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The Effects of Reference Pricing on Ex-factory Prices of Rx Drugs in Germany – A Panel Data Approach

Abstract

This paper examines effects of reference pricing for prescription drugs in German social health insurance based on econometric panel data methods. We analyze the effect on ex-factory prices. Moreover, we investigate whether manufacturers adapt prices of their products not subject to reference pricing as a consequence of changes in reference prices of their products subject to reference pricing. We use a large panel data set of nearly all German prescription drugs on a monthly basis between October 1994 and July 2005. Altogether, the data comprise almost 4 million observations. They provide information on ex-factory prices, reference prices, manufacturers, type of prescription drug, and market entries and exits. Our results show that there is no full price adjustment: A 1%-change in reference prices leads to a 0.3%-change in market prices. Price adjustment, however, is fast, it mostly happens in the first month. Furthermore, the first introduction of a reference price reduces market prices of the affected products by approximately 14%. Finally, we observe a significant time effect which is positive in the market without reference prices and negative in that with reference price.

JEL Classification: I11, I18

Keywords: Price elasticity, temporal development, fixed effects model

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1 Introduction

Since the introduction of reference pricing for prescription drugs in German social health insurance in 1989, it has been a topic of heated debate in health policy in Germany and elsewhere. Manufacturers argue that any kind of price regulation in general and particularly reference pricing decreases incentives to develop innovative products. On the other hand, policy makers and third-party payers rely on reference prices as an important tool to increase price competition for prescription drugs and, ultimately, to contain costs. Physicians need to take reference prices into account when they prescribe products that are subject to reference pricing, since patients have to cover the balance between reference prices and retail prices.

After the introduction of reference pricing in Germany, other countries such as the Netherlands, Canada (British Columbia) and New Zealand have adopted reference pricing as well. A recent review of the literature on the effects of reference pricing has found that most scientific studies examine the effects on patients if manufacturers do not adopt their prices to reference prices (Puig-Junoy 2005). In a nutshell, these studies found that cost-savings for third-party payers as a consequence of the introduction of reference-pricing and increased price competition are evident. Moreover, there has been no evidence for negative therapeutic consequences for patients (Grootendorst et al. 2005; Schneeweiss et al. 2003; Schneeweiss et al. 2002) although patients are very sensitive to surcharges for products with a price above the reference price (Danzon and Ketcham 2003).

The focus of this paper is different from the studies mentioned above. Since the introduction of reference pricing, manufacturers are very reluctant to charge prices above the reference price. Manufacturers are afraid of losing market shares.[2] This paper contributes to the literature on the effects of reference pricing in two ways. Firstly, we were able to obtain a unique data set, i.e. we use a large panel data set of nearly all German prescription drugs on a monthly basis between October 1994 and July 2005. Altogether, the data comprise almost 4 million observations. Secondly, we measure the effect of the introduction of or changes in the reference price on ex-factory prices of manufacturers. Moreover, we investigate whether manufacturers adapt prices of their products *not* subject to reference pricing as a consequence of changes in reference prices of their products subject to reference pricing.

The following section gives an overview over the German reference price system.

[2]There has been one notable recent exception to this rule. When Pfizer's product Sortis has been subject to reference pricing in 2004, Pfizer did not change the price. As a consequence, the market share for Sortis has fallen dramatically.

Section 3 presents the data, section 4 the econometric model. Results are discussed in section 5.

2 The reference price system in Germany

Reference pricing in Germany was adopted in 1989. Besides, similar to other countries, the legislator also uses other instruments to regulate prices for prescription drugs. Legislation defines only very broad parameters for the system of reference pricing. This is true for the clustering of groups as well as for setting of reference prices. Prescription drugs are grouped into clusters by a committee of health care providers and sickness funds (Gemeinsamer Bundesausschuss). Reference prices for clusters are determined by the peak association of sickness funds. Price setting is based on a regression which standardizes different formulations (strengths and package sizes). The reference price is not the lowest in the respective cluster. Since 2004 regulation determines that the reference price needs to be above the lowest third of cluster prices. Furthermore, reference prices are to be adjusted on a regular basis.

Reference prices are applicable for generic as well as for therapeutic substitutes. Generic substitutes are pharmaceuticals with the same active ingredients and formulation as an original drug. Therapeutic substitutes are pharmaceuticals with different active ingredients and formulations but with comparable therapeutic effects for the same indication. While generic substitutes have been covered by the reference price system since 1998, this is not true for therapeutic substitutes. Only since the 2004 health care reform has the legislator allowed the committee of health care providers and sickness funds to establish groups of therapeutic substitutes – including me-too patents. Therapeutic reference pricing had been suspended from 1996 to 2003.

In principle, manufacturers are free to set prices for all prescription drugs even if a reference price has been set. However, third-party payers (sickness funds) will reimburse only the reference price. If physicians prescribe products with a price above the reference price, patients must pay the surcharge out-of-pocket. As a consequence, manufacturers have a strong incentive for charging prices that are equivalent to the reference price. Patients are very sensitive to surcharges for products with a price above the reference price (Danzon and Ketcham 2003) and prices above the reference prices *ceteris paribus* lead to losses in market share (Pavcnik 2002).

If the price is below the reference price, only third-party-payers and – if user charges are proportional to price – patients profit from the lower price. Nevertheless, price

setting of the manufacturers might be determined by the regulations for physicians, too. If physicians face drug budgets that set a limit on outpatient drug expenditures – as they did in Germany from 1993 until 2001 – manufacturers may realize a competitive advantage setting their prices below reference prices. Since 2002 physicians face spending limits that are less tight. However, exceeding individual physician's budget still may entail individual audits of drug expenditures.

3 The data

We use a panel data set of 67,515 prescription-only drugs in Germany on a monthly basis from October 1994 until July 2005, in sum 130 months. In order to eliminate a possible price bias caused by imported drugs we exclude about 19,900 drugs that have been imported in at least one month during the observed period. Moreover, we exclude drugs that leave the market at some point in time and re-enter some months later. The remaining number of drugs in the data set is 43,920, the total number of observations is 2,701,418. The data do not contain information about the number of packages sold per drug. However, we know (categorized) market shares of each RP-drug within defined subgroups that consist of drugs with a similar therapeutical use and similar package size as well as similar strength. For some drugs there might be almost no sales. Therefore, for our analysis we exclude observations with a market share within their group smaller than 1%. This leads to a remaining sample size of 38,534 drugs[3]

The data set is an unbalanced panel. During the period of observation drugs entered as well as left the market. The monthly percentage of drugs that enter the market is about 1.1%, the percentage that exit the market about 0.5%. These numbers are higher in the non-RP-market (1.5% entries, 0.8% exits) and lower in the RP-market (0.7% entries, 0.2% exits). While the total number of drugs in the sample amounts to 38,000, the average number of drugs at the market per month is about 16,200, with 6,800 in the non-RP and 9,400 in the RP-market.

In detail, the data provide the following information: price of the drug (ex-factory,

[3]In our data, drugs that are sold directly to pharmacies do not provide information on their ex-factory prices. If this occurs in six months or more of the period of observation, we remove these observations from the sample. If this occurs in less than six months in a row of the period of observations we decided to impute ex-factory prices based on the known ex-factory prices before and after these months. The results are not sensitive to these imputations. Furthermore, from 2002 onwards some 200 reference prices at ex-factory level are missing per month. If they are missing for less than six months in a row we impute them in the same way as the ex-factory prices above.

pharmacy purchase and selling price), the reference price (ex-factory as well as regarding the pharmacy selling price), drug name, manufacturer, form of administration, package size, and an indicator for being an import or not. For RP-drugs, the data additionally comprise information about the active substance, the active substance group as well as the reference price level. We add further data which comprise a measurement of the standardized strength of drugs and information about the reference price subgroup. The combination of this information and the active substance group allows us to determine which drugs build a reference price group. As mentioned above, our sample also includes categorized information about the market share. Table 1 displays the variables.

Table 1: **Variables of the data set**

Variable	RP-market	Non-RP-market
Ex-factory price	X	X
Pharmacy purchase price	X	X
Pharmacy selling price	X	X
Name of drug	X	X
Manufacturer	X	X
Form of administration	X	X
Package size	X	X
Import (yes/no)	X	X
Active substance	X	
Active substance group	X	
Reference price	X	
Standardized strength of drug	X	
Reference price subgroup	X	
Reference price group	X	
Market share within groups	X	

We distinguish between four main different subgroups of drugs in our sample

(i) *Always-RP*: Drugs that are in the RP market during the whole period of observation.

(ii) *Never-RP*: Drugs that are in the non-RP market during the whole period of observation.

(iii) *Change from non-RP into RP*: Drugs that change from the non-RP into the RP-market.

(iv) *Change from RP into non-RP*: Drugs that change from the RP into the non-RP-market.

Since only 1.5% of all drugs in our sample fall into the last group, we ignore that group. Moreover, this means that once a drug moves from the non-RP market into the RP-market it stays there. Hence, we do not take into consideration more than one change between the two markets. 49.1% of all drugs in our sample are always, 40.7% are never in the RP-market, and 8.7% changed from the non-RP- into the RP-market. However, we remove those drugs that change in the last month we observe. This reduces the number of (changing) drugs from 3,346 to 2,003.

In our empirical analysis the dependent variable is the ex-factory price p_{it} of drug i in month t. The development of ex-factory prices of all drugs included in the regression analysis is presented in figure 1. The (unweighed) average nominal price of the non-RP drugs increased during the period of observation, whereas the average price of the RP-drugs remained almost constant.

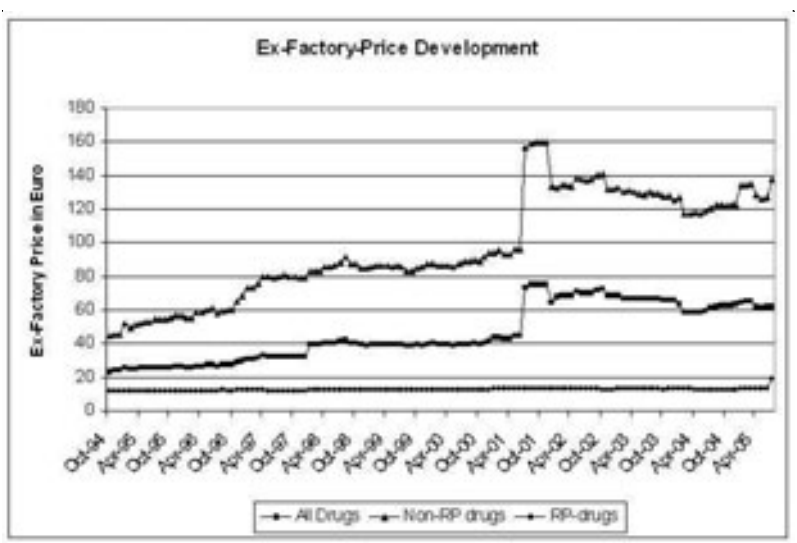

Figure 1: Ex-Factory-Price Development

Figure 2 presents the development of the ex-factory and reference prices of the subgroup of changers. The time of change for all drugs is standardized such that at

month 0 the system change occurs. Only drugs enter this calculation that are in the sample at least four month before and four months after the first implementation of a reference price. Figure 2 indicates a decline in prices that starts some months before the introduction of a reference price for non-RP drugs. Price declines afterwards are probably due to reference-price adjustments.

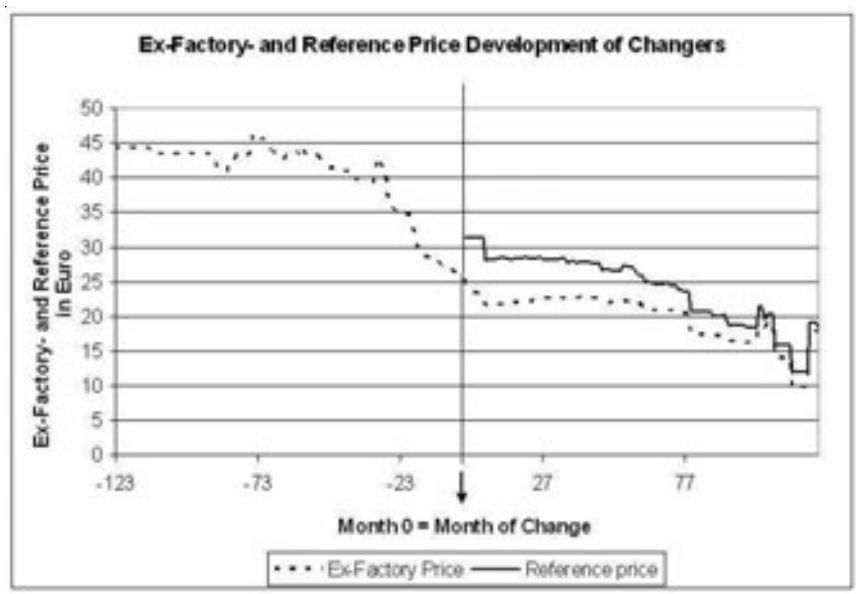

Figure 2: Ex-Factory- and Reference Price Development of Changers

Tables 6 and 7 in the appendix give an overview of the number of drugs changing from the non-RP market to the RP-market as well as the number of drugs being subject to reference price adjustments.

4 Econometric model

For each of the three main subgroups we estimate a separate fixed effects model. Let p_{it} be the price of drug i at time t and f_{it} be the reference price for RP-drugs i at time t. Time-invariant variables will not be considered. They are absorbed by

the fixed effect. Let m_{it} be a dummy variable indicating the RP market

$$m_{it} = \begin{cases} 0 & \text{if} \quad i \in \text{non-RP}, \\ 1 & \text{if} \quad i \in \text{RP}. \end{cases}$$

Thus, the three main subgroups are defined as follows

- Always-RP: $\{i \,|\, \forall t : m_{it} = 1\}$
- Never-RP: $\{i \,|\, \forall t : m_{it} = 0\}$
- Changers: $\{i \,|\, \exists t' : m_{it'} = 0 \wedge \exists t'' : m_{it''} = 1, t' < t''\}$

For each group, we estimate a separate model.

Model for Always-RP

We assume that the logarithm of the price depends on the logarithm of the current reference price and of J past reference prices and on a fixed effect η_i. In addition, we add a quadratic time effect. ε_{it} captures stochastic noise.

$$\log p_{it} = \sum_{j=0}^{J} \alpha_j \log f_{i,t-j} + \tau_0 t + \tau_1 t^2 + \eta_i + \varepsilon_{it}. \tag{1}$$

On the one hand, since we have no information on J, it should be chosen large enough. On the other hand, the larger we choose J the more observations we lose at the beginning of the period of observation. In principle, f might be endogenous. According to the legal regulations f has to be set such that the prices of at least one third of all drugs within a reference group are below f. However, f is not updated on an annual basis, in fact it remains quite constant over time. During the whole period of observation, the average number of reference price adjustments among the always-RP-drugs was 2.1. Therefore, we assume endogeneity of f being a minor problem. The coefficients α capture the relative effect of changes of reference prices on the prices of the affected drugs and are of main interest in this model.

$$\alpha_j = \frac{d \log p_{it}}{d \log f_{i,t-j}} = \frac{dp_{it}/p_{it}}{df_{i,t-j}/f_{i,t-j}} \quad j = 0, ...J. \tag{2}$$

In case of fast price reactions we expect large values of α for small j and low values for large j.

Model for Never-RP

Our data do not contain time-variant information on drugs without reference prices. The fixed-effect captures all time-invariant explanatory factors. Thus, we specify the following model for the non-RP market

$$\log p_{it} = \tau_0 t + \tau_1 t^2 + \eta_i + \varepsilon_{it}. \tag{3}$$

In this simple model there is no interaction between the non-RP market and the RP market. The public debate, however, assumes that the pharmaceutical industry tries to compensate slumps in sales of drugs with reference prices by increasing their prices of drugs without reference prices in order to earn the large fixed costs of research and development. Therefore, we extend (3) on the manufacturer's level in order to capture possible inter-market effects.

Let $h = 1, ..., H$ index the manufacturers in our data set. In sum, there are 799 different manufacturers. Each one produces various drugs, some of them subject to reference prices, some not. Price setting of the latter may depend on the reference prices of the first. For each manufacturer we divide their drugs into the following two subsets

$$\begin{aligned} \mathcal{I}_h^{RP} &= \{\, i \,|\, i \text{ is drug with reference price of company } h\}, \\ \mathcal{I}_h^{NRP} &= \{\, i \,|\, i \text{ is drug without reference price of company } h\}. \end{aligned}$$

Manufacturers might set their prices in the non-RP market with regard to the average reference price of their RP-products. We consider two different weighted averages

(i) the log of the weighted arithmetic average of reference prices

$$b_{ht}^a = \log\left(\frac{\sum\limits_{i\in\mathcal{I}_h^{RP}} f_{it}}{|\mathcal{I}_h^{RP}|}\right),$$

(ii) the arithmetic average of the log of reference prices, i.e. the geometric average

$$b_{ht}^g = \frac{\sum\limits_{i\in\mathcal{I}_h^{RP}} \log f_{it}}{|\mathcal{I}_h^{RP}|} = \log\left(\prod_{i\in\mathcal{I}_h^{RP}} f_{it}^{(1/|\mathcal{I}_h^{RP}|)}\right).$$

Since b might be disturbed by changes of drugs from the non-RP market into the RP market we restrict this analysis on those drugs that never change their regime. b

might also be disturbed by drugs that enter the market. Therefore we use only drugs for the calculation of b that already were on the market in October 1994. Usually, changes from the non-RP- to the RP-market are driven by political decisions and, thus, should be exogenous. Moreover, the proportion of changers in the whole sample is only 9%. Therefore, we do not see severe econometrical problems by restricting our sample as mentioned here. Finally, we estimate the additional model for never-RP drugs

$$\log p_{it} = \beta b_{h_i t} + \tau_0 t + \tau t^2 + \eta_i + \varepsilon_{it}, \tag{4}$$

with $b_{h_i t} = b_{ht}$ for $i \in \mathcal{I}_h^{NRP}$. We expect $\beta < 0$.

Model for Changers

Once a reference price for a non-RP drug is set for the first time the pharmaceutical industry adapts its price because demand for RP drugs becomes considerably more elastic than for non-RP drugs. Therefore, we expect prices to fall after introducing a reference price. We specify the following model

$$\log p_{it} = \delta m_{it} + \eta_i + \varepsilon_{it}. \tag{5}$$

where δ measures the effect of the change. If there are different time trends in both RP- and non-RP-market the effect δ might also depend on time. Hence, we further specify

$$\log p_{it} = (\delta_0 + \delta_1 t + \delta_2 t^2) m_{it} + \eta_i + \varepsilon_{it}. \tag{6}$$

5 Results

Model for Always-RP

Table 2 presents the results of the model for drugs with a reference price during the whole period of observation. As expected, results exhibit that a decrease in the (ex-factory) reference price by 1% leads to a significant reduction of the (ex-factory) price by about 0.27% in the same month and 0.03% in the following month. Afterwards, the coefficients do not differ significantly from 0. Yet, the coefficients on the log reference price six and seven months ago turn out to be significantly positive. Put another way, the main part of the price adjustment is fast and happens in the first month. Moreover, results indicate a decreasing price trend.

Table 2: **Results for always-RP-drugs**

	(1)	
Variable	Coefficient	Std. Error
log RP	0.2693**	0.003
log RP 1 month ago	0.0321**	0.004
log RP 2 months ago	0.0060	0.004
log RP 3 months ago	0.0056	0.004
log RP 4 months ago	0.0013	0.004
log RP 5 months ago	0.0038	0.004
log RP 6 months ago	0.0189**	0.004
log RP 7 months ago	0.0710**	0.003
Time	-0.0008**	0.000
$Time^2$	2.21e-06**	8.67e-08
R^2	0.3575	
number of observations	978,733	
number of drugs	16,968	

Note: Dependent variable: logarithm of ex-factory price. ** significant at the 1%-level; * significant at the 5% level.

Model for Never-RP

The corresponding results of the model for drugs without reference price can be seen in table 3. Column two presents the results of equation (3). In contrast to the RP-market a positive price trend can be observed. As expected, results confirm the thesis that the pharmaceutical industry tries to compensate reduced revenues in the RP-market by price increases of their non-RP-drugs (columns (3a) and (3b) table 3), even though the effect seems quite small. However, when the analysis is done separately for both halves of the observed period, the significantly negative coefficient of the b's is only confirmed for the first half but not confirmed or even reversed for the second half (see tables 8 and 9 in the appendix).

Model for Changers

The estimated time-independent price effect of introducing a reference price for non-RP-drugs for the first time (model (5)) is presented in table 4, column (4). The ex-factory price decreases on average by 14% if so far non-RP-drugs become

Table 3: **Results for never-RP-drugs**

	(2)		(3a)		(3b)	
Variable	Coeff.	Std. Error	Coeff.	Std. Error	Coeff.	Std. Error
log average RP in RP market: b^a_{ht}	–	–	-0.0077**	0.000	–	–
log average RP in RP market: b^g_{ht}	–	–	–	–	-0.0039**	0.000
Time	0.0029**	0.000	0.0031**	0.000	0.0031**	0.000
Time square	-7.29e-06**	8.85e-08	-9.85e-06**	1.02e-07	-9.77e-06**	1.02e-07
R^2	0.2986		0.3107		0.3102	
number of observations	688,506		491,722		492,780	
number of groups	13,380		10,153		10,213	

Note: Dependent variable: logarithm of ex-factory price. ** significant at the 1%-level; * significant at the 5% level. For drugs by manufacturers that produce only in one market b^a_{ht} and b^g_{ht} are set to missing.

referenced priced. However, due to the decreasing price trend of RP-drugs and the increasing trend of non-RP-drugs this effect is not constant over time. Column (5) displays the coefficients of equation (6), which show an increasing negative effect over time from 2.3% at the beginning in 1994 up to -22.3% in July 2005.

Table 4: **Results for changers**

	(4)		(5)	
Variable	Coeff.	Std. Error	Coeff.	Std. Error
Change of market m_{it}	-0.1374**	0.001	-0.0232**	0.002
Market change * time	–	–	-0.0009**	0.000
Market change * time square	–	–	-3.48e-06**	3.55e-07
R^2	0.1021		0.1747	
number of observations	151,696		151,696	
number of groups	2,000		2,000	

Note: Dependent variable: logarithm of ex-factory price. ** significant at the 1%-level; * significant at the 5% level.

6 Conclusion

In this paper we used a unique panel data set of Rx drugs to analyze the effect of changes in the reference prices on drugs' prices in the RP market, the effect of the introduction of a reference price for the first time, and the effect of reference prices on prices in the non-RP market. First, we find that there is no full price adjustment: A 1%-change in reference prices leads to a 0.3%-change in market prices. Price adjustment, however, is fast, it happens mainly in the first month. Second, the first introduction of a reference price reduces market prices of the affected products by approximately 14%, whereas this effect increases over time: it starts with 2.3% at the end of 1994 and increases to 22% in July 2005. Third, manufacturers seem to increase their prices in the non-RP market as reference prices of their products in the RP market fall. However, this effect is small and does not seem to hold for all subperiods. Finally, we observe a significant time effect which is positive in the market without reference prices and negative in that with reference prices.

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8 Appendix

Table 5: **Descriptive Statistics**

Variable	Obs.	Mean	Std. Dev.	Min.	Max.
Always-RP					
Price	978,733	11.32	18.57	0.15	644.34
Reference price	978,733	14.37	22.38	0.16	787.89
Never-RP					
Price	688,506	109.63	399.13	0.36	50,539.16
Avg. ref. price in RP-market b^a_{ht}	491,722	16.10	13.45	0.74	138.31
Avg. ref. price in RP-market b^g_{ht}	492,780	11.20	11.25	0.68	138.31
Changers					
Before Change					
Price	42,709	34.80	38.08	0.83	528.27
After Change					
Price	108,987	19.86	33.96	0.68	706.54
Reference price	108,987	24.52	40.39	0.76	795.94

Note: All values in euro.

Table 6: **Number of drugs with adjustment of the reference price (Always-RP drugs)**

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
January		1,180	2,363	1,308	1	267	137	155	5,979	171	240	104
February		8	3	7	3	5	3	2	0	0	0	1
March		3	0	56	0	6	6	0	0	403	0	1
April		6	8	2	6,238	3	1	0	0	0	7,478	651
May		13	3	6,149	1	0	0	0	0	0	0	0
June		2	0	0	1	0	0	0	0	3	0	0
July		1,103	2,935	16	1	6	3	428	0	0	0	0
August		0	12	0	1	0	2	0	0	0	0	
September		1	5	4	0	0	2	0	0	0	557	
October	0	16	15	3	1	9	1	0	0	0	0	
November	5	3	1	2	1	0	7	0	0	0	0	
December	0	0	2	1	0	0	0	0	0	0	0	

Table 7: **Number of Changing Drugs per Month**

	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005
January		299	75	123	90	76	0	80	0	2	4	104
February		2	1	2	1	0	0	3	0	1	4	1
March		9	0	2	0	0	0	0	0	0	0	1
April		9	5	0	5	1	1	0	8	3	0	651
May		1	0	0	6	2	0	1	0	1	0	0
June		2	0	0	0	1	0	0	0	0	0	0
July		175	69	19	6	2	53	0	20	0	2	1343
August		1	0	2	5	0	4	0	0	0	6	
September		10	0	0	0	0	0	0	0	0	0	
October	0	9	19	1	2	3	42	0	0	2	0	
November	0	4	1	1	1	0	7	0	0	0	0	
December	0	0	0	0	0	3	0	2	0	0	0	

Table 8: **Results for never-RP-drugs - October 1994 until February 2000**

	(2)		(3a)		(3b)	
Variable	Coeff.	Std. Error	Coeff.	Std. Error	Coeff.	Std. Error
log average RP in RP market: b^a_{ht}	–	–	-0.0162**	0.001	–	–
log average RP in RP market: b^g_{ht}	–	–	–	–	-0.0152**	0.001
Time	0.0027**	0.000	0.0026**	0.000	0.0026**	0.000
Time square	-8.93e-06**	3.67e-07	-5.75e-06**	4.31e-07	-5.56e-06**	4.31e-07
R^2	0.2612		0.2776		0.2775	
number of observations	289,592		217,103		217,103	
number of groups	7,473		5,689		5,689	

Note: Dependent variable: logarithm of ex-factory price. ** significant at the 1%-level; * significant at the 5% level. For drugs by manufacturers that produce only in one market b^a_{ht} and b^g_{ht} are set to missing.

Table 9: **Results for never-RP-drugs - March 2000 until July 2005**

	(2)		(3a)		(3b)	
Variable	Coeff.	Std. Error	Coeff.	Std. Error	Coeff.	Std. Error
log average RP in RP market: b^a_{ht}	–	–	0.0021**	0.001	–	–
log average RP in RP market: b^g_{ht}	–	–	–	–	0.0024**	0.000
Time	0.0043**	0.000	0.0044**	0.000	0.0044**	0.000
Time square	0.0000**	3.39e-07	-0.0000**	3.84e-07	-0.0000**	3.83e-07
R^2	0.1185		0.0991		0.0992	
number of observations	389,914		274,619		275,677	
number of groups	10,802		8,019		8,079	

Note: Dependent variable: logarithm of ex-factory price. ** significant at the 1%-level; * significant at the 5% level. For drugs by manufacturers that produce only in one market b^a_{ht} and b^g_{ht} are set to missing.