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Pharmaceutical Prices under Regulation: Tiered Co-payments and Reference Pricing in Germany

Annika Herr* Moritz Suppliet†

April 2012

Abstract

Many countries with national health care providers and health insurances regulate the market for pharmaceuticals to steer drug demand and to control expenses. For example, they introduce reference pricing or tiered co-payments to enhance drug substitution and competition. Since 2006, Germany follows an innovative approach by differentiating drug co-payments by the drug's price relative to its reference price. In this two-tier system, prescription drugs are completely exempted from co-payments if their prices undercut a certain price level relative to the reference price.

We identify the effect of the policy on the prices of all affected prescription drugs and differentiate the analysis by firm types (innovative, generic, branded generic or importing firms). To identify a causal effect, we use a differences-in-differences approach and additionally exploit the fact that the exemption policy had been introduced successively in the different clusters. We use quarterly data from 2007 to 2010 and find empirical evidence for differentiated price setting strategies by firm types, ranging from price decreases of -13.1% (branded generics firms) to increases of +2.0% (innovators) following the introduction of potential reductions in co-payments. We refer to the latter result as the "co-payment exemption paradox." Our competition proxy (no. of firms) suggests a significant but small negative correlation with prices.

JEL: D22, D40, I18, I11, L11

Keywords: pharmaceuticals, prices, co-payments, reference pricing, regulation, firm behavior

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1 Introduction

In most countries, pharmaceutical markets are regulated to control prices and total expenses. Health insurances and regulators try to increase the price elasticity of demand in markets with mostly full insurance coverage. They try to steer demand to low-priced drugs by coverage rules, reference prices or co-payments [compare Hellerstein [1998] or the literature on the RAND Health Insurance Experiment]. Both latter demand side instruments let patients freely choose their medication but, at the same time, guide them to cost-efficient drug use.[1] This in turn impacts the strategic price setting of the firms (e.g., reference pricing: Pavcnik [2002]). Furthermore, firms differentiate prices even if drugs are based on the same active ingredient. Indeed, innovators set higher prices than producers of generics [Frank and Salkever, 1992].

As in other countries, public and private expenses on health and more specifically on drugs are tremendously increasing in Germany. In 2010, the German Statutory Health Insurances [SHI] spent 18% of its budget (about €34bn) on drugs. In 1992, this number was at 16% or €18bn (=€24bn in 2010 prices) which implies a real increase of 40% over 18 years compared to an increase of 20% of total expenditures of the SHI [Bundesamt, 2012]. In 2006, the German SHI implemented a new regulation to decrease selling prices and to incentivize switching to low-price drugs within the reference price cluster: patients are exempted from co-payments if firms set a price 30% or more below the reference price.

Our study analyzes the pricing behavior of firms before and after the introduction of co-payment exemptions for relatively low-price drugs. We observe the quarterly price data of all prescription drugs marketed in reference price clusters from 2007 to 2010 in Germany. We conduct a differences-in-differences approach where we exploit the within variation of the repeated observations over time by applying first-differences and fixed-effects models. The estimated price effect of the policy ranges from -13.1% for branded generic manufacturers to +2.0% for innovative producers. We call price increases due to the new policy the "co-payment exemption paradox." Our findings suggest a negative price effect of competition. Our results are robust to several specifications and samples. In addition to our preferred differences-in-differences approach, we also apply two two-level fixed-effects estimators and control for the heterogeneity of reference price clusters and heteroscedasticity. Finally, our estimation strategy enables us to measure the causal effects of the reform on pharmaceutical prices.

Our contribution is different to the literature in two aspects. First, we evaluate the policy to tier co-payments by introducing exemption levels relative to the reference price. Second, it extends the empirical literature on the price-setting behavior of firms in regulated pharmaceutical markets by combining reference pricing and co-payments.

After a literature overview in Section 2, we explain in brief 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 parameters. Sections 6 and 7 present and discuss our results.

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

2 Literature review

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. In an early review of the literature on reference prices, Lopez-Casasnovas and Puig-Junoy [2000] conclude that RP systems better achieve their postulated goals if (1) price differences among drugs are high and (2) there is potential for price decreases. Puig-Junoy [2010] also provides a comprehensive review on the effect of regulation on prices in Europe. 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 €108m 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-Castello, 2003].

In the US, at first sight regulation differs considerably from the European markets.[2] There is neither reference pricing nor parallel trade. However, consumers face considerable co-payments where different designs (two-tier, three-tier, four-tier, etc) have been analyzed regarding their effects on drug consumption and expenses. When drug insurance was first introduced, the consumer typically paid the same coinsurance rate for any drug, but now the price paid by the customer depends on which "tier" the drug is placed. The first tiered plans typically had two tiers, but now there are usually three or even four. In such an arrangement, generic drugs will typically be on the lowest or cheapest (to the consumer) tier, seldomly also off-patent drugs. Depending on the result of negotiations, for a given therapeutic class of drugs the insurer has one or more preferred brands on the second tier, involving a higher fixed co-payment per prescription. Brands for which the insurer was unable to negotiate a favorable price (from its perspective) are placed on the third tier for which co-payments are considerably higher than for the second tier. Finally, certain very costly drugs may be placed on a fourth tier. Even if the lower three tiers have increasingly higher co-payments (say $10, $25, and $50 per 30-day prescription, resp.), the fourth tier, if the plan has four tiers, almost always has a coinsurance rate, perhaps 20-30% [Berndt and Newhouse, 2010].

[2] Berndt and Newhouse [2010] give a comprehensive overview on pricing and reimbursement in US Pharmaceutical Markets.

Co-payment exemption levels introduce a second tier of drug co-payments in Germany. Now, firms can choose to exempt patients from co-payments by decreasing prices. We focus on the question of wether this policy leads to a reduction of pharmaceutical prices. The focus of earlier empirical studies dealing with co-payments mainly lies on the question of 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 the 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 a 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 the 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 relatively low demand elasticity for prescription drugs for patients whose benefit plans changed from a two-tier to a three-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.

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 in Denmark and find price elasticities ranging from -0.08 to -0.25. 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. Haustein [2008] differentiates by drug type and summarizes his findings on statins and proton pump inhibitors as follows: Producers of patent drugs decrease prices by less than producers of off-patent originals following a change in the reference price policy between 2004 and 2007. This may be explained by a utility advantage for patent producers through unique active ingredients or the German role model function for other countries with price regulation mechanisms. The level of generic price reductions differs depending on the competitive environment, where an increasing number of firms decreases product prices on average.

We also analyze the effect of competition - defined by the number of firms in the relevant market - on prices. In a study about the 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 entry of parallel imports increasing competition.

3 The market for pharmaceuticals: regulating supply and demand

Several reimbursement and pricing policies are simultaneously in place in the German market for pharmaceuticals.[3] In 1989, Germany was the first country to introduce an internal reference pricing scheme in order to lower pharmaceutical expenses. Since 2006, co-payment exemption levels (CELs) have been introduced successively in selected reference price clusters (see Subsection 3.3) which -as we will show in the following- indeed led to price reductions.

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 69.5m people (or about 85% of the population) in 2010 [BMG, 2011].[4]

In general and in short, pharmacists only have limited influence on the patient's drug choice in Germany while they have a low financial incentive to hand out more expensive drugs. Demand is mainly driven by the patient's health insurance or the patient herself who is represented by the physician. The physician acts as the perfect agent and, basically, may subscribe all approved drugs. However, physicians have to meet drug prescription volume benchmarks and might face audits in terms of cost effectiveness of their prescription behavior. If the physician does not restrict substitution of the drug, pharmacies have to hand out the product for which a rebate contract between health insurance and the manufacturer is in place. If a rebated product is not available, the pharmacy has to offer one of the three cheapest products with the same active ingredient and dosage form; otherwise, patients receive the drug specified on the prescription. Co-payments depend on the drug's price as explained below.

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*)[5] 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

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

[4] There are several exceptions, for example, a high income, being civil servant or self-employed, allow people to switch to a private health insurance.

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

Committee pooled only on-patent drugs in one reference price cluster, so-called "jumbo groups." Before becoming effective, pharmaceutical firms can comment on 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 is based on prices of 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.[6]

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

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

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 per package) in 2010 [ABDA, 2011]. The costs for prescribed drugs per capita amounted to €474 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 is based 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 is based on normalized packages and

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

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 have been common in the US since the early 1990s. 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 exempt 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 was 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]. Since we cannot observe these negotiated prices and can only see higher list prices, our estimates probably underestimate the negative effect of co-payment exemptions on prices.

4 Firms' and patients' incentives

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

Before the introduction of CELs, there was little incentive to set prices below the reference price for products with selling prices up to €5 and between €50 and €100. Up to €5, the patient saves every cent of a price reduction below the reference price. For the latter case, for each Euro below the reference price, patients co-pay 10 percent less. However, we consider demand elasticity to be low and, thus, no incentive to set prices below the reference price, 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 [Danzon and Liu, 1996].

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 the eventual health problems patients face when they consume a less suitable drug because it is low-priced. Merino-Castello [2003] shows, theoretically, how product differentiation and inelastic demand for brand-name products effect the pricing behavior in a reference price system.

Other firms might face higher costs 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 in 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 (CEL) 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 patient's savings due to the co-payment exemption reaches its maximum of €10. Thus, we postulate that the new CEL increases the price elasticity of demand. Over time, reference prices decrease stepwise when prices decrease on average. In this process, firms might decide not to decrease their prices further 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. We differentiate the effects by four firm types:

(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) Innovators may build on their reputation and the fact that long-term consumers of their drugs may face high switching costs (experience and credence goods) [Crawford and Shum, 2005, Ching, 2010]. Merino-Castello [2003] argues that the drugs (former patented versus generics) are observed as differentiated products although the active ingredients may be equivalent. Miraldo [2009] also concludes that product differentiation in terms of quality leads to higher prices (product differentiation). Innovative products may also 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 higher priced drugs (composition effect), increasing average prices further. All three reasons may lead to price increases after the introduction of a CEL although competition in the low-price sector increases.

(4) Importers can specialize in 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 and exit those markets which become too competitive.

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

5 Estimation strategy and data

5.1 Data

We observe quarterly price data on the product level of all drugs belonging to a reference price cluster in Germany for the years 2007 to 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.[7] 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 augment the data with product-specific co-payment exemption levels, where applicable. The Federal Association of Statutory Health Insurance Funds in Germany (FASHI) has been providing data since May 2006 publicly [FASHI, 2011]. CELs also apply to those drugs which enter the reference price cluster after the last publication of the FASHI. Thus, we imputed the missing information on the CEL if the CEL had been observed for the other drugs within a narrowly defined group (around 35,000 out of 395,000 observations).[8] If we do not impute this information, our sample of switchers would be artificially doubled (44,000 instead of 22,000 observations). However, our main results would qualitatively not be altered (compare Section 6.1).

We classified 364 companies[9] according to their web page into six groups: generic firms, branded generic firms, innovators, traders, importers, and herbal drug firms.[10] Table 1 explains the main four classes[11] and Table 8 in the Appendix relates each firm we observe to a specific classification.

[Table 1 about here]

We restrict our sample to prescription drugs to ensure homogeneous market conditions.

In order to reveal the effects of co-payment exemptions we reduce our sample to those clusters in which co-payment exemption thresholds have been introduced after the first period and before the last period, i.e., between April 2007 and October 2010. In the final sample, we focus on 2,072 out of 35,629 different packages which split up into 952 drugs of generic firms, 455 drugs of branded generic firms, 356 drugs of innovative firms, and 309 drugs of importers.

[Table 2 about here]

Table 2 presents the timing of the treatment. Co-payment exemption levels have been introduced in 64 reference price clusters between April 2007 and Dec 2010. The heterogeneity in cluster size is clearly visible in Quarter 5, where three clusters and 673 drugs are treated versus Quarter 14 (189 drugs out of 21 clusters). To observe at least two time periods after the introduction, drugs

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

[8] CEL was imputed if the active ingredient, the reference price group (1-9), the reference price level (="Festbetragsstufe", 1-3), package size, strength, dosage form, and the reference price itself coincided in the respective quarter.

[9] We do not observe conglomerates or multi-brand companies and probably underestimate market power.

[10] Firms which are active in more than one type are classified according to their main activity.

[11] We exclude 719 products from trading firms and 48 drugs from herbal companies due to their seldom classification.

which are treated the first time in Quarter 16 do only enter the analysis as the control group.

[Table 3 about here]

Table 3 provides a descriptive overview of the treatment group facing the policy and separates products belonging to clusters before and after the introduction of co-payment exemption thresholds. We deflate prices and reference prices to the base year 2007. Mean prices in Euro are similar for products from generic and branded generic firms; importers tend to focus on higher priced drugs, at least after the treatment. Innovative firms price highest in both time periods. On average, prices are lower after the introduction of a co-payment exemption level for all groups. This relative price increase becomes clearer when looking at (P-RP)/RP, the relative price difference. Before the treatment, all firm types price between 47% and 7% below the reference price on average, while after the introduction, innovators and importers price above the reference price. Patients would have to pay the absolute difference plus the co-payment if choosing one of these high-price drugs as compared to exempted low-price products. 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.

Furthermore, Table 3 shows that about 100% of the generic and branded generic firms set prices below the reference price both before and after the policy. About one quarter of the innovative firms switch to prices above the reference price. The number of low-pricing importers decreases only slightly.

The last column shows the proportion of products actually available below the CEL. As expected, the majority of products offered by generic firms is exempt from co-payments while innovative firms only offer 7% of their drugs below the threshold.[12] The number of firms within one competitive cluster (around 23, standard deviation 7.5-8.5) used as a proxy for competition in our analysis does not alter significantly across firm types and periods.

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 define a price equation for each drug i at quarter t.

This equation shows our preferred specification in first-differences.[13]

$$\begin{aligned}
\Delta \ln p_{i,t} \quad = \quad & \beta_0 + \beta_1 \Delta \ln rp_{i,t} + \beta_2 \Delta(gen_i \times CEL_{i,t}) && (1)\\
& + \beta_3 \Delta(bgen_i \times CEL_{i,t}) + \beta_4 \Delta(inno_i \times CEL_{i,t}) && (2)\\
& + \beta_5 \Delta(imp_i \times CEL_{i,t}) + \beta_6 \Delta m_{i,t} + \sum_{t=2}^{15} \delta_t \tau_t + \alpha_i + \epsilon_{i,t}
\end{aligned}$$

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 add the cluster's reference price to our model to control for adjustments which may also influence prices simultaneously. A reference price adjustment is published a few months before the new reference price is valid. This gives the firms time to adjust their

[12] Innovative firms may offer generics.

[13] The fixed-effects model is defined analogously and can be derived by deleting Δ from (1).

prices accordingly. We separate the effect of a CEL by the type of firm: *gen* (generic), *bgen* (branded generic), *inno* (innovative) and *imp* (importing).[14] These variables are set to one from the quarter onwards in which the CEL is introduced for the reference price cluster and zero before.

We further include the number of firms, m, within its reference price cluster, to capture competitive pressure and size of the market. 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.

When estimating this linear regression with fixed effects, the F-test on the fixed effects $u_i = 0$ can be rejected. Thus, as expected, the products exhibit unobserved heterogeneity. Product-specific time invariant effects are controlled for by applying linear first-difference estimators (FD) and fixed-effects estimators (FE). Both estimators exploit the panel data structure similarly and are solely based on the variation within one drug, not between the drugs. Time invariant heterogeneity is canceled out in both cases. This comprises all observable product specific characteristics like package size, strength, active ingredient or dosage form as well as unobservable characteristics like side effects or differences in perceived quality. The FE estimator would be more efficient than the FD estimator if the error term was serially uncorrelated. Furthermore, FE is less sensitive to violation of the strict exogeneity assumption. So FE is preferred when the processes are weakly dependent over time. However, performing a Wald-test we can reject the null of no autocorrelation (F(1,1975) = 1938.394). Thus, the first-difference model is our preferred specification assuming first-order autocorrelation of the prices.[15]

Furthermore, we apply a difference-in-difference approach to estimate a causal effect of the treatment. The idea is that the control group is similar in all other aspects except that it is not exposed to the treatment during either period. In the case where the same units within a group are observed in each time period, the average price change in the control group is subtracted from the average price change in the treatment group. This removes biases in post-treatment comparisons between the treatment and control group that could be the result from permanent differences between those groups, as well as biases from comparisons over time in the treatment group that could be the result of trends.

Finding a suitable control group is essential for this estimation strategy. Here, the control group consists of those drugs which receive a CEL in the last quarter 16. It contains 751 packages with very similar descriptive statistics in terms of price and pricing behavior (compare Table 4). In our analysis, we include all products but estimate only from quarter one to 15 and, thus, pretend that the control group is not treated. We assume the products in the treatment and control group to be comparable as both are chosen to receive the treatment but differ only in the timing of the introduction. However, our results do not change qualitatively whether the control group is excluded from the analysis or whether it is included into the treatment group (more details in Section 6.1).

[Table 4 about here]

[14] Firm types are described in Table 1.

[15] The modified Wald test for groupwise heteroscedasticity suggests heteroscedastic error terms, where applicable.

Table 4 further shows that most of the drugs already face a CEL before April 2007 (CEL before Q2). These drugs are more expensive on average and are thus having given more scope for price decreases at the early stage of treatment. However, to draw more general conclusions, we postulate from Table 3 that the monetary effect of the introduction of a CEL is underestimated in our analysis on later treatments, since the average price is significantly higher for early treatments (CEL before Q2 versus treat). Observations from clusters without any CEL and all others enter the last line of Table 4 for a comparison.

Identification

Our identification strategy relies on the assumption of an exogenous and independent introduction of the co-payment exemption level. The decision as to which reference price cluster to treat is taken by the FASHI as explained in Section 3.3. Firms can neither influence the decision itself nor the timing but only react to the introduction of a CEL.

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. For example, prices of drugs with less than 1% market share are not considered. Since on average 23 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 to be a causal driver for prices but to be correlated with prices. Nonetheless, the new policy may even reduce the likelihood of collusion since price decreases may lead to high increases in demand.

The key identifying assumption in our estimation strategy is that prices pre and post treatment are only affected by the introduction of a CEL and that this policy variable is not correlated with the error term. One may argue that 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 April 2006 and March 2008 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. Furthermore, and most important, CELs are introduced successively at different points in time distributed over 15 quarters. A potential omitted variable which is correlated with the policy variable and enters the error term would have to affect each exempted reference price cluster exactly at these different points in time. Nevertheless, we assure this assumption by including time dummy variables and eliminating all product specific time-invariant characteristics by first differences or fixed effects. In addition, we control for fixed effects on the reference price cluster level (2 level fixed effects) and get identical results, see Table 6 in the Appendix.

6 Results

Table 5 summarizes the results of our empirical models described in section 5. The first-difference coefficient β_2 can be interpreted as follows. Everything else equal, the introduction of the CEL decreases the drug's price by -13.1%. That means that the price decreases 13.1% more than if the CEL had not been introduced.

[Table 5 about here]

Our preferred specification FD.RP shows negative price changes due to the introduction of a co-payment exemption threshold for products from branded generic (-13.1%), generic (-4.9%) and importing firms (-2.4%) given the change in the reference price, if any. The effect for generic firms is smaller than for branded generic firms which may be due to the competitive market for generics. Surprisingly, our estimates show that innovative firms increase their prices by +2.0% given the change in the reference price after the introduction of a co-payment exemption for low-priced drugs. Since the policy was implemented to decrease expenditures, we call this finding the "co-payment exemption paradox." This may be explained by the theory on trust and credence goods or perceived quality differences [Crawford and Shum, 2005, Merino-Castello, 2003]. Some products might also provide a higher quality which is unobserved by the regulator and allows firms to increase prices after the new policy. References prices are supposed to be verified annually and only adjusted if considered necessary. However, if the cluster-specific reference price decreases by 1% the drug's price decreases by 16.5% on average. Thus, the adaptation to the new reference price is the most important factor for price reductions.

If the number of firms increases by 10% prices decrease by 1%. This negative correlation is small but significant and underlines the negative effect of competition on prices.

The fixed effects model fe.rp gives very similar results although the following coefficients are slightly different. Innovators increase prices by 5% compared to the non-treated control group and given the reference price. Importers do not statistically significantly alter prices.

Columns fd and fe present the model suppressing the reference price. The most important difference to columns fd.rp and fe.rp lies in the coefficient of the innovating firms. It switches from a positive to a negative sign (if significant). This means that the "co-payment exemption paradox" holds only with respect to the reference price, but not in absolute terms. Still, the former is surprising since patients need to pay the full positive difference to the reference price.

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 slightly higher than our estimates (0.16% and 0.19%). 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.

Less competition, measured by a decreasing number of firms, increases prices. Other studies point 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 one to 10 firms; for anti-invectives. Wiggins and Maness [2004] present a price decrease of 52% as the number of sellers increases from between six 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.

6.1 Robustness checks

Robustness Table 6 shows our robustness checks with respect to different methodological approaches. First, we estimate the fixed-effects model additionally instrumenting the reference price (FE.IV) to deal with its possible endogeneity. Until now reference prices have been assumed to be exogeneous because, on average, 65 product-prices per cluster from earlier quarters are utilized to calculate the maximum reimbursement. In addition, the calculation procedure is enriched with numerous special rules to avoid any strategic price-setting behavior of firms.

Still, we use the average reference price of all other reference price clusters as the instrumental variable for the reference price (FE.IV). We postulate that the average reference price of all other clusters reflects price shocks or common regulatory shocks well but averages out possible collusion or the political influence of big firms or small clusters. The summary results for the first-stage regressions of the two-stage least squares approach show that the chosen instrument is relevant. The F-value of the first-stage regression is $5107 > 10$ and the test of excluded instruments can be significantly rejected ($F(1, 20222) = 21519.67$). We argue that it is also valid since reference price clusters are very heterogeneous with respect to competition, technological change or any demand shocks. The results change only slightly in the magnitude of the coefficients. The reference price and the price change of innovating firms after the treatment are less important while the negative coefficients on generics and branded generics slightly decrease.

Second, we estimate two linear models with two levels of fixed effects (FE.2level and FE.2level.robust). The first is based on an algorithm by Guimaraes and Portugal [2009] where we extend equation (FE.rp) by a cluster-specific fixed effect, ρ_r. This approach gives the correct standard errors under the assumption that the error term is homoscedastic and independently distributed. In the second model, we estimate (FE.rp) by applying Cornelissen [2008] which is a two-level fixed-effects estimator with robust standard errors (FE.2level.robust). Here, the cluster effect is included as dummy variables, while the individual drug effect is eliminated by subtracting group means (`felsdvreg` in Stata). Interestingly, both models provide estimates which are very close to the IV estimates.

Table 8 shows additionally, that our general results are robust with respect to the chosen sample. A before-after analysis with all prescription drugs that had ever switched (FD.before-after, including quarter 16) as well as with only those treated before Q16 (FD.treat) result in very similar coefficients and significance as the final first-differences analysis. Reporting results of the original data set (non-imputed co-payment exemption levels when incorrectly missing which results in an artificially bigger treatment group) does surprisingly not alter much either.

7 Discussion

Our results suggest differentiated pricing patterns by different firm types. Generic, branded generic and importing firms decrease their prices due to the introduction of a co-payment exemption threshold by 5%, 13% and 2.4%, respectively. However, innovators' strategies seem to be unaffected by higher consumers' co-payments. They increase prices by about 2.0% on average relative to the reference price. Our results are similar to Grabowski and Vernon [1992] and Frank and Salkever [1992] in the way that we find firms increasing prices although the policy had been 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.

Although co-payments for products with a price below the reference price are limited to 10%, max €10, the demand elasticity seems to be considered as important by the firms. Otherwise, we would not observe these quite significant reactions in prices.

Generic firms decrease prices by less than branded generic firms. The generic market is considered to be competitive (prices close to marginal costs even before the reform) which makes 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]. Therefore, the price effect after the introduction of the policy is only of limited magnitude for generics which face already low prices.

We may 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.

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.[16]

In a first attempt to quantify the effect, we estimated a model with one parameter capturing the average effect of the reform across all firm types (Table

[16] For an overview of alternative regulations see Kanavos et al. [2008].

6, last column FE.average). Multiplying the estimate of -2.6% with the total spending of the SHI on prescription drugs under reference pricing of €12,14bn in 2010 results in savings of €315m given that this reform would be introduced for all drugs sold in 2010 for the first time.

Apart from this simple calculation, to analyze the true 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. However, 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. Reference prices can be an instrument to put so-called 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 exemption thresholds on pharmaceutical prices. A differences-in-differences model reveals that firms react differently to this policy: firms producing (branded) generics or importing drugs decrease prices after the possible exemption of out-of-pocket payments for low-priced drugs. Firms that invest in R&D (innovators) increase prices of their products relative to the reference price. While the average price of drugs sold by innovative firms is 14% below the reference price (rp) before the reform, it exceeds the rp by 11% after the reform. 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. In a future project, we plan to analyze the welfare effects of regulatory reforms by estimating structural demand and supply models containing the detailed analysis of substitutional behavior and price elasticities of patients or health insurances.

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Tables

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
importing	import drugs from EU countries, e.g. KohlPharma

Source: own classifications.

Table 2: Number of Packages facing new Introduction of Co-Payment exemption level (CEL)

Quarter	Q3	Q5	Q7	Q9	Q14	Q16
# Packages	673	277	117	12	189	751
# clusters	8	3	15	1	21	16

Table 3: Descriptive statistics: Mean and standard deviation (in ()) of selected variables by firm class and before/after the introduction of co-payment exemption thresholds, only Treatment group Q1-Q15

CEL	Before	After	Before	After	Before	After	Before	After	After
Firm type	N		Price		P-RP/P		P<RP		P<CEL
Generic	1,998	4,780	31.39	20.64	-0.47	-0.16	0.99	0.99	0.6
			(33.89)	(19.32)	(0.48)	(0.15)	(0.12)	(0.11)	(0.49)
Branded	1,074	3,191	42.84	23.97	-0.29	-0.13	0.95	1	0.38
Generic			(61.26)	(32.62)	(0.40)	(0.14)	(0.21)	(0.04)	(0.49)
Innovator	667	1,701	57.23	40.81	-0.11	0.14	0.88	0.64	0.07
			(78.5)	(53.5)	(0.41)	(0.28)	(0.32)	(0.48)	(0.26)
Importer	687	1,512	33.21	30.64	-0.07	0.09	0.87	0.74	0.001
			(24.68)	(24.72)	(0.21)	(0.24)	(0.33)	(0.44)	(0.04)

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. Standard errors in parenthesis.

Table 4: Descriptive comparison of samples, Q1-Q15

Sample	Price	Price<RP	Price<CEL	CEL available? (1=yes)	N
treat	29	0.92	0.28	0.72	15,609
control	33	0.93	.	0	6,356
CEL before Q2	54	0.96	0.52	1	269,919
All	45	0.95	0.39	0.76	368,881

Data Source: Federal Association of Statutory Health Insurance Funds. Own calculations with data on German drugs clustered into reference price groups, Jan 2007 to Oct 2010. Treat: introduction of CEL after January 2007 and before October 2010; control: introduction of CEL Oct.-Dec. 2010; All: all drugs in a reference price cluster (with and without CEL). Prescription drugs only.

Table 5: Main results

	fd.rp b/se	fd b/se	fe.rp b/se	fe b/se
Δ ln(reference price)	0.165***			
	(0.014)			
ln(reference price)			0.194***	
			(0.015)	
Δ generics × CEL	-0.049***	-0.095***		
	(0.006)	(0.006)		
generics × CEL			-0.044***	-0.096***
			(0.008)	(0.008)
Δ branded generics ×	-0.131***	-0.171***		
	(0.009)	(0.009)		
branded generics × CEL			-0.075***	-0.118***
			(0.011)	(0.010)
Δ innovator × CEL	0.020***	-0.016**		
	(0.006)	(0.006)		
innovator × CEL			0.052***	0.016
			(0.009)	(0.008)
Δ importer × CEL	-0.024*	-0.059***		
	(0.011)	(0.014)		
importer × CEL			-0.006	-0.033*
			(0.012)	(0.014)
Δ # of firms in cluster	-0.001**	-0.002***		
	(0.000)	(0.000)		
# of firms in cluster			0.000	-0.001***
			(0.000)	(0.000)
constant	-0.034***	-0.034***	2.654***	3.382***
	(0.003)	(0.003)	(0.054)	(0.014)
quarter dummies	yes	yes	yes	yes
product dummies	no	no	yes	yes
N	20,204	20,204	22,313	22,313
R-sqr	0.21	0.18	0.52	0.48
BIC	-51,790	-51,068	-49,221	-47,797

Robust t-values in parentheses. Significance level: * p<0.05, ** p<0.01, *** p<0.001 *** 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.

Appendix

Table 6: Estimated price effects using different methodological approaches

log(price)	FE.IV[1] b/se	FE.2level[2] b/se	FE.2level.robust[3] b/se	FE.average[4] b/se
log(reference price)	0.149***	0.386***	0.384***	0.206***
	(0.009)	(0.008)	(0.009)	(0.015)
generics × CEL*	-0.056***	-0.055***	-0.096***	
	(0.005)	(0.003)	(0.004)	
branded generics × CEL*	-0.085***	-0.083***	-.0833***	
	(0.007)	(0.004)	(0.006)	
innovator × CEL*	0.043***	0.049***	0.049***	
	(0.005)	(0.005)	(0.004)	
importer × CEL*	-0.014	-0.013**	-.012	
	(0.008)	(0.005)	(0.007)	
co-payment dummy				-0.026***
				(0.005)
log(# of firms)	0.019**	0.018*	-0.002	0.043***
	(0.006)	(0.007)	(0.002)	(0.011)
constant			3.388***	2.493***
			(0.044)	(0.063)
product dummies	yes	yes	yes	yes
quarter dummies	yes	yes	yes	yes
cluster fixed effects	no	yes	yes	no
N	22,279	22,313	22,313	22,313
R-sqr	0.51	0.47	0.48	0.50
BIC	-49041	-50262	-47769	-48725

Robust std. errors 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; * CEL=1 after introduction of a co-payment exemption level. [1]: ln(reference price) instrumented with average price across all other reference price clusters. [2] and [3] two-level fixed effects accounting for the reference price cluster, [4] average treatment effect across all firm types

Table 7: Estimated price effects using different Samples to check robustness

Δ log(price)	FD.before-after b/se	FD.treat only b/se	FD.original b/se
Δ log(reference price)	0.182***	0.167***	0.194***
	(0.013)	(0.015)	(0.004)
Δ generics × CEL	-0.042***	-0.049***	-0.019***
	(0.005)	(0.006)	(0.009)
Δ branded generics × CEL	-0.108***	-0.127***	-0.108***
	(0.008)	(0.009)	(0.003)
Δ innovator × CEL	0.007	0.021**	0.016***
	(0.006)	(0.006)	(0.003)
Δ importer × CEL	-0.011	-0.023*	-0.025***
	(0.008)	(0.011)	(0.003)
Δ log(# of firms)	-0.006	0.028	-0.016**
	(0.008)	(0.015)	(0.005)
constant	-0.034***	-0.038***	-0.035***
	(0.003)	(0.004)	(0.002)
quarter dummies	yes	yes	yes
N	21,944	15,613	41,061
R-sqr	0.21	0.24	0.19
BIC	-54986	-40009	-116495

Robust std. errors 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 Dec 2010. With CPI deflated prices and reference prices; base year 2007; [2] CEL=1 after introduction of a co-payment exemption level. FD.before-after: includes control group (switching in last quarter) as treated, FD.treat only: drops control group, simple before-after. FD.original: original dataset, CEL not imputed, i.e. including 22,000 would-be switchers

Table 8: 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 9: 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 10: 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).

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