OVERVIEW ON GENERICS POLICIES AND PHARMACEUTICAL PRICING IN THE EUROPEAN COUNTRIES AND THE REPUBLIC OF MACEDONIA

Merita Dauti, MSc
Edita Alili- Idrizi, MSc
Sihana Ahmeti-Lika
State University of Tetovo, Faculty of Medicine
Department of Pharmacy, Tetovo, Republic of Macedonia
Ledjan Malaj, PhD
University of Medicine, Tirana, Faculty of Pharmacy, Albania

Abstract

Continued growth of spending on drugs in Health care, especially in the public sector encouraged initiatives for reforms in the system of determining the prices of medicines. These initiatives that were undertaken, were primarily aimed at reducing the cost of drugs but parallel to become a generic medications simultaneously promoting an adjustment of reimbursement procedures in the pharmaceutical sector. The policies for the regulation of the pharmaceutical market come as a response to health care classical market failures. This article will focus on the features, implementation and impact of these policies in some EU member states. Most EU countries, apply the external reference system of prices, whereupon the price of a certain medication is determined based on the price of the same product in other countries. On the other hand, in twenty other EU member states, prices are determined by comparing the prices of the same products according to chemical, pharmacological or therapeutic grouping. The reference pricing system has been adopted by governments as a mechanism to reduce the costs in the public health care system. By setting a price limit, competition among producers has been stimulated.

Keywords: Generics policy, reference prices, reimbursement.

Introduction

Legal regulations that deal with the determination of medication prices and their reimbursement comprise the greatest deal of organizing the

pharmaceutical system. The need for establishing a legal framework related to the determination of medication prices emerged as a result of the constant increase in the expenditure of medical products in healthcare, especially in the public sector.

All European countries are facing growing pharmaceutical expenditure, particularly in the public sector (OECD,2008) given that Europe has a comparatively higher coverage of publicly funded health care compared to the rest of the world (WHO, 2004). Based on this fact, in many EU countries there have been plenty of reforms in order to control the expenditures of medical products as well as promote generic medications with low prices as a mechanism to reduce the costs. In some European countries this system of regulation of medication prices dates back to late eighties and early nineties. Many European countries have alredy installed a reference pricing system as a reimbursement policy (Dylst et al.,2012). Pro-generic drug policies applied in the form of reference pricing system, initially implemented in developed countries also includes the low and middle income countries (Kaplan et al.,2012). In this context, the national authorities are free to set the prices of medicinal products and to designate the treatments that they wish to reimburse under their social security system. However, the European Union has defined a common procedural framework through the adoption of Council Directive 89/105/EEC, which is generally known as the "Transparency Directive". This instrument aims to ensure that national pricing and reimbursement decisions are made in a transparent manner and do not disrupt the operation of the Internal Market (Council Directive 89/105/EEC,1988)

This paper aims at reviewing policies that determine medication prices and their reimbursement in EU member countries, focusing on the characteristics, application and consequences of these policies by promoting generic medications in some EU countries and we will also analyze the “Methodology on the manner of estabilishment of medication prices“ in Macedonia and the consequences that derive from this system.

Methods

Research carried out based on National Price Sources, international literature, scientific articles. Research in the literature has focused on items that aim at analyzing the consequences of reference pricing system in the EU countries and studies conducted in recent years, mainly from 2012 that highlighted generic medicine pricing in Europe. Search terms included,“medicines“, „pricing“, „generics“, „refernce pricing“, „EU countries“.

Results

In 2010, EU member states devoted on average (unweighted) 9.0% of their GDP to health expenditures, significantly higher than 7.3% in 2000, but slightly lower than the peak of 9.2% reached in 2009. Following the economic crisis, which started in many countries, public expenditures on health were maintained in 2009 while GDP was falling strongly, but this was followed in 2010 by the implementation of a range of measures to reduce government health spending as a part of broader efforts to reduce large budgetary deficits and debts (OECD,2012). Parallel to the increase of expenditures in healthcare, there has been a considerable increase in pharmaceutical expenditures, which has caused policy makers in the field of healthcare in EU countries focus on lowering their prices. They are aware that by correctly regulating the pharmaceutical market, savings are possible without compromising the quality in healthcare. Policies that promote the usage of generic medications are often at the front of attempts to increase the cost-effectiveness of medical products. The implementation of the Reference Pricing System in many EU countries and those looking forward to their accession marks an important step in controlling the price of reimbursed medications. In Europe, this system was adopted in countries with high medication prices and then widely spread in many other European countries. This system enables involved parties to determine an acceptable price level for "equivalent" medications with huge difference in price (set by the producers). The reference price of a medical product implies the maximal amount, which is reimbursed by the Healthcare Insurance Fund. If the price of a medical product is higher than the reference price, then the patient pays only the difference between the price of a medical and the reference price or h/she gets a comparable therapeutic product (without additional charges). It is interesting to note that seven EU member states did not implement (Ireland, the United Kingdom, Austria, Luxembourg, Cyprus and Malta) or abandoned (Sweden) a reference price system in 2002(Vrijens et al.,2010); however, there are other systems that motivate the prescription of generic medications in these countries.

Based on a review of the Reference Pricing System (RPS) in some EU countries, three main differences have been noticed:

- The way the system has been organized (which medications are included).
- The way the reference price has been set, and
- The measures (for physicians, pharmacists and patients) taken to stimulate the use of low cost drugs.

Different EU countries implement different systems in setting the prices. In most EU countries, the price of medications is determined based on the external reference pricing system.

External reference pricing

Applied in 24 EU Member States (except Denmark, Sweden and the UK), it is a form of price control by setting a maximum price, based on the price of the same product in another country (Kanavos et al.,2011). Countries choose mostly the lowest or an average price within the specified basket of prices of other countries. The choice of reference countries made based on the level of economic development and geographical proximity that enables the determination of an acceptable price.

Internal reference pricing

20 EU Member States set the price to be paid by the public payers by comparing prices of equivalent or similar products in a chemical, pharmacological or therapeutic group. The reference price of a medical product implies the maximal amount, which is reimbursed by a third payer ("reference price"). The patient pays the difference between the retail price and the "reference price". A condition for IRP is to have therapeutically interchangeable medicines, often generics, available on the market.

The way the value of the reference price is going to be set, different EU countries implement different methods of determining the prices. The reference price is generally calculated as a function of market prices of medicines.

Different methods of calculating the referent price

In different European countries apply different methods to set reference prices. A country may employ one or a combination of methods to establish reference prices(Dylst et al.,2012). Some of methods to set refernce price are as follows:

Based on the lowest priced medications (applied in some countries such as: Denmark, Italy, Poland, Slovenia, France, Hungary, Turkey)

Based on the percentage of original drug (Belgium)

Based on the econometric model (Germany)

Based on the average price of medications (Croatia, Hungary)

The measures (for physicians, pharmacists and patients)

It is important that during the drafting of policies on setting medication prices, the implementation of policy measures should be carried out having in mind the characteristics of that particular country. Even though the experience from other countries is used as e point of reference, it is not always easy to adapt these policies in countries with different socio-economic peculiarities (Carone et al.,2012)

Measures focused on the physicians - in all countries, physicians are obliged to prescribe generic medications (INN) and respect the guidelines for

treating illnesses. In some countries (France, Germany, Spain) they have direct financial incentives to prescribe low cost drugs (Vrijens et al.,2010).

Measures focused on the pharmacists -in all countries, pharmacists are mandated to distribute cheaper bio-equivalent medications. In some countries (France, Germany, Spain) they have direct financial incentives to dispense low cost drugs. It is worth mentioning that in developing countries there is still collaboration between pharmaceutical companies and pharmacists, who are rewarded for distributing the company-specific medications.

Measures focused on the patients – awareness and information about rational utilization of medications such as antibiotics in some of the developing countries.

Pharmaceutical pricing in the Republic of Macedonia

Within the numerous reforms undertaken in recent years in the pharmaceutical sector in the Republic of Macedonia, can be said that a great achievement was realized with the implementation of „ Methodology on the manner of estabilishment of medication prices“ in 2011. This Methodology defines the manner of establishing the wholesale and retail prices of drugs that have obtained Marketing Authorization, issued by the Agency for Drugs (hereinafter “the Agency”) and are prescription medications. The reference countries, within the meaning of this methodology, are as follows: Republic of Slovenia, Republic of Bulgaria, the Netherlands, Republic of Poland, the United Kingdom, Republic of France, Republic of Croatia, Republic of Serbia, Republic of Greece, Federal Republic of Germany, Republic of Turkey and the Russian Federation. (Official Gazette RoM). Limitation of price for producers on the one hand and the promotion of generic drugs through mechanisms other than brought a continuous increase in the number of reimbursable drugs on the positive list, especially the part that drugs with a minimum additional payment. The Health Insurance Fund reported that in 2013 the total of 391 generic drugs that are included in the positive list, 299 are provided at no additional charge or 76.5%, which constitutes a major difference compared to 2009 when the figure was only 20% of the drugs included in the positive list. In this context, the increasing number of drugs without additional payment reached a mutual savings of financial instruments for the insured as well as for Health Insurance Fund(Tulevska E et al.,2014)

Conclusion

Pharmaceutical policies have been adopted as a mechanism by governments to reduce the cost of expenses in the public healthcare system.

By setting a limit price, competition among producers is fostered. The establishment of a reference value also makes the patients more aware of the medication prices. The determination of prices by using this system influences the compilation of positive lists whose main objective should be cost-saving. Policies are targeted toward pharmacists and physicians. For pharmacists, generic substitution offers the obligation to dispense the cheapest equivalent medicine. Physicians may face a number of regulations: monitoring of their prescription patterns, prescription guidelines, budget ceilings and educational and informational policies.

However, even though this system has been implemented in almost all European countries, there are still no sufficient analyses of the achieved results and outcomes.

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