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PRICE REGULATION FOR MEDICINAL PRODUCTS IN SLOVENIA

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Abstract:
The reference price system is applied in a practice in Slovenia with an aim to manage and reduce public expenditures for medicinal products. This paper aims to investigate whether the reference price system has had the effect on real price reductions for medicinal products. We present the reference price regulation system for medicinal products and empirically estimate the effect of price regulation on development of real prices for medicinal products, the economic rationale and efficiency of the system. The main thesis that the nominal and real prices for medicinal products have declined during the price regulation system is revealed by the Laspeyres index and Wilcoxon signed ranks test by confirming the existence of statistically significant differences in prices for medicinal products. Therefore, we adopt the alternative hypothesis that prices for medicinal products have declined during the price regulation system. The reference price regulation system with an efficient use of medicinal products and their efficient supply could have positive effects on management and reduction of public expenditure for medicinal products.

Keywords: prices for medicinal products, reference price system, public expenditures for medicinal products.

1. INTRODUCTION

Demands for health services have increased by the population aging. This causes increases in expenditures for health care and health services. In Slovenia, most of the health services are covered within the public health system. To rationalize the public health expenditures, the economic policy aims to rationalize costs for these services. Among them are also measures to rationalize spending for medicinal products (Bojnec & Kajdiž, 2010). We aim to analyze how the reference price system causes prices for medicinal products. We present the reference price system for medicinal products and its implications for nominal and real prices for medicinal products.

The paper is structured in the following way. In the next two sections, second and third parts, we present the reference price system in general and in Slovenia in particular. The fourth part presents methodology, main thesis and hypotheses, and data used. The methodology is based on the Laspeyres index and the nonparametric Wilcoxon signed ranks test using time-series data. The fifth part analyzes development of nominal and real prices, and tests the hypotheses by Laspeyres index and Wilcoxon signed ranks test. Final section derives conclusions and policy implications.

2. REFERENCE PRICE SYSTEM FOR MEDICINAL PRODUCTS

In the marketing theory, there is developed concept of a reference price, which compares internal stand and observed prices (Kalyanaram & Winer, 1995). The consumers' evaluates and make decisions on the basis of own comparisons between observed phenomena with internal reference points. However, this is different from the concept of the reference price system in the pharmaceutical industry (Dickson & Redwood, 1998; Knavos & Reinhardt, 2003). The reference price for medicinal products with the price regulation system sets the maximum limit price for each the medicinal product in consistence with all medicinal products in this category of medicinal products and it is not associated with perception of consumers about the price. The most typical feature of the reference price for the medicinal products is the maximum price, which the health insurance companies are willing to reimburse as a whole for each price of medicinal product. In a case that the price for medicinal product is higher than the reference price, consumer has to pay the difference (Podnar, Molj & Golob, 2007).

During the last decades more European Union countries (Germany, the Netherlands, Sweden, Denmark, Poland, Spain, Italy and Slovenia) as well as some other countries in the world (New Zealand, Australia, and British Columbia in Canada) have implemented different forms of the reference price system. The objective of the implementation of the reference price system is to control costs of the health expenditures for medicinal products on prescription and not to reduce the price for medicinal products on general. The price regulation system has become one of the main instruments of the economic policy to control and reduce costs for medicinal products (Giuliani, Selke & Garattini, 1998).

Germany is used as one of the reference countries for price setting and price formation for medicinal products in Slovenia. Paris and Docteur (2008) find that prices for medicinal products in Germany have been relatively stable since 1989. This general stability pattern has been the result of two diverging tendencies: first, prices of medicinal products, which are not formed on the basis of the reference price system and are driven by market forces, have increased by 20 %. Second, prices of medicinal products, which are formed on the basis of the reference price system, have declined by 35 %. This implies that the reference price system has contributed to relative stability of prices

for medicinal products in the German market. However, in addition to the reference price system, this can be also due to some other factors such as the impact of the generic medicinal products. They are by the definition equivalent to original medicinal products, because they contain identical active substances and their market sale is possible after the whole patent protection of the original medicinal product (Aaserud et al., 2006).

Schröder, Nick and Lankers (2006) argue that the reference price system has the opposite effect on prices for generic products because it does not provide incentive for competitive price formation below the reference price. In spite of a fact that the difference between the original and generic medicinal products has declined to 31.2 % in 2005, the German prices for generic products are relatively high in comparison with international prices (Schröder, Nick & Lankers, 2006).

With the maximum limit price system for which the system of health insurance companies wholly reimburses costs for medicinal products under a regime of a prescription, and the reference price system, the government policies are focusing towards reduction in prices of medicinal products in two ways. First, the reduction of the consumer eligible needs for expensive medicinal products. Second, the reduction of prices for medicinal products set for the producers of medicinal products. The reference prices still provide opportunities for pharmaceutical companies to sell above the reference price level, but with a risk to lose market share due to cheaper, wholly reimbursable medicinal products (Dickson & Redwood, 1998; Lopez-Casasnovas & Puig-Yunoy, 2000). The reference price system is envisaged to help a patient in a decision what kind of costs is associated with the medical care with implications to rationalize use of mutually substitutable medicinal products (Lopez-Casasnovas & Puig-Junoy, 2000).

3. METHODOLOGY AND DATA USED

We test main thesis that prices for medicinal products in Slovenia have declined during the price regulation system by the reference price with possible impacts on management and reduction of public expenditures for medicinal products. The methodological approach by using time-series data is based on the Laspeyres index and the nonparametric Wilcoxon signed ranks test.

The null hypothesis assumes that the prices for medicinal products due to the price regulation system by the reference prices and the system of mutual substitutes of medicinal products have not changed. The alternative hypothesis assumes that the price regulation by the system of reference prices and system of mutual substitutes has caused the reduction in prices for medicinal products. We expect that the reference price system causes price reductions for majority of medicinal products in this system of price regulation.

The Laspeyres index is used to test whether the prices for medicinal products that are regulated and financed from public expenditures have declined over time. This is also tested by the Wilcoxon signed ranks test. With the Laspeyres index, which is used for calculation of price indices, we calculate changes in the price level considering the base period in 2007. The sum of quantities for the base period is multiplied by the prices of the medicinal products on cross-date periods over time and divided by the sum of quantities of the base period multiplied by prices of the medicinal products of the base period:

$$P_L = \frac{\sum (p_{ct} * q_{ct_0})}{\sum (p_{ct_0} * q_{ct_0})}$$

where P_L = change in the price level, q_{cto} = quantity in the base period, p_{ct_0} = price of the medical products in the base period, q_{ct} = quantity in the period t and p_{ct} = price of the medicinal products in the period t.

On the basis of the nominal price values of medicinal products we calculate Laspeyres indices for all medicinal products over time. The medicinal products are then divided into three groups according to their price regime: regulated prices on the basis of the Regulation on price formation for medicinal products (R), additionally regulated prices by the Decree on list of mutual substitutable medicinal products (MSP), and prices, which are formed in rotation on the basis of the Regulation of price formation for medicinal products and the Decree on list of mutual substitutable medicinal products (R+MSP). For each group of medicinal products we then calculate Laspeyres indices. Nominal prices for medicinal products are deflated by consumer price index (CPI) and by medicinal products price index (MPI) with the base period, Year 2003=100, to obtain real prices for medicinal products.

The hypotheses are additionally tested by nonparametric Wilcoxon signed ranks test for testing hypotheses of recurring measuring on the single sample, when it is not possible to assume normal distribution of the sample. Similar as t-test also Wilcoxon test contains comparison of the difference between the measuring. Due to this all variables should be on the interval or rational level, but do not require special anticipation on distribution of measuring. Due to this, the Wilcoxon test is used when the conditions for use of t-test are not fulfilled.

We assume null hypothesis that prices for medicinal products in different time periods are greater or equal to zero (H_0: $\theta = 0$). The null hypothesis envisages that both analyzed population samples are with equal median. The null hypothesis can be confirmed in a case that there are no differences between the first and second observation of variable. The Wilcoxon test excludes those measuring, where are no differences between both observations. With the signed ranks is set the average rank between them. The sum of ranks is calculated separately for positive and negative deviations from the mean value. The value S is defined as less between the both sums of signed ranks. The S is then compared with the values of all possible distributions for ranks. The estimated p is the statistical probability of achieved value for S with population achievements, which are symmetrically distributed around the mean value. The greater the number of sample observations (numerous) leads to greater normal distribution. In a case that the number of sample observations is greater than 20, then for calculation of statistical importance is used approximation. Some authors argue that approximation is used for numerous greater than 10, some other greater than 25 (Siegel, 1956). Approximation is defined:

$$z \approx \frac{S - \frac{N(N+1)}{4}}{\sqrt{\frac{N(N-1)(2N+1)}{24}}}$$

where N is the number of sample observations (numerous) and S is less between two sums of signed ranks. Siegel (1956) uses instead of symbol S symbol T. Due to this for Wilcoxon signed ranks test are used T tables (Siegel, 1956).

We test the samples of nominal and real prices deflated by CPI and by MPI with nonparametric Wilcoxon signed ranks test. We first test the sample of medicinal products as a whole, and then separately for the three groups of medicinal products: R, MSP, and R+MSP.

Data on quantity of consumed packages of medicinal products in Slovenia, which are financed by the public sources, are obtained from data published in Ambulance prescription of medicinal products in Slovenia for the years 2003–2008 from the Institute for Health Protection (http://www.ivz.si). Data on prices of medicinal products are obtained from the website of the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (http://www.jazmp.si). Data on prices of medicinal products and on grouping of medicinal products into lists of medicinal products, which are completely or partly financed from the public sources, are obtained from data published on the website of the Institute for Health Insurance of Slovenia (http://www.zzzs.si). Into the empirical analysis are included 813 medicinal products, which are financed from the public sources. They are in the system of the regulated prices. The empirical analysis is conducted for the years 2003–2008. We start calculations with the nominal price values for medicinal products. The CPI and MPI deflators are obtained from the Statistical Office of the Republic of Slovenia. They are used to obtain real price values for medicinal products.

4. EMPIRICAL RESULTS

We first test the hypotheses by the Laspeyres index for the regulated prices for medicinal products. We confirm the decline in the regulated nominal and real prices for medicinal products (Table 1). The price declines are the greatest for medicinal products on the R+MSP list and MPS list. The lowest price declines are found for medical products on the R list.

Table 1: Laspeyres price indices for medicinal products

	2003	2004	2005	2006	2007	2008
1) Number of medicinal products R+MSP	106	106	106	106	106	106
Laspeyres index for R+MSP (2003=1)	1	0.967	0.914	0.788	0.604	0.562
Change in Laspeyres index for R+MSP (in % to 2003)	0	-3.34	-8.61	-21.18	-39.62	-43.78
Laspeyres index deflated by CPI (2003=1)	1	0.965	0.960	0.723	0.534	0.471
Change in deflated by CPI (in % to 2003)	0	-3.47	-13.98	-27.69	-46.62	-52.87
Laspeyres index deflated by MPI (2003=1)	1	1.011	0.930	0.812	0.630	0.584
Change in deflated by MPI (in % to 2003)	0	1.11	-6.97	-18.82	-37.04	-41.56
2) Number of medicinal products R	627	627	627	627	627	627
Laspeyres index for R (2003=1)	1	1.007	1.008	0.938	0.901	0.903
Change in Laspeyres index for R (in % to 2003)	0	0.72	0.84	-6.20	-9.88	-9.66
Laspeyres index deflated by CPI (2003=1)	1	0.972	0.950	0.862	0.810	0.758
Change in deflated by CPI (in % to 2003)	0	-2.78	-5.05	-13.79	-19.02	-24.21
Laspeyres index deflated by MPI (2003=1)	1	1.018	1.027	0.966	0.940	0.940
Change in deflated by MPI (in % to 2003)	0	1.84	2.68	-3.43	-5.98	-6.05
3) Number of medicinal products MSP	80	80	80	80	80	80
Laspeyres index for MSP (2003=1)	1	0.909	0.896	0.726	0.605	0.578
Change in Laspeyres index for MSP (in % to 2003)	0	-9.08	-10.38	-27.43	-39.46	-42.24
Laspeyres index deflated by CPI (2003=1)	1	0.878	0.844	0.667	0.544	0.485
Change in deflated by CPI (in % to 2003)	0	-12.21	-15.61	-33.30	-45.60	-51.54
Laspeyres index deflated by MPI (2003=1)	1	0.919	0.913	0.747	0.632	0.601
Change in deflated by MPI (in % to 2003)	0	-8.07	-8.75	-25.29	-36.85	-39.92
4) Number of medicinal products TOTAL	812	813	813	813	813	813
Laspeyres index for TOTAL (2003=1)	1	0.977	0.961	0.856	0.796	0.750
Change in Laspeyres index TOTAL (in % to 2003)	0	-2.33	-3.88	-14.38	-20.44	25.04

Laspeyres index deflated my CPI (2003=1)	1	0.943	0.905	0.787	0.687	0.629
Change in deflated by CPI (in % to 2003)	0	-5.73	-9.49	-21.31	-31.28	-37.11
Laspeyres index deflated MPI (2003=1)	1	0.988	0.979	0.882	0.798	0.780
Change in deflated by MPI (in % to 2003)	0	-1.25	0.21	-11.85	-20.22	-22.03

The non-parametric Wilcoxon signed ranks test confirmed statistically significant differences in prices for medicinal products for nominal prices and real prices deflated by the CPI and MPI (Table 2). In these cases we can reject the null hypothesis – that prices have not changed or they have even increased – and adopt the alternative hypothesis that the prices for medicinal products have declined over time.

Table 2: Wilcoxon signed ranks test

	Z (nom)	sig nom	Z (deflated by CPI)	sig deflated by CPI	Z (deflated by MPI)	sig deflated by MPI
			R+MSP			
2004[a]	-1.785	0.074	-8.937	0.000**	-2.107	0.035*
2005[a]	-4.293	0.000**	-8.937	0.000**	-0.786	0.432
2006[a]	-7.216	0.000**	-8.909	0.000**	-6.091	0.000**
2007[a]	-8.341	0.000**	-8.817	0.000**	-7.815	0.000**
2008[a]	-8.600	0.000**	-8.937	0.000**	-8.212	0.000**
			R			
2004[a]	-11.434	0.000**	-16.911	0.000**	-17.737	0.000**
2005[a]	-11.817	0.000**	-19.762	0.000**	-18.377	0.000**
2006[a]	-4.551	0.000**	-18.869	0.000**	-2.943	0.003*
2007[a]	-7.075	0.000**	-17.780	0.000**	-1.469	0.142
2008[a]	-6.653	0.000**	-19.052	0.000**	-1.556	0.120
			MSP			
2004[a]	-5.309	0.000**	-7.765	0.000**	-2.504	0.012*
2005[a]	-5.774	0.000**	-7.770	0.000**	-3.516	0.000**
2006[a]	-7.410	0.000**	-7.770	0.000**	-6.672	0.000**
2007[a]	-7.559	0.000**	-7.770	0.000**	-7.343	0.000**
2008[a]	-7.583	0.000**	-7.770	0.000**	-7.367	0.000**
			Total			
2004[a]	-6.731	0.000**	-20.566	0.000**	-15.276	0.000**
2005[a]	-5.222	0.000**	-23.207	0.000**	-14.250	0.000**
2006[a]	-9.817	0.000**	-22.483	0.000**	-2.628	0.000**
2007[a]	-12.579	0.000**	-21.557	0.000**	-7.385	0.000**
2008[a]	-12.495	0.000**	-22.672	0.000**	-7.841	0.000**

[a] to year 2003; **sig<0.001; * sig<0.05. N=106 for R+MSP, N=627 for R, N=80 for MSP and N=813 for total.

In the case of regulated R+MSP medicinal product prices, for nominal R+MSP prices for the year 2004 and for the MPI deflated R+MSP prices for the year 2005 we do not find statistically significant differences, z>-1,645, at significance level greater than 0.05. In these two cases the null hypothesis can be rejected and adopted the alternative hypothesis that prices in this period declined. In other cases for R+MSP prices we cannot reject the null hypothesis (H_0: $\theta > 0$) that prices have remained equal or even increased and thus we cannot adopt the alternative hypothesis that the price changes over time are less than zero (H_1: $\theta < 0$) or that they have declined at degree of risk α =0.05.

In the case of regulated R medicinal product prices that are deflated by MPI we find that for the analyzed years 2007 and 2008 there are no statistically significant differences, z>-1,645,

at significance level greater than 0.05. For these two cases we cannot reject the null hypothesis (H_0: $\theta > 0$) that prices have remained equal or even increased and thus we cannot adopt the alternative hypothesis that the price changes over time are less than zero (H_1: $\theta < 0$) or that they have declined at degree of risk α =0.05. The null hypothesis for regulated R medicinal product prices can be rejected for the analyzed years 2004, 2005, and 2006 when we can adopt the alternative hypothesis that prices in these periods declined.

The null hypothesis can be rejected and adopted the alternative hypothesis that prices for regulated MSP medicinal products and regulated total medicinal products on average declined over the years 2004-2008.

The largest number of differences is found in the case of real prices, which are deflated by MPI. In general there are statistically significant differences in the changes of prices for medicinal products over time, while for the change between the base period (2003) and the years 2005 for R+MSP, and 2007 and 2008 for R are not found statistically significant differences. In these cases we cannot reject the null hypothesis (H_0: $\theta > 0$) that prices for medicinal products have remained similar or that they have even increased and thus we cannot adopt the alternative hypothesis that the price changes between these two periods are less than zero (H_1: $\theta < 0$) or that the prices have declined at degree of freedom α =0.05.

5. CONCLUSION

We have focused on the effects of the price regulation system for medicinal products, which are financed from the public sources. The Laspeyres indices of nominal and real prices for medicinal products confirm that these prices have declined vis-à-vis the base period. The greatest declines in the Laspeyres price indices are for the medicinal products, which are on the R+MSP list and MSP list. The reason for this finding is that according to the price regulation system they should be lower than the regulatory adopted price. This is the condition that a medicinal product can be included on the MSP list. The least have declined prices for medicinal products on the R list. These findings are also confirmed with the Wilcoxon signed ranks test.

The greatest differences in the obtained results between the nominal and real prices depend on the deflator used. The inflation rates measured by CPI have been positive, while MPI shows deflation. In general, both the Laspeyres indices and Wilcoxon signed ranks test confirm the decline in prices for the regulated medicinal products in Slovenia. This finding is similar to studies that have been conducted for Germany (Paris & Docteur, 2008). The system of reference prices for the purchase of medicinal products causes lower costs for the purchases of the medicinal products and has affected on more rational use of medicinal products. Therefore, it can be important for management and reduction of the public expenditures for the purchase of the medicinal products.

Finally, we have to underline that our focus have been on the evaluation of the implications of the reference price system on the price decline for the medicinal products, which are financed from the public sources. We have not segmented these markets on the markets for the original and generic medicinal products. The declined in the medicinal product prices have been associated with the reference price system. However, this is not necessary the only reason for the price decline for the analyzed medicinal products. Among the additional factors for the price declines can be more efficient bargaining between the health insurance companies, the registered distributors of medicinal products and producers of the medicinal products. The

results are also biased to the classification of the medicinal products on the lists and with the implementation of the MSP system with setting the maximum limited values. These are issues for a future research.

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