the 1 percent level with a t-value of 64.37. The *submarkid* parameter was significant at the 1 percent level with a t-value of 1199.09. These parameters both indeed have a significant effect on the normalized price of the medicine, therefore they are included in the model.

Table 6: Regression output equation 3

	(1)	t-value
HH_index ($\boldsymbol{\beta_1}$)	-10.9291***	-50.53
Regulation ($\boldsymbol{\beta_2}$)	.1856593***	4.70
Treatment_moment($\boldsymbol{\beta_3}$)	.3302407***	9.69
HH_index * Regulation * Treatment_moment ($\boldsymbol{\beta_4}$)	-1.411184***	-6.64
HH_index * Regulation($\boldsymbol{\beta_5}$)	-2.012069***	-12.06
HH_index * Treatment_moment ($\boldsymbol{\beta_6}$)	-0.9243428***	-6.32
Regulation * Treatment_moment ($\boldsymbol{\beta_7}$)	.820512***	16.31
Firmid ($\boldsymbol{\beta_8}$)	n/a***	64.37
Submarkid ($\boldsymbol{\beta_9}$)	n/a***	1199.09
Constant	10.76284***	19.83
Observations	369049	-
R-squared	0.6482	-
Adj. R-squared	0.6473	-

Source: AIOCD data.
*Note rel_p is the dependent variable, HH_Index is a contiguous variable, regulation is a dummy variable, treatment_moment is a dummy variable, firmid is a categorical variable, submarkid is a categorical variable. *** p<0.01*

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4.2 Results robustness checks

Regarding the regression concerning equation 6 and 7, the detailed output can be observed in table 7. In the section below the outputs of the different regression analyses will be compared, and side notes will be placed to the possibility of drawing conclusions out of the output of regression equation 3.

Remarkable is that the coefficient of the variable used as an indicator for competition (HH_Index for equation 3 and 6, and nfirm_m) is not everywhere the same. Although all the coefficients are significant, the results of the robustness checks give mixing results. The results of equation 3 compared to equation 6 (column 1 and 2 respectively) show a different relationship between the HH_index and the relative price. But equation 7 does support the outcome of equation that a higher indicator of competition increases the relative price. Here it must be noted that nfirm is higher when competition is higher and HH_index is lower when competition is higher. Furthermore, the same problem arises when the coefficients of the three-way-interaction effect are investigated (β_4). Where the regression concerning equation 3 shows a negative interaction effect between regulation and competition, the opposite is true for the regression dealing with equations 6 and 7.

Table 7: Regression output equation 3(1), equation 6(2) and equation 7(3).

	(1)	(2)		(3)
HH_index ($\boldsymbol{\beta_1}$)	-10.9291***	.1519762***	nfirm (β_1)	.0418429***
Regulation ($\boldsymbol{\beta_2}$)	.1856593***	.0112512*	Regulation (β_2)	.5908297***
Treatment_moment($\boldsymbol{\beta_3}$)	.3302407***	.0255795***	Treatment_moment(β_3)	.3894707***
HH_index * Regulation * Treatment_moment ($\boldsymbol{\beta_4}$)	-1.411184***	.2201133***	nfirm * Regulation * Treatment_moment (β_4)	.0071619***
HH_index * Regulation($\boldsymbol{\beta_5}$)	-2.012069***	-.3319725***	nfirm * Regulation(β_5)	-.0067823***
HH_index * Treatment_moment ($\boldsymbol{\beta_6}$)	-.9243428***	.0237052***	nfirm * Treatment_moment (β_6)	-.002471***
Regulation * Treatment_moment ($\boldsymbol{\beta_7}$)	.820512***	-.1076058***	Regulation * Treatment_moment (β_7)	-.1917543
Firmid ($\boldsymbol{\beta_8}$)	n/a***	n/a***	Firmid (β_8)	n/a***
Submarkid ($\boldsymbol{\beta_9}$)	n/a***	n/a***	Submarkid (β_9)	n/a***
Constant	10.76284***	1.084834***	Constant	2.18932***
Observations	369049	369049	Observations	369049
R-squared	0.6482	0.1286	R-squared	0.6448
Adj. R-squared	0.6473	0.1264	Adj. R-squared	0.6439
	(1)	**(2)**	**(3)**	

Source: AIOCD data
*Note: norm_p is the dependent variable for the regressions displayed in column 1 and 3, nw_norm_p is the dependent variable for the regression displayed in column 2, HH_Index is a contiguous variable, nfirm_m is a contiguous variable, regprod is a dummy variable, regprod * HH_Index is a interaction effect, Regprod * nfirm_m is a interaction effect, str_num is a contingious variable, firmid is a categorical variable, submarkid is a categorical variable. *** p<0*

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4.3 Limitations

In my opinion the main limitation of this research is the difficulty of comparing different medicine with each other. This limitation was also introduced by Puig-junoy (2010) in his critical review of the literature he reviewed in his research. The problem lays in the lack of before-and-after comparison. Therefore, other factors influencing price are left out of the equation. Although the use of therapeutic purpose can give insight on the different markets. Big dispersion of the prices suggests that this might not all be competitors after all. This problem is also tipped on by Danzon and Chao (2000) stating that: "Evidence of competition between therapeutic substitutes is less conclusive owing to data limitations". This limitation arises in the difference in difference method used in the regression analyses in this research. This method hinges on the assumption that the difference in price of regulated medicine without the factor of regulation, would follow the same trend as medicine without regulation. Here together with the difficulty of comparing medicine, the problem of exogenous regulation arises.

Regarding the problem of exogenous regulation, Puig-junoy (2010) argues that this might not be the case, this results in an omitted variable bias that regulation might be caused by something that also is an explanatory variable for the price. It seems logical for regulators to only apply regulation on medicines that have a price which is not considered a reasonable price. This limitation throws a big shadow on the results of this research, and the consequences will be discussed in section 5. Discussion and conclusion.

Furthermore, this research was only focused on plain tablets and capsules, for a broad understanding of the pharmaceutical market it is crucial to evaluate all the different medicine. As consumers might switch from tablets to injections, if the regulation is not able to regulate evenly over all different drug types.

Lastly, the normalization method used, comparing the medicine prices per submarket j for period t, is useful for the scope of this research. Although, it leaves valuable information about price changes over time in the dark, further research possibilities to the time effect on price and the interaction of regulation and competition could be valuable for a better understanding of implications of regulatory policies.

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5. Discussion and conclusion.

The main regression analyses gave some remarkable results, results which will be discussed down below. First the results of the main regression analyses will be analyzed and further discussed. Secondly, it will be discussed how these results must be interpreted considering the results of the different robustness checks performed.

Regarding the effect of competition on price, as discussed in the results the results imply that a market with perfect competition knows a price where the relative price is around 10 points higher than in a monopolistic market. The main conclusion drawn from this result is that there is no clear evidence that a lower concentration of a market – so a lot of firms with low market shares – results in a lower normalized price. The mistake must not be made to interpret this an evidence that lower competition results in a lower price. The only real conclusion which can be drawn regarding the concentration is that submarkets with a low concentration – and so inherently a high HH-Index – probably often have a big share of the competitors operating in the lower pricing scales. This conclusion is further supported by the robustness check using median price (regression equation 4). This fits into the results of (Lexchin, 1993) that a spread in a regulated market is lower than in an unregulated market, and that brand-named medicine producers will apply a high pricing strategy when faced with generic competition.

The results showing that regulation has a positive relationship with the weighted relative price and the median relative price are also indicators that regulation might not be exogenous. The weighted relative price shows a positive and significant relationship between the dummy variable regulation and the normalized price, which indicates that if regulation is involved the relative price of a medicine is often higher. Difficult is to examine the causal relation between these two factors, and interpreting this relationship goes beyond the scope of this research.

Regarding the main research question of this research paper concerning the interaction effect of regulation and competition the following. The regression analyses of equation 3 shows evidence that regulation interacting with higher competition (lower concentration in the market) results in a higher relative price. So, the positive effect of competition on price is even more substantial on products which are under price regulation. This fits in the framework laid down by Puig-Junoy (2010) implying that regulation creates a barrier for dynamic competition, and therefore no lower price. But also here the limitations of taking the regulation as exogenous must be added. It is possible to state that there is a relationship, but to identify a causal relationship is beyond the scope of this research.

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Concluding, as Puig-Junoy (2010) brought forward, the pharmaceutical market is a difficult market to grasp. This research has tried to overcome some of the limitations of the pharmaceutical market, but an even comparison between different medicines is still difficult. One of the main results of this research is the fact that there is a relationship between price and regulation but identifying the nature of this relationship is hard. Medicine which fall under price regulation are priced higher in the submarkets then not regulated medicine. These further fuels the question whether regulation is exogenous. Further research on the effects of competition on price is necessary to fully understand the effects of regulation.

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