

THE IMPORTANCE OF METHODOLOGY OF CREATING REFERENCE PRICES OF DRUGS

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INTRODUCTION

If we try to define the reference price may describe the same as a system where patient insurance payments do not depend on the price of drugs, but also the price of alternative therapies. This term of this notion makes us realize that the same defines the patient's insurance rates as the difference between the price of retail drugs or price list and "reference" of the product.

In order to be able to reduce the use of pharmaceutical products, many countries have chosen to use reference prices for drugs. Standard economic theory of the customer's choice suggests that proponents of reference price for prescription drugs see it as a form of fair competition and efficient market that could avoid completely the regulation of prices by the government and make "consumers and doctors sensitive to relative prices of drugs used for treating a certain disease.

On the other hand, scholars who oppose the same, they highlight that patients may not have the information required for an effective system of reference price and may choose therapy less optimal of drugs and such a step would be not only ineffective, but even unfair, where families with low incomes are more likely to respond in this way than households with higher income. It also suggests that the same reference prices can effectively undermine the patent scope and reduce incentives for investment in the pharmaceutical industry in research and development.

Moreover, the reference price is not a form of price regulation; but the same is a tool to limit the cost for reimbursement of drugs using drugs equivalent to the national market and establishing a reimbursement fee for groups of drugs that are considered interchangeable.

Also worth noting is that the use of national reference prices has been the subject of much debate within government institutions and interest groups such as industry, the medical profession and certain patient groups.

The techniques used to determine the price level of reimbursement vary from country to country. As a rule, countries calculate their reimbursement price for a particular class of drugs using an average (weighted) price of drugs in the group sold in the domestic market.

The reference price system for the first time has been implemented decades ago, some studies have been conducted to assess the effects of such a system. However, the assessment is not yet complete, that despite several years of implementation, there is still very little information about Integrated health outcomes with the use of drugs.

Basically pharmaceutical prices in affected classes of drugs are adapted to the reference price reimbursement levels in European systems

Finally, the reference price approach has become increasingly popular among European countries, but the principle remains controversial. Highlights of the debate are raised objections to the system by an industry or clinical perspective, defining classes of drugs, the breadth of application of the system and the level of reimbursement that would be enough to ensure the continued availability of medicines, etc.

Also worth noting that the views on reference prices within government agencies, industry, the medical profession and patient groups are very different. Efforts to perfect the method of grouping and classification of the product in order to make them as realistic as possible, will continue further.

LITERATURE REVIEW OF REFERENCE DRUGS

To reduce the use of pharmaceutical products, many countries have chosen to use reference prices. The reference price is a system where patient insurance payments depend not only on the price of drugs, but also on the price of alternative therapies. As can be understood from its name, it determines the reference price of insurance rates to the patient as the difference between the price of retail of the drug or product price list and "reference". Often a reference product presents a general version of a product, or cost-effective molecule available in a class. Patients pay a portion of the difference between the list price and the price reference. For example, if we consider the case of a drug A costs \$ 1,000 per month, drug R (drug reference)

costs \$ 200, and the coinsurance of the patient is conditionally 10% over the reference price. In this case, the patient would pay \$ 80 / month [ie, (1000-200) *. 1] for the most expensive drug.

Reference price is widely used worldwide. Once the reference price was introduced in Germany in 1989, it quickly spread. By 2010, 24 of 32 EU states have pharmaceutical reference price used alone or in combination with other policies of pharmaceutical price regulation.

A reference price system of drugs is a system that creates a level of reimbursement or the reference price for a group of interchangeable drugs. If a drug is priced above the reference price, the patient pays the difference between the price of medicine and the reference price, in addition to any other co-payment, eg In prescription fees, the proportion of co-payments.¹

A reference price system defines a common level of reimbursement, ie the reference price, for a group of drugs, generating savings for third-party payers. Producers are in principle free to set prices, although price of drugs over the reference price will incur a co-payment and additional generic medicines to patients in several countries, eg in Belgium, it should be priced below the reference price in order to be reimbursed.

The reference price will help governments contain pharmaceutical costs and control public drug reimbursement level. A reference price system can promote the general medical use of drugs since the price above the reference price is likely to lose market share as a result of additional patient co-payment.

Many European countries have already installed a system of reference prices, see Table 1. Sweden has adopted a reference price system in 1993, but abandoned it in 2002.² In Norway, the reference price is applied from 1993 until the end 2000. In 2003, the Norwegian government has installed a system called 'price index' with a group of off-patent drugs, which has many similarities with a reference price system.

The reference price is in many European countries combined with other policies such as the definition of unprotected or generic name of the international replacement, as this combination of policies appear to affect each other positively.³

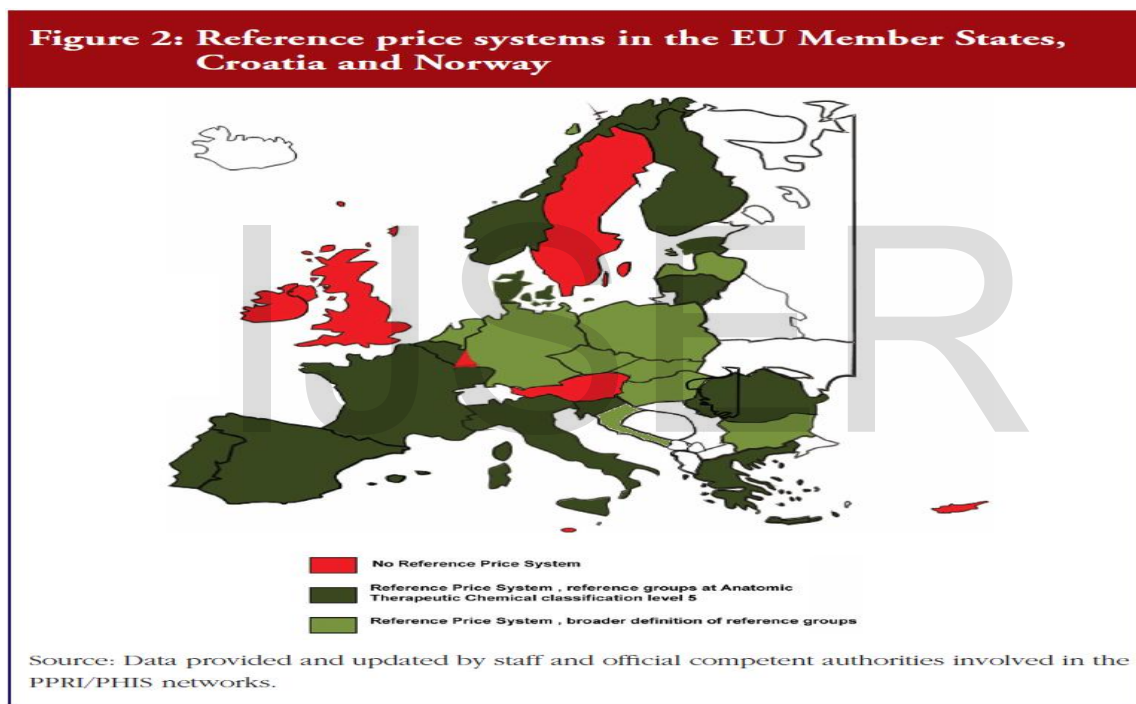
Table 1. Some of the European countries with and without reference price system of drugs

System with reference price	System without reference price
Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, Netherlands, Poland, Portugal, Spain. Turkey	Austria, Norway, Sweden, United Kingdom.

Source: P. Dulist et. al: Reference pricing systems in Europe: characteristics and consequences, 2012, <http://gabi-journal.net/reference-pricing-systems-in-europe-characteristics-and-consequences.html>

Moreover, as regards to the European countries which are and are not included in the group of countries that apply the pricing reference system, figure 1 below shows a map of the European countries that are branded and are being implemented reference price system.

Figure 1. European countries with reference price system



Source: <http://gabi-journal.net/the-impact-of-pharmaceutical-pricing-and-reimbursement-policies-on-generics-uptake-implementation-of-policy-options-on-generics-in-29-european-countries%E2%94%80an-overview.html>

Although the reference price is not popular in developed countries like the US, the motivation behind the reference price affects commercial insurers in terms of participation rates. Commercial insurers often will put drugs in levels of participation not only based on their cost and effectiveness, but also on the basis of how these parameters vary in terms of competing therapies.

There are two types of reference prices and that are the reference price of the external and internal. External reference price determines the reference price as a function of the price of substitute products in other countries; internal reference pricing sets the reference price as a function of the price of domestic substitutes. A paper by Kaiser et al. (2014) examines how the reference price is used in Denmark. In this study, it is noted that the price of pharmaceutical products in Denmark is free. Changes in pharmacies dealing with wholesale prices are reported and assessed by the Danish Medicines Products Agency (DMPA). Any new information about the prices are submitted by the agency every 14 days and submit them online to be available to the public. Prices are identical throughout the country and low by European standards.

Moreover, the products are classified into replacement groups. A replacement set consists of products with the same active substance, form management, similar strength and size of packaging. Package size can not be changed by more than ten percent within a substitution group. Pharmacists must first offer the patient the cheapest product in a substituent group if the recipe does not explicitly require its replacement, where such are "laws of mandatory replacement," also known in other countries where they contribute to growth generics selling. Finally, the patient can decide whether or not to buy the cheapest product or a substitute with a higher price. There are other measures in place to raise awareness of the cost of doctors treating a patient. First, doctors tend to follow the recommendations issued by Rational Drugs Institute (RDI), which is an institution that seeks to promote more efficient use of medical products. Second, the regional governments of Denmark, which is responsible for all matters related to health care, local physicians offer advice about the most cost effective and recipes to monitor their behavior.

The reference price in the United States is in line with efforts to change the current private coverage, and perhaps Medicare from a defined-benefit approach for a defined Contribution approach.

Insurers have three methods for patients looking to share the cost of covered prescription drugs. First, they can require patients to make a certain participation for each prescription that is independent of where the insurer pays the price in the pharmacy distribution. Secondly, they may require patients to pay a certain percentage of insurance for that price. (Both methods can "spin", looking for lower copayments or the coinsurance rates for drugs that are "preferred" by the insurer.) Thirdly, insurers can require patients to pay the full difference between the price

of the retail charge at the pharmacy and the so-called reference price that is reimbursed by the insurer, the latter being the price of a low-cost drug to a group of therapeutic drug thought to be clinically equivalent - or at least similar, to treat disease and help control the volume of drugs used, in which case the insurer may pay only a portion (say 80 percent) of the price of the reference drug at low cost, based on the coinsurance of reference prices .

The first method, fixed coinsurance, fully protects patients from full price retail insurers pay for prescription drugs. Advocates of "consumer-driven" health insurance may see this as a major shortcoming. Other policy analysts, however, point out that as an advantage. During the criticism of the reference prices, author Patricia Danzon argues that with the method "copayment" patients cope alone with an additional limit for medications not favorite, so have good insurance. This should reduce the administrative costs of the appeal and save incentives for manufacturers to develop improved drugs in certain classes.⁴

Health insurance system used in Germany, is generally seen as a pioneer in this regard, introduced for prescription drugs in 1989, which was followed in Europe by the Netherlands in 1991, Denmark and Sweden in 1993, Spain in 2000 Belgium and Italy in 2001. Norway also adopted a reference price in 1993, but has abandoned the same in 2001 due to expected cost savings and that does not materialize outside Europe. The reference price is also adopted by Australia, the Canadian province of Columbia and New Zealand.⁵ In a recent publication, Haiden Huskamp and others suggested that the reference price be approved by the clerks of the US Medicare, and Congress should add benefit of drugs in that program.⁶

With the appeal of standard economic theory of choice of consumers, proponents of reference prices for prescription drugs see it as a form of fair competition and efficient market that could avoid completely the regulation of prices by the government and make "consumers and doctors (as customer agents) sensitive to relative prices of drugs used for treating a certain disease.⁷

In this paper we review the analytical decisions complex and politically sensitive that will be made by policymakers to contain or support the notion of reference price.

Not including the experience of the reference price system abroad, although there may be provided detailed descriptions and comprehensive of these systems within the limits of this paper.⁸ Furthermore this research is necessary to evaluate apparently functioning systems of reference price terms of health policy, the obstacles encountered by this research, and what is known as the effect of the reference price on the cost and quality of health care.

Reference price is not a form of price regulation; it is a tool to limit the cost for reimbursement of drugs making use of the existence of equivalent drugs on the national market and the establishment of a fee reimbursement (called price reference) for groups of drugs that are considered to be "interchangeable" . However, the prices of medicines in the "interchangeable"

may differ greatly with new products often are more expensive than others. Agreeing that public funds should cover the costs regardless of the product group that provides a doctor, then a system of clerks put a price acceptable price level. This may be the average of the different prices, or may not reflect the price of one of the items with the lowest cost or an average grade of various low prices; alternative may be the price of the product is considered to be the most cost-efficient in its category. If a doctor wants to prescribe a more expensive bar within the group, he may be called to give specific justification, or the patient has needed to cover these additional costs.

The price of reference as defined above, and as discussed further in the paper, is simply based on a comparison of prices in the country of origin. However, there is also an alternative type of reference prices that can apply, in which prices charged for drugs in other countries are also taken into consideration. When a country has a system that requires official approval to prices of drugs, a comparison with prices in other countries is often used in determining the price that can be charged at national rate. In this situation, the lowest prices are found in other places can also be used as a reference for pricing reimbursement.

The use of national reference prices has been the subject of much debate within government institutions and with stakeholders such as industry, the medical profession and patient groups. If we focus on Europe, the system has been adopted in countries such as Germany in 1989, Denmark in 1991, the Netherlands in 1993, Italy in 1995 and Spain in 1999. The same has not been used in major markets such as France and the UK, although in last place acceptable pricing for generics follow a similar approach. Moreover, the reference price has also been widely adopted in the countries of Central and Eastern Europe - CCEE. Historically the use of price national reference in Europe for the first time attracted countries with prices higher drugs, a large market overall competitive and great differences in prices between different versions of the drugs multi-source - a several factors that have given this approach as necessary and feasible. Last countries have adopted the access to medicines at low prices (for example, Spain and CCEE). Outside Europe, the reference price approaches are applied in Canada since 1995 and in New Zealand. The possibility of adopting the system was discussed as well as in Japan during 1998.

In some countries like the EU member states, where social health insurance funds are the biggest buyers of drugs, the national reference price can have a significant effect on corporate strategies for R & D and marketing policy.

Establishing a national reference price system includes four major decisions as follows:

- Determination of the number and scope of each class of "interchangeable" drugs, for which the reference price is to be determined;

- Determination of the manner in which the level of reimbursement reference is to be calculated for each particular class of drugs;
- Establish a procedure for determining the classes and determining acceptable levels of reimbursement;
- Establishment of mechanisms to allow for the same exceptions when justified.

In order to implement such a system should be set different classes in which drugs considered "exchangeable" and should determine the market segment in which the system should be implemented. In this case there are several options: one of them is where the system may be limited to certain categories of drug, usually representing a large part of the budget of medicines; may apply different criteria for different categories, to decide on the degree of internal change within each of the drugs; and they can choose to introduce the method gradually, experimentally or perhaps in order to arrive ultimately at a comprehensive reference system.

The criteria used to determine grades of drugs vary from country to country and by market segment that is considered to reference prices.

The following are some examples of countries in the definition and scope of classes of medications for a national reference price system.

Germany was the first country in Western Europe to implement a reference price system, originally based on classes of drugs that have the same active ingredient and then move on comparability therapeutic classes. The system is designed to apply research based and generic drugs, which were included three years after the expiration of the patent. The length of this period is judged sufficient to ensure that competition would allow generics a fair representation of market prices.

There are three types of classes of drugs which are defined in the following:

1. Drugs that have identical active ingredient (Level I).
2. Drugs that have active therapeutic ingredient comparable (particularly drugs that contain similar chemical compounds) (Level II).
3. Drugs with a comparable pharmacological profile (especially fixed combinations).

Level I drugs are easily grouped, but decisions II and III level are more complex and only a selection of these drugs are collected within the system of reference prices.

Spain has introduced more restrictive reference prices, limited classes of drugs in the definition of Tier I German, including 50 drugs with identical compound.⁹

Canada, as part of its Pharmacare program, introduced reference prices only five classes of drugs, selected mainly due to the level of expenditure in the budget which represent drugs.

Holland uses its system of reference prices (known as GVS), under the principle of therapeutic substitution.¹⁰ Government identifies the classes of drugs that have the same therapeutic indication, mainly using the ATC classification. This classification is considered as an adequate basis for therapeutic classification for the purpose of reimbursement. The Dutch government also has introduced some modifications to take into account relevant therapeutic side effects that are not reflected in the ATC classification, but in some cases provide a reason for the classification of certain drugs to specific target groups.

The techniques used to determine the price level of reimbursement vary from country to country. As a rule, countries calculate their reimbursement price for a particular class of drugs using an average of the prices of medicines in the group that sold in the domestic market. However, in countries where generics competition is essential and leads to large price differences between products, health funds or government agencies / commissions make decisions that give a greater importance to the free prices. With increasing economic evaluation studies and investigations on cost effectiveness, some policymakers introduce other criteria to calculate an acceptable level of reimbursement based on the most cost-effective therapy available (eg, British Columbia).

Usually the price information used to determine the level of reimbursement reflects domestic price structure that is implementing the system. Therefore, it is influenced by the results of various trades in the domestic price negotiations that have led to the prevailing national price structure within each class of drugs. Some countries may, however, as mentioned above, choose to rely partly international sources of price information in determining their levels of reimbursement reference prices. The Netherlands, for example, uses price comparisons with other European countries, such as France, Germany, Great Britain and Belgium, to determine the maximum prices which then in turn affect the price of reimbursement. The choice of countries in such a case is based on similar criteria identical purchasing power.

EFFECTS OF REFERENCE PRICE SYSTEM

The reference price system is first implemented ten years ago, where some studies have been conducted to assess the effects of such a system. However, the assessment is not yet complete. Despite several years of implementation, there is still little evidence of health outcomes related

to the use of drugs.¹¹ Even that is not much research to provide scientific evidence to assess the impact of such a system in different health outcomes.¹² A major initiative in this field is taken from Canada to oppose strong system of doctors from the pharmaceutical industry and several other providers of health care. An independent project for the scientific evaluation of the program of reference price drugs is mandated by several leading research studies from Canadian academic centers (Harvard University, MacMaster University, University of Washington) and US.

However, there are some conclusions from the facts readily available, as the evolution of prices of drugs during certain periods of time is recorded. As a rule, prices of pharmaceutical drugs affected grades are adapted to the reference price reimbursement levels in European systems. Very occasionally, companies are trying to keep prices high, but when they did this, it usually was only for a limited period. The scope of the reference price, however, is generally limited to specific market segments (especially those with very similar products) and usually it is possible to observe that the prices have gone up in other market segments. In Germany for example, the prices of medicines in certain areas were covered by the system of reference prices that were over a certain period reduced by 1.5%, while prices of medicines not covered by the system increased by 4.1%.¹³

There are some recent contributions in this area that have evaluated the impact of reference pricing systems for the use of drugs by the patient and the use of other services. A series of epidemiological studies that are based on semi-experimental designs, have provided scientific evidence on health outcomes of reference prices. For example, the study of Schneeweiss, Soumerai Mclure of ACE inhibitors ¹⁴ shows a decrease of 29% in the use of inhibitors with high cost and price - sharing ACE immediately after the implementation of policies. After a transition period, the overall rate of post-policy use all ACE inhibitors which was 11% lower than previously projected.

Several such interruption of therapy were observed among groups with low incomes; however, according to the authors of such a thing should not lead to an interruption of anti-hypertensive therapy as such. Giving patients other anti-hypertensive drugs, under the influence of the system of reference prices, is leading to a slight increase in the use of medical services. One of the reasons why there is the study of the impact of system exposure to drugs or health care use by patients has so far been largely untrue, especially in Europe, to legal restrictions with respect to privacy and the protection of individuals. There is inter-institutional administrative databases in the use of drugs in individual level. ¹⁵ In program in Canada, privacy is assured by encryption of data.

Even if the Canada initiatives and its cooperative work with the US Centers provide scientific evidence for results in health, should still exist research certain and estimates of actual impact

or potential price reference on the adequacy of treatment drugs that patients receive. Thomas Mann in his study emphasizes that 16 prescribing in New Zealand to provide some evidence on the negative effects of the use of certain products within this class of drugs.

Regarding the impact of health care costs, budget savings for drugs are achieved within classes generally covered by a reference price system (Germany, Netherlands). As the impact on other services usually measured not conditionally, it is not easy to assess the impact on global health budgets. However, so far the budgetary savings achieved with the reference prices are considered to be relatively low.¹⁷

Access to the reference price is becoming increasingly popular among European countries, but the principle remains controversial. Highlights of the debate are contradictions in the system established by an industry or prospective clinical definition of classes of drugs, the breadth of application of the system and the level of reimbursement that would be enough to ensure continuous availability of drugs, etc. The first programs of benefit of medications aimed to use general competition in order to provide coverage of drugs with the best price available (eg, Medicaid program in the US), the difference between the concept between original brands and generic drugs have similar bioequivalence applied.

Reference price, however, can use the concepts of inter - change that goes beyond replacing general and could be controversial from an industry standpoint, the doctor or the patient. During the application of reference prices, policymakers have addressed such issues usually by increasing the number of classes of drugs (small groups) or considered "protective mechanisms" or providing exemptions. However, experiments or incremental approaches pursued by countries such as Spain or Canada aimed to seek solutions in particular to the dilemma of balancing the need for innovation with the need to contain health care budgets.

Industry generally opposes the reference prices on the basis that it does not take into account the characteristics of innovation in enhancing the process of discovering the drugs related to a class of medicines. Pharmaceutical companies have their drugs recently developed the unique advantages claims to justify a higher level of prices and reimbursement than other products with which the authorities have sought in their group. A system of reference prices can cause R & D resources are diverted to therapeutic areas that are not covered by the reference systems, such as price setting in these categories be basically free. Clinicians or patients may question grouping against drugs: physiological responses of patients by the use of individual drugs "similar" can be different, in term of quality, absorption, indications, secondary effects, method of preparation, application forms , the frequency of adverse effects and contraindications. The same may be eligible for health professionals and patients. Payers and healthcare organizations can review medications and switching classes of drugs, since the use of a drug that may require greater involvement of other sources of health care (eg, more doctor visits) the use of another

source; it can also affect the timing and extent of treatment, the consequences of direct and indirect cost of the health care. 18

CONCLUSIONS AND RECOMMENDATIONS

When describing the theoretical literature and empirical results presented by different authors we can understand that in order to be able to reduce the use of pharmaceutical products, many countries have chosen to use reference prices for medicines. Moreover, we noticed that the economic theory of consumers selection, suggests reference prices for prescription drugs to be seen in the form of fair competition and efficient market that could avoid completely the regulation of prices by the government and at the same time make consumers and doctors significantly in terms of relative prices of drugs used for treating a certain disease. But on the other hand, other researchers emphasize that patients may not have the information required for an effective system of reference price and may choose therapy less optimal drugs and such a step would be not only ineffective but also unfair . Even a suggestion is going even further by emphasizing that the reference price does not represent a form of price regulation, but the same is a tool to limit the cost for reimbursement of drugs.

Recently, there are some recent contributions in this area that have evaluated the impact of reference pricing systems for the use of drugs by the patient and the use of other services. Access to the reference price is becoming increasingly popular among European countries, but the principle remains controversial. Highlights of the debate are raised objections to the system by an industry or clinical perspective, defining classes of drugs, the breadth of application of the system and the level of reimbursement that would be enough to ensure the continued availability of drugs, etc.

Moreover it is worth noting that efforts to perfect the method of grouping and classification of the product in order to make them as realistic as possible, will continue further, because such a consensus has not been achieved in practice .

Reference pricing is a popular policy for governments to contain pharmaceutical expenditures and seems to be effective in the different European countries.

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