Pharmaceutical Prices under Regulation: Co-Payment Exemptions and Reference Prices in Germany

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Abstract

Many countries use reference pricing to reduce expenses via substitution and competition in selected drugs' clusters. Since 2006, the German Statutory Health Insurance follows an innovative and unique regulation by further differentiating drug co-payments by the drug's price relative to its reference price. We answer the question how effective the co-payment exemption policy is in order to reduce overall prices for pharmaceuticals. We analyze prices of all drugs marketed in reference price clusters and being subject to the German policy using quarterly data from January 2007 to October 2010 published by the Federal Association of Statutory Health Insurance Funds. We find empirical evidence for differentiated price setting strategies by firm types, ranging from price decreases of -3.6% (branded generics firms) to increases of +1.6% (innovators) relative to the reference price following the introduction of co-payment exemption threshold. We refer to the latter result as the "co-payment exemption paradox". Our competition proxies (no. of firms and share of products by firm in the respective market) suggest a significant negative impact on prices.

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1 Introduction

Many countries use reference pricing to reduce expenses via substitution and competition in selected drugs' clusters. Since 2006, the German Statutory Health Insurance follows an innovative and unique regulation by further differentiating drug co-payments by the drug's price relative to its reference price. We answer the question how effective the co-payment exemption policy is in order to reduce overall prices for pharmaceuticals.

In 2010, the German Statutory Health Insurances (SHI) spent 18% of its budget (about €30bn) on drugs [FASHI, 2011]. In particular the generic market is regulated to achieve reductions in total expenses. The share of generic pharmaceuticals amounts to 63% terms of sales and to 28% in terms of turnover in Germany [ProGenerika, 2011]. Several supply side instruments aim at enhancing price competition, e.g. by less regulated market access. The main aim at the demand side is to exploit possible elastic demand, e.g. by reference pricing and co-payment schemes.[1] Both latter demand side instruments let patients freely choose their medication and, in addition, guide them to cost-efficient drug use. In 2006, the German SHI implemented a new regulation to decrease selling prices and to enhance switching to low-price drugs within the reference cluster: patients are exempted from co-payments for selected active clusters if firms set a price 30% or more below the reference price.

Reference pricing is one important way to regulate drug prices. In short, the goal is to lower expenses by steering demand to low price drugs. If firms set prices above the reference price, the consumer pays the full difference.

Starting in Germany in 1989, reference pricing has been introduced e.g. in Australia, British Columbia, Italy, Spain, Denmark, Sweden and The Netherlands.

In the U.S., the main ways to regulate pharmaceutical prices....

reference pricing often discussed...

Our contribution is different to the literature in several aspects (compare Section 2. First, it extends the empirical literature on price setting behavior of firms in regulated pharmaceutical markets by combining reference pricing and co-payments. Second, we look at potential co-payment exemptions for selected low-price drugs within a reference price cluster as opposed to overall co-payment increases. Additionally, our estimation strategy enables us to measure causal effects.

Our study analyzes the pricing behavior of firms before and after the introduction of co-payment exemptions for drugs priced below a certain level within selected reference price clusters. We observe quarterly price data of all drugs marketed in reference price clusters from January 2007 to October 2010 in Germany. We present results of static and dynamic linear panel data models and consider exits and entry in our extended specification. The estimated price effect of the policy ranges from -3.6% for branded generic manufacturers to +1.6% for innovative producers; we call price increases after the new policy as the "co-payment exemption paradox". Our findings suggest a negative price effect of competition. Differentiating the effects by market dynamics and firm types, we find evidence for decreasing prices for younger products entering after Jan

[1] For an overview see Kanavos et al. [2008], Puig-Junoy [2010], Schneeweiss [2007] and Berndt et al. [2011].

2007 and mixed effects for exits. Our results are robust to several specifications. We also control for two-level fixed effects, the heterogeneity of active ingredient clusters, autocorrelation, and heteroscedasticity.

After a literature overview, we explain shortly the German market for pharmaceuticals and its specific regulatory framework in Section 3. Section 4 condenses the theoretical ideas of the firms' price setting behavior and the incentives of the demand side. In Section 5 we discuss our data, the estimation strategy, and identification of our key parameter. Sections 6 and 7 present and discuss our results.

2 Literature Overview

Both, theoretical and empirical literature on reference pricing is vast. Today, researchers and policy makers agree that reference prices indeed reduce prices on average within the respective reference price cluster [Zacher, 2000]. Puig-Junoy [2007] finds that reference pricing leads to price convergence down to the reference price. He also provides a comprehensive review on the effect of regulation on prices in Europe [Puig-Junoy, 2010]. In descriptive studies, Puig-Junoy [2004] finds no increasing competition under reference pricing in Spain. Brekke et al. [2009] estimate an overall reduction of prices after the introduction of reference pricing in Norway in 2003.

In Germany, Pavcnik [2002] finds price reductions of 10% to 26% and a higher price reduction for products from branded firms after the introduction of a reference price. Augurzky et al. [2009] utilize a panel data set on German prescription drugs from 1994 to 2005 and find price decreases of about 7% due to the introduction of a reference price. Using micro data of patients of a German sickness funds, Stargardt [2010] estimates savings in the market of statins of €94 to €108 m due to reference prices. More studies focus on European health care systems: for Denmark, Kaiser et al. [2010] estimate a list price decrease of 26% on average due to a reform of the reference price scheme in 2005 using a nested logit demand model.

In a theoretical work, Miraldo [2009] evaluates the effectiveness of reference price setting strategies and finds an incentive to coordinate price setting in systems where the total reimbursement is defined by the average price of all products in the market. In a vertical product differentiation model, reference prices decrease prices but are not successful in promoting generic drugs [Merino-Castelló, 2003].

Here, we deal with the question whether possible co-payment exemptions lead to further price decreases within the selected reference price cluster. The focus of empirical studies dealing with co-payments mainly lies on the question whether higher co-payments or cost-sharing lead to a reduction of medical use and thus expenses. For the US, the RAND Health Insurance Experiment is an important study about drug co-payments and price elasticity. It finds that although use of medical care decreases in all groups when facing higher co-payments, health status declines only but strongly for those people who are less healthy and have lower-income [Gruber, 2006]. Manning et al. [1987] survey the early literature analyzing the experiment. Chandra et al. [2010] provide a recent survey and an analysis of co-payment increases in Medicare. Their results for elderly people are very similar to the results of the RAND Health Insurance

Experiment. Li et al. [2007] also look at elderly when cost sharing increases and find that while prescription drug use decreases, the number of physician visits increases (negative cross-price elasticity). Baicker and Goldman [2011] provide a survey on studies analyzing the effects of increases in cost-sharing. These studies suggest a price elasticity of 0.2-0.6 similar to the results from the RAND Health Insurance Experiment where the range depends on the drug class and its importance [Goldman et al., 2004].

Landsman et al. [2005] find a relative low demand elasticity for prescription drugs for patients whose benefit plans changed from a 2-tier to a 3-tier co-payment design in the US. Moreover, Gaynor et al. [2007] estimate a decrease in drug spending and use following an increase of prices. Similar to our approach, Duggan and Morton [2011] use a price equation and first-differences to identify the negative effect of Medicare Part D membership on pharmaceutical prices for Medicare recipients.

There are only a few studies on drug co-payments in Germany. Zweifel and Crivelli [1996] provide an early theoretical work about the German reference pricing system and model a change in the co-payment scheme in 1994. Simonsen et al. [2010] analyze the drug price responses to a kinked reimbursement scheme and find price elasticities ranging from -0.08 to -0.25 for Germany. They find a higher elasticity for low income and low educated people.

We do not estimate price elasticities. Our focus lies on strategic pricing of firms offering generics versus innovative firms, both facing the same change in the regulatory framework.

We also analyze the effect of competition - defined by market size and the number of products per firm in the market - on prices. In a study about pricing behavior of firms and generic competition in the US, Wiggins and Maness [2004] find that competition decreases prices. In contrast, Frank and Salkever [1997] and Grabowski and Vernon [1992] find price increases for products from branded firms facing generic competition, the so-called "generic paradox" or "generic competition paradox" [Scherer, 1993]. The empirical literature about competition in the European market includes Ganslandt and Maskus [2004] who find decreases of manufacturer prices by 12% to 19% after the introduction of parallel imports regime.

3 The market for pharmaceuticals: Regulating supply and demand

Several reimbursement and pricing policies are simultaneously in place in the German market for pharmaceuticals.[2] In 1989, Germany was the first country which introduced an internal reference pricing scheme in order to lower pharmaceutical expenses. Since 2006, co-payment exemption levels (CELs) have been introduced in selected reference price clusters (see Subsection 3.3).

The co-payments and the reference price scheme we focus on in this study, only apply to members of the "gesetzliche Krankenkassen" (German *Statutory Health Insurances* (SHI)). The SHI comprises 160 independent, but highly regulated, non-profit insurance companies. It covered more than 69.5 m people (or

[2]For a detailed overview of regulatory instruments see Kanavos et al. [2008], Studies [2008].

about 85% of the population) in 2010 [BMG, 2011].[3]

In general and in short, physicians and pharmacists only have limited influence on the patient's choice in Germany, while the first has no and the latter has a low financial incentive to subscribe/sell more expensive drugs. Demand is mainly driven by the patient's health insurance or the patient herself.

3.1 Reference Pricing in Germany

Setting up a Reference Pricing Scheme requires two steps. First, a *reference price cluster* is defined which comprises all exchangeable products in a therapeutic market (curing one specific disease). A reference price cluster should contain –in terms of their effectiveness– substitutable generic and originator drugs of different active ingredients [Zweifel and Crivelli, 1996, Danzon and Ketcham, 2004]. The "Gemeinsamer Bundesausschuss" (*Federal Joint Committee*)[4] is responsible for the decision to set up reference price clusters. From 2007 to 2010, on- and off-patent drugs could be included if the on-patent product did not add any additional benefit ("me-too drugs"). In some cases, the Federal Joint Committee pooled only on-patent drugs in one reference price cluster, so-called "jumbo groups". Before becoming effective, pharmaceutical firms can comment the decision and present objections.

Second, the "Spitzenverband Bund der Krankenkassen" (Federal Association of Statutory Health Insurance Funds (FASHI)) defines a maximum reimbursement, the reference price, on a per package basis. After normalization of prices according to package size, dosage form, and concentration the reference price has to lie below 30% of the total price interval. In addition, at least 20% of all packages and of all prescriptions must be available for prices equal to or below the reference price. Products with less than 1% market share are not considered in the calculations. The calculation bases on prices from the former year. Special market characteristics are considered by physicians and pharmacologists of the FASHI. The normalized reference price is adapted to all available package sizes, dosage forms, and concentrations and published online. The FASHI reviews reference prices regularly (at least every year) and adjusts them if necessary.[5]

3.2 Co-Payments

The SHI applies cost sharing of pharmaceuticals since 1923 when patients had to cover 10%-20% of the costs [Zacher, 1973]. Since January 2004, patients pay 10% of the pharmacy's selling price, p_i, within the minimum of €5 and the maximum of €10. The co-payment must not exceed the price and, thus, shows the following form for product i

$$co-payment_i = \begin{cases} p_i & if \quad p_i \leq €5 \\ €5 & if \quad 5 < p_i \leq 50 \\ 0.1p_i & if \quad 50 < p_i \leq 100 \\ €10 & if \quad p_i > 100 \end{cases} .$$

[3] Several exceptions, for example a high income, being civil servant or self-employment, allow people to switch to a private health insurance.

[4] The Federal Joint Committee consists of five representatives of the SHI, five physicians, one dentists, one hospital representative, and three non-party members.

[5] Stargardt et al. [2005] provide a detailed description of the German reference pricing.

Patients have to co-pay for each single package of drugs they buy in a pharmacy. Drug co-payments added up to €1.76 billion (2.40 euro per package) in 2010 [Bundesvereinigung deutscher Apothekenverbände (ABDA), 2011]. The costs for prescribed drugs per capita amounted to 474 euro on average (incl. VAT) [ABDA, 2011]. Compared to other European countries and to the US, the fraction of drug co-payments is small in Germany [Aaserud et al., 2009].

3.3 Co-payment Exemptions

Since 2006, the SHI can introduce co-payment exemption levels (CELs) for selected clusters of reference priced drugs. If firms decrease their prices below this exemption level patients do not co-pay for their drugs. The selection of clusters to be exempted from co-payments bases on expectations to generate savings by the new policy. According to personal discussions with managers of the FASHI the decision depends on assumptions about the patients' substitutional behavior, the budget effects of canceled co-payments, and characteristics of the therapeutic market. Regarding the market characteristics, the FASHI consults physicians, pharmacists and drug experts before introducing a co-payment exemption level. The calculation of a CEL bases on normalized packages and is then converted to a per package basis. In general, the maximum price of an exempted drug lies 30% below the respective reference price.

Most likely, the idea of the new policy originates in tiered co-payment schemes, which are common in the US since the early 1990ies. Tiered co-payments steer consumption to preferred (by the insurers) drugs and usually differentiate between products from generic and branded producers [Kanavos et al., 2008]. In Germany, the co-payment only depends on prices.

In July 2006, 50 producers sold 2,102 products in 63 reference price clusters which were actually exempted from co-payments due to the new policy. The number of products and manufacturers rose to 12,887 products sold by 128 manufacturers in 173 reference price clusters in March 2010. Since then, the number of exempted products reduced to about 6,618 in December 2010 while the number of manufacturers and reference price clusters decreased only slightly.

Since 2004, health insurances and manufacturers are allowed to conclude exclusive rebate contracts, an instrument intensively used since 2007. Patients are often exempted from co-payments when consuming the rebated drugs independent of the CEL (most likely, the health insurance has negotiated a price below the CEL). In early 2010, 185 insurers concluded rebate contracts for over 2.5 million drugs with 141 pharmaceutical companies. Altogether, 47.5% of all prescriptions were covered by rebate contracts [KBV, 2011].

4 Firms' and Patients' Incentives

Patients can choose to buy a more expensive drug than prescribed (with the same active ingredient) and to pay the difference to the price the SHI would cover. This fact insures non-zero demand for high priced products. Physicians and pharmacists are assumed to act as perfect agents due to the strict regulation.

We assume that firms maximize profits. Firms are free in setting prices.

Before the introduction of CELs, there is a small incentive to set prices below the reference price for products with selling prices up to €5 and between €50

and €100 only. Up to €5, patients save every cent a price is reduced below the reference price. For the latter case, for each Euro below the reference price, patients pay €0.1 less co-payments. However, we consider demand elasticity to be low and, thus, the incentive to set prices below the reference price as low if any, as discussed by Schneeweiss [2007] and Puig-Junoy [2004]. For drugs sold for €100 and above or between €5 and €50 we cannot identify incentives to decrease prices further than the reference price.

Why do we observe prices above the reference price? Some firms might set prices above the reference price due to the product's higher pharmacokinetic quality or efficacy [Brekke et al., 2009]. Differences in observed quality and trust in so-called experience and credence goods may drive patients to pay more for their preferred brand. For instance, Brekke et al. [2007] discuss eventual health problems patients face when they consume a less suitable drug because it is low-priced.

Other firms might face marginal costs which are higher than the reference price due to low productive efficiency or high advertising costs. Although direct to consumer advertising for prescription drugs is not allowed in Germany firms can advertise their non-prescription drugs and thereby create a brand name. Advertising for non-prescription drugs can affect the market for prescription drugs because the brand name is the same on both markets. Indeed, branded generics are a feature of the German market, as pointed out by Kanavos et al. [2008].

We differentiate our analysis by firm types: (1) generic and (2) branded generic firms, (3) innovators, and (4) importers.

In general, after the treatment, firms have an incentive to lower prices on or below the exemption level as long as the increase in demand exceeds the price loss. This incentive is stronger for higher priced drugs of €100 per package or more where the savings due to the co-payment exemption reaches its maximum of ten euro. Thus, the new CEL increases price elasticity of demand.

(1) Generic firms usually face low marginal costs. However, the generic drug market is already very competitive today. Especially for low-price generics, there is little scope for price reductions left.

(2) Branded generic firms price only slightly higher than generic firms. They can build on their brand margin but also face higher costs for advertising. After a CEL has been introduced in a cluster, branded generic firms will behave similar to generic firms given the small scope of possible price reductions. Thus, we hypothesize that generic firms (1) and branded generic firms (2) are not affected as strongly as the other firm types by the new policy.

(3) Innovative products can become more exclusive if some competitors decrease their prices. Facing fewer products in the high-price-high-quality market the remaining firms can set higher prices (competition effect). However, this might also induce entry of innovative and high priced drugs (composition effect). Both effects may lead to prices increase after the introduction of a CEL although competition in the low-price sector increases.

(4) Importers can specialize on drugs which are expensive in Germany but less expensive elsewhere in Europe (selection effect). Since these firms do not face manufacturing costs, they can reduce prices parallel to the producers but on a lower level.

Firms which set prices above the CEL have either marginal costs above the CEL (inefficient firms) or rationalize their strategy by unobserved product qual-

ity, thus facing inelastic demand. Firms might also collude. However, reference price clusters comprise several huge international multi-product firms making coordination difficult.

Over time, reference prices decrease stepwise when prices decrease on average. In this process, firms might face higher marginal costs than reference prices and decide not to decrease their prices or to exit the market. However, firms may also consider strategic price increases to keep up the average price in the cluster and to subsidize their low-price packages.

5 Estimation Strategy and Data

5.1 Data

We observe quarterly price data on product level of all drugs belonging to a reference price cluster in Germany from January 2007 to October 2010. Prices are defined as pharmacies' selling prices including VAT and the pharmacist's reimbursement. We trace products by a unique identification number (PZN) by active ingredient, package size, strength, form of administration, and reference price cluster. Information on reference prices are publicly available.[6] We augment the data with product specific co-payment exemption levels, where applicable. The Federal Association of Statutory Health Insurance Funds in Germany (FASHI) provides data since May 2006 publicly [FASHI, 2011]. By the end of 2010, the data covered 71.7% of all drug packages sold and 36.6% of all pharmaceutical expenses in Germany [ProGenerika, 2011].

We observe product level data over 16 quarters. In the full sample, out of 35,629 products 12,252 drugs entered the market and 9,128 exited the market during that time period. We classified the 364 companies according to their web page into six groups: generic firms, branded generic firms, innovators, traders, importers, and herbal drug firms.[7] Table 1 explains the 6 classes and Table 9 in the Appendix relates each firm we observe in our data to a specific classification.

In order to reveal effects of co-payment exemptions we reduce our sample to those clusters in which co-payment exemption thresholds have been introduced in the second period, in April 2007, or later. In addition, we exclude 719 products from trading firms and 48 drugs from herbal companies due to their seldom classification; and we condition the sample on prescription drugs to ensure homogeneous market conditions. The selection leaves us a sub-sample of 49,184 out of 468,234 observations which split up into 26,189 observations of generic firms, 9,071 observations of branded generic firms, 6,122 observations of innovative firms, and 7,802 observations of importers. We analyze a very similar sub-sample compared to all products that ever got a co-payment exemption (Table 2).

Table 2 provides a descriptive overview of our sample and separates products belonging to clusters with (yes) and without (no) co-payment exemption thresh-

[6] In cooperation with the German Drug Regulatory Authorities the German Institute for Medical Documentation and Information (DIMDI) is a central information platform for pharmaceutical products in Germany and updates its database of reference prices quarterly [DIMDI, 2011].

[7] Belonging to e.g. the class of innovative firms does not mean that these firms never sell generics.

Table 1: Firm Classification

Firm Classification	**Definition of the Classification**
generic	market mainly generic products, do not invest in R&D for new pharmaceuticals, and do not advertise their non-prescription products publicly, e.g. AbZ Pharma
branded generic	market mainly generic products, do not invest in R&D for new pharmaceuticals, and advertise their non-prescription drugs publicly, e.g. Ratiopharm
innovative	invest in R&D for new pharmaceuticals, e.g. Pfizer
trading	trade drugs, e.g. Bestphago
importing	import drugs from EU countries and brand products with their name, e.g. KohlPharma
herbal	produce mainly non-prescription products such as health supplements and food supplements, e.g. Hevert

Source: own classifications.

olds. We deflate prices and reference prices to the base year 2007. Mean prices in € are similar for products from generic and branded generic firms; importers and innovative firms tend to focus on higher priced drugs. On average, prices are lower after the introduction of a co-payment exemption level. Since reference prices are adjusted regularly and often simultaneously to the introduction of co-payment exemption thresholds, it is hard to disentangle the effects descriptively without controlling for the reference price. Generic and branded generic firms sell on average below the reference price. Innovators and importers set prices above the reference price after the introduction of a co-payment exemption level.

Figure 1 provides an overview of pricing behavior around the introduction of a co-payment exemption threshold in period 0 by firm classification. The upper graph illustrates decreasing prices from three quarters before the introduction of the threshold for all firm types. After the treatment, mean prices are fairly constant for importers, generic and branded generic firms tend to decrease prices further and innovative firms slightly increase their prices. Remember that these average prices of e.g. branded firms may include generic drugs if these are offered by the same firm. Furthermore, average prices may also change just because of composition effects. The lower graph is more important and illustrates how firms set prices with respect to the reference price. For all types of firms prices are converging towards the reference price from below before the treatment. This continues for generic and branded generic firms. However, innovators and importers set prices above the cluster's reference price after the treatment.

Our descriptive data in Table 4 supports the findings: about 100% of the generic and branded generic firms set prices below the reference price both before and after the treatment. However, innovative firms show more dynamics. One quarter of the innovative firms switches from below to above the reference price: the average decreases from 95% pricing below the reference price six quarters

Table 2: Descriptives: Mean of selected variables by firm class and before/after the introduction of co-payment exemption thresholds

Firm type	Co-payment Exemption Level	Products (#)	Price (€)	Reference Price (€)	Difference P-RP (% of price	Products in Cluster (#)
Generic	no	15,679	46.43	65.8	-24.97	48.72
	yes	10,510	35.54	41.6	-12.71	37.14
Branded Generic	no	4,437	48.55	63.16	-18.1	43.76
	yes	4,634	30.27	33.91	-9.83	25.74
Innovative	no	3,531	71.79	85.14	-8.93	47.95
	yes	2,591	65.47	60.35	28.32	31.74
Importing	no	4,520	63.9	69.2	-4.64	40.54
	yes	3,282	45.32	45.23	10.13	39.78
Total	no	28,167	52.75	68.35	-18.61	46.53
	yes	21,017	39.59	42.78	-3.45	34.37

Data Source: Federal Association of Statutory Health Insurance Funds (FASHI). Own Calculations. Sub-sample of German drugs clustered into reference price groups, Jan 2007 to Oct 2010. Prices deflated to 2007

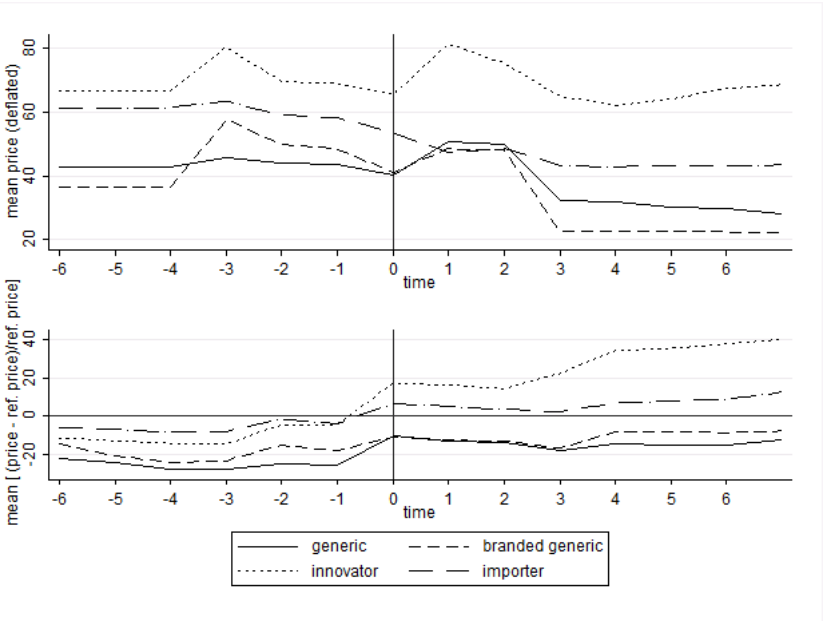
Table 3: Descriptive Comparison of Samples

	Products (#)	Price (?)	Reference Price (?)	Difference P-RP (% of price)	Products in Cluster (#)
final sample	49,184	47.13	57.43	-12.13	41.33
full sample	295,710	50.69	58.95	-11.77	39.69
total sample	395,997	44.75	51.91	-9.70	37.08

Data Source: Federal Association of Statutory Health Insurance Funds (FASHI). Own Calculations. Sub-samples of German drugs clustered into reference price groups, Jan 2007 to Oct 2010. Final sample: introduction of CEL after January 2007 used for before-after analysis, full sample: introduction of CEL before and after Jan. 2007, total: all clusters with and without CEL. Prescription drugs only.

Final sample: introduction of CEL after January 2007 used for before-after analysis, full sample: introduction of CEL before and after Jan. 2007, total: all clusters with and without CEL. Prescription drugs only.

Figure 1: Prices (mean) and *(price-reference price)/reference price*-ratio around the introduction of a co-payment exemption for low priced drugs (time=0) by firm classification.



Data Source: FASHI. Own Calculations. Sub-sample of German drugs clustered into reference price groups, Jan 2007 to Oct 2010. Prices deflated (base year: 2007).

before the treatment to 70% six quarters after the treatment. The number of low-pricing importers decrease only slightly.

These results let us conclude that the different firm types indeed react differently to the new policy. Innovative firms increase the products' prices to overcome the loss in demand while almost all generic and branded generic firms price below the reference price and some price below the newly introduced co-payment exemption level.

5.2 Estimation Strategy and Identification

We exploit the panel structure of our data to quantify the impact of a potential co-payment exemption and to estimate the relation between competition and prices. We set up a price equation for each drug i at quarter t clustered into the reference price cluster r, and marketed in the competitive market c:

$$\ln p_{i,t} = \beta_0 + \beta_1 \ln rp_{i,t} + \beta_2 genCEL_{r,t} + \beta_3 bgenCEL_{r,t} + \beta_4 innoCEL_{r,t}$$
$$+\beta_5 impCEL_{r,t} + \beta_6 [n]_{c,t} + \beta_7 [\tfrac{n}{m}]_{c,t} + \textstyle\sum_{t=1}^{16} \delta_{7+t}\tau_t + \gamma_i + \epsilon_{i,t}. \quad (1)$$

The price for each drug, $\ln p$, depends on its reference price, $\ln rp$, and on the introduction of a co-payment exemption level (CEL). We separate the effect of a CEL according to the type of firm: *gen* (generic), *bgen* (branded generic), *inno* (innovative) and *imp* (importing).[8] These variables are set to one from the quarter onwards in which the CEL is introduced for the reference price cluster, r, and zero before.

Furthermore, we define competitive markets, c, and include the number of products, n, and the ratio $[\frac{n}{m}]$ where m are the number of firms within c. We define the market as drugs from the same reference price cluster with the same administration and consider products from trading or herbal firms as competitors. We relax the market definition in our robustness checks. Time dummy variables, τ_t, control for quarter specific shocks common to all drugs. The parameter γ_i captures all product specific effects that are constant over time (such as quality, efficacy or the firm's management quality), and $\epsilon_{i,t}$ is a time and product specific random error term.

First, we estimate static and dynamic first-differences models. The modified Wald test for group wise heteroscedasticity suggests heteroscedastic error terms, where applicable. We reject the null that all time constant effects are zero and include quarter fixed effects. The data is first order serial correlated because we reject the null hypothesis of the Wooldridge-test for serial correlation in the error terms [Wooldridge, 2002, Drukker, 2003]. We reject the Hausman test (p-val$<$0.00) and assume product specific unobserved heterogeneity. Therefore, we set up an estimation strategy by taking first differences. We rationalize our estimation strategy in the subsection Identification below. A differences-in-differences analysis is not feasible for two reasons: First, the most important criterion to introduce the possibility of a co-payment exemption is the potential to decrease expenses within the cluster. Thus, we assume non-selected clusters not to be a valid control group. Second, the policy becomes effective for different

[8] Firm types are described in Table 1.

clusters at different points in time. In the following analysis we present four models:

1. We start with a **first-differences estimation (FD)**

2. We add a first lag of prices, $p_{i,t-1}$ to Equation 1, and estimate a dynamic model with **instrumental variables (FD.IV)** which results in consistent parameter estimates. To instrument for $p_{i,t-1}$ we utilize the mean price of all competitors, *meanpother*, the ratio of reference prices to prices, $[\frac{rp}{p}]$, and the ratio of reference price to the mean price of the competing products, $[\frac{rp}{meanpother}]$. Given our final specification, the lag of prices is true state-dependent.

3. To check for robustness, we estimate a linear model with **two levels of fixed effects (2FE.IV)** using the command `gpreg` based on an algorithm by Guimaraes and Portugal [2009] where we extend equation (2) by a cluster specific fixed effect, ρ_r. This approach gives the correct standard errors under the assumption that the error term is homoskedastic and independently distributed.

4. Last, we estimate (3) by applying `felsdvreg` (2FE.IV2) with robust standard errors. Here, the cluster effect is included as dummy variables, while the individual drug effect is eliminated by subtracting group means [Cornelissen, 2008].

To gain more insights into the dynamics of the market, we estimate the first-difference estimation (FD) (as in (1)) and separate the coefficient capturing the CEL by entry, exit, and incumbent. Entering drugs enter the market after the first quarter, exits leave the market before quarter 16, and incumbent firms stay in the sample over the whole period. We interact each CEL by firm type and by entry, exit, or incumbent.

Identification

Estimation strategies that rely on differencing, either first lags or means, and include a lagged dependent variable result in inconsistent estimates. We use instrumental variables for the first lag of prices to ensure consistent results. Prices of competitors reflect price shocks of input goods, e.g. electricity or labor costs, and indicate the degree of competition in the market. Thus, all prices in the market react to external shocks in a similar way. We use the third lag of the mean price of competitors to ensure exogeneity of our instrumental variable. Less competition in a reference price cluster might allow firms to set higher prices for their products while more competition can decrease prices in relation to the respective reference prices. We use the third lag of the ratio $[\frac{rp}{meanpother}]$ to ensure exogeneity of our instrumental variable. Furthermore, firms know the quality of their goods and set optimal prices. The distance $[\frac{rp}{price}]$ indicates how much firms value their product with respect to the average reference price. Again, we use the third lag to ensure exogeneity.

Our instrumental variables are significant in the first-stage (see Table 8 in the Appendix) and do not reject the F-test of excluded instruments. Furthermore, we reject the null of the Stock-Yogo weak identification test (Cragg-Donald Wald F statistic of 32,41) and do not reject the null that endogenous regressors can actually be treated as exogenous. The identifying assumption for instrumental

variables can be tested by the over-identification test of all instruments: we reject the null that instruments are valid instruments with Hansen J statistic's p-value of 0.19.

Our identification strategy relies on the assumption of an exogenous introduction of the co-payment exemption level. The decision to treat a reference price cluster bases on assumptions of cluster-intern substitutional behavior of patients. Physicians, pharmacists and economists are involved in the decision process. The FASHI finally considers the individual market structure of each drug and potential savings for the health insurance due to increasing competition. Firms cannot influence the decision itself or the timing but only react to the introduction of a CEL.

In our sample we include only clusters in which a CEL had been introduced after January 2007. CELs were already in place for some reference price clusters since mid 2006, thus, we restrict our analysis to "late introductions", if any. However, to draw more general conclusions, we show that our selected sample is not systematically different from early treatments (full sample). Observations from clusters without a CEL, however, show a different price structure (compare Table 2).

Furthermore, reference prices are based on average prices of all products in the cluster. We argue that the rules to set these prices do not allow single firms to individually influence reference prices. Since on average 7.5 firms belong to one reference price cluster we assume that the firms do not interact strategically. Lastly, the environment is considered as very competitive.

On the one hand, the probability of collusion might decrease with the number of firms and more competing products might decrease mark-ups and prices. On the other hand, high prices might attract firms to enter a competitive market. Thus, we cannot separate these two effects in our estimation and assume the market structure to be exogenous. However, we do not interpret market structure as a causal driver for prices but as correlated with prices.

The key identifying assumption in our estimation strategy is that prices pre and post treatment are only affected by the introduction of a CEL. We assure this assumption by including time dummy variables and eliminating all product specific fixed effects by first differences. In addition, we control for fixed effects on the reference price cluster level and get identical results, see Table 5. Furthermore, CELs are introduced at different points in time distributed over 15 quarters. A potential omitted variable would have to affect each exempted reference price cluster at a different point in time which supports our assumption of the exogenous introduction of CELs. We add the cluster's reference price to our model to control for adjustments which may also influence prices simultaneously. We reject the idea to compare treatment and control groups because first, clusters are selected because of potential to reduce expenses and are thus different to non-selected clusters.

6 Results

Table 5 summarizes the results of our empirical models described in section 5.

Our preferred specification FD.IV shows negative price effects due to the introduction of a co-payment exemption threshold for products from branded generic (-3.6%) and importing firms (-3.7%). We do not find significant effects

Table 4: Percentage of Firms Pricing Below the Reference Price Before and After the Treatment (time=0)

	Generics		Branded generics		Innovators		Importers	
time	mean	N	mean	N	mean	N	mean	N
-9	1.00	693	0.98	179	0.88	161	0.86	179
-6	0.98	1,265	1.00	293	0.95	280	0.94	417
-3	0.99	2,008	0.99	548	0.95	437	0.96	617
0	0.96	2,261	0.99	755	0.73	565	0.83	748
3	0.99	711	1.00	307	0.77	183	0.90	294
6	0.99	688	1.00	303	0.68	150	0.86	242
9	0.97	606	1.00	281	0.61	133	0.69	159
Total	0.98	26,166	0.99	9,071	0.82	6,122	0.87	8,101

Data Source: Federal Association of Statutory Health Insurance Funds (FASHI). Own Calculations. Sub-sample of German drugs clustered into reference price groups, Jan 2007 to Oct 2010.

Table 5: Results

	OLS	FE	FD
$\triangle$Price ($\ln p$)	Coeff.	Coeff.	Coeff.
	(t-val.)	(t-val.)	(t-val.)
$\triangle$Reference Price ($\ln rp$)	0.907***	0.257***	0.207***
	(661.0)	(25.94)	(23.04)
$\triangle$CEL[1], generic firms	0.028***	-0.035***	-0.019***
	(10.83)	(-8.802)	(-5.861)
$\triangle$CEL, branded generic firms	0.059***	-0.071***	-0.083***
	(22.49)	(-10.02)	(-14.65)
$\triangle$CEL, innovative firms	0.341***	0.017**	0.012***
	(43.57)	(2.896)	(2.695)
$\triangle$CEL, importing firms	0.247***	-0.013***	-0.03***
	(49.16)	(-2.21)	(-5.505)
$\triangle n$, competitive products	-0.001***	-0.001***	-0.001***
	(-26.58)	(-6.129)	(-7.521)
$\triangle[\frac{n}{m}]$, products/firms	0.068***	0.012***	0.015***
	(28.77)	(2.737)	(4.145)
Constant	0.048***	2.557***	-0.027***
	(8.84)	(68.60)	(-27.81)
Product FE	no	yes	yes
Cluster FE	no	no	no
Quarter Dummies	yes	yes	yes
N	49,184	49,184	44,836
F	35,419	392.40	150.96
$R^2 adj.$	0.91	0.49	0.21

Robust t-values in parentheses. Significance level: *** indicates $<$ .01, ** indicates $<$ .05, * indicates $<$ .1; Data Source: Federal Association of Statutory Health Insurance Funds (FASHI). Own Calculations. Sub-sample of German drugs clustered into reference price groups in which a CEL had been introduced after Jan 2007. Time: Jan 2007 to Oct 2010. With CPI deflated prices and reference prices; base year 2007; [1]CEL=1 after introduction of a co-payment exemption level.

Table 6: Effects of CEL differentiated by Entry, Incumbents, and Exits

	Entry	Incumbents	Exits
Generic firms	-0.001	-0.006	0.044***
	(-0.182)	(-0.771)	(5.37)
observations	16,220	9,008	1,791
Branded generic firms	-0.026***	-0.062***	-0.067***
	(-3.659)	(-4.883)	(-2.301)
observations	3,701	4,928	527
Innovative firms	-0.001	0.057***	0.036*
	(-0.103)	(3.699)	(1.715)
observations	3,483	2,032	802
Importing firms	-0.032***	0.036	-0.087***
	(-4.08)	(3.792)	(-4.023)
observations	4,478	2,208	1,456

Robust t-values in parentheses. Significance level: *** indicates $< .01$, ** indicates $< .05$, * indicates $< .1$
Data Source: Federal Association of Statutory Health Insurance Funds (FASHI). Own Calculations. Sub-sample of German drugs clustered into reference price groups, Jan 2007 to Oct 2010.

With CPI deflated prices and reference prices; base year 2007.

for generic firms which may be due to the competitive market for generics. Surprisingly, our estimates show that innovative firms increase their prices by +1.6% after the introduction of a co-payment exemption for low-priced drugs. Since the policy was implemented to decrease expenditures and prices, we call this finding the "co-payment exemption paradox". Some products might provide a higher quality which is unobserved by the regulator and allows firms to increase prices after the new policy. If the cluster-specific reference price decrease by 1% the price decrease by 0.23% on average. In our specification, reference prices have a weaker influence on prices than the first-order lag of prices. Results, interpreted as true state-dependency, indicate a delay in price adjustments possibly due to strategic price setting.

Augurzky et al. [2009] use similar price data and estimate an (ex-factory) price increase of 0.29% when the reference prices increases by 1% which is close to our estimate. Stargardt [2011] uses data of one German health insurance (2004 to 2006) and finds that patients are not price sensitive because they may not have enough information about the co-payment scheme or are exempted from co-payments. Our results contrast his findings because we find that firms decrease their prices due to price sensitive patients. Our results are in line with Pavcnik [2002] who finds substantial decreases in prices after a potential rise of the patients out of pocket payments.

More competition, measured by a growing number of products and an increasing ratio of products per firm, decreases prices. Other studies are pointing in the same direction: in Stargardt [2011] an additional firm in the active ingredients cluster reduces the price per package by 0.031% per quarter; Reiffen and Ward [2005] estimate a structural model and present a generic wholesale price decline of about 30% following the entry of 1 to 10 firms; for anti-invectives. Wiggins and Maness [2004] present a price decrease of 52% as the number of sellers increases from between 6 and 15 to more than 40; and for Sweden, Ganslandt and Maskus [2004] present a reduction in manufacturer's price of 12-19% if the number of firms increases by one in generic markets.

We interact the 28,336 entries, 16,934 incumbents, and 4,681 exits with firm types and with the variable which indicates co-payment exemptions. In Table 6 we present the 12 coefficients of interest.

All significant coefficients show a positive price effect for innovative products and a negative price effect of branded generic firms. Generic firms leaving the market tend to increase prices after the introduction of a CEL which may also indicate inefficient firms with high marginal costs. All entries decreases prices in view of the CEL, although coefficients are only significant for products from branded generic and importing firms. Even for innovative products, entry seems to increase competition and decrease prices. However, cheaper products may enter the market later, thus reducing average prices. The large negative price effect for exits from branded generic and importing firms indicate a price decrease to a level where firms sell at or below marginal costs and then leave the market because production is not profitable anymore.

6.1 Robustness Checks

In our final sample we excluded firms classified as trading and herbal. Including both firm types does not change the signs of the presented coefficients and does only slightly change their magnitude and significance. Prices increase by 3% for products from trading companies and by 4.9% for products from herbal producer. Additionally, our general results are robust in sample size. An estimation with all prescription drugs classified into any reference price cluster (365,696 observations) results in very similar coefficients and significance. However, it is more difficult to find valid instruments (not rejected by the over-identification test).

Alternative instrumental variables are available, such as higher-order lags of the presented ones or higher-order lags of prices. Our selected instrumental variables are based on economic rationales and show good econometric characteristics. Results using further lags of the price as instrument for prices lagged one period yield similar results in magnitude and significance of our coefficients. However, Hansen's J statistics of the over-identification test of all instruments reject the null when using prices lagged by 11 quarter and more as instruments.

Alternatively, we used other measures of competition, e.g. the number of firms as opposed to the number of products/firm. All our measures confirmed the negative price impact of competition. We test for three market sizes with strict, normal, and wide definitions of the competitive environment. Strict markets include products with the same form, reference price cluster, active ingredients, package size, and concentration per quarter. The widest market definition includes all products with the same active ingredient per quarter as the relevant market. The effect of an additional product is larger in stricter market definitions (per additional firm -0.4%). In our final specification we define a competitive market by the same form, active ingredient, administration, and per quarter and present a price effect of -0.1% per additional firm. Results for all specifications are available from the authors upon request.

Our third and fourth specification (2FE.IV and 2FE.IV2) in Table 5 are based on a 2-level fixed effects approach and result in similar conclusions as our preferred specification.

7 Discussion

Our results suggest differentiated pricing patterns by firm types. Branded generic and importing firms decrease their prices due to the introduction of a co-payment exemption threshold by -3.6% and -3.7%, respectively. However, this is not true for all firms: innovators tend to ignore co-payments and increase prices by about 1.6% on average. Our results are similar to Grabowski and Vernon [1992] and Frank and Salkever [1992] in the way that we find firms increasing prices due to a policy introduced to reduce pharmaceutical expenditures. Prices above the exemption levels or even above the reference price can be a sign for market power. Differences in observed quality and trust in so-called experience and credence goods may drive patients to pay more for their preferred brand. For instance, Brekke et al. [2007] discuss eventual health problems patients face when they consume a less suitable drug because it is low-priced.

We observe negative but small price reductions due to the recently introduced policy. Given the small effect for only two firm types (out of four) it is questionable to interpret the policy as a success as its goal was to enhance competition in order to reduce prices.

A first reason for the small price reaction of generic/branded generic firms may be that co-payments for products with a price below the reference price are limited to 10%, max €10. Thus, the maximum amount a patient can save is €10.

Second, the generic market is considered to be competitive (prices close to marginal costs) which would make significant reductions in prices difficult for the firms. Additional information from the FASHI indicates that less products are sold below the decreasing co-payment exemption level today. In March 2010, 12,887 products were exempted from co-payments while 6,672 drugs were exempted in January 2011 [FASHI, 2011]. Moreover, descriptive data confirms that less products are exempted from co-payments immediately after the adjustment of reference prices and co-payment exemption levels. These findings suggest that co-payment exemption thresholds are too low for many firms. Therefore, the price effect after the introduction of the policy is only of limited magnitude for these two groups.

We may also underestimate the real effect of co-payment exemption levels due to missing information about rebate contracts. Rebate contracts are settled between health insurances and producers to directly negotiate lower prices given a certain demand. Sometimes, insurers offer co-payment exemptions for these selected low priced drugs to their insureds. This implies that list prices (which we observe) must be higher than the prices health insurances pay for the drugs under rebate contracts. Therefore, estimates including price data about rebate contracts would possibly increase a negative price effect of co-payment exemptions for contracted drugs.

Fifth, co-payment exemption levels are often introduced simultaneously with a bundle of instruments, such as rebate contracts and non-reimbursement of price increases for generic drugs ("price stop") between Jan 2007 and Jan 2010 and the mandatory rebate for generic drugs of 10%. However, the first policy was not applied to drugs priced above their reference prices and the latter was not applied to drugs exempted from co-payments. Nevertheless, we control for these influences econometrically using time dummies and reference prices.

Our study evaluates the price effect of the introduction of a co-payment

exemption threshold in a given regulatory health care system. However, the question arises how effective the co-payment exemption is compared to other instruments. Puig-Junoy [2010] points out that from an economic perspective it is not necessary to intervene in markets for generic drugs. Therefore, to rationalize a regulation like reference prices or co-payment exemptions, these have to prove to be more efficient than the economically optimal solution: strict generic substitution. Indeed, e.g. Italy, the Netherlands and Poland set the maximal reimbursable price equal to the lowest price in the reference price cluster [Puig-Junoy, 2010]. Furthermore, some countries regulate generic markets with a strict generic substitution policy, e.g. Norway.[9]

To analyze welfare effects of the policy one would need information on sales to observe substitutional behavior after a possible co-payment exemption for low-priced drugs. For an analysis of the full costs it is not sufficient to observe drug prices and quantities only: data on physician's or hospital's visits and follow-up costs should be taken into account. Moreover, policy makers should pay attention to innovators that do not decrease prices after the introduction of a co-payment exemption threshold. Drugs are selected for reference price clusters when they have the same or very similar quality and efficacy in curing a specific disease. Thus, products of innovative firms are classified by the health insurance as having the same quality as all other drugs in the cluster. Here, we cannot speak of an innovation but more of an imitation, a "me-too" drug. Reference prices can be an instrument to put me-too drugs under price pressure. However, innovations with a superior quality have to pay off to reward pharmaceutical innovation.

8 Conclusion

In this study we utilize data on German reference price drugs of the years 2007 to 2010 to evaluate the effect of the introduction of co-payment exemptions thresholds on pharmaceutical prices. A first-difference model with instrumental variables for lagged values of the price reveals that firms react differently to this policy: firms producing branded generics or importing drugs decrease prices after the introduction of a possible co-payment exemption. Firms that invest in R&D (innovators) tend to increase prices of their products. We call this result the "co-payment exemption paradox" similar to the so-called "generic paradox". Furthermore, competition has a significant negative effect on prices. However, the constitution of our data allows us only limited conclusions. To estimate welfare effects and price elasticities of patients or health insurances we would need to utilize sales data of drugs. Then, a structural demand and supply system would reveal more information about the behavior of firms, patients, and health insurances.

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Appendix

Table 7: Results using different methodological approaches to check robustness

	FD.IV[1]	FE.2*level*[1]	FD.2level
△Price ($\ln p$)	Coeff.	Coeff.	Coeff.
	(t-val.)	(t-val.)	(t-val.)
△Price$_{t-1}$($\ln p$)	0.322***	0.494***	
	(2.69)	(0.028)	
△Reference Price ($\ln rp$)	0.235***	0.220***	0.225***
	(22.60)	(0.008)	(24.42)
△CEL[3], generic firms	0.002	-0.002	-0.017***
	(0.662)	(0.002)	(-5.427)
△CEL, branded generic firms	-0.036***	-0.032***	-0.083***
	(-5.64)	(0.004)	(-14.63)
△CEL, innovative firms	0.016**	0.019***	0.013***
	(2.498)	(0.005)	(2.93)
△CEL, importing firms	-0.037***	-0.025***	-0.032***
	(-5.632)	(0.005)	(-5.588)
△n, competitive products	-0.001***	-0.001***	-0.001***
	(-6.138)	(0.000)	(-7.744)
△$[\frac{n}{m}]$, products/firms	0.019***	0.002	0.016***
	(4.558)	(0.003)	(4.45)
Constant	-0.018		-0.028
	(-6.614)		(-29.75)
Individual FE	yes	yes	yes
Cluster FE	no	yes	yes
Quarter Dummies	yes	yes	yes
N	31,911	36,209	44,836
F	99.60		
$R^2 adj.$	0.184		0.211
Hansen J, $\chi^2(2)$, p-value	0.203		
F test of excl. instr.	70.20		

Robust t-values in parentheses. Significance level: *** indicates < .01, ** indicates < .05, * indicates < .1; Data Source: Federal Association of Statutory Health Insurance Funds (FASHI). Own Calculations. Sub-sample of German drugs clustered into reference price groups in which a CEL had been introduced after Jan 2007. Time: Jan 2007 to Oct 2010. With CPI deflated prices and reference prices; base year 2007; Instrumental variables used: third lag of mean prices of competitors, the ratio of reference price and prices, and the ratio of reference price and mean price of competing products; [2] CEL=1 after introduction of a co-payment exemption level.

Table 8: First-Stage Results of FD.IV

	FD.IV
$\text{Price}_{t-1}(\ln p)$	Coeff.
	(t-val.)
Reference Price ($\ln rp$)	0.014***
	(0.003)
CEL[3], generic firms	0.005***
	(0.001)
CEL, branded generic firms	0.010***
	(0.001)
CEL, innovative firms	0.013***
	(0.003)
CEL, importing firms	0.008***
	(0.001)
n, competitive products	0.000*
	(0.000)
m, competing firms	-0.005**
	(0.002)
RP/P_{t-3}	0.024***
	(0.005)
$[\text{RP}/\text{mean price of competitors}]_{t-3}$	-0.053***
	(0.005)
$\text{Mean Price of Competitors}_{t-3}$	-0.031***
	(0.006)
Constant	-0.014***
	(0.002)
N	
Centered R^2	
Angrist-Pischke multivariate F test of excluded instruments:	

Data Source: Federal Association of Statutory Health Insurance Funds (FASHI). Own Calculations. Sub-sample of German drugs clustered into reference price groups with introduction of CEL after Jan 2007 to Oct 2010. Robust t-values in parentheses. Significance level: *** indicates $< .01$, ** indicates $< .05$, * indicates $< .1$.

[3] CEL=1 after the introduction of a co-payment exemption threshold, zero before.

With CPI deflated prices and reference prices; base year 2007.

Table 9: Firm Classification

Firm's Type	**Firm's Name**
generic	1 A Pharma GmbH,AAA-Pharma GmbH, ACCEDO Arzneimittel GmbH, ALIUD PHARMA GmbH, ALMUS Deutschland GmbH, APOCARE Pharma GmbH, AWD.pharma GmbH & Co. KG, AbZ-Pharma GmbH, Alhopharm Arzneimittel GmbH, Alpharma-Isis GmbH & Co. KG, Apothekamed S.A., Apotheke in der Droote, Aristo Pharma GmbH, Aurobindo Pharma, Axea Pharma GmbH, AxiCorp GmbH, BOLDER Arzneimittel GmbH & Co. KG, Basics GmbH, Bendalis GmbH, Berco - Arzneimittel Gottfried Herzberg, Billix Pharma GmbH, Blanco Pharma GmbH, Bluefish pharmaceuticals AB, Byk Tosse Arzneimittel GmbH, C.P.M. ContractPharma GmbH & Co. KG, CONCEPT HEIDELBERG GmbH, CT Arzneimittel GmbH, Cefak KG., Combustin Pharmaz. Präparate GmbH, Cordes Pharma GmbH, D.A.V.I.D. Pharma GmbH, DENK PHARMA GmbH & Co. KG, DOLORGIET GmbH & Co. KG, Dermapharm AG, Desitin Arzneimittel GmbH, Desma Healthcare, Dexcel Pharma GmbH, Docpharma bvba, Dr. K. Hollborn & Söhne GmbH & Co.KG, Dr. Loges + Co., Dr. Ritsert Pharma GmbH & Co KG, Dr. Robert Winzer Pharma GmbH, Drossapharm AG, Duopharma Biotech Bhd., Engelhard Arzneimittel GmbH & Co KG, Ethinerics Pharmaceutical GmbH, Euro OTC Pharma GmbH,FLEXOPHARM GmbH & Co. KG, Febena Pharma GmbH, GALENpharma GmbH, GIB Pharma GmbH, Grnwalder Gesundheitsprodukte GmbH, HAEMATO PHARM AG, Heumann Pharma GmbH & Co. Generica KG, Heunet Pharma GmbH, Hofmann Pharma GmbH & Co. KG, Holsten Pharma GmbH, Hormosan Pharma GmbH, INRESA Arzneimittel GmbH, InfectoPharm Arzneimittel und Consilium, Institut für industrielle Pharmazie For, JULPHAR Pharma GmbH, Juta Pharma GmbH, Key Pharmaceuticals Pty Ltd., Kohne Pharma GmbH, LIBRA-PHARM Gesellschaft fr pharmazeut, LINDEN ARZNEIMITTEL-VERTRIEB-GmbH, Lindopharm GmbH, Lionpharm Regulatory Consulting GmbH, LšNpharma GmbH, MIP-Holding GmbH, MR Pharma GmbH, Mylan dura GmbH, Optopan Pharma GmbH, Pelpharma Handels GmbH, People's Pharma B.V., Pharma Funcke GmbH, Pharma Stulln GmbH, Pharma Wernigerode GmbH, Pharmapol Arzneimittelvertrieb-GmbH, Pharvita GmbH, Profusio Gesundheits GmbH Deutschland, Pädia Arzneimittel GmbH, QUISISANA PHARMA AG, Ranbaxy Laboratories Limited, Ravensberg GmbH Chemische Fabrik, Retorta GmbH, Rodleben Pharma GmbH, Rottapharm Madaus GmbH, RubiePharm Arzneimittel GmbH, Rudolf Lohmann GmbH KG, Ruhrpharm AG, S & K Pharma Schumann und Kohl GmbH, Sophien-Arzneimittel GmbH, Spreewald-Pharma GmbH, Steiner & Co. Deutsche Arzneimittelgesellschaft, Strathmann GmbH & Co. KG, Sdmedica GmbH Chem. Pharm. Fabrik, TAD Pharma GmbH, TEVA GmbH, Uropharm AG, VERON PHARMA Vertriebs GmbH, Versandapotheke DocMorris N.V., Vipharm GmbH, WERO-MEDICAL Werner Michallik GmbH & Co, Winthrop Arzneimittel GmbH, ZYO PHARMA TRADE GmbH & Co. KG, ZytoJen GmbH Jena, acis Arzneimittel GmbH, axcount Generika AG, axios PHARMA GmbH, betapharm Arzneimittel GmbH, biomo pharma GmbH, bittermedizin Arzneimittel-Vertriebs-GmbH, bluepharma GmbH & Co.KG, corax pharma GmbH, esparma GmbH, gepepharm GmbH, medac Gesellschaft für klinische Spezial.,medphano Arzneimittel GmbH, mibe GmbH Arzneimittel, neuraxpharm Arzneimittel GmbH, norispharm GmbH, onkovis GmbH, pharma service Grünewald GmbH, propharmed GmbH, r.p.pharma.gmbh, ribosepharm division Hikma Pharma GmbH
branded generic	Actavis Deutschland GmbH & Co. KG, Amgen GmbH, Apotheker Walter Bouhon GmbH, Astrid Twardy GmbH, Chauvin ankerpharm GmbH, HEXAL AG, Hemopharm GmbH, MEDICE Arzneimittel Pütter GmbH & Co. KG, Merck Selbstmedikation GmbH, Merckle GmbH, Procter & Gamble Germany GmbH & Co Oper, SANOL GmbH, STADA Arzneimittel AG, Sandoz International GmbH, Sandoz Pharmaceuticals GmbH, TOGAL-WERK AG, Trommsdorff GmbH & Co. KG Arzneimittel, Töpfer GmbH, Wick Pharma, ratiopharm GmbH

Table 10: Firm Classification (cont'd)

Firm's Type	**Firm's Name**
innovative	ADL GmbH Anti-Dekubitus-Lagerungssystem, ALCON Pharma GmbH, ALLERGAN, INC., APOGEPHA Arzneimittel GmbH, APS Pharma GmbH, Abbott GmbH & Co. KG, Acino Holding AG, almirall, S.A., Amdipharm Limited, Arzneimittel ProStrakan GmbH, Astellas Pharma GmbH, AstraZeneca GmbH, Axcan Pharma Inc., B&B-Pharma GmbH, B. Braun Melsungen AG, BC Biochemie GmbH, BENSAPHARM GmbH & Co. KG, Baxter Deutschland GmbH, Bayer AG, Berlin-Chemie AG, Boehringer Ingelheim Pharma GmbH & Co., Bristol-Myers Squibb GmbH & Co. KGaA, CARINOPHARM GmbH, CNP Pharma GmbH, CYATHUS EXQUIRERE PharmaforschungsGmbH, Carl Hoernecke Chem. Fabrik GmbH & Co., Chemische Fabrik Kreussler & Co. GmbH, Chiesi GmbH, DAIICHI SANKYOÿDEUTSCHLAND GmbH, Deutsche Chefaro Pharma GmbH, Dr. August Wolff GmbH & Co. KG Arzneimittel, Dr. Falk Pharma GmbH, Dr. Felgenträger & Co. ™ko.-chem. und P, Dr. Gerhard Mann chem.-pharm. Fabrik GmbH, Dr. Kade Pharmazeutische Fabrik GmbH, Dr. R. Pfleger Chemische Fabrik GmbH, Dr. Ritsert Pharma GmbH & Co KG, Dyckerhoff Pharma GmbH & Co. KG, Eisai GmbH, Essex Pharma GmbH, FERRING Arzneimittel GmbH, Firma Krewel Meuselbach GmbH, Fresenius SE & Co. KGaA, G. Pohl-Boskamp GmbH & Co. KG, Galderma Laboratorium GmbH, GlaxoSmithKline GmbH & Co. KG, Goldshield Group Limited, Grünenthal GmbH, HENNIG ARZNEIMITTEL GmbH & Co. KG, HEYL Chemisch-pharmazeutische Fabrik, Hospira, Inc., ICHTHYOL-GESELLSCHAFT CORDES, HERMANNI, InnovaPharma, Intendis GmbH, Interpharma, Verband der forschenden ph, Janssen-Cilag GmbH, Jenapharm GmbH & Co. KG, Johnson & Johnson GmbH, Kwizda Agro GmbH, LEO Pharma GmbH, Laves Arzneimittel GmbH, Lilly Deutschland GmbH, Louis Widmer GmbH, Lundbeck GmbH, MCM Klosterfrau Vertriebsgesellschaft, MEDA Pharma GmbH & Co. KG, MSD SHARP & DOHME GMBH, MTT Pharma & Bio-technology Co.,Ltd, MaxMedic Pharma GmbH Merck KGaA, Merck Serono GmbH, Merz GmbH & Co. KGaA, Mundipharma GmbH, NeoCorp Aktiengesellschaft, Nordmark Arzneimittel GmbH & Co. KG, Novartis Pharma GmbH, Novo Nordisk Pharma GmbH, NycomedÿGermany Holding GmbH, ORION Pharma GmbH, OmniVision GmbH, Oncosachs Pharma GmbH, Onkoworks Gesellschaft für Herstellung, Ortho-McNeil Janssen Scientific Affairs, PARI GmbH, PB Pharma GmbH, PCR Pharmaceutical Consultancy in Regis, Pentatop Pharma GmbH, Pfizer Deutschland GmbH, Pharma Medico Group, PharmaCept GmbH, Pierre Fabre Dermo-Kosmetik GmbH, RIEMSER Arzneimittel AG, Roche Deutschland Holding GmbH, Rotexmedica GmbH Arzneimittelwerk, SANUM-Kehlbeck GmbH & Co. KG, SERAG-WIESSNER KG, SERVIER Deutschland GmbH, SIGA Laboratories, SOLVAY GmbH, Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis Deutschland GmbH, Sanorell Pharma GmbH & Co KG, Schwarz Pharma Deutschland GmbH, Serumwerk Bernburg AG, Shire Deutschland GmbH, Spirig Pharma AG, Stiefel Laboratorium GmbH, Synthon BV, TEOFARMA S.R.L. Takeda Pharma GmbH, Taurus Pharma GmbH, Temmler Pharma GmbH & Co. KG, Tha Pharma GmbH, UCB Pharma GmbH, URSAPHARM Arzneimittel GmbH, VARIPHARM Arzneimittel GmbH, Valeant Pharmaceuticals International, Vifor Pharma Deutschland GmbH, Warner Chilcott Deutschland GmbH, Whitehall Munch GmbH, Wyeth Pharma GmbH, Wörwag Pharma GmbH & Co.KG, ZAMBON SVIZZERA S.A., bene-Arzneimittel GmbH, cell pharma Gesellschaft für pharmazeutisch., curasan AG, laboratoires genopharm, lapharm GmbH Pharmazeutische Produkte, sigma-tau Arzneimittel GmbH
importing	ACA Müller ADAG Pharma AG, APS ALL Pharma Service GmbH, Abis-Pharma, BERAGENA Arzneimittel GmbH, CC-Pharma GmbH, EMRA-MED Arzneimittel GmbH, EurimPharm Arzneimittel GmbH, GPP Pharma Arzneimittelvertriebsgesellschaft, Vertriebs Aktiengesellschaft, MILINDA GmbH & Co. KG, MTK-PHARMA Vertriebs-GmbH, Opti- Arzneimittel GmbH, Pharma Gerke GmbH, Pharma Westen GmbH, kohlpharma GmbH

Table 11: Publication Date of Reference Prices and Co-payment Exemption Levels (CEL)

Coming into effect	RP published by the DIMDI	RP published by the FASHI	CEL published by FASHI
01.01.2007	Prices from 01.01.2007	Prices from 05.10.2006 Decision from 23.10.2006	Prices from 05.10.2006 Decision from 23.10.2006
01.04.2007	Prices from 01.04.2007		
01.07.2007	Prices from 01.07.2007	Prices from 01.01.2007 Decision from 07.05.2007	Prices from 01.01.2007 Decision from 07.05.2007
01.10.2007	Prices from 01.10.2007		
01.01.2008	Prices from 01.01.2008	Prices from 01.07.2007 Decision from 26.10.2007	Prices from 01.07.2007 Decision from 26.10.2007
01.04.2008	Prices from 01.01.2008		
01.06.2008	Prices from 01.07.2007	Decision from 07.04.2008	
01.07.2008	Prices from 01.07.2008		
01.10.2008	Prices from 01.10.2008		
01.01.2009	Prices from 01.01.2009	Prices from 01.07.2008 Decision from 03.11.2008	Prices from 01.07.2008 Decision from 03.11.2008
01.04.2009	Prices from 01.04.2009		
01.07.2009	Prices from 01.07.2009		
01.10.2009	Prices from 01.10.2009		
01.11.2009	Prices from 01.04.2009	Prices from 01.04.2009 Decision from 26.08.2009	
01.01.2010	Prices from 01.01.2010		
01.04.2010	Prices from 01.04.2010	Prices from 01.04.2009 Decision from 01.02.2009	Prices from 01.04.2009 Decision from 01.02.2009
01.07.2010	Prices from 01.07.2010		
01.09.2010	Prices from 01.07.2009	Prices from 01.07.2009 Decision from 29.06.2010	
01.10.2010	Prices from 01.10.2010		
01.11.2010	Prices from 01.04.2010	Prices from 01.04.2010 Decision from 27.08.2010	
01.01.2011	Prices from 01.01.2011	Prices from 01.10.2010 Decision from 01.10.2010	Prices from 01.10.2010 Decision from 01.10.2010

Own table with data from the Federal Association of Statutory Health Insurance Funds (FASHI).