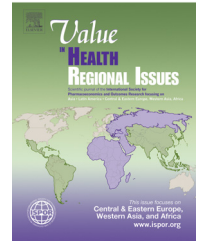


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Impact of the Pharma Economic Act on Diffusion of Innovation and Reduction of Costs in the Hungarian Prescription Drug Market (2007–2010)

Rok Hren, PhD, MSc, IHP (HE)*

University of Ljubljana, Ljubljana, Slovenia

ABSTRACT

Objective: In this study, we examined the impact of the Pharma Economic Act, which was introduced in Hungary in 2007. **Methods:** We used detailed data on the Hungarian prescription drug market, which had been made publicly available by the authorities. We evaluated the effect of the Pharma Economic Act on both dynamic and static efficiencies and also on equity, which has been historically a controversial issue in Hungary. We analyzed the overall prescription drug market and statin and atorvastatin markets; as a proxy for determining dynamic efficiency, we examined the oncology drug market for some specific products (e.g., bortezomib) and the long-acting atypical antipsychotic drugs market. **Results:** There is no denying that the authorities managed to control the overall prescription drug costs; however, they were still paying excessive rents for off-patent drugs. Examples of oncology and long-acting atypical antipsychotic drugs showed that the diffusion of innovation was on per-capita basis at least comparable to G-5 countries. While the share of

out-of-pocket co-payments markedly increased and the reimbursement was lowered, the concurrent price decreases often meant that the co-payment per milligram of a given dispensed drug was actually lower than that before the Act, thereby benefiting the patient. **Conclusions:** It appears that strong mechanisms to control volume rather than price on the supply side (marketing authorization holders) contained the drug expenditure, while offering enough room to strive for innovation. Making data on prescription drug expenditures and associated co-payments publicly available is an item that should be definitely followed by the surrounding jurisdictions.

Keywords: austerity measures, cost-containment, prescription drug spending.

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Introduction

In this study, we examined the impact of the Pharma Economic Act (PEA) [1], which was introduced in Hungary in 2007. The motivation to analyze this particular legislative measure within a single midsize country is in its comprehensiveness and unique approach toward marketing authorization holders (MAHs). Moreover, the recent economic crisis is making such a “laboratory of cost-containment tools” attractive for authorities and payers not only among the Central and Eastern European (CEE) countries but also among Western (e.g., European Union [EU]-15) jurisdictions. The final reason for the analysis is the availability of detailed data on the Hungarian prescription drug market, which are provided to the public by the authorities [2].

Controlling prescription drugs spending is fraught with difficulties, and particularly notable are examples of the GP Fund-holding scheme in the United Kingdom [3–5] and prescribing drug budgets [5–7]. The difficulties arise because of multifactorial reasons for pharmaceutical expenditure growth, which are usually addressed only partially with national prescription drug policies. Typically, the authorities/payers introduce two groups of policies: one group on the so-called demand side (e.g.,

physicians, pharmacists, and patients) and one group on the supply side (e.g., MAHs). If we use a simple equation that expenditure for prescription drugs E is

$$E = \sum p_i \times V_i$$

where p_i is the price of a given drug and V_i is its corresponding volume, then supply-side policies target mostly the price side of the equation, while demand-side policies work mostly on the volume side of the equation. For example, international reference pricing [8] has been widely embraced by authorities/payers in CEE jurisdictions as a particular supply-side tool geared toward regulating prices of primarily branded drugs; while such an approach may indeed result in a short-term reduction in prescription drug expenditure, the long-term effects may be ambiguous because the volume of prescribed drugs may readily expand.

Hungarian authorities/payers with PEA took a somewhat different approach and included—among a plethora of other measures—strong mechanisms to control volume on the supply side, with MAHs (i.e., branded and generic firms) being responsible to cover any overshoot of the preagreed volume. In that sense, PEA is unique among CEE jurisdictions; however, at its

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* Address correspondence to: Rok Hren, University of Ljubljana, Jadranska 19, 1000 Ljubljana, Slovenia.

E-mail: rok.hren@fmf.uni-lj.si.

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conception there were serious warnings that the austerity act may jeopardize innovation and could even lead to withdrawals of breakthrough branded drugs [9]. Accordingly, we are here specifically evaluating the effect of the PEA on both dynamic and static efficiencies [10–12], which present well-known and fundamental microeconomic framework, and also on equity, which has been historically a controversial issue in Hungary (see, e.g., [13–15]). Throughout this article, we will present data in local currency—Hungarian forint (HUF), with the conversion rate (as of March 28, 2013) of 1 euro (EUR) for 304.24 HUF, which means that 1 billion HUF equals approximately 3.3 million EUR.

Policy Drivers of the PEA

It is impossible to consider the PEA outside of the wider package of the Hungarian governmental austerity measures aimed at reducing the then (in 2006) whopping budget deficit of 10.1% of the gross domestic product (GDP) to the Maastricht level of 3% of the GDP by 2010, with special focus on reducing the health care spending by 0.9% of the GDP by 2009. While Hungary spent 8.3% of the GDP on health care in 2006 (vs. 8.9% of the Organisation for Economic Co-operation and Development [OECD] members' average), the prescription drug spending appeared a convenient cost-containment target because of (1) its high proportion in the total health care expenditure (in 2006, 26.7% vs. 15.5% of the OECD average) [16] and (2) the fifth highest growth rate in the 1998 to 2003 period among the OECD members, following Ireland, Korea, the United States, and Australia, which all are jurisdictions with substantially higher GDP per capita than Hungary [17].

National Health Insurance Fund-Országos Egészségbiztosítási Pénztár (NHIF-OEP) data [2] reveal that total public health

expenditure stood at 6% in 2006, with public pharmaceutical expenditure of 25%; the compound annual growth rate (CAGR) in the period 1998 to 2006 was 13%.

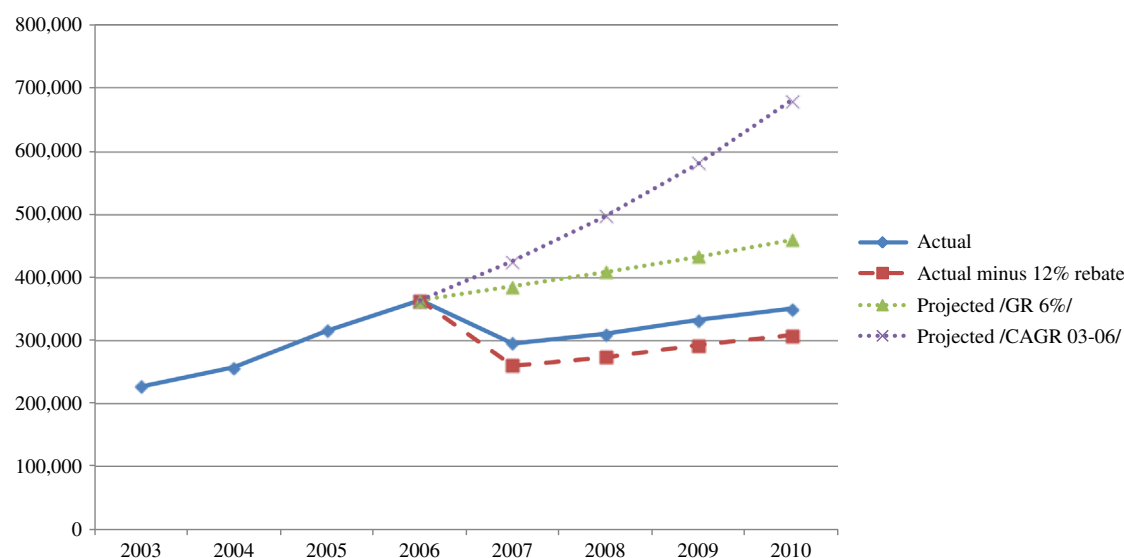
Although these data appear intuitively supportive of austerity measures, it is noteworthy that population health of Hungary has been severely lagging behind the EU-15 jurisdictions; for example, life expectancy at birth is 73.3 years versus 80.9 years in Sweden, infant mortality rate is 5.82 versus 2.56 in Sweden, and coronary heart disease death rate is 169 versus 30 in France [18]. Hungary's population health indicators are among the worst even among CEE countries.

Cost-Containment Tools of the PEA

Cost-containment measures had not started in 2007: The NHIF-OEP already in 2003 mutually agreed with the pharmaceutical industry to introduce the so-called claw-back system (firms required to cover overspending the budget for reimbursable drugs) and later negotiated with the industry the price freeze of drugs in exchange for allowing new products to enter the reimbursement list. The industry in fact under the claw-back regime paid back to the NHIF-OEP the amount of 20 billion HUF (66 million EUR) and 23 billion HUF (76 million EUR) in 2005 and 2006, respectively. The PEA thus built on this general claw-back system by bringing additional broad cost-containment policies described below to the prescription drug market.

Supply-side control—MAHs

In this review, we will focus on cost-containment policies applied to the MAHs. The first bold measure was an introduction of 12% statutory rebate/payback on reimbursed expenditure for both branded and generic firms, which substantially reduced the profit



mio HUF	2003	2004	2005	2006	2007	2008	2009	2010	
Actual	228,050	257,370	316,196	364,250	295,845	310,973	332,929	350,416	
Actual minus 12% rebate				364,250	260,344	273,656	292,978	308,366	
Projected /GR 6%/				364,250	386,105	409,271	433,828	459,857	
Projected /CAGR 03-06/				364,250	425,784	497,713	581,794	680,078	
year-on-year Actual change, including rebate		13%	23%	15%	-29%	5%	7%	5%	Σ
Savings 07-10 = Actual minus Projected /GR 6%/					90,260	98,298	100,899	109,441	398,898
12% rebate 07-10					35,501	37,317	39,951	42,050	154,820

Fig. 1 – Public prescription drug expenditure in Hungary between 2003 and 2010 [2], shown in million HUF. Two counterfactual curves are displayed: one for 6% annual growth rate and one for the CAGR of 16.9% for the period 2003 to 2006. CAGR, compound annual growth rate; GR, growth rate; HUF, Hungarian forint.

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