The influence of reference price policy changes on the pricing of patent and original pharmaceuticals

Robert Haustein[1]

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IGES Institut GmbH
Friedrichstraße 180, 10117 Berlin
Tel.: 030 – 23 08 09·0; E-Mail: hau@iges.de; www.iges.de

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The introduction of reference prices, maximum reimburesment for a precribed medicine; in the German SHI system leads to changes in the pricing strategies of pharmaceutical producers. Little is known about the effects of the reference price induced changes in the patients co-payment schema on the pricing of patent, original and generic drugs. In this artice the simultanious introduction of patent, original and generic drugs to the reference price system in 2005 and the recalculation of reference prices in 2006 were used to examine the price reactions of the different types of producers to reference price policy changes. Using a product-level panel data set that covers two major therapeutic groups before and after the reference price policy changes the results of a two way fixed effect regression show that for one group of products the prices of patent drugs and original drugs decreased more than the prices of generic products. For the other group the prices of patent and original products decreased less than for generic products. For both therapeutic groups the prices of original drugs decreased more than for patent drugs. All products decrease their prices more when facing more competition. The decrease is smaller for patent and original drugs in comparison to generic products.

1 Introduction

The increase in drug expenditures is one of the most urgent problems the German healthcare system is facing. The German government introduced different instruments to control the rising cost for prescription drugs (Rx drugs). In 1989 the reference price system, an indirect method for controlling the prices of prescription drugs was introduced. Unlike other prescription drugs, the Statutory Health Insurance has to reimburse drugs which fall under the reference price rule only up to a certain price. If the price of the reference price drug is above that amount, the consumer has to pay the difference. From 1996 to 2004 drugs under patent protection were excluded from the reference price system. As a consequence only off-patent drugs and their generic competitors were included in reference price groups. This approach was changed in 2005, making it possible to create new reference price groups which include therapeutically and pharmacologically comparable patent, off patent (original) and generic drugs. The determined reference price, which is settled below the prices of original and patent drugs[2], offers those producers the choice to either decrease their prices at least on the reference price level or to risk co-payments for the patients. History shows, that most producers choose to decrease their prices to be competitive. However little is know how patent drugs which are in a the special position in comparison to original drugs through the absence of generic competitors and a possible utility surplus for the patient, react on the introduction of the reference price system than original off-patent drugs. Pavcnik (2002) compared the price development of the therapeutic groups of oral antidiabetics and antiulcerants after the introduction of reference price system. She distinguished between branded drugs and their generic competitors. Her results indicate a bigger price decrease for branded drugs that for generics, which was as greater as more generic competition a brand product was facing. Brekke et al. (2007) used the introduction of the reference price system in Norway in 2003 for a sub-sample of off-patent drugs to estimate the effects of the policy change on the pricing strategies of pharmaceutical firms. The results are in line with Pavcnik (2002). Both generics and brand drugs decrease their prices significantly but the effect is stronger on the prices of brand drugs. Yet the study focuses on the effects of a reference

[2] Since the reference price is located on the price level of the generic competitors, which are cheaper than their original counterpart.

price introduction for off-patent drugs and their generics. The theoretical reference of these studies can be found in Danzon and Lui (1996) and Zweifel and Crivelli (1997). The first authors argue that all prices within a reference price cluster converge towards the determined reference price. They conclude, that the prices of brand name products decrease on the level of the reference price but the prices of generic drugs increase. Zweifel and Crivelli developed a theoretical model that suggests that the reference price system has a primary effect on the prices of branded products while the prices of generics remain stable. Both motivations are not in line with the recent results of Pavnic (2002), Aronsson et al. (2001) and Brekke et al. (2007). All these empirical studies suggest that the reference price system has an effect on branded products as well as on generic products. While these studies analyze the effects of reference pricing on branded products, none of the workings distinguishes the two kinds of branded drugs, on-patent drugs and original drugs with a suspended patent protection.

The differentiation between these types of branded drugs seems crucial for the explanation of price reactions on the introduction of reference pricing. The research of Ellison et al. (1997) and Morton (1997) identifying the main competition between branded and generic products with the same active ingredient rather than between products with different active ingredients as patent drugs and originals. Following this is seems reasonable that the producer of on-patent drugs faces a lower price elasticity than producers of original drugs. As a result the price reaction of patent drugs on the introduction of reference pricing should be different to the price reactions of original drugs. Since none of the existing empirical studies regarded this aspect, this paper analyses the differences in the price reactions of original and patented products after the introduction of a reference price. Since price reactions can depend on the number of competitors within the same active ingredient, the price responses of generic drug on reference pricing are also analyzed.

In this article the introduction of two of the major therapeutic groups, the HMG-CoA reductase inhibitors also called statins and the proton pump inhibitors (PPI) to the reference price system in 2005 and the recalculation of reference prices in 2006 are used to analyze the effects of a major reference price policy change on the pricing of patent, original and generic drugs by the pharmaceutical companies. Both groups were chosen since they are treatments against major diseases in civilized countries and therefore are widely prescribed. Statins are used in the therapy of high cholesterol levels and therefore to reduce the risk of cardiovascular diseases. PPI“s are a treatment for dyspepsia, peptic ulcer disease and the laryngopharyngeal reflux disease. Additionally both therapeutic groups include patent drugs as well as original drugs and their generic versions. After the introduction of

the reference price system all of the three kinds of drugs, faces the same reference price.

In 2007 1.26 billion DDD of PPI"s were dispended in the German SHI market, leading to drug expenditures of 1.01 billion euro. Therefore PPI"s was the therapeutic group with the highest revenues in the German SHI market The second observed group, HMG-CoA reductase inhibitors caused health insurance expenditures of 365 million euro. Statins were ranked Number 16 of the therapeutic groups with the most revenues in 2007. Physicians prescribed 3.2 billion DDDs of PPI, making Statins to the most dispended therapeutic group in 2007.[3]

Increasing the reliability of the results the analysis was conducted using two different important reference price policy changes. These changes were the introduction of the reference price system for both groups in 2005 and the recalculation of Phase 2 and 3 reference prices in 2006.

The results indicate, that the prices of all types of products are sensible to the change in the co-payment regime. The prices of branded drugs, that means patent and off-patent (original) drugs, as well as generic drugs decreased after the reference price policy change. The producers of generic drugs lowered their prices least. The price decrease for original drugs was stronger than for patent drugs even the prices for on-patent drugs were higher before the introduction of the reference price system. The results also show that competition has a negative impact on the pricing of observed drugs. The higher the competition in the market, alternatively measured with the Herfindahl index, the more the prices decreases.

The paper is structured as follows.

The next section focuses on the German SHI market for Rx drugs especially the history of the reference price system. Section 3 shows the theoretical motivation why prices of patent drugs changes differently from the prices of original drugs. The description of the database and the descriptive statistics for both therapeutic groups are provided in Sections 4 and 5. The econometric model and the discussion of the empirical results are presented in Section 6. The article concludes with a résumé of the results and possible explanations of the pricing strategies for the different types of drugs.

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[3] Based on NVI Dataset, provided by the German market research company INSIGHT Health, contains approximately 99 percent of the drugs prescriptions in the German SHI market.

2 The German SHI market for Rx pharmaceuticals

The German Health System possesses a statutory public health insurance which includes most of the German population (90 %)[4] The insurance system covers the costs for most drugs where only prescription freed drugs (OTC-Drugs) and certain specific drugs are excluded from reimbursement. The German market for Rx Pharmaceuticals is highly regulated.[5] They apply to the way pharmaceuticals are distributed, how drugs are allowed to enter the market and especially in which ways the expenditures for pharmaceuticals in the market for prescription drugs are restricted. The regulation authority of the German SHI market, the Federal Ministry of Health, uses various instruments to contain the drug expenditures. Those regulations include forcing the pharmaceutical industry to give discounts to the Statutory Health Insurance, restricting the retail pharmacist to dispense one of the cheapest comparable drug to the customer (aut-idem) or affect the prescription behavior of physicians with patient related drug budget In 1989 an additional instrument to control the drug expenses was introduced in the form of the reference price scheme. It represents a maximal reimbursement schema for Rx Pharmaceuticals. If the price of a drug which is included in a reference price group exceeds the stipulated reference price, the patient is forced to make out-of-pocket payments, covering the difference between the retail price and the reference price.

Which drugs are covered by the reverence price system is decided by the Federal Commission of Physicians (“Kassenärztliche Vereinigungen”) and the Statutory Health Insurances. The implementation of the reference prices is left to the Association of Sickness Funds (“Bundesverband der Krankenkassen”). It also decides about the level of the reference price in agreement with the Federal Ministry of Health. The method for setting the reference price levels is divided into different steps. First the reference price is set for a standard package/strength with in a corridor set by the manufacturer prices and by law. After that a quasi-hedonic regression equation (Cobb Douglas form) is used to estimate coefficients which are applied to determine the relative reference prices for different package sizes and

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[4] Source: Federal Statistic Office

[5] This analysis is focused on the Statutory Health Insurance Market. The private health insurance market is not part of the analysis.

strengths. The reference prices are revised annually. In contrast to some other countries the German SHI system knows generic but also therapeutic reference pricing. This fact is reflected in the different ways of product groupings. A drug which is proposed to be covered by the reference price system can be sorted into:

- Phase 1: Drugs with the same active ingredient (generic reference pricing)
- Phase 2: Drugs with therapeutically and pharmacologically similar active ingredients (therapeutic reference pricing)
- Phase 3: Drugs with comparable therapeutic effect, especially combinations (therapeutic reference pricing)

Since 1996 patented products were excluded from reference pricing and had to be reimbursed at full retail price by the Statutory Health Insurance. With the introduction of the SHI Modernization Act (Gesetz zur Modernisierung des Gesundheitswesens (GMG)) in 2005 the special status of patented drugs ended. Since then it is possible to create a Phase 2 reference price group which includes the patented drug and original drugs and their generics with similar active ingredients. For example all statins became subject to reference pricing in January 2005. This includes patented active ingredients like Atorvastatin but also active ingredients like Simvastatin or Fluvastatin whose patent status was already expired. As a result of the policy change the pharmaceutical companies producing patented drugs were facing a new situation. Instead of having the security of a full reimbursement and a monopolistic position for the patent duration, the patent drug has now to compete with drugs which are possibly far cheaper.

3 Theoretical Motivation

Motivating our empirical approach, the following section presents a simple theoretical model which explains the impact of reference price policy changes on the pricing of patent, original and generic drugs. The model follows Brekke et al. (2007). Suggesting a therapeutic market with a patent drug (drug P), an off-patent original (drug O) and a generic drug (drug G). The patients are fully insured and only have to pay a co-payment of c_i where $i = P,O,G$. c_j describes the co-payment for a substitute drug with $j = P,O,G$. The demand for drug i is $D_i(c_p, c_O, c_G)$, where $\frac{\partial D_i}{\partial c_i} < 0$ and $\frac{\partial D_i}{\partial c_j} > 0$. The revenue of company i π_i should be given by $\pi_i = p_i D_i(c_p, c_O, c_G)$. The demand response to rising prices is different for generic, original and patent drugs. In the German Health System the prescribing physician chooses which kind of drug will be dispended by the pharmacies. In the case of bioequivalence the choice between original and generic product should not be difficult for the physician. To lower the costs to patients and to maximize patients' utility (less co-payment and maximum health increase), the prescription of the cheaper generic product should the rational choice for the physician. Still original drugs, which normally are higher priced as generics are sold. This suggests that these drugs have an additional subjective utility for the physician and/or the patient. Possible additional benefits of original drugs could be the reduction of side effects for the patients or the long term drug experiences of the physicians. It seems reasonable to assume that a original drug can have a higher price without a complete loss of demand, suggesting that $\frac{\partial D_O}{\partial c_O} > \frac{\partial D_G}{\partial c_G}$. For a patent drug, this coherence should be even more distinct. Since patent drugs contain a unique active ingredient it could be possible that the effectiveness of the patent drug is higher than of any original drug and therefore of every generic drug. This aspect can be used by the pharmaceutical companies to take higher prices than original and generic drugs without losing its complete demand, leading to $\frac{\partial D_G}{\partial c_G} < \frac{\partial D_B}{\partial c_B} < \frac{\partial D_P}{\partial c_P} < 0$. That also means that even patent, original and generic drugs are considered therapeutic similar through the positioning into a joint reference price group, they are, at least

partly not substitutes. The reaction on the introduction of a reference price for all drugs in the reference price group should be different for patent, original and generic drugs. Let the reference price be set below the price of the original and patent drug but above the price of the generic drug, $p_g < p_{RP} < p_O < p_P$. If the price of a drug exceeds the reference price, the difference between p_i and p_{RP} has to be paid be the patient, i. e., $c_i = \alpha p_i + \max(p_i - p_{RP}, 0)$, where $0 < \alpha < 1$ is the co-payment rate of the patients that is equal for all drugs. The first order conditions for the patent, original and generic drugs are:

(1.1) $$\frac{\partial \pi_P}{\partial p_P} = D_P(c_P, c_O, c_G) + p_P \frac{\partial D_P[\cdot]}{\partial c_P}(\alpha + 1)$$

(1.2) $$\frac{\partial \pi_O}{\partial p_O} = D_O(c_P, c_O, c_G) + p_O \frac{\partial D_O[\cdot]}{\partial c_O}(\alpha + 1)$$

(1.3) $$\frac{\partial \pi_G}{\partial p_G} = D_G(c_P, c_O, c_G) + p_G \frac{\partial D_G[\cdot]}{\partial c_G}(\alpha)$$

Given that $0 < \alpha < 1$, the demand responsiveness to price changes is higher for patent and original products than for generics. The introduction of reference pricing leads to higher co-payments for both patent and original drugs. The demand for both types of drugs should be lower for given prices. Since $\frac{\partial D_P}{\partial c_P} > \frac{\partial D_O}{\partial c_O}$ the demand of patent drugs is higher than the demand for originals. Still both producers of on-patent drugs and off-patent originals are stimulated to decrease their prices to secure their market shares. The situation of generic drugs is more ambiguous. Since the reference pricing leads to higher co-payments for patent and original drugs for given prices, the demand for generic drugs should increase. As a reaction generic producers should increase their prices. If patent and original drug producers lower their prices to decrease the patients co-payment, the effect of increasing prices is uncertain for generic demand. Using (1.1) – (1.3) the model shows that if patent and original producers decrease their prices and so reduce the co-payments for the patients, generic producers should respond with a price reduction.

The theoretical model predicts that through differences in the demand structure the producers of on-patent drugs should reduce their prices by less than the manufacturers of original drugs. The incentive for generic producers to reduce their prices is possible weaker than for patent and original drugs, but still there.

In the next sections an empirical model will be developed to prove these theoretic suggestions.

4 Data base

The following analysis is based on data of the SHI market for prescription drugs. The data, provided by the German market research company INSIGHT Health, contains approximately 99 percent of the drugs prescriptions in the German SHI market. The data base covers the relevant market from 2004 to 2007 on a monthly base. This study uses the data of two therapeutic groups, which became part of the reference price system in 2005. The first group, the HMG-CoA reductase inhibitors, also known as statins are applied to lower cholesterol levels and therefore to reduce the risk of cardiovascular diseases. The other therapeutic group incorporated in this study are the proton pump inhibitors (PPI) are used in the treatment of acid secretion. Both groups contain patented drugs and original drugs with generic competition. Also statins and PPI entered the reference price system simultaneously in January 2005. For that all drugs containing the active ingredients with the ATC-Code[6] C10AA* (for statins) and A02BC* (for PPI"s) were included into the reference price system. The data contains the sales volume and quantity of dispensed drugs in both therapeutic groups. The sales volume was denoted in retail prices to enable a comparison with the reference prices, which are also quoted in retail prices. The quantity were delivered in number of prescriptions. The number of prescriptions per presentation of a drug were transformed to the amount of dispensed Daily Defined Doses (DDD) using the official measured value of DDD per package of the drug from WiDO[7]. Following this procedure the DDD for all incarnation of a drug with a specific active ingredient were added up for each manufacturer. This standardization makes it possible to compare prices and volumes over different package sizes, strengths and also across different of

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[6] In the Anatomical Therapeutic Chemical (ATC) classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified in groups at five different levels. The drugs are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance.

[7] WiDO is the scientific institute of the Local Health Care Fund (AOK), Germanys largest health insurance fund. One of its task is the adjustment of the international DDD levels, issued by the WHO on yearly base, for the German health care market

the active ingredient.[8] Following Stern (1995), Ellison et al. (1997) and Pavcnik (2002) the price was derived by dividing the total sum of sales of a product of a specific manufacturer through the total quantity sold of the product measured in DDD. In the following price always refers to average price per Daily Defined Doses. Taking inflation into account a price deflator from the German Federal Statistical Office was used to express the prizes in 2005 Euro prices. The dataset contains additional information about the name of the manufacturer, drug status (patent, original or generic drug) and if the drug is a re-import. To increase the clarity of the results a balanced panel including only products that were available during the whole time period were used. As a result the number of observations is identical for every year. Since the competition through new products could have a significant influence on the results I take into account the changing number of generics, when controlling for competition.

[8] For example, a product x of a specific manufacturer has a DDD of 6g. This is equivalent to 12 standard (500mg) tablets. If a patient consumes forty eight (500mg) tablets (i.e. 24g of the drug in total) over the space of six days, he can have said to have consumed 8 DDDs of this drug.

5 Descriptive Results

5.1 Summarized statistics

It seems useful to start the descriptive results Section with an overview about the summarized statistics about the two different therapeutic groups which are covered in this research. Since the dataset is strongly constricted, outliers could strongly bias the descriptive results when using non weighted prices. To solve this problem the prices were weighted with their monthly market share in the corresponding ATC 7 group. For statins these statistics are viewed in Table 1.

Table 1: Summarized Statistics for statins (prices in euro)

Variable	Mean	Standard Deviation	Minimum	Maximum
Average weighted price per DDD	0.079	0.019	0.057	0.107
Average weighted price per DDD of Patent Products	0.419	0.078	0.323	0.532
Average weighted price per DDD of Original Products	0.199	0.063	0.134	0.304
Average weighted price per DDD of Generic Products	0.019	0.003	0.016	0.022

Prices in 2005 Euro, Source: INSIGHT Health, Price Deflator from Federal Statistical Office

The average weighted price for statins was 0.079 euro per DDD. Between 2004 and 2007 the maximum average weighted monthly price was 0.107 euro per DDD while the lowest average weighted price was 0.057 euro per DDD. The average weighted price of patent drugs was 0.419 euro per DDD, with a maximum average price of 0.532 and a minimum average price of 0.323 per DDD. The mean weighted price of original drugs was 0.199 euro which is below the average weighted price of patented drugs. The minimum (0.134 euro per DDD) and maximum average weighted prices (0.304 euro per DDD) of originals are also located below the prices of patent drugs.

Generic drugs are, as assumed, the cheapest type of drugs in the therapeutic groups of statins. In the mean the average weighted price per DDD was 0.019 which is below the average weighted prices of the branded competitors. The same result was found for the minimum and maximum average weighted price (0.016 euro and 0.022 euro) of generic statins.

Table 2 shows the summarized statistics for proton pump inhibitors.

Table 2: Summarized Statistics for PPI (prices in euro)

Variable	Mean	Standard Deviation	Minimum	Maximum
Average weighted price per DDD	0.216	0.049	0.158	0.291
Average weighted price per DDD of Patent Products	0.361	0.073	0.276	0.482
Average weighted price per DDD of Original Products	0.352	0.093	0.246	0.491
Average weighted price per DDD of Generic Products	0.222	0.051	0.163	0.301

Prices in 2005 Euro, Source: INSIGHT Health, Price Deflator from Federal Statistic Office

The mean average price in the therapeutic group of proton pump inhibitors was higher than in the group of statins. Between 2004 and 2007 the average weighted price per DDD was 0.22 euro, with a maximum average price of 0.29 euro and a minimum average price of 0.16 euro per DDD. As for the group of statins the average price of patent drugs (0.36 euro) was higher than the average price for off-patent originals (0.35 euro). The same result was found for the maximum and minimum average weighted prices. While the maximum average weighted price for patent drugs was 0.48 euro per DDD, the average weighted price of original drugs was 0.49 euro per DDD. The minimum average price per DDD was 0.28 euro for patent drugs and 0.25 euro for original drugs. The price difference between the average prices of branded drugs and their generic competitors was smaller than for the therapeutic group of statins. The average weighted price of generic proton pump inhibitors was 0.22 euro with a average maximum of 0.30 euro and a minimum price of 0.16 euro.

5.2 Price development of statins and PPI“s

For both statins and PPI“s the average weighted price of a daily dose of a patent protected drug is higher than the average weighted prices of their therapeutic competitors. The average weighted prices of original drugs are located below that of patent drugs but above the average weighted prices of generic competitors. This results support the theoretic motivation in Section 3, that predicted that the price level of patent drugs should be above that of original drugs and generics.

Also following the implications in Section 3 after the change of the co-payment schema the prizes of patent drugs should decreases less as those of the other groups. Figure 1 plots average weighted prices per DDD over the time for the therapeutic group of statins while Figure 2 does the same for the therapeutic group of proton pump inhibitors.

Figure 1: Average weighted prices of patent, original and generic statins

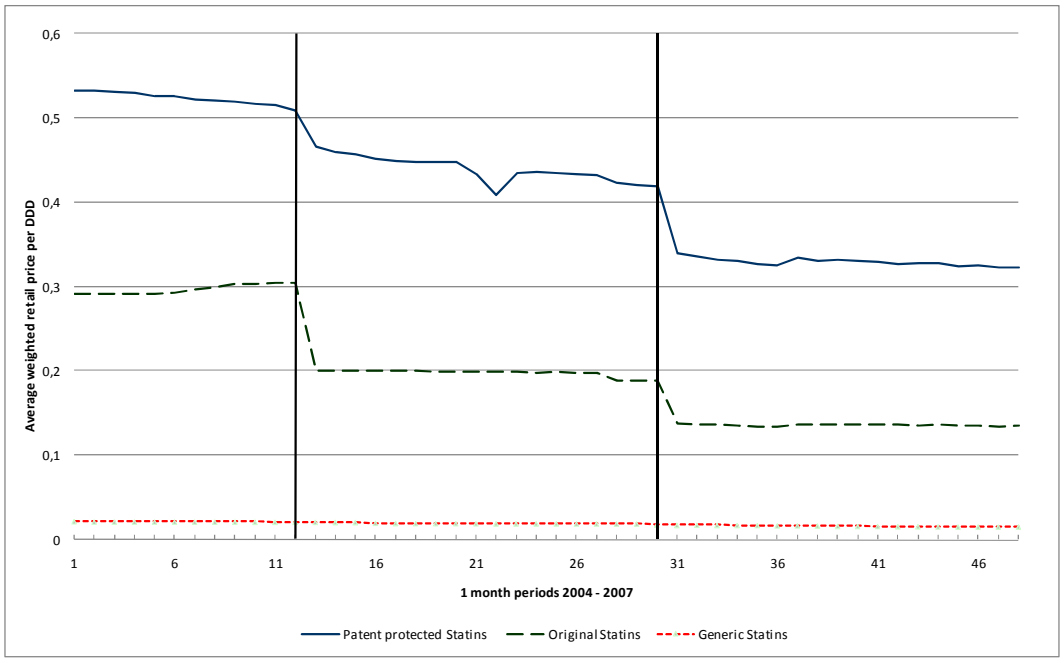
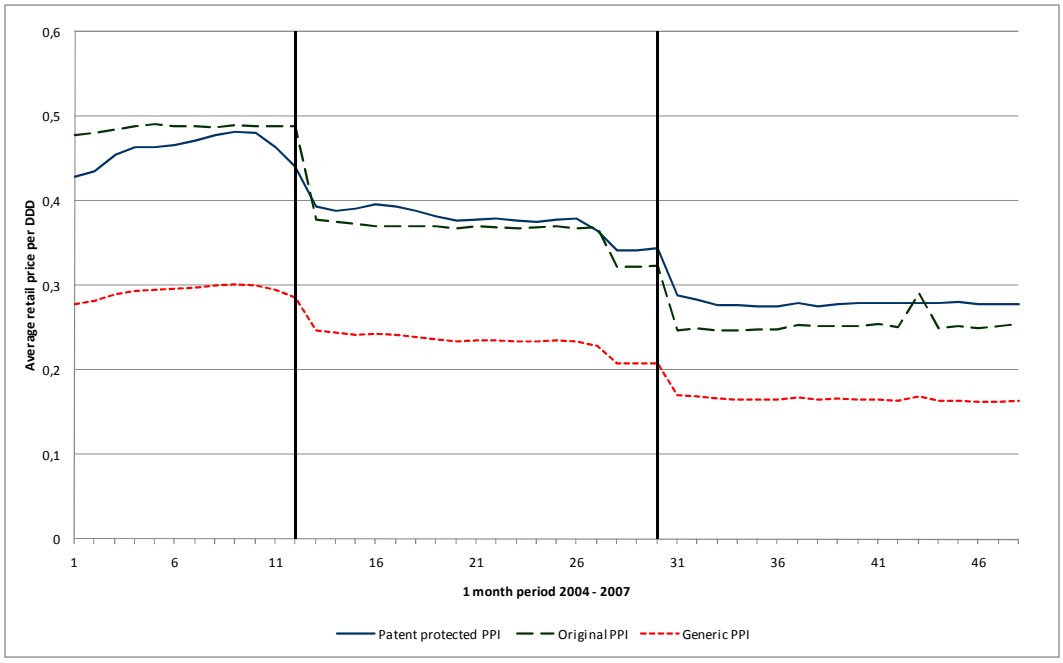


Figure 2: Average weighted prices of patent, original and generic PPI“s



The price development of both therapeutic groups follows a similar pattern. The average weighted prices of patented drugs are located above the average weighted prices of original drugs. The price level of generics below that of the branded drugs. The difference in the price level of generic statins and generic PPI"s is caused through the weighting of the prices with their market share. Since the number of generic statins exceeded the number of generic versions of proton pump inhibitors, the generic competition in the market of PPI"s was weaker, leading to a higher generic price level. While the weighted prices of patent and original drugs decrease sharply with the changes in the reference price scheme, the prices of generic drugs are effected less. The first price decrease for patent and original drugs was observed after period 12, following the introduction of the reference price system for statins an PPI in January 2005. The second strong subsidence was observed in July 2006 (period 30).The reason for the second rapid decrease was the recalculation of the reference prices for reference groups of Phase 2 and 3 in 2006. This lead to strongly reduced reference prices. Table 3 shows the average weighted prices for statins before and after the introduction and recalculation of reference prices in 2005 and 2006.

Table 3: Average weighted prices for statins before and after reference price introduction and recalculation of the reference prices

	Prices before RP Introduction	**Prices after RP Introduction**	**% price change**	**Prices before RP recalculation**	**Prices after RP Change**	**% price change**
Drug subject to reference price	0.106 (0.001)	0.069 (0.011)	-0.352	0.079 (0.019)	0.061 (0.006)	-0.222

Patent drug subject to reference price	0.523 (0.007)	0.385 (0.057)	-0.265	0.419 (0.078)	0.343 (0.033)	-0.182
Original drug subject to reference price	0.296 (0.006)	0.167 (0.031)	-0.438	0.199 (0.063)	0.143 (0.019)	-0.279
Generic drug subject to reference price	0.021 (0.001)	0.018 (0.002)	-0.158	0.019 (0.002)	0.017 (0.001)	-0.110

Standard errors are in parentheses.

The average weighted prizes of statins before the introduction of reference pricing was 0.11 euro, while after the implementation of the regime it decreases to 0.07 euro. This implies a price reduction of more than 35 percent. Focusing on the policy change in 2006 the average prices before were 0.08 euro and decreased over 20 percent after the change. The steepest price decrease in the therapeutic group of statins was found for original drugs. Their prices sank approximately about 40,4 (18,2) percent which was significant more than the average price decrease. The average prices of patent drugs decreased about 26,5 (18,2) percent. For the therapeutic group of the proton pump inhibitors results are similar. The average weighted prices of generic statins dropped by 15,8 (11,0) percent, which was less than for patent and originals. As shown in Table 4 the average prices of drugs subjected to the reference price group of the PPI decreased about 31,6 respectively 22,5 percent. The average weighted prices of original drugs after the reference price schema implementation dropped down about 36,9 percent, which is more than for patented drugs (28,9 percent). In opposite to the observations for statins, the average price of original drugs before the introduction of the reference pricing was higher than for patented drugs. This results does not hold for the second policy change, where the average price of patent drugs was higher than the average price of originals. The average weighted prices of generic PPI“s declined by 31,9 (22,7) percent.

Table 4: Average prices for PPI before and after reference price introduction and recalculation of the reference prices

	Prices before RP Introduction	**Prices after RP Introduction**	**% price change**	**Prices before RP recalculation**	**Prices after RP Change**	**% price change**
Drug subject to reference price	0.283 (0.007)	0.193 (0.033)	-0.316	0.216 (0.049)	0.167 (0.014)	-0.225
Patent drug subject to reference price	0.461 (0.018)	0.329 (0.051)	-0.289	0.361 (0.073)	0.288 (0.023)	-0.202

Original drug subject to reference price	0.486 (0.004)	0.307 (0.058)	-0.369	0.352 (0.093)	0.262 (0.027)	-0.255
Generic drug subject to reference price	0.292 (0.007)	0.199 (0.035)	-0.319	0.222 (0.051)	0.172 (0.015)	-0.227

Standard errors are in parentheses.

For both observed therapeutic groups the strongest decrease in prize was found for the original drugs. In line with the theoretic motivation the average price change for patent drugs was smaller. The price change for generics was higher for PPI"s compared to statins. A reason could be differences in the competitive environment. While the number of generics is large in the market of statins, only a few generic proton pump inhibitors existed in the observation periods. Through the stronger competition the prices of generic statins could be lower before the introduction of the reference price system. As a consequence, the price drop was smaller for generic statins than for generic PPI, that faces less generic competition.

5.3 Sales volume development for statins and PPI"s

In Figure 3 and Figure 4 the prescribed DDD for both therapeutic groups are plotted over time. Since patients and physicians are motivated to use and prescribe generic drugs[9], it seems reasonable that for both therapeutic groups the most DDD were sold in this group. Surprisingly the number of DDD sold of patent drugs exceed the number of DDD of original drugs, although the average price for patent drugs is higher[10] then that of original drugs.

Figure 3: DDD sales of statins

[9] There are various incentives for physicians to prescribe generics, for example the already mentioned physician drug budget For patient demanding generic drugs can result in a relief of co-payments.

[10] The effect is even stronger, recalling the mechanism how the price of a drug is obtained in this paper. price per period = (sales in a period /volumes of sales in DDD in a period).

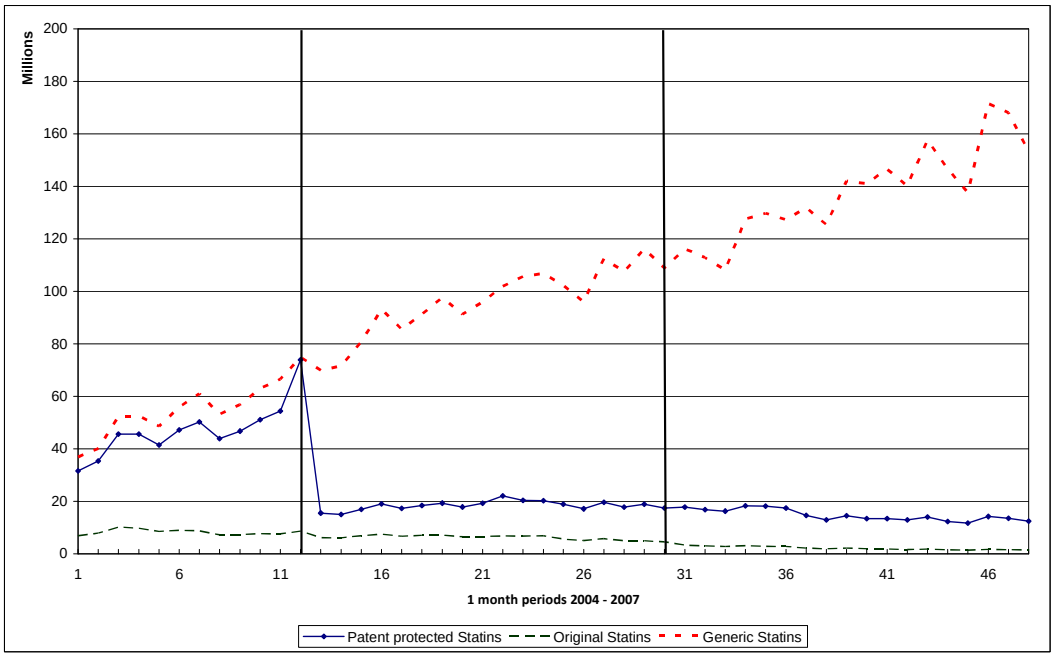
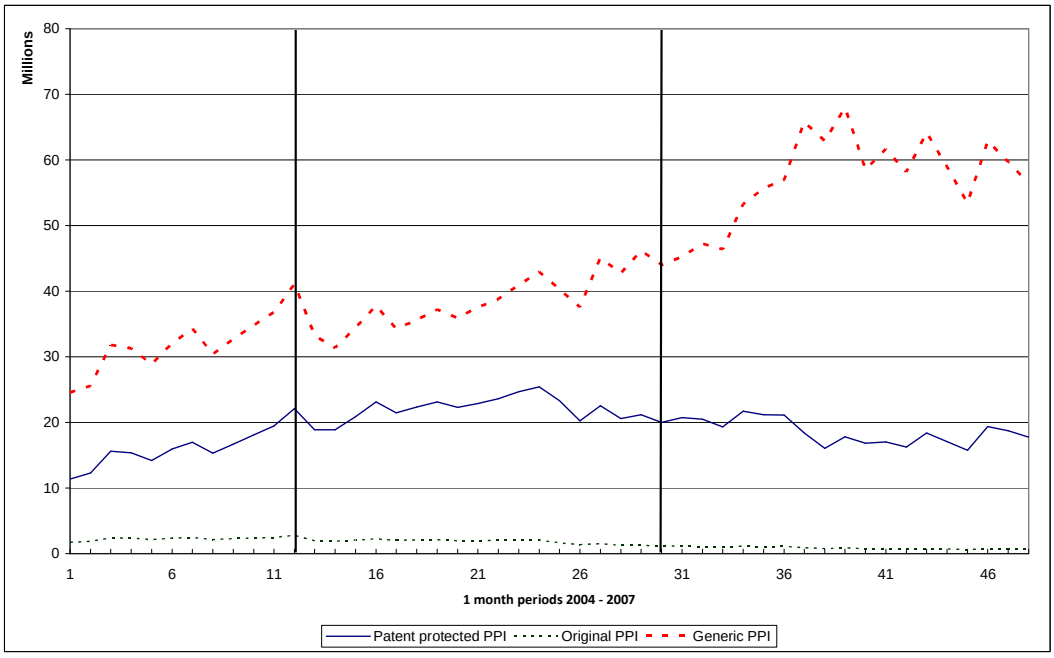


Figure 4: DDD sales of PPI“s



After the introduction of the reference price system for both statins and PPI“s the amount of sold DDD declined slightly for all types of products except for the on-patent statins. For this group a sharpest reduction was observed. Responsible for that development was the active ingredient Atorvastatin that lost over 80 percent of its sales after the introduction of reference prices. After the small decrease following the introduction of the ref erence price system for both therapeutic groups the sales of patent and or

original drugs remained stable in the observed time periods. In contrast to that development, the number of prescribed generic DDD rose significant. Since the amount of DDD sold of patent and original drugs did not change substantial, the increase can be explained by a rise in demand for the treatment of high cholesterol levels and acid secretion.

6 Empirical Analysis

6.1 The econometric model

The descriptive statistics in Section 5 indicate different price reactions of patent and original drugs which are exposed to changes in the co-payment scheme. Following these figures the price decrease of original drugs should be stronger than that of on-patent medicine. To analyze those effects more carefully a econometric model based on the models of Lavy (2002), Brekke et al. (2007) and especially Pavcnik (2002) is used. Since all statins and PPI"s entered the reference price system at the same time, a group of therapeutic competitor drugs which are not part of the reference price system does not exist. Therefore the analysis is concentrated on the variation of prices over time. The relationship between out-of-pocket expenses and pricing of pharmaceuticals is considered by analyzing the variation in prices before and after policy changes concerning the reference price system. For that I use this semi logarithmic specification:

$$(2.1)\ln(p_{it}) = \beta_1 RPPC_t + \beta_2(RPPC_t * Patent_i) + \beta_3(RPPC_t * Original_i) + FE_i + \delta_t + \varepsilon_{it}$$

where p_{it} is the retail price of product i at time period t, $RPPC_i$ is a dummy variable indicating if period t is covered by a reference price policy change. The dummy variables $Patent_i$ and $Original_i$ state if a drug is a drug under patent protection or a off-patent original. If both variables posse the value of zero, the drug is declared a generic drug. Since a two way fixed effect panel regression model[11] is used, the variables for the product fixed effects are FE_i [12] and for the time period specific effects δ_t (in this paper year indicators). The variables are included to capture product specific attributes like the active ingredient and time shocks that could affect all products in a given period. To prevent multi-co linearity two year indicators have to be excluded. Since the observation periods includes only 4 years the first year 2004 and the year the reference price policy change happened (2005 or

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[11] I tested for the applicability of the fixed effect model using the Hausman-test

[12] I capture the fixed effects using dummy variables for each product, following Woolridge 2002, (272-274)

2006 respectively)[13] is chosen. At last, ε_{it} represents unobserved effects that affect prices. Following the specifications of the fixed effect model the error term ε_{it} is allowed to be correlated with FE_i and i.i.d. Using this model it is possible to explore if the change of reference price policy has a different influence on generics, patent drugs and original drugs. Using the structure which was outlined in equation (1) and assuming the non-existence of any uncontrolled price affecting factors which vary in the observation period, β_1 endorse the impact of reference price policy changes on the pricing of generic drugs. The interaction term between $RPPC_t$ and $Patent_i$ β_2 describes the additional effect for a patent drug. Following that the complete effect of the Reference price change on the price of a patent drug is $\beta_1 + \beta_2$. For example if the coefficient of the interaction between $RPPC_t$ and $Patent_i$, β_2 is negative, the price of a on-patent drug decreases more than the price of a generic drug[14]. The coefficient β_3 prescribes the additional effect if the drug is a original product. Since all products of the observed therapeutic groups entered the reference price system simultaneously, I can not compare the pricing of the products covered by the reference price group with price development in a unaffected treatment group.[15] Since generic competition could possible affect the prices of original drugs and generics[16], different measurements to control this factor were incorporated. Following Morton (1997) a variable measuring the number of competitors NC_i in the active ingredient group for each product i was included. This leads to an extended version of equation (2.2):

$$(2.2)\ln(p_{it}) = \alpha + \beta_1 RPPC_t + \beta_2 (RPPC_t * Patent_i) + \beta_3 (RPPC_t * Original_i) + \beta_4 NC_i + FE_i + \delta_t + \varepsilon_{it}$$

I suggest that an increasing number of competitors has a negative effect on the price of products. Thus the corresponding coefficient β_4 should be negative. Since the price effect through the number of generics per active ingredient group could differ between branded (patent or original drugs) and ge-

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[13] I performed the analysis with all other possible combinations of year indicators. I also let Stata decide, which year indicators should be removed. The results were not very different to them described in section 0.

[14] Under the assumption that β_1 is also negative.

[15] See Pavcnik (2002) and Brekke et al. (2007) for analysis considering a control group.

[16] Patent drugs per definition normally do not have competition through other products with the same active ingredient. Still they have competition through re-importers.

neric drugs, equation (2.2) is expanded by a variable measuring the number of generics if the product is a branded drug ($NG_i * Brand_i$).

$$(2.3)\ln(p_{it}) = \alpha + \beta_1 RPPC_t + \beta_2 (RPPC_t * Patent_i) + \beta_3 (RPPC_t * Original_i) + \beta_4 NC_i + \beta_5 (NC * Brand_i) + FE_i + \delta_t + \varepsilon_{it}$$

Using the number of competitors of an active ingredient can lead to a number of problems. That includes possible negative reactions concerning the quality of the generic drugs by patients and physicians resulting in a low market share of those products.[17] Also the price could be related to the number of competitors. For example, a market segment with low prices could prevent possible competitors (in particular generics) from entering the market Concerning these issues the Herfindahl index is used as an alternative measurement for the competition. The index is calculated regarding the active ingredient group as the relevant market Following the logic of the index, a therapeutic subgroup should be more competitive the lower the Herfindahl index is. To get comparable results with equation (2.3) a variable for the interaction of the Herfinadahl index with branded products (original or patent protected drugs) is introduced. The corresponding equations (2.4) and (2.5) show the regression functions using the Herfindahl index:

$$(2.4)\ln(p_{it}) = \alpha + \beta_1 RPPC_t + \beta_2 (RPPC_t * Patent_i) + \beta_3 (RPPC_t * Original_i) + \beta_4 Herfindahl\ index + FE_i + \delta_t + \varepsilon_{it}$$

$$(2.5)\ln(p_{it}) = \alpha + \beta_1 RPPC_t + \beta_2 (RPPC_t * Patent_i) + \beta_3 (RPPC_t * Original_i) + \beta_4 Herfindahlindex + \beta_5 Herfindahlindex * Brand + FE_i + \delta_t + \varepsilon_{it}$$

The always relevant endogeneity problem can be toned down in this analysis. Since a producer cannot enter a market immediately, the entry of competitors is not necessarily connected to present prices. Also if endogeneity comes from influences linked with competition or prices, which are unobserved and constant over-time, the product fixed effects capture these influences. The database is a product level panel. The data was checked for first-order serial correlation in errors, as Woolridge (2002) proposes. The test rejected the hypothesis that there is no first-order serial correlation ($p < 0.01$) In addition the data was tested for heteroskedastcity of the residuums using a modified Wald test. The results indicate group wise heteroskedasticity. For controlling both problem product-clustered robust standard errors

[17] For the observed therapeutic groups that suggestion is not correct. The market share of generic drugs is higher than that of patent or original drugs. See Section 5.3

are estimated. These standard errors are robust to heteroskedasticity as well as to any form of autocorrelation.[18]

6.2 Empirical results

6.2.1 HMG-CoA reductase inhibitors (statins)

The first empirical results are for the therapeutic group of statins. Since statins were introduced in 1987[19] the group consists a variety of different active ingredients. The market is characterized by a large number of generic drugs, which increases after 2005 and nearly no re-importers. To capture the effects of increasing competition the methods mentioned in section 6.1 are used. Reference prices for statins firstly were introduced in January 2005. Table 5 shows the results of the panel data regression.

Table 5: Price effects of the introduction of the reference price system for statins in 2005

Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**
RPPC	-0.105***	-0.049***	-0.015***	-0.01***	-0.091***
	(0.014)	(0.014)	(0.011)	(0.013)	(0.009)
RPPC * Patent	-0.079	-0.144***	-0.179***	-0.098*	-0.110**
	(0.057)	(0.054)	(0.051)	(0.058)	(0.052)
RPPC * Original	-0.288***	-0.263***	-0.365***	-0.276***	-0.300***
	(0.05)	(0.048)	(0.035)	(0.054)	(0.055)
Number of Competitors (NC)		-0.029***	-0.045***		
		(0.005)	(0.003)		
NC * Brand			0.038***		
			(0.007)		
Herfindahl Index				0.242	0.673
				(0.23)	(0.56)
Herfindahl Index * Brand					-0.521
					(0.65)

[18] See Kezdi (2005) for additional information about cluster robust standard errors in fixed effect models

[19] The statin Lovastatin was approved by the FDA in August 1987

Constant	-0.592***	0.235	0.490***	-0.643***	-0.691***
	(0.016)	(0.016)	(0.084)	(0.044)	(0.062)
Product dummies	Yes	Yes	Yes	Yes	Yes
Year Indicator 2006	-0.174***	-0.166***	-0.166***	-0.169***	-0.164***
	(0.014)	(0.014)	(0.013)	(0.013)	(0.012)
Year Indicator 2007	-0.348***	-0.330***	-0.326***	-0.337***	-0.332***
	(0.033)	(0.028)	(0.027)	(0.027)	(0.023)
Number of observations	2733	2733	2733	2733	2733
Number of Products	57	57	57	57	57
R-squared	0.68	0.71	0.73	0.68	0.68

Columns 1 - 3 show the results of the models (1) – (3) Columns 4 – 5 the results of the models (4) and (5). Cluster robust standard errors are in parentheses. *** indicates Significance at the 1 % - Level; ** indicates Significance at 5 % - Level; * indicates Significance at the 10 % - Level.

The results of the regression approve the theoretic approach of section 3. For all tested models, the prices of generics decreases after the introduction of the reference price system. For all models the prices of original drugs decreased more than the prices of generic statins. The small price decrease for generic statins can be explained with their already low price level as it was shown in section 5.2. The results are in line with the empiric results of Pavcnik (2002) and Brekke et al (2007). As predicted the prices of patent drugs decreased less than the price of original drugs. The differences range from 11.9 % to 18.6 %. The findings support the thesis, that since on-patent drugs have the exigency to refinance themselves and a unique net-value for patients and physicians, producers of those drugs can establish a higher price for their products. The effects of competition, measured with the number of competitors (NC) and the Herfindahl index are as anticipated. The number of competitors per active ingredient has a negative impact on the pricing behavior. For that, the more competitors are in the market, the lower the prices are. Also the interaction term between branded drugs and the number of competitors (coefficient is 0.038) states, that a original drug or patent drug facing competition decreases his price less than a generic drug facing the same competition. The Herfindahl index in Column 4 shows the expected positive prefix but is not significant. The higher the Herfindahl index, a sign for weaker competition, the higher should be the prices for the

products in the relevant market The coefficient of the Herfindahl index interacting with brand name products supports the results in column (3) but is also not significant. The findings for the reference price policy change in 2006 are depicted in Table 7 in the appendix. The results for the price difference between patent drugs and original drugs follows the same pattern as after the introduction of reference pricing in 2005. The number of competitors has a negative impact on the pricing behavior of the producers and the producers of branded products reduce their price by less facing competition. The Herfindahl index as well as the interaction between the Herfindahl index and branded products have the expected suffix and are significant.

6.2.2 Proton Pump Inhibitors

The market of Proton Pump Inhibitors differs from that of statins in various ways. One important difference lies in the number of generics. In comparison to the therapeutic group of statins, the number of generic versions of original drugs which were available on the market since 2004 was far lower for PPI"s. In fact, only one active ingredient, Omeprazol, faced continuous generic competition in the complete observation period.[20] In addition the market is characterized by a large number of re-importers, which was not the case for the market of statins. Table 7 shows the impact on the prices of patent, original and generic drugs through the introduction of the reference price system for PPI"s in 2005.

Table 6: Price effects of the introduction of the reference price system for PPI"s in 2005

Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**
RPPC	-0.195***	-0.189***	-0.057**	-0.198***	-0.189***
	(0.012)	(0.017)	(0.021)	(0.012)	(0.005)
RPPC * Patent	0.139***	0.130***	-0.016	0.118***	0.07***
	(0.037)	(0.039)	(0.004)	(0.036)	(0.035)
RPPC * Original	0.095***	0.098**	-0.067	0.134***	0.062***
	(0.039)	(0.039)	(0.047)	(0.047)	(0.046)
Number of Competitors		-0.002	-0.043***		

[20] It was only in 2006 generics of another active ingredient, Lansoprazol, entered the market of PPI"s.

(NC)		(0.005)	(0.008)		
NC * Brand			0.044*** (0.009)		
Herfindahl Index				0.161* (0.08)	4.748*** (0.58)
Herfindahl Index * Brand					-4.650*** (0.37)
Constant	0.539*** (0.011)	0.565*** (0.055)	0.874*** (0.075)	0.473*** (0.035)	0.112*** (0.052)
Product dummies	Yes	Yes	Yes	Yes	Yes
Year Indicator 2006	-0.207*** (0.01)	-0.204*** (0.012)	-0.186*** (0.012)	-0.197*** (0.012)	-0.166*** (0.067)
Year Indicator 2007	-0.347*** (0.025)	-0.344*** (0.026)	-0.317*** (0.025)	-0.343*** (0.024)	-0.233*** (0.006)
Number of observations	1824	1824	1824	1824	1824
Number of Products	38	38	38	38	38
R-squared	0.77	0.77	0.77	0.77	0.82

Columns 1 - 3 show the results of the models (1) – (3) Columns 4 – 5 the results of the models (4) and (5). Cluster robust standard errors are in parentheses. *** indicates Significance at the 1 % - Level; ** indicates Significance at 5 % - Level; * indicates Significance at the 10 % - Level.

Equal to the results of the therapeutic group of statins the introduction of the reference price system decreased the prices for generic drugs approximately by 19 %. The prices of branded drugs descend after the introduction of the reference price system, but not as much as the prices of generics. Yet the decrease pattern for original and patent drugs was similar to that observed on the statin market The prices for patent drugs without controlling for competition, depicted in column 1 decreased about 5.6 % while the prices of original drugs decent about 10 %. The gap between the two types of branded drugs remains the same after controlling for competition as column (2) shows. The influence of competition is similar to the group of statins. The results suggest that the number of competitors has a negative influence on the prices. The results in Column (3) indicate, that the effect of an

increasing number of competitors is smaller for branded products than for generics. The Herfindahl index, used as an alternative method to capture competition, was used in Column (4) and (5). The results are in the same line as the results of Model 2 and 3. The Herfindahl index, significant on the 10 % level, has a positive influence on the price setting of the pharmaceutical producers. The higher the concentration in the specific market segment, measured through a high value of the index, the higher the price will be. This result also applies for the expanded model in column 5, which expands the model with an additional term capturing the interaction between Herfindahl index and branded products. This coefficient has a negative suffix, indicating that the influence of competition is weaker for branded products in comparison to generic competitors. In addition both coefficients are significant on the 1 % level. The results of the second observed reference price policy change are shown in Table 8 in the appendix. Overall not very different from the results in Table 6 the Herfindahl index in Model 4 has now a significant influence on the pricing behavior of the observed products.

7 Conclusion

This paper analyses the effects on the price setting behavior of producers of generic, original and patent drugs through major changes in the reference price system. Therefore the unique opportunity of the simultaneous introduction of generic, original and patent drugs of the relevant therapeutic groups of statins and proton pump inhibitors to the reference price system and a major change in reference price policy in 2006 were used. At least for this two major groups of drugs the prices for all kind of drugs decreased after the reference price policy change. More important the prices of original drugs, facing generic competition were lowered by a greater extent by the producers than the prices of patent drugs, which are confronted only by therapeutic competition through other active ingredients. The analysis shows that depending on the therapeutic group and the specifications of the model the approximation of price reduction for generic drugs ranged from 1.0 % to 32.2 % for statins and 6.0 % to 42.2 % for PPI“s. Original drugs decreased between 3.8 % and 50.7 % for statins and 1.0 % to 32.8 % for PPI“s while on-patent drugs prices decent among 9.2 % to 42.2 % for statins and 5.6 % to 31.3 % for the group of proton pump inhibitors.

The results also indicate that the competition situation plays an important role for the price setting behavior in both therapeutic groups. Still there are differences in the extend of the usefulness of the number of competitors per active ingredient as a measurement for competition between the two groups. For statins, where the competitive environment is dominated by generic competitors, the results follows the findings of Ellison et al. (1997). For them the main source of competition in the pharmaceutical market is between generic and brand name products of the same active ingredient. The increase in generic competition should decrease the prices. The results for statins confirm this suggestions. For the therapeutic group of proton pump inhibiter these results are different. Instead of the competition between original drugs and their generics the main source of competition is between original products and re-importers. This also explains, why the prices of generics decreased stronger than the prices of branded drugs for the group of PPI“s. Other than in the therapeutic groups of statins, where a strong competition between generic producers was existing before the introduction of the reference price, only a few number of generics were available in the observation period, resulting in low generic competition. This weak generic competition could lead to higher prices before the reference price introduction, resulting in a stronger price decrease for generic PPI“s after the policy

change in comparison to the generic statins. As an alternative of competition the Herfindahl index instead of the number of competitors should be used. For both statins and PPI"s the coefficient of the Herfindahl index had a positive suffix, indicating that prices increase more the lesser the competition in the market is. Also the results show that the prices of branded products increase lesser than the prices of generic products facing the same competition.

There are different potential reasons why the prices of patent drugs decreases less than the prices of original drugs. One important argument for the acceptance of the higher prices for patent drugs could be a good reputation by patients and physicians. Studies by Hellerstein (1998) and Coscelli (2000) concluded that the market share of branded products remains considerable since physicians and patients develops consistent choice habits. Their results imply that both parties exhibit strong state dependence and are far from being indifferent between branded and generic drugs.

By using a new active ingredient both parties could expect a better treatment for the patient and/or lesser adverse effects. This could lead to the acceptance of a higher price. Patent producers could build on this reputation and the quasi monopolistic market situation for the specific active ingredient to demand higher prices. Unlike patent drug producers, the manufacturers of original drugs do not have this unique market position. To remain competitive in the face of the generic competition they have to decrease their prizes strongly after the reference price policy change.

Another explanation for the lesser price decrease of patent drugs could be the high research and development cost for the new product. DiMasi et al. (2003) estimate the cost to develop a new product at 802 Million USD. Other studies [21]speak of 250 to 350 Million USD. Even with the huge difference between the two numbers it becomes obvious that the development of a new drug is very expensive. To refund these expenditures, producers of patent drugs have to demand higher prices than the manufacturers of off-patent originals, which were able to refinance their investments during the time their products was under patent protection.

Finally, the results of this article, independent of the possible explanation, strongly suggest that changes in out-of-pocket expenses affect generic, original and patent drugs differently. Especially the role of the demand side, represented by the physicians and their patients for the pricing of brand especially patent drugs needs further research.

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[21] Source: Pharma Information (2001) p.39

8 Appendix

Table 7: Price effects of recalculation of reference prices for statins in 2006

Model	(1)	(2)	(3)	(4)	(5)
RPPC	-0.322***	-0.254***	-0.245***	-0.284***	-0.262***
	(0.031)	(0.023)	(0.02)	(0.032)	(0.022)
RPPC * Patent	-0.067	-0.118	-0.127	-0.153	-0.18
	(0.079)	(0.085)	(0.084)	(0.01)	(0.097)
RPPC * Original	-0.185**	-0.114	-0.154*	-0.141	-0.195**
	(0.79)	(0.099)	(0.091)	(0.09)	(0.085)
Number of Competitors (NC)		-0.039***	-0.045***		
		(0.005)	(0.004)		
NC * Brand			0.0154**		
			(0.008)		
Herfindahl Index				1.132***	1.837***
				(0.19)	(0.43)
Herfindahl Index * Brand					-0.845***
					(0.46)
Constant	-0.661**	0.458***	0.564***	-0.888***	-0.963***
	(0.013)	(0.14)	(0.095)	(0.037)	(0.043)
Product dummies	Yes	Yes	Yes	Yes	Yes
Year Indicator 2005	-0.101***	-0.048***	-0.042**	-0.086***	-0.084***
	(0.014)	(0.017)	(0.017)	(0.013)	(0.013)
Year Indicator 2007	-0.096***	-0.087***	-0.086***	-0.067***	-0.053***
	(0.014)	(0.016)	(0.016)	(0.016)	(0.014)
Number of observations	2733	2733	2733	2733	2733
Number of Products	57	57	57	57	57

R-squared	0.61	0.7	0.7	0.63	0.63

Columns 1 - 3 show the results of the models (1) – (3) Columns 4 – 5 the results of the models (4) and (5). Cluster robust standard errors are in parentheses. *** indicates Significance at the 1 % - Level; ** indicates Significance at 5 % - Level; * indicates Significance at the 10 % - Level.

Table 8: Price effects of recalculation of reference prices for PPI"s in 2006

Model	**(1)**	**(2)**	**(3)**	**(4)**	**(5)**
RPPC	-0.422***	-0.414***	-0.394***	-0.411***	-0.342***
	(0.017)	(0.024)	(0.027)	(0.018)	(0.016)
RPPC * Patent	0.175***	0.166***	0.157***	0.127***	0.029***
	(0.031)	(0.027)	(0.024)	(0.031)	(0.032)
RPPC * Original	0.133***	0.144***	0.066	0.248***	0.008
	(0.028)	(0.037)	(0.057)	(0.07)	(0.065)
Number of Competitors (NC)		-0.002	-0.009		
		(0.004)	(0.055)		
NC * Brand			-0.015		
			(0.001)		
Herfindahl Index				0.295***	4.328***
				(0.011)	(0.7)
Herfindahl Index * Brand					-4.158***
					(0.74)
Constant	0.539***	0.565***	0.587***	0.419***	0.123***
	(0.01)	(0.044)	(0.034)	(0.048)	(0.054)
Product dummies	Yes	Yes	Yes	Yes	Yes
Year Indicator 2005	-0.129***	-0.126***	-0.119***	-0.137***	-0.153***
	(0.013)	(0.017)	(0.02)	(0.013)	(0.015)
Year Indicator	-0.140***	-0.140***	-0.137***	-0.152***	-0.079***
	(0.019)	(0.019)	(0.019)	(0.018)	(0.02)

2007					
Number of observations	1824	1824	1824	1824	1824
Number of Products	38	38	38	38	38
R-squared	0.79	0.79	0.79	0.8	0.82

Columns 1 - 3 show the results of the models (1) – (3) Columns 4 – 5 the results of the models (4) and (5). Cluster robust standard errors are in parentheses. *** indicates Significance at the 1 % - Level; ** indicates Significance at 5 % - Level; * indicates Significance at the 10 % - Level

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