Impact of the Reference Price System on the Pharmaceutical Market: a Theoretical Approach*

Anna Merino-Castelló†

First version: February, 2000
This version: June, 2003

*This paper corresponds to Chapter 1 of my PhD Thesis. Acknowledgments: I am especially grateful to Bruno Cassiman and Jaume Puig for their guidance. I would also like to thank Antonio Cabrales, Julio García-Cobos, Iñigo Herguera, Pedro Marín, Nadine Watson and participants at the Pompeu Fabra University seminar, Carlos III and Complutense Industrial Organization workshops.

†Departament d'Economia i Empresa, Universitat Pompeu Fabra, Ramon Trias Fargas 25-27, 08005 Barcelona, Spain. e-mail: anna.merino@upf.edu.

Abstract

This paper studies the impact of the reference price (RP) system on the price-setting strategies of pharmaceutical firms. The RP system is equivalent to setting an additional but avoidable copayment for those drugs whose price exceeds the reference level. Using a vertical product differentiation model, we show that branded drug producers decrease prices substantially after the introduction of this new copayment regime while generic prices remain more or less constant. As a consequence, price competition increases under the new regulatory framework, however, market share for generic drugs remain constant or even decreases. We can finally conclude that, although the social planner succeeds in promoting price competition, it completely fails in raising generic drug usage among the population. Both the implementation of the RP system and the potential entrance of generics constitute a sufficiently credible threat to make branded drug producers decrease price, thus fostering effective competition.

Keywords: Brand-name and generic drugs, pricing strategies and optimal price regulation.

JEL codes: I18, L11, L15, L51.

1 Introduction

Several European countries have already established this new reimbursement mechanism - RP system- as a regulatory measure aimed at containing national pharmaceutical spending through the promotion of price competition and the increased usage of generic drugs. Although there are several variations in the RP calculation method, we employ a general expression that could be adapted to all European versions; therefore, our conclusions could be extrapolated to those countries with similar regulatory frameworks.

We analyze two different scenarios: (i) we first solve quality and price equilibrium before the RP system enters into force; in this case, we assume that consumers must pay a constant copayment rate k for both branded and generic drugs and (ii) in the second scenario, we introduce the effect of the RP system which entails an additional but avoidable copayment for those drugs whose price exceeds the reference level.

Until now, several economists have deeply examined what happens to the prices of innovator drugs when generic versions enter the market and, although the majority of them agree about the existence of a non-zero effect, there is some dispute about the direction of such impact (Section 2.1). However, once the competitive framework has been distorted due to the implementation of the RP system, previously reached conclusions are not valid any more because they were obtained under the assumption of non-price regulation.We now require a different scenario in which a new regulatory measure is introduced (Section 2.2).

According to a recent review on the RP system (López-Casasnovas and Puig-Junoy, 2001), the existing literature on the impact of such reimbursement mechanism has been mainly descriptive and the absence of a common theoretical framework has hindered the design of an optimal regulatory measure. However, few authors have recently looked into the problem from a theoretical or empirical viewpoint (Zweifel and Crivelli 1996, Aronsson et al 2001, Pavnick 2002, Cabrales 2003, Mestre-Ferrándiz 2003).

We use a *vertical product differentiation model* with two firms operating in the market: one firm produces the brand-name drug whose patent has already expired (B) and the other produces the corresponding generic version or branded copy (G). We assume a two-stage game where, in the first stage, firms choose the "perceived" quality of the good they want to produce and, in the second stage, a competitive process occurs whereby firms set prices.

Furthermore, at each stage of the game, firms make their decisions about

quality and prices both simultaneously and sequentially. Therefore, we obtain four different models. We solve the quality game taking into account two different assumptions about entry temporality: branded copies or "me-too" drugs enter the market simultaneously with the original product while generic drugs enter the market after the patent on the corresponding brand-name drug has already expired. We solve the price-setting sub-game by taking into account Bertrand and Stackelberg price competition. It is widely accepted that price is one of the main strategic variables in the pharmaceutical industry, however, some researchers assume simultaneous price competition while others accept sequential price competition (Section 3).

We find that, under the RP system, branded drug producers decrease prices substantially in order to adapt to the new competitive situation while generic prices remain more or less constant. In Bertrand models, market share percentages do not change after the introduction of reference prices while, in Stackelberg models, the market share of branded drugs even increases and that of generic drugs decreases. In both cases, the branded drug producers compensate for the decline of profits by selling greater quantities instead of charging higher prices. Our theoretical results are in line with recent empirical findings (Section 4). We also carry out a social welfare analysis and compare price competition under the RP system and Ramsey pricing. We find that the reference price system maximizes price competition when the penetration of generic drugs exceeds 70% of the market; otherwise, Ramsey prices can better ensure price competition and maximization of social welfare (Section 5).

This paper is organized as follows. Section 2 provides an in-depth description of the main regulatory frameworks and the characteristics of supply and demand in the pharmaceutical market. Section 3 introduces the assumptions regarding both simultaneous and sequential product differentiation models. Section 4 explores the impact of the RP system on price and quantity strategies. Section 5 presents a social welfare analysis and calculates the Ramsey prices; finally, Section 6 summarizes the results and presents the conclusions of the paper.

2 Characteristics of the Pharmaceutical Market

The purpose of this paper is to examine the impact of the reference price (RP) system on the price-setting strategies of pharmaceutical firms, dealing with both branded and generic drug producers. RP is a regulatory measure aimed at containing pharmaceutical spending by promoting the usage of lower-cost generic drugs. Although we mainly focus on the Spanish case due to proximity, we are able to extend our conclusions to those European countries with similar regulatory frameworks.

The entry process of generic drugs follows a parallel pattern worldwide, nevertheless, owing to different political, social and cultural contexts, some countries exhibit high penetration rates while others are unable to attain a significant market share.[1] Several European countries, such as Denmark, Germany, Iceland, Norway, Sweden, Spain and The Netherlands, have introduced different types of RP mechanisms with substantial variations between them. However, the principle always remains the same: the price paid by the third-party is established with reference to interchangeable drugs, with any excess cost being borne by the consumer as an out-of-pocket expense.

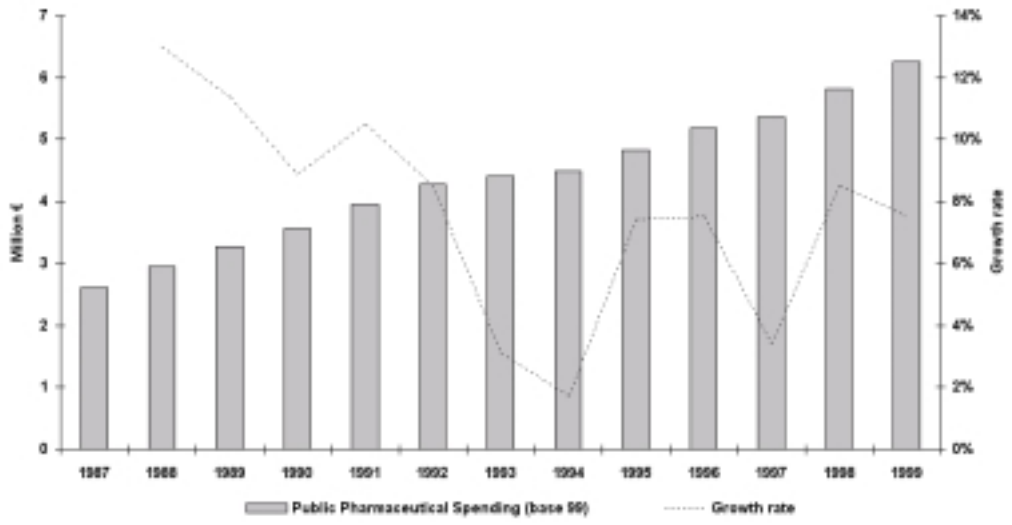
2.1 Generic Drugs Entry

One of the primary goals of Law 13/96 was to set up a competitive framework in the Spanish pharmaceutical market by promoting the availability of lower-cost generic drugs.[2] The so-called generic drugs are those medicines that contain the same active ingredient as a brand-name drug and enter the market once the patent on the latter has expired.

[1] Countries such as Germany (32%), The Netherlands (39.9%) and UK (46.45%) enjoy a high "generics over total drugs" ratio while Belgium (1%), France (4%), Italy (0.75%) and Spain (3.6%) are characterized by low generic drug penetration rates *(Source: "Gasto Farmacéutico (I) en Europa. Comparación del Año 2000", El Global, 2001; available at www.elglobal.net).*

[2] Law 13/96, 30 December, entitled "Medidas administrativas, fiscales y del orden social" that modifies Law 25/1990 also called "Ley del Medicamento". In the USA, the act commonly known as the Waxman-Hatch Act aimed to reduce expenditures on prescription drugs by encouraging generic drug entry. It eliminated the strict requirements for FDA approval of generic substitutes and replaced them with conditions that require much less stringent testing.

Generic drugs cost less than their innovator counterparts because of their lower initial investment in R&D. In this sense, they become very attractive for national health systems because they are expected to play an active role in holding down pharmaceutical spending. The rise of pharmaceutical spending in the last decade has led governments to encourage the use of these cheaper drugs amongst the population and medical centers with the aim of fostering price competition between branded and generic versions (Figure 1.1).[3]



Source: Spanish Ministry of Health (data available at www.pmfarma.com)

Figure 1.1. Public Pharmaceutical Spending in Spain (1987-1999)

In order to obtain official approval from *Agencia Española del Medicamento*, generic versions are only required to certify "bioequivalence" to the corresponding innovator drug; in other words, to show that the active ingredient is released and absorbed at the same rate for the generic drug as for the corresponding innovator.[4] However, although brand-name drugs and

[3] Accumulated growth rate of Spanish public pharmaceutical spending for the period 1987-1999 is 140%.

[4] The task of *Agencia Española del Medicamento* in Spain corresponds to that of the Food and Drug Administration (FDA) in the USA. Generally speaking, generic drugs obtain official approval under a shorter process than innovator drugs.

their corresponding generic versions are supposed to be perfect substitutes in terms of quality and therapeutic effects, in fact, from the consumers' and physicians' point of view, they are not.

Demand Side: Once generic drugs enter the market, uncertainty about their quality arises. Consumers tend to re-use those medicines that have worked for them in preference to taking the risk of trying drugs that they have not tested before and that may not suit them. In pharmaceutical markets, consumers behave as if they face a switching cost equal to the maximum premium that they would be willing to pay to be guaranteed a product of the same value as that of a product they have previously purchased (Klemperer, 1995). That is, a product of unknown quality is inherently riskier than a product of known quality. Because it is less risky, consumers will pay a higher price for the product with the known quality (Conrad, 1983).

In our model, we assume that a fraction of consumers face high switching costs and manifest strong preferences for brand-name drugs while the remainder is more price-sensitive and show negligible switching cost. Loyal consumers are extremely committed to brand-name drugs and exhibit a state of dependence in their purchasing patterns because their preferences depend on their past history of prescriptions (Coscelli, 2000). This uncertainty about quality creates an *artificial vertical differentiation* that segments consumers' demand.

Doctors are also responsible for this artificial product differentiation because they are relevant decision-makers in the drug purchasing process. As Hellerstein (1998) found, almost all physicians prescribe two types of drug, but some of them are more likely to prescribe generic drugs while others are more likely to prescribe brand-name versions. The latter exhibit habit persistence, in other words, they have a tendency to prescribe repeatedly the same brand-name drug (Coscelli, 2000). There are several possible reasons why physicians do not prescribe generic drugs more often, but the one that stands out most is the lack of information about the availability and efficacy of generic versions.

Under the new regulatory framework, pharmacists also play an important role:[5] if physicians prescribe a brand-name drug whose price exceeds the reference level, pharmacists are able to substitute it for its corresponding generic version as long as the consumer agrees. Masson and Steiner (1985)

[5]In Spain, Law 66/1997, 30 December, entitled "Medidas Fiscales, Administrativas y del Orden Social" that modified article 94 of the "Ley del Medicamento."

have performed an analysis of the initial period after the new state substitution law in the United States and found that these new laws have indeed increased the price sensitivity and, consequently, the amount of generic drug usage in the market.

There is a close relationship between experts -both physicians and pharmacists- and patients. Patients place blind trust in their doctors' opinion and are reluctant to switch to generic drugs if physicians do not advise them to do so. The asymmetric information between doctors and patients certainly suggests the possibility that the former could use their position of superior knowledge for their own financial benefit. In the absence of incentives, physicians are more likely to continue prescribing brand-name drugs instead of generic versions. In Health Economics, this phenomenon is commonly known as the *supplier-induced-demand effect*.

Therefore, under the new regulatory scenario, the demand for drugs can be characterized as follows: the physician prescribes, the pharmacist dispenses and substitutes whenever possible, the patient consumes and pays a fraction of the drug cost as an out-of-pocket expense and, finally, the third-party pays the rest. In this framework, there is an agency relationship between physician and patient and another between pharmacist and patient, however, analysis of this does not fall within the scope of this article. In our model, we assume that patients are the unique decision-makers.

Supply Side: The supply side in pharmaceutical markets is characterized by a *first mover pricing leadership*. Once a breakthrough drug is introduced, its manufacturer enjoys a period of exclusivity until the patent expires. Several authors have argued that a pioneering brand is able to establish a reputation which later entrants cannot overcome without large promotional expenditures or drastic price cuts.

The period of exclusivity grants some *monopoly rents* and market advantages for the innovator such as high market shares, locked-in consumers and high-quality products reputation. Furthermore, this period of exclusivity allows the branded drug producer to enjoy a future price leadership. Once a patent expires, all interested producers can manufacture the generic version and enter the market. Generally speaking, we can assume that there are relatively low barriers to entry because the generic approval process does not take long, it is not very costly and producers of generic drugs do not need to duplicate research costs.

2.1.1 Impact of Generic Drugs Entry on Pricing Strategies

The impact of generic drug entry on the price-setting strategies of branded drug producers has been a source of controversy. Several economists have examined what happens to the prices of innovator drugs when generic copies enter the market and, although the majority of them agree about the existence of a non-zero effect, there is some dispute about the direction of such impact. Another point to emphasize is the fact that all empirical studies use data from the United States market, thus assuming non-price regulation.

Grabowski and Vernon (1992) found that innovator prices continued to rise faster than inflation after generic entry. On the contrary, Caves et al (1991) attempted to estimate the rate of price increase that would have occurred without generic entry, concluding that although the prices of many brand-name drugs kept on rising after generic entry, those prices were still lower than they would have otherwise been.

Frank and Salkever (1997) found that brand-name drug prices increased at a faster rate than would have been the case had generic entry not occurred. More recently, Mestre-Ferrándiz (1999) found that brand-name drug producers also have incentives to produce generic alternatives; this leads to an increase in the price of the brand-name drug produced by this firm. Ching (2000) argued that consumer heterogeneity in terms of price elasticity could explain the pricing pattern that caused branded price increases in response to generic drug entry. The above-mentioned studies assume *demand market segmentation*; that is, when generics enter the market, price sensitive consumers switch to low cost versions and, consequently, the branded drug firm faces a more price inelastic demand and can hence raise its price. This is called the *Generic Competition Paradox.*

On the other hand, Ellison et al (1997) found that in one antibiotic market, demand for a brand-name drug is more sensitive to changes in the price of its generic substitutes than to changes in the price of a competing brand-name drug.

2.2 Reference Price System and Promotion of Generics

Increases in national pharmaceutical spending over the last decade have led governments to adopt several regulatory measures aimed at promoting price competition through generic drug entry, controlling sale prices and profit

margins, and establishing new reimbursement mechanisms. The lower price of generic drugs with respect to branded versions has encouraged public administrations to promote generic drug usage as a mechanism to contain national pharmaceutical spending and monitor the quality of pharmaceutical care. Each country has implemented slightly different pharmaceutical policy mechanisms and their success has been closely related to the political, social and cultural context within which each health care systems operates. One of the most popular measures has been the promotion of prescribing, dispensing and consuming lower-price generic drugs through the introduction of reference prices and substitution laws (Table 1.1).

	A	B	DK	FIN	F	G	GR	IC	IRL	I	L	NL	N	P	S	Sw	CH	GB
Laboratory sale price control	-	✓	-	✓	-	-	✓	✓	-	-	✓	-	✓	✓	✓	-	-	-
New drugs reimbursement control	✓	✓	✓	✓	✓	-	✓	-	-	✓	✓	✓	✓	✓	✓	✓	✓	-
International comparison	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-
Reference price system	-	-	✓	-	-	✓	-	✓	-	-	-	✓	✓	-	✓	✓	-	-
Devolution/contracts	✓	-	-	-	✓	-	-	-	✓	✓	-	-	-	-	✓	✓	-	✓
Profits control	-	-	-	-	-	-	-	-	-	-	-	-	-	-	✓	-	-	✓
Promotional spending control	-	-	-	-	✓	-	-	-	-	-	-	-	-	-	✓	-	-	✓
Prescription drugs budget	-	-	-	-	-	✓	-	-	✓	-	-	-	-	-	-	-	-	✓
Pharmaco-economic evidence recommendation	-	-	-	✓	-	-	-	-	-	✓	-	✓	✓	✓	-	✓	-	✓
Wholesaler fixed margins	✓	✓	-	-	✓	✓	✓	-	✓	✓	✓	-	-	✓	✓	-	✓	✓
Pharmacists fixed margins	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Generic substitution	-	-	✓	✓	✓	-	-	✓	-	✓	✓	✓	✓	-	✓	-	-	-
Copayment rates	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-	✓	✓	✓	✓	✓	✓
OTC price control	-	✓	-	-	-	-	✓	-	-	-	✓	-	-	-	-	-	-	-
Price control for hospital use drugs	-	✓	-	-	-	-	✓	-	-	✓	-	-	-	-	✓	-	-	-

A=Austria; B=Belgium; DK=Denmark; FIN=Finland; F=France; G=Germany; GR=Greece; IC=Iceland; IRL=Ireland; I=Italy; L=Luxembourg; NL= Netherlands; N=Norway; P=Portugal; S=Spain; SW=Sweden; CH=Switzerland; GB=Great Britain.

Source: "Diagnóstico y Perspectiva del Gasto Farmacéutico en España", NERA. Report published by Farmaindustria.

Table 1.1. The Main Mechanisms for Controlling Pharmaceutical Spending in European Countries

2.2.1 Reference Price System

In Spain, Royal Decree 1035/1999 regulates the mechanism by which government calculates the reference price for those drugs funded by Social Security and included in the submarket of drugs whose patent has already expired.

Since the introduction of the RP system in Germany in 1989, different versions have been implemented in various European countries with substantial modifications. However the principle always remains the same: the price paid by the third-party is established by reference to interchangeable drugs, with any excess cost being borne by the consumer as an out-of-pocket expense.

The main objectives of a RP system are to increase price competition and, ultimately, reduce public expenditure on pharmaceuticals. The first aim can be achieved by making patients more "cost aware" via savings incentives when they ask for generic drugs. More specifically, the RP system is equivalent to setting an *avoidable* copayment for those drugs whose price is superior to the reference level. This new regulatory measure should thus reduce the costs incurred by the third-party or Social Security.

Most of the countries which were first to introduce the RP system have three characteristics in common:(i) pharmaceutical prices are not directly regulated, (ii) generic drugs account for a significant market share and (iii) public pharmaceutical spending accounts for more than half of total drugs sales. Although Spain satisfies the third of these features, the first two are not accomplished. These drawbacks could explain why the Ministry of Health repeatedly postponed the introduction of the RP system until December 2000.

In Germany, the reference price (maximum reimbursement) is taken to be the price of the least expensive generic drug in a homogeneous group and costs are only reimbursed up to this maximum; that is, if the retail price exceeds the maximum reimbursement, the patient bears the excess cost. Otherwise, the patient does not need to copay. The pharmacist is not allowed to substitute to a generic product unless the doctor explicitly permits it on the prescription (Pavcnik, 2002). The Swedish RP system came into effect on January 1, 1993 and specifies that any cost exceeding the price of the least expensive generic version by more than 10% must be borne by the patient (Aronsson et al, 2001).

In Spain, the reference price is determined endogenously as a function of the prices of both brand-name and generic versions: (i) the reference price is defined for each homogeneous group (in each homogeneous group there is at least one generic drug), then the reference price is calculated as the weighted average of the minimum prices until 20% of the market sales are covered; (ii) in those cases where the difference between the reference price and the maximum market price is less than 10%, the reference price will be set at 90% of the maximum price; (iii) if the difference between the maximum price

and the reference price is greater than 50%, the reference price will be set at 50% of the maximum price and (iv) in all cases, the reference price can not be lower than the minimum supplier price and it will be revised every year.

Under this new regulatory framework, the conclusions shown in the previous section about the impact of generic drug entry on pricing strategies are not valid any more because they were obtained under the assumption of non-price regulation.We now require a different scenario where a new reimbursement mechanism is able to distort price competition. A few economists have recently studied this phenomenon.

Aronsson et al (2001) empirically analyzed the impact of the RP system in Sweden and found that it lowered the price of the original drug relative to the price of the generic versions. The price-reduction effect of the RP system appears to be reasonable since the introduction of this system may have provided strong incentives for manufacturers of brand name products to lower their prices.

Cabrales (2003) studies oligopolistic competition in off-patent pharmaceutical markets using a vertical product differentiation model. His model explains the fact that countries with stronger regulation have smaller generic market shares. He assumes a price ceiling that corresponds to a RP system and finds that the relative market share of the high quality good is a decreasing function of the maximum price, that is, the lower the maximum price, the higher the relative market share of the high quality product. Mestre-Ferrándiz (2003) shows that the Spanish RP system achieves the objectives of increasing price competition and reducing public pharmaceutical costs only if the reference price is set within a certain interval.

Finally, Pavcnik (2002) empirically examines the link between potential patient out-of-pocket expenses and pharmaceutical pricing using a unique policy experiment from Germany. Using data on oral antidiabetic and antiulcerant drugs, she finds that producers significantly decrease prices after the change in potential out-of-pocket expenses. Price declines are most pronounced for brand name products. Furthermore, branded products that face more generic competitors reduce prices to a greater extent.

Cabrales (2003) and Mestre-Ferrándiz (2003) are closer to us in the sense that they both introduce the RP system as a market distortion. This notwithstanding, the assumptions about product differentiation and reference price construction differ substantially. Our theoretical results are in line with recent empirical findings (Aronsson et al, 2001 and Pavcnik, 2002).

3 The Model

We analyze two different scenarios: (i) we first solve quality and price equilibrium before the RP system enters into force; in this case, we assume that consumers must pay a constant copayment rate k for both types of drug and (ii) in the second scenario, we introduce the effect of the RP system. As explained above, the RP system is a reimbursement mechanism that sets an additional but avoidable copayment for those drugs whose price exceeds the reference level.

We use a *vertical product differentiation model* with two firms operating the market: one firm produces the brand-name drug whose patent has already expired (B) and the other produces the corresponding generic version or branded copy (G). We assume a two-stage game where, in the first stage, firms choose the "perceived" quality of the good they want to produce and, in the second stage, a competitive process occurs whereby firms set prices.

Although there are no administrative barriers to enter the market once the patent on the breakthrough product has expired, both the low profit margins in the generic drug submarket and the initial lack of confidence make potential competitors reluctant to enter. Therefore, there exists a transition period during which the market is duopolistic. Two different scenarios can arise; either the innovator firm decides to produce the generic version as well applying *third degree price discrimination* or a third company decides to enter the market producing the generic version. In our case, we assume the existence of a third company.

Demand Side: Consumers have the same utility function however they differ in their tastes, which is represented by parameter v.

$$\begin{array}{c} U(v,\theta_i) = v\theta_i - kp_i \text{ if consumer buys one unit} \\ U(v,\theta_i) = 0 \text{ otherwise} \end{array} \quad i = B, G \qquad (1)$$

Let consumers' taste for drug "perceived" quality be denoted by v and assume a continuum of consumers indexed by their valuation v on the interval $[0, 1]$. The benefit from purchasing one unit from producer i (B,G) is $v\theta_i$ where θ_i is the "perceived" quality for each producer. The perception of quality can be either high or low. High perceived quality is associated with the brand-name drug (θ_B) and low perceived quality is associated with its generic version (θ_G). Consumers with a higher v are more willing to pay for a higher quality good, that is, they are relatively insensitive to price variations and exhibit high switching costs or brand loyalty. Those consumers with a

lower v, on the other hand, react to small changes in the relative price of the two goods and thus exhibit low switching costs. The cost is kp_i where k is the copayment rate paid by the consumer and p_i is the sale price set by the company.[6]

$U(v, \theta_i)$ should be thought of as the *surplus* derived from the consumption of the good. The utility is separable in quality and price. We assume that consumers always have enough money to buy one unit if it is optimal to do so and when a consumer is indifferent between buying and not buying, they buy, and when they are indifferent between buying the two types of drug, they buy the brand-name drug. In order to obtain the demand functions for brand-name and generic drugs, we maximize the utility function as follows:

The consumer buys the brand-name drug as long as:

$$\begin{array}{c} v\theta_B - kp_B \geq v\theta_G - kp_G \Longrightarrow v^* \geq \frac{k(p_{\mathsf{B}} - p_{\mathsf{G}})}{\theta_{\mathsf{B}} - \theta_{\mathsf{G}}} \text{ and} \\ v\theta_B - kp_B \geq 0 \Longrightarrow v^- \geq \frac{kp_{\mathsf{B}}}{\theta_{\mathsf{B}}} \end{array} \tag{2}$$

The consumer buys the generic version if:

$$\begin{array}{c} v\theta_G - kp_G > v\theta_B - kp_B \Longrightarrow v^* < \frac{k(p_{\mathsf{B}} - p_{\mathsf{G}})}{\theta_{\mathsf{B}} - \theta_{\mathsf{G}}} \text{ and} \\ v\theta_G - kp_G \geq 0 \Longrightarrow v_- \geq \frac{kp_{\mathsf{G}}}{\theta_{\mathsf{G}}} \end{array} \tag{3}$$

Taking into account that $v \in [0, 1]$, the demand functions for high and low quality firms are given respectively by:

$$q_B = 1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G} \text{ and } q_G = \frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G} \tag{4}$$

Otherwise, the consumer will not buy.

Supply Side: The competition between the two firms takes place in two stages. In the first stage, they decide on the quality θ to be produced with $1 > \theta_B > 0.5 > \theta_G > 0$. There is no a priori upper bound to the level of quality, but we assume that there exists a lower bound to it. The latter can be interpreted as a *Minimum Quality Standard* (MQS) requirement (Ronnen, 1991). In our model, the MQS refers to the bioequivalence test that generic firms should obtain before entering the market and the minimum advertising investment needed to obtain a commercial position. On the other hand, branded firms should engage in R&D and advertising to improve perceived

[6] In Spain, there is a copayment of 40% of the sale price for both the brand-name and the generic drug. The rest is paid by the third-party.

quality. Therefore, each firm incurs a fixed cost of quality improvement while variable costs do not change with quality (Motta, 1993):

$$C_i = \frac{\theta_i^2}{2} \qquad i = B, G \tag{5}$$

We assume that, at each stage of the game, firms make their decisions about quality and prices both simultaneously and sequentially. Therefore, we obtain four different models (Figure 1.2).

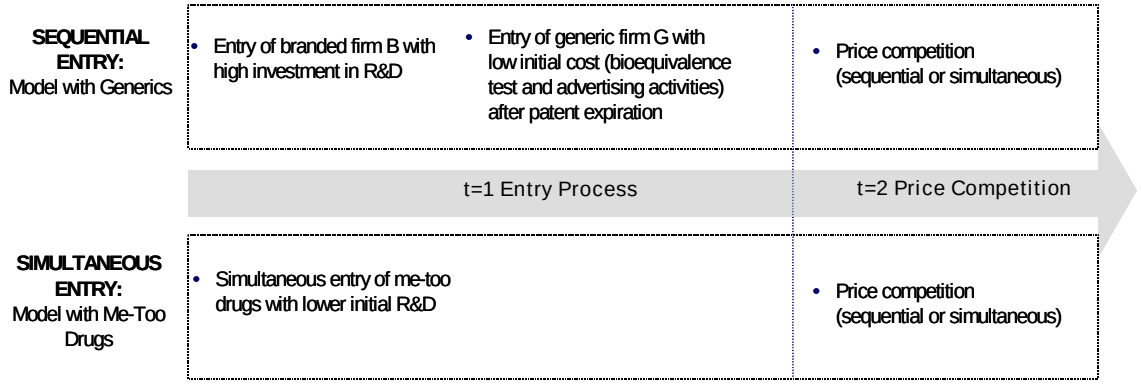


Figure 1.2. Two-stage Game: Entry Process and Price Competition

We solve the quality game taking into account two different assumptions about entry temporality. In the first model, we assume that firm B (innovator) registers the breakthrough drug but, due to the lack of product patent protection, firm G can enter the market simultaneously with a copy of the original product. This is the case of me-too drugs or branded copies.[7] In the second model, we assume that the product patent protection is accomplished and, therefore, firm G enters the market with the generic version after the patent on the branded drug has expired, thus implying a sequential entry.

In the second stage, firms set prices. Costs of quality development have already been sunk and constant unit production costs are incurred. Without loss of generality, we take these costs to be zero (Motta, 1993). We solve

[7]This is a consequence of an unusual patent system. For example, in Spain, under the old patent system, only processes for the preparation of new chemical entities were patentable. Under the new patent system, processes, and in most cases uses, have been patentable since 1986 but products only since 1992.

the price-setting sub-game by taking into account Bertrand and Stackelberg price competition. It is widely accepted that price is one of the main strategic variables in the pharmaceutical industry, however, some researchers assume simultaneous price competition while others accept sequential price competition. For example, Zweifel and Crivelli (1996) suppose a simple duopoly model where both, innovator and generic imitator, regard price as their strategic variable, thus resulting in a Bertrand equilibrium. On the other hand, several economists have studied the existence of first-mover pricing advantages in the pharmaceutical industry and concluded that first movers have brand loyalty advantages that permit them to charge higher prices and retain substantial market shares in the future.

In summary, we solve four different models taking into account all possible combinations (Table 1.2). We look for the sub-game perfect Nash equilibrium of the game. As usual, this will be obtained by backward induction. As stated before, we solve these four models taking into account both the fixed copayment and the RP scenario, therefore we are able to compare how firms respond to a change from a copayment regime to a reference price system.

Model	Quality Game	Price Competition
Model 1	Simultaneous (branded copies)	Sequential (Stackelberg)
Model 2	Sequential (generic drugs)	Sequential (Stackelberg)
Model 3	Simultaneous (branded copies)	Simultaneous (Bertrand)
Model 4	Sequential (generic drugs)	Simultaneous (Bertrand)

Table 1.2. Simultaneous and Sequential Models

3.1 Stackelberg Model

In this section,we solve models 1&2 where the characteristic in common is sequential price competition. Actually, we assume first mover advantage where the brand-name producer is the price *leader* (B) and generic producer is the *follower* (G). The quality game is solved both simultaneously (branded copies) and sequentially (generic drugs).

3.1.1 Price-setting Game

In the second stage, firms choose prices under the assumption that costs of quality development have already been sunk. Therefore, firms' profits are

given by:[8]

$$\Pi_B = p_B \left[1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G}\right] \text{ and } \Pi_G = p_G \left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] \tag{6}$$

Firm G's price-setting problem is:

$$\underset{p_G}{Max}\ \Pi_G(p_B, p_G) = p_G \left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] \tag{7}$$

and the first-order condition (FOC) is:

$$\frac{\partial \Pi(p_G, p_B)}{\partial p_G} = \left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] + p_G \left[\frac{-k}{\theta_B - \theta_G} - \frac{k}{\theta_G}\right] = 0 \tag{8}$$

The *reaction function* that gives the optimal choice of p_G as a function of p_B is:[9]

$$p_G = \frac{\theta_G}{2\theta_B} p_B \tag{9}$$

Then the leader, firm B, maximizes the following expression subject to G's reaction function:

$$\begin{aligned} \underset{p_B}{Max}\ \Pi_B(p_B, p_G) &= p_B \left[1 - \tfrac{k(p_B - p_G)}{\theta_B - \theta_G}\right] \\ \text{s.t.} \quad p_G &= \tfrac{\theta_G}{2\theta_B} p_B \end{aligned} \tag{10}$$

whose FOC is given by:

$$\frac{\partial \Pi_B}{\partial p_B} = \left[1 - \frac{kp_B - k\frac{\theta_G}{2\theta_B} p_B}{\theta_B - \theta_G}\right] + p_B \left[\frac{-k}{\theta_B - \theta_G} + \frac{k\frac{\theta_G}{2\theta_B}}{\theta_B - \theta_G}\right] = 0 \tag{11}$$

We solve p_B and substitute in order to get p_G :

$$p_B = \frac{\theta_B(\theta_B - \theta_G)}{k(2\theta_B - \theta_G)} \text{ and } p_G = \frac{\theta_G(\theta_B - \theta_G)}{2k(2\theta_B - \theta_G)} \tag{12}$$

[8] We assume that firms' profits are equal to $\prod_i = p_i q_i$ where q_i is consumers' demand derived from the maximization of the utility function and p_i is the sale price. Therefore, we obtain the profit function by adding together the direct revenues from the consumers $k * p_i q_i$ and those paid by the third-party$(1 - k) * p_i q_i$. This model focuses on publicly funded pharmaceutical drugs.

[9] Notice that from this equation, it can be verified that $v^* > v^-$ and $v^* > v\_$.

Substituting the price equilibrium levels into the quantity equations yields the following market shares:

$$q_B = \frac{1}{2} \text{ and } q_G = \frac{\theta_B}{2(2\theta_B - \theta_G)} \tag{13}$$

The relative price ratio, $\frac{p_B}{p_G} = \frac{2\theta_B}{\theta_G}$, shows that the brand-name price is always higher than the generic price due to price leadership effect. The relative market share ratio, $\frac{q_B}{q_G} = \frac{2\theta_B - \theta_G}{\theta_B}$, shows that the demand for brand-name drugs is always higher than that for generic drugs due to first mover advantage. These features fit the Spanish pharmaceutical market quite well.

3.1.2 Quality Game

We now look for the solutions to the quality game. We assume fixed costs of quality improvement and zero variable costs. This may be thought of as a situation where firms should engage in high initial R&D and advertising activities to improve quality and strengthen market position. More specifically, generics or branded copies firms (G) have to pass the bioequivalence test to obtain permission to enter the market and they should invest in promotional activities to get market reputation. On the other hand, branded drug firms (B) should engage in R&D and advertising activities to launch new chemical products. As would be expected, the cost of the bioequivalence test is not comparable to the cost associated to the R&D activities necessary to bring out a new chemical compound. The advertising and promotional spending oriented to health professionals, both physicians and pharmacists, is translated to consumers through *supplier inducement*.

Firms will choose their quality specification in order to maximize their profits:

$$\Pi_B = \frac{\theta_B(\theta_B - \theta_G)}{2k(2\theta_B - \theta_G)} - \frac{\theta_B^2}{2} \text{ and } \Pi_G = \frac{\theta_B\theta_G(\theta_B - \theta_G)}{4k(2\theta_B - \theta_G)^2} - \frac{\theta_G^2}{2} \tag{14}$$

Firstly, we solve the model taking into account the simultaneous decision regarding quality; that is, we assume the entry of an imitator firm at the same time as the innovator company launches the new chemical compound without product patent protection. The FOCs are:

$$\frac{\partial \Pi_B}{\partial \theta_B} = \frac{2\theta_B - \theta_G}{2k(2\theta_B - \theta_G)} - \frac{\theta_B(\theta_B - \theta_G)}{k(2\theta_B - \theta_G)^2} - \theta_B = 0 \tag{15}$$

$$\frac{\partial \Pi_G}{\partial \theta_G} = \frac{\theta_B \theta_G (\theta_B - \theta_G)}{2k(2\theta_B - \theta_G)^3} + \frac{\theta_B^2 - 2\theta_B \theta_G}{4k(2\theta_B - \theta_G)^2} - \theta_G = 0 \tag{16}$$

Now, we rewrite (1.15) and (1.16) by bringing θ_B and θ_G on the right-hand side of their respective equalities. After substituting and rearranging and taking into account that $k = 0.4$, we obtain:

$$6.875\theta_B^3\theta_G + 5\theta_G^3\theta_B - 7.5\theta_B^2\theta_G^2 - 1.25\theta_G^4 - 1.25\theta_B^4 = 0 \tag{17}$$

Set $\theta_G = \mu\theta_B$ with μ 6 1 (recall that θ_B is the higher quality which allow us to do this transformation), so that we can rewrite (1.17) as:[10]

$$6.875\mu + 5\mu^3 - 7.5\mu^2 - 1.25\mu^4 - 1.25 = 0 \tag{18}$$

The only solution in real numbers and lower than one is $\mu = 0.2319$. By substituting this value back into the first order condition, we obtain:[11]

$$\theta_B = 0.6358 \text{ and } \theta_G = 0.1475 \tag{19}$$

and

$$p_B = 0.6904 \text{ and } p_G = 0.0800 \tag{20}$$

We also solve the quality game sequentially. We assume that the entry of the generic firm occurs once the patent of the corresponding brand-name drug has expired. In this case, the solution is more complicated and requires the application of Newton's interpolation with Mathematica.[12] We obtain:

$$\theta_B = 0.6240 \text{ and } \theta_G = 0.1471 \tag{21}$$

and

$$p_B = 0.6758 \text{ and } p_G = 0.0797 \tag{22}$$

In both models 1&2, the second order derivatives are negative and there are no incentives for firm G to leapfrog the rival firm and produce the highest quality itself. Therefore, we can ensure we have found Nash equilibrium.

[10] We use the same idea as Motta (1993), however, instead of assuming θ_B = $\mu\theta_G$ with μ > 1, we do it the other way round.

[11] We obtain the same results with Mathematica.

[12] In this case, we maximize:

$\underset{\theta_B}{Max} \prod_B = p_B q_B - \frac{\theta_B^2}{2}$

s.t. $\frac{\partial \prod_G}{\partial \theta_G} = 0$

3.2 Bertrand Model

In this section,we solve models 3&4 where firms compete à la Bertrand by choosing prices simultaneously. The quality game is also solved simultaneously (branded copies) and sequentially (generic drugs).

3.2.1 Price-setting Game

Under Bertrand competition, we have to maximize the profit functions of brand-name and generic drugs producers simultaneously:

$$\underset{p_B}{Max}\ \Pi_B(p_B, p_G) = p_B\left[1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G}\right] \tag{23}$$

$$\underset{p_G}{Max}\ \Pi_G(p_B, p_G) = p_G\left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] \tag{24}$$

The FOC of the branded firm B is:

$$\frac{\partial \Pi_B}{\partial \theta_B} = \left[1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G}\right] + p_B\left[\frac{-k}{\theta_B - \theta_G}\right] = 0 \implies p_B = \frac{(\theta_B - \theta_G) + kp_G}{2k} \tag{25}$$

The FOC of the generic firm G is:

$$\frac{\partial \Pi_G}{\partial \theta_G} = \left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] + p_G\left[\frac{-k}{\theta_B - \theta_G} - \frac{k}{\theta_G}\right] = 0 \implies p_G = \frac{\theta_G}{2\theta_B}p_B \tag{26}$$

Substituting, we get the *price reaction functions*:

$$p_B = \frac{2\theta_B(\theta_B - \theta_G)}{k(4\theta_B - \theta_G)} \text{ and } p_G = \frac{\theta_G(\theta_B - \theta_G)}{k(4\theta_B - \theta_G)} \tag{27}$$

Quantities are:

$$q_B = \frac{2\theta_B}{4\theta_B - \theta_G} \text{ and } q_G = \frac{\theta_B}{4\theta_B - \theta_G} \tag{28}$$

In Bertrand models, we obtain a constant market share ratio, $\frac{q_B}{q_G} = 2$, so that the penetration of the branded product always doubles that of the generic drugs.

3.2.2 Quality Game

Firms will choose their quality specification in order to maximize their profits:

$$\Pi_B = \frac{4\theta_B^2(\theta_B - \theta_G)}{k(4\theta_B - \theta_G)^2} - \frac{\theta_B^2}{2} \text{ and } \Pi_G = \frac{\theta_B\theta_G(\theta_B - \theta_G)}{k(4\theta_B - \theta_G)^2} - \frac{\theta_G^2}{2} \tag{29}$$

Firstly, we solve the model taking into account the simultaneous decision regarding quality, that is, we assume the entry of an imitator firm at the same time as the innovator company launches the new chemical compound without product patent protection. The FOCs are:

$$\frac{\partial\Pi_B}{\partial\theta_B} = \frac{12\theta_B^2 - 8\theta_B\theta_G}{k(4\theta_B - \theta_G)^2} - \frac{32\theta_B^2(\theta_B - \theta_G)}{k(4\theta_B - \theta_G)^3} - \theta_B = 0 \tag{30}$$

$$\frac{\partial\Pi_G}{\partial\theta_G} = \frac{\theta_B^2 - 2\theta_B\theta_G}{k(4\theta_B - \theta_G)^2} + \frac{2\theta_B\theta_G(\theta_B - \theta_G)}{k(4\theta_B - \theta_G)^3} - \theta_G = 0 \tag{31}$$

Now, we rewrite (1.30) and (1.31) by bringing θ_B and θ_G on the right-hand side of their respective equalities. After substituting and rearranging and taking into account that $k = 0.4$, we obtain:

$$5\theta_B\theta_G^3 - 35\theta_B\theta_G^2 + 62.5\theta_B^2\theta_G - 5\theta_B^2\theta_G^2 + 20\theta_G^3 - 10\theta_B^3 = 0 \tag{32}$$

Set $\theta_G = \mu\theta_B$ with $\mu \leq 1$ (recall that θ_B is the higher quality which allow us to perform this transformation), so that we can rewrite (1.32) as:

$$25\mu^3 - 40\mu^2 + 62.5\mu - 10 = 0 \tag{33}$$

The only solution in real numbers and lower than one is $\mu = 0.1780$.By substituting this value back into the first order condition, we obtain:[13]

$$\theta_B = 0.6332 \text{ and } \theta_G = 0.1205 \tag{34}$$

and

$$p_B = 0.6729 \text{ and } p_G = 0.0640 \tag{35}$$

We also solve the quality game sequentially. We assume that the entry of the generic firm occurs once the patent of the corresponding brand-name

[13] We obtain the same results with Mathematica.

drug has expired. In this case, the solution is more complicated and requires the application of Newton's interpolation with Mathematica.[14] We obtain:

$$\theta_B = 0.6129 \text{ and } \theta_G = 0.1195 \tag{36}$$

and

$$p_B = 0.6484 \text{ and } p_G = 0.0632 \tag{37}$$

In both models 3&4, the second order derivatives are negative and there are no incentives for firm G to leapfrog the rival firm and produce the highest quality itself. Therefore, we can ensure we have found Nash equilibrium.

By way of a summary, Table 1.3 below shows a comparison of the results:

Model	θ_B	θ_G	$\theta_B - \theta_G$	p_B	p_G	$p_B - p_G$	$\frac{q_B}{Q}$	$\frac{q_G}{Q}$
Model 1	0.6357	0.1474	0.4883	0.6904	0.0800	0.6104	58%	42%
Model 2	0.6240	0.1471	0.4769	0.6758	0.0797	0.5961	59%	41%
Model 3	0.6332	0.1205	0.5127	0.6729	0.0640	0.6089	67%	33%
Model 4	0.6129	0.1195	0.4934	0.6484	0.0632	0.5851	67%	33%

Table 1.3: Results Comparison

Generally speaking, when firms compete à la Bertrand (model 3&4), the degree of quality differentiation is larger than in Stackelberg models (model 1&2) and, paradoxically, firms also compete more aggressively in terms of prices. In Stackelberg models, new entrants (G) choose both quality and prices in order to be positioned closer to established firms (Figure 1.3).

[14] In this case, we maximize:
$\underset{\theta_B}{Max} \prod_B = p_B q_B - \frac{\theta_B^2}{2}$
s.t. $\frac{\partial \prod_G}{\partial \theta_G} = 0$

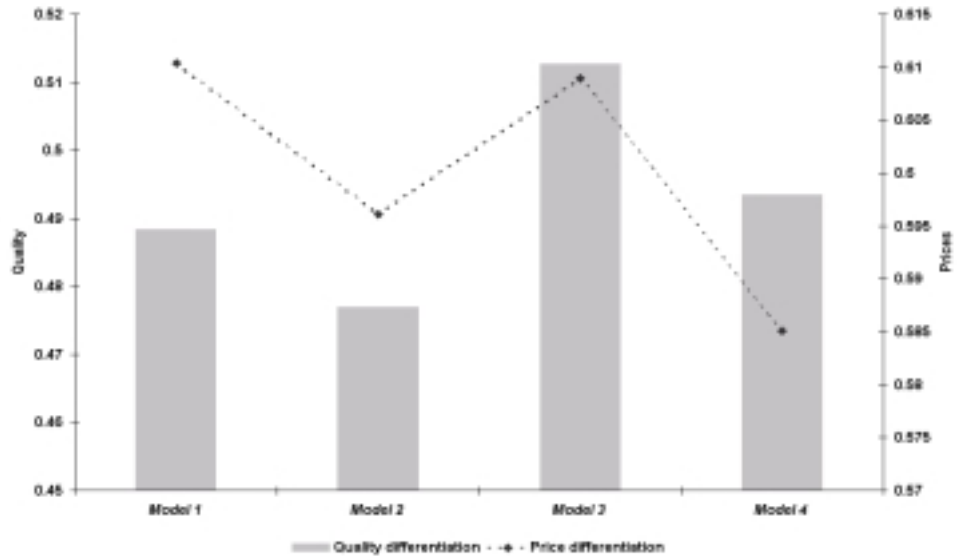


Figure 1.3. Quality and Price Differentiation

Models 1&3 solve the quality game simultaneously, thus assuming the entrance of branded copies, while models 2&4 solve the quality game sequentially taking into account the entry of generic drugs. The degree of differentiation is always higher in branded copy scenarios than in generic drug scenarios. This is not always satisfied in pharmaceutical markets where imitator laboratories try to make themselves easily confused with original ones. Market shares are more extreme in Bertrand models -67% branded drugs and 33% generic drugs- than in Stackelberg models -52% branded drugs and 48% generic drugs. In Bertrand models, market share distribution remains constant because branded producers decrease prices in order to maintain market penetration.

4 The Reference Price System

It is clear from Royal Decree 1035/1999 that the reference price for each homogeneous group is determined endogenously using the previous-year drug prices. For simplicity, we work in one shot period and assume that the reference price is a linear function of both branded and generic drug prices; more specifically, it takes the following form where α and β are exogenous

weights that represent respective market shares:

$$p_R = \alpha p_G + \beta p_B \tag{38}$$

This is a general expression and, therefore, it can be adapted to other RP system variations, for example, assuming $\alpha = 0$ and $\beta = 1, (p_R = p_B)$, $\alpha = 1$ and $\beta = 0$ $(p_R = p_G)$ or a fixed proportion of both.

We also assume that $\alpha > k$ which ensures that the reference price will be never lower than the generic price. This is the reason why we can consider an additional but avoidable copayment for the branded product but no additional copayment for the generic drug. Therefore, the RP system modifies the demand function for both branded and generic drugs as follows.

The consumer buys the brand-name drug as long as:

$$\begin{gathered} v\theta_B - kp_B - (p_B - \alpha p_G - \beta p_B) \geq v\theta_G - kp_G \implies v^* \geq \tfrac{(k+1-\beta)p_B - (k+\alpha)p_G}{(\theta_B - \theta_G)} \text{ and} \\ v\theta_B - kp_B - (p_B - \alpha p_G - \beta p_B) \geq 0 \implies v^- \geq \tfrac{(k+1-\beta)p_B - \alpha p_G}{\theta_B} \end{gathered} \tag{39}$$

The consumer buys the generic drug if:

$$\begin{gathered} v\theta_G - kp_G > v\theta_B - kp_B - (p_B - \alpha p_G - \beta p_B) \implies v^* < \tfrac{(k+1-\beta)p_B - (k+\alpha)p_G}{(\theta_B - \theta_G)} \text{ and} \\ v\theta_G - kp_G \geq 0 \implies v_- \geq \tfrac{kp_G}{\theta_G} \end{gathered} \tag{40}$$

Substituting and rearranging, we obtain the new demand functions:

$$q_B = 1 - \frac{(k+1-\beta)p_B - (k+\alpha)p_G}{(\theta_B - \theta_G)} \text{ and } q_G = \frac{(k+1-\beta)p_B - (k+\alpha)p_G}{(\theta_B - \theta_G)} - \frac{kp_G}{\theta_G} \tag{41}$$

Changes in patient out-of-pocket expenses affect the prevailing demand conditions in the market and might alter the markup that pharmaceutical firms charge over marginal cost (Pavcnik, 2002). According to our model, price competition is now distorted due to the implementation of a new regulatory framework. At this stage, the quality game is over and fixed quality costs are already sunk, therefore, firms can only react through price movements. We solve the price-setting subgame again taking into account the new demand functions.

Using the same procedure as before, we obtain the following price equilibrium for Stackelberg and Bertrand respectively:

$$p_B = \frac{(\theta_B - \theta_G)(k\theta_B + \alpha\theta_G)}{(k+1-\beta)\left[(\alpha - k)\theta_G + 2k\theta_B)\right]} \text{ and } p_G = \frac{\theta_G(\theta_B - \theta_G)}{2\left[(\alpha - k)\theta_G + 2k\theta_B)\right]} \tag{42}$$

$$p_B = \frac{2(\theta_B - \theta_G)(k\theta_B + \alpha\theta_G)}{(k+1-\beta)\left[4(\alpha\theta_G + k\theta_B) - \theta_G(k+\alpha)\right]} \text{ and } p_G = \frac{\theta_G(\theta_B - \theta_G)}{4(\alpha\theta_G + k\theta_B) - \theta_G(k+\alpha)} \tag{43}$$

According to the assumptions about α and β, we could have a great number of scenarios for each model. In Table 1.4, we just consider two different scenarios: one in which α and β take the market share values that existed before the introduction of the RP system (Table 1.3), and another in which an ideal situation where branded and generic drugs share the market is assumed ($\alpha = \beta = 0.5$).

Model	θ_B	θ_G	$\theta_B - \theta_G$	α	β	p_B	p_G	p_R	$\frac{q_B}{Q}$	$\frac{q_G}{Q}$
Model 1	0.6357	0.1474	0.4883	0.42	0.58	0.3681	0.0704	0.2430	62%	38%
Model 1	0.6357	0.1474	0.4883	0.50	0.50	0.3400	0.0688	0.2044	61%	39%
Model 2	0.6240	0.1471	0.4769	0.41	0.59	0.3644	0.0701	0.2437	62%	38%
Model 2	0.6240	0.1471	0.4769	0.50	0.50	0.3332	0.0683	0.2007	61%	39%
Model 3	0.6332	0.1205	0.5127	0.33	0.67	0.3797	0.0570	0.2732	67%	33%
Model 3	0.6332	0.1205	0.5127	0.50	0.50	0.3118	0.0539	0.1829	67%	33%
Model 4	0.6129	0.1195	0.4934	0.33	0.67	0.3660	0.0561	0.2637	67%	33%
Model 4	0.6129	0.1195	0.4934	0.50	0.50	0.3006	0.0531	0.1768	67%	33%

Table 1.4: Comparison of Results with Reference Price

Doing comparative statics and using the scenario $\alpha = \beta = 0.5$ as a benchmark , we can gain some insights into how firms react when parameters of the model change. In our model, the higher the weight of the generic drug (α), the lower the weight of the branded drug (β) and, therefore, the lower the reference price (remember that $p_B > p_G$); as a consequence, both branded and generic firms decrease prices ($\frac{\partial p_B}{\partial \alpha} < 0$ and $\frac{\partial p_G}{\partial \alpha} < 0$). On the other hand, the higher the weight of branded drug, the higher the reference price and, as a consequence, both branded and generic firms increase prices ($\frac{\partial p_B}{\partial \beta} > 0$ and $\frac{\partial p_G}{\partial \beta} > 0$).

	p_B	p_G	$\frac{q_B}{Q}$	$\frac{q_G}{Q}$
Model 1				
Before	0.6904	0.0800	58%	42%
After	0.3681	0.0704	62%	38%
Model 2				
Before	0.6758	0.0797	59%	41%
After	0.3644	0.0701	62%	38%
Model 3				
Before	0.6729	0.0640	67%	33%
After	0.3797	0.0570	67%	33%
Model 4				
Before	0.6484	0.0632	67%	33%
After	0.3660	0,0561	67%	33%

Table 1.5. Before and After RP System

Under the RP system, branded producers decrease prices substantially in order to adapt to the new competitive situation while generic prices remain more or less constant. In Bertrand models (3&4), market shares do not change after the introduction of reference prices while in Stackelberg models (model 1&2), the market share of branded drugs even increases and that of generic drugs decreases. In both cases, the brand-name producers compensate for the decline of profits by selling greater quantities rather than charging higher prices (Table 1.5).

Contrasting our theoretical results with recent empirical findings, we realize that our conclusions are in the same line. Pavcnik (2002) found that producers significantly decrease prices after the change in patient out-of-pocket expenses and, furthermore, these price declines are most pronounced for brand-name products.

5 Social Welfare Analysis: Ramsey Prices

Comparing the relative price ratio prevailing before and after the introduction of the RP system, it is clear that price competition has increased. In this sense, government has achieved one of the main objectives that this new reimbursement mechanism intends to accomplish.

$$(\frac{p_B}{p_G})_{\text{copayment}} > (\frac{p_B}{p_G})_{\text{RP system}} \tag{44}$$

Unfortunately, actual regulation often deviates considerably from an optimal regulation that aims to limit market inefficiencies and maximize social welfare. The problem of how to set prices so as to maximize social welfare whilst ensuring that all costs are covered can arise in many contexts. Ramsey prices are designed to address the situation where it is necessary to increase prices above the level of marginal cost. More specifically, the standard Ramsey pricing rule says that "in order to maximize social welfare, prices in different market segments should be set such that the mark-up over marginal cost in each segment is inversely proportional to the price sensitivity of demand".

Social welfare is defined as the sum of consumer and producer surplus and profits are equal to the sum of revenues in each demand segment less the cost (without loss of generality, we assume variable costs to be zero, however, we introduce a minimum profit level). In greater detail:

$$CS_B = (v\theta_B - kp_B)\left[1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G}\right] \text{ and } CS_G = (v\theta_G - kp_G)\left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] \tag{45}$$

and the profit functions are:

$$\Pi_B = p_B q_B = p_B\left[1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G}\right] \text{ and } \Pi_G = p_G q_G = p_G\left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] \tag{46}$$

Although there are two different firms in the market, the innovator and the generic imitator, we add their profits together as if only one firm produced the two types of drug:

$$\Pi_T = p_B\left[1 - \frac{k(p_B - p_G)}{\theta_B - \theta_G}\right] + p_G\left[\frac{k(p_B - p_G)}{\theta_B - \theta_G} - \frac{kp_G}{\theta_G}\right] \tag{47}$$

We maximize consumer surplus subject to the constraint that profits must achieve at least a pre-specified minimum profit level Π :

$$\begin{aligned} \underset{p_B, p_G}{Max} \;\; & CS = (v\theta_B - kp_B)\left[1 - \tfrac{k(p_B - p_G)}{\theta_B - \theta_G}\right] + (v\theta_G - kp_G)\left[\tfrac{k(p_B - p_G)}{\theta_B - \theta_G} - \tfrac{kp_G}{\theta_G}\right] \\ & \text{s.t. } \Pi \leq p_B\left[1 - \tfrac{k(p_B - p_G)}{\theta_B - \theta_G}\right] + p_G\left[\tfrac{k(p_B - p_G)}{\theta_B - \theta_G} - \tfrac{kp_G}{\theta_G}\right] \end{aligned} \tag{48}$$

We solve the maximization problem using Kuhn-Tucker theorem and set up the Lagrangian:

$$\begin{aligned}\$ = (v\theta_B - kp_B)\left[1 - \tfrac{k(p_B - p_G)}{\theta_B - \theta_G}\right] + (v\theta_G - kp_G)\left[\tfrac{k(p_B - p_G)}{\theta_B - \theta_G} - \tfrac{kp_G}{\theta_G}\right] - \\ -\lambda\left[\Pi - p_B\left[1 - \tfrac{k(p_B - p_G)}{\theta_B - \theta_G}\right] - p_G\left[\tfrac{k(p_B - p_G)}{\theta_B - \theta_G} - \tfrac{kp_G}{\theta_G}\right]\right]\end{aligned} \tag{49}$$

where λ is the Lagrange multiplier that measures the value, in terms of social welfare, of relaxing the profit constraint by a small amount.

We take derivatives with respect to prices and finally get:

$$p_{BRamsey} = \frac{\theta_B(\lambda - k - kv)}{2k\lambda - 2k^2} \text{ and } p_{GRamsey} = \frac{\theta_G(\lambda - k - kv)}{2k\lambda - 2k^2} \tag{50}$$

Now, we proceed to compare the degree of price competition under two different regulatory framework: the RP system and Ramsey pricing. We thus calculate the relative price ratio under both scenarios: [15]

$$(\frac{p_B}{p_G})_{RP} = \frac{2(k\theta_B + \alpha\theta_G)}{(k + 1 - \beta)\theta_G} \text{ and } (\frac{p_B}{p_G})_{Ramsey} = \frac{\theta_B}{\theta_G} \tag{51}$$

Price competition will be stronger under Ramsey pricing as long as:

$$(\frac{p_B}{p_G})_{RP} > (\frac{p_B}{p_G})_{Ramsey} \implies 2\theta_G + \theta_B(k - 1 + \beta) > 0 \tag{52}$$

and competition will be stronger under the RP system when the above expression becomes negative. Table 1.6 shows that Ramsey pricing should be the optimal regulatory system as long as the penetration of generic drugs is not very high while the RP system should become the most efficient price control mechanism once the generic market share has reached a significant percentage. Under Stackelberg price competition (models 1&2), the RP system will be the most efficient form of regulation as long as generic drug market share exceeds 80% ($\alpha = 0.8$) while this threshold decreases to 70% under Bertrand price competition models.[16]

[15] The relative price ratio under Bertrand and Stackelberg models coincide.

[16] "The share of generic drugs must increase if we want the reference price system to work properly", Gaceta de los Negocios, November 1998.

α	β	Model 1	Model 2	Model 3	Model 4
0	1	+	+	+	+
0.1	0.9	+	+	+	+
0.2	0.8	+	+	+	+
0.3	0.7	+	+	+	+
0.4	0.6	+	+	+	+
0.5	0.5	+	+	+	+
0.6	0.4	+	+	+	+
0.7	0.3	+	+	-	-
0.8	0.2	-	-	-	-
0.9	0.1	-	-	-	-
1	0	-	-	-	-

Table 1.6. Optimal Price Regulation

6 Concluding Remarks

This paper analyzes the impact of the RP system on the price-setting strategies of pharmaceutical firms. Several European countries have already established this new reimbursement mechanism as a regulatory measure aimed at containing national pharmaceutical spending through the promotion of price competition and the increased usage of generic drugs. Although there are several variations in the RP calculation method, we employ a general expression that could be adapted to all European versions; therefore, our conclusions could be extrapolated to other countries with a similar regulatory framework.

Using a vertical product differentiation model, we compare a copayment regime under which consumers must pay a fixed out-of-pocket expense with the new RP system which entails an additional but avoidable copayment for those drugs whose price exceeds the reference level.

The mentioned changes in the copayment regime affect the prevailing demand conditions and might alter the markup that pharmaceutical firms charge over marginal cost. At this point, the quality game is over and fixed quality costs are already sunk, therefore, firms can only react through price movements.

We find that, under the RP system, branded producers decrease prices substantially in order to adapt to the new competitive situation while generic prices remain more or less constant. In Bertrand models, market shares do

not change after the introduction of reference prices while in Stackelberg models, the market share of branded drugs even increases and that of generic drugs decreases. In both cases, the brand-name producers compensate for the decline of profits by selling greater quantities rather than charging higher prices. Contrasting our theoretical results with recent empirical findings, we realize that our conclusions are in the same line. Econometric studies found that producers significantly decrease prices after the change in patient out-of-pocket expenses and, furthermore, these price decreases are most pronounced for brand-name products.

We also carry out a social welfare analysis and compare price competition under RP system and Ramsey pricing. We find that the reference price system maximizes price competition when the penetration of generic drugs exceeds 70% of the market; otherwise, Ramsey prices can better ensure price competition and maximization of social welfare.

Finally, we can conclude that, from a theoretical point of view, the RP system achieves the objective of increasing price competition, however, we are not in a position to say anything about the impact on the public pharmaceutical spending, as it is beyond the scope of this paper. An interesting observation is the fact that, although the social planner succeeds in promoting price competition between branded and generic drugs, it completely fails in raising generic drug usage among the population. Actually, both the implementation of the RP system and the potential entrance of generic drugs constitute a sufficiently credible threat for branded producers to decrease prices. Therefore, it is not necessary to count on an effective large generic drug market share for price competition to increase. In this sense, generic firms in Spain and other countries with similar regulatory frameworks could feel disappointed with a regulatory measure that do not *de facto* promote the use of lower-cost generic drugs.

References

[1] Aronsson T., Bergman M.A. and Rudholm N. (2001), "The Impact of Generic Competition on Brand Name Market Shares- Evidence from Micro Data," *Review of Industrial Organization* 19: 425-435.

[2] Cabrales A. (2003), "Pharmaceutical Generics, Vertical Product Differentiation and Public Policy," *working paper Pompeu Fabra University.*

[3] Caves R., Whinston M. and Hurwitz M. (1991), "Patent Expiration, Entry and Competition in the US Pharmaceutical Industry," *Brookings Papers on Economic Activity: Microeconomics*: 1-48.

[4] Ching A.T.T. (2000), "Dynamic Equilibrium in the U.S. Prescription Drug Market After Patent Expiration," *Department of Economics at University of Minnesota.*

[5] Conrad C. (1983), "The Advantage of Being First and Competition Between Firms," *International Journal of Industrial Organization.* 1983(1): 353-364.

[6] Coscelli A.(2000), "The Importance of Doctors' and Patients Preferences in the Prescription Decision," *Journal of Industrial Economics* 48(3).

[7] Ellison S.F., Cockburn I., Griliches Z. and Hausman J. "Characteristics of Demand for Pharmaceutical Products: an Examination of Four Cephalosporins," *RAND Journal of Economics* 28(3): 426-446.

[8] Frank RG. and Salkever DS.(1997), "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics and Management Strategy* 6(1): 75-90.

[9] Grabowski H. and Vernon J.(1992), "Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act," *Journal of Law and Economics* 35: 331-350.

[10] Hellerstein J.(1998), "The Importance of the Physician in the Generic versus Trade-Name Prescription Decision," *RAND Journal of Economics* 29(1): 108-136.

[11] Klemperer P.(1995), "Competition when Consumers Have Switching Costs: an Overview with Applications to Industrial Organization, Macroeconomics and International Trade," *Review of Economic Studies* 62: 515-539.

[12] López-Casasnovas G. and Puig-Junoy J. (2001), "Review of the Literature on Reference Pricing," in G. López-Casasnovas and B. Jönsson Eds. *Reference Pricing and Pharmaceutical Policy*, Barcelona, Springer Verlag.

[13] Mestre-Ferrándiz J. (1999), "The Impact of Generic Goods in the Pharmaceutical Industry," *Health Economics* 8:599-612.

[14] Mestre-Ferrándiz J.(2003). "Reference Price: the Spanish Way," *Investigaciones Económicas* XXVII(1):125-149.

[15] Motta M. (1993), "Endogenous Quality Choice: Price vs Quantity Competition," *Journal of Industrial Economics* 41:113-131.

[16] National Economic Research Associates (NERA), "Diagnóstico y Perspectiva del Gasto Farmacéutico en España", a report published by *Farmaindustria*, 2001.

[17] Pavcnik N. (2002), "Do Pharmaceutical Prices Respond to Potential Patient Out-of-Pocket Expenses?," *RAND Journal of Economics* 33(3): 469-487.

[18] Ronnen U. (1991), "Minimum Quality Standards, Fixed Costs and Competition," *RAND Journal of Economics 22(4)*:490-504.

[19] Zweifel P. and Crivelli L.(1996), "Price Regulation of Drugs: Lessons from Germany," *Journal of Regulatory Economics* 10: 257-273.