

# Parallel Imports of Pharmaceutical Products and National Health Policies in European Union

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## Abstract:

The European Union allows parallel imports of brand-name pharmaceutical products within the common internal market but not from outside this market. The debate over the benefits of parallel imports is fueled by advocates of strong intellectual property rights (opposing parallel trade). The model presented in this paper is used to analyze welfare effects of parallel imports, while taking into account differences in national health policies among EU members.

The results suggest that differences in national health policies (co-payment levels) will foster price convergence between two member countries while moving towards a common health policy might result in price divergence.

## 1. Introduction

Contrary to some believes, parallel imports are genuine products manufactured under the protection of a patent and sold in one market and then imported by an intermediary into a second market without the permission of the owner of the intellectual property rights.

Despite the efforts to integrate national pharmaceutical markets, there is significant price divergence within the European Union. Part of this divergence can be explained by the fact that pharmaceutical manufacturers (with some degree of monopoly power) have an incentive to charge different prices in different markets (price discrimination). Another reason would be that the prices of pharmaceutical products are not determined by free competition laws. National governments of member countries have different policies regarding the price of pharmaceutical products. Last, price differences can be a result of exchange rate variations. As more countries adopt the common currency, the previous condition becomes less and less important in explaining price differences across EU.

Arbitrage tends to reduce price discrimination by encouraging wholesalers to buy an item where the price is low and resell it where the price is high. Arbitrage can be practiced as long as the buyers are not prohibited from reselling. At international level, brand-name pharmaceuticals cannot be resold from one country to another without the consent of the patent holder. Such an operation would infringe intellectual property rights. If two countries agree to allow parallel imports of pharmaceutical imports between them, than the prices in these two countries tend to converge to the same price.

The European Union adopted the policy that the first sale within its territory exhausts the rights of the original patent holder firm to restrict further trade of the product. This decision allows for parallel imports of pharmaceutical products between member countries. The introduction of parallel trading within EU should results in price convergence across countries.

This decision increased the parallel trade in pharmaceuticals within EU and the lobby of pharmaceutical industry for its suppression. The basic motivations behind these opposing forces are: cutting health costs versus stimulating innovation.

The benefits of parallel imports are ambiguous. In countries where pharmaceutical costs are high, governments authorize parallel imports to help cut health care costs. Lower prices faced by consumers means lower returns to producers which would discourage innovation and development of new drugs.

Pharmaceutical firms can benefit from the creation of a common pharmaceutical market by reducing their distribution costs. They can consolidate product distribution within EU taking advantage of economies of scale and reduce costs related to product certification for each market.

Another possible benefit of parallel imports for consumers can be the possibility of product reallocation towards a country in need (due to an epidemic) when the production capabilities constraints do not allow a manufacturer to increase its supply.

It is important to determine who benefits from parallel imports and the size of these benefits. The major actors involved in this market are producers, wholesalers, retailers and consumers. In the next section a few recent studies that answered that answered this question will be presented.

The nature of this market is very important when we discuss welfare implications of parallel trade. Countries regulate their pharmaceutical markets and prices are some times determined by negotiations between health authorities and drug manufacturers (or wholesalers).

If we consider the system of co-payments, a lower level of co-payments benefit patients as it reduces the out-of-pocket expenses but increases government/insurance organization expenditure. Parallel imports of pharmaceutical products between countries with different co-payment levels might lead to allocation inefficiencies, reducing welfare.

Every country's concern is how to design a health policy that allows an optimal distribution of pharmaceuticals at an affordable price without distorting the industrial policy intended to foster innovation.

The purpose of this paper is to provide a short-run welfare analysis of allowing parallel imports relative to market segmentation, while taking into account differences in national health policies.

While parallel imports are already implemented in the European Union, the same principle can be applied to other areas such as NAFTA

The model presented in this paper was developed by Ganslandt and Maskus (2006). In this model the manufacturer sets wholesale prices for single distributors (one for each market) while distributors compete with each other in a Cournot fashion as parallel imports are allowed.

Now, the importance of national health policies regarding price behavior and welfare effects is acknowledged by specifically including different co-payments for patients from different countries. Although the pharmaceutical market is a common market, individual countries within European Union promote national health policies to achieve their goals.

The paper observes that changes in co-payment levels in one country will affect retail prices in all countries. To be more specific, as countries become more similar (regarding the level of patient co-payments), the prices faced by them will move apart.

The paper is organized as follows. In the next section a literature review is presented. Section three provides background information about the European Union pharmaceutical market. In the fourth section the model is developed and the welfare analysis is performed. The fifth section concludes.

## **2. Previous work**

The impact of price convergence on consumers and welfare seems ambiguous, as some customers are hurt while other may benefit from lower prices.

Varian (1985) provides the necessary conditions for price uniformity to result in a welfare (defined as the sum of all consumer surpluses and profits) loss. Even when we consider only the combined consumer surplus the result of price uniformity is ambiguous.

Maskus and Chen (2004) examine the nature of contractual relationships between a domestic manufacturer and foreign distributor to determine when parallel trade will be optimal. They show that the manufacturer will take account of the threat of parallel trade when fixing wholesale prices, and therefore reduces social welfare. Encouraging parallel trade can raise welfare, at least in part, if it reduces the incentive to create such distortions. They are unable, however, to reach any unambiguous conclusion on the effect of parallel trade on global welfare.

Ganslandt and Maskus (2004) did an empirical study regarding parallel trading of brand-name pharmaceuticals in Sweden over the period 1994 - 1998. They found that the prices of drugs subject to parallel imports increased less than other drugs. It was estimated that approximately 60-75% of this effect was due to lower prices of parallel imports while the rest was attributed to lower prices charged by manufacturing firms.

Kanavos, Costa-i-Font, Merkur and Gemmill (2004) looked at empirical evidence regarding parallel imports of pharmaceutical products (19 products) in EU countries. They found that wholesale traders realize significant benefits relative to the other parties involved (consumers, manufacturers and retailers). They didn't find evidence of price convergence and concluded that parallel imports are not necessarily increasing welfare.

Ganslandt and Maskus (2006) developed a theoretical model where the manufacturing firms charge different prices in different markets but parallel trading is allowed at distributor level. They found that the retail prices could diverge as a result of decreasing trading costs. Manufacturers incur a significant share market loss. They found that parallel trade can be welfare (defined as combined consumer surplus) reducing under certain conditions.

## **3. Background information**

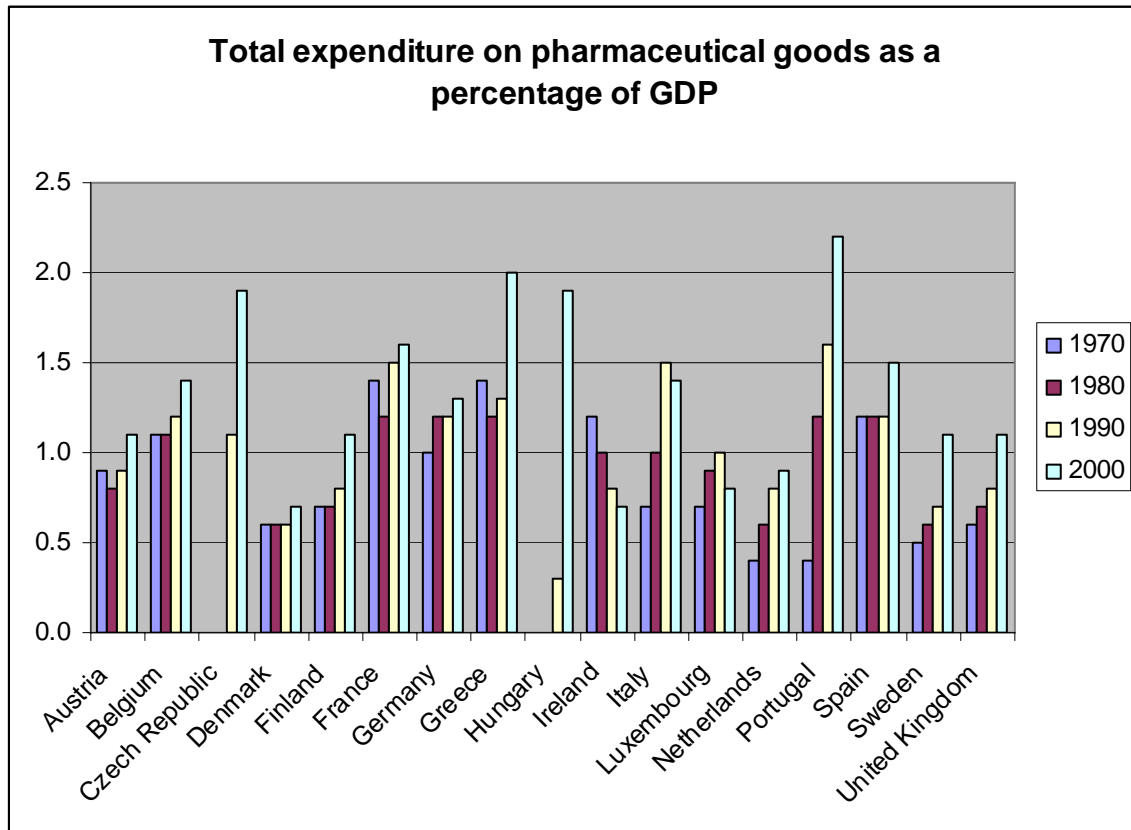
The following data was collected from the Organisation for Economic Co-Operation and Development (OECD) database.

The European Union represents a large share of the world pharmaceutical market. Each member country developed its own national drug licensing system. In 1993 The European Medicines Evaluation Agency was formed. In 1998 the Agency implemented a new centralized procedure for drug approval: you can obtain one country's license and wait another five years to apply to another country, or you can apply for a pan-European license. The European Commission regulates entry into the market, but the national authorities finance health policies. The European Court of Justice has ruled that patients can import cheaper over-the-counter drugs for their own use from another member country provided that the product is authorized in their country, and it ruled in favor of parallel imports.

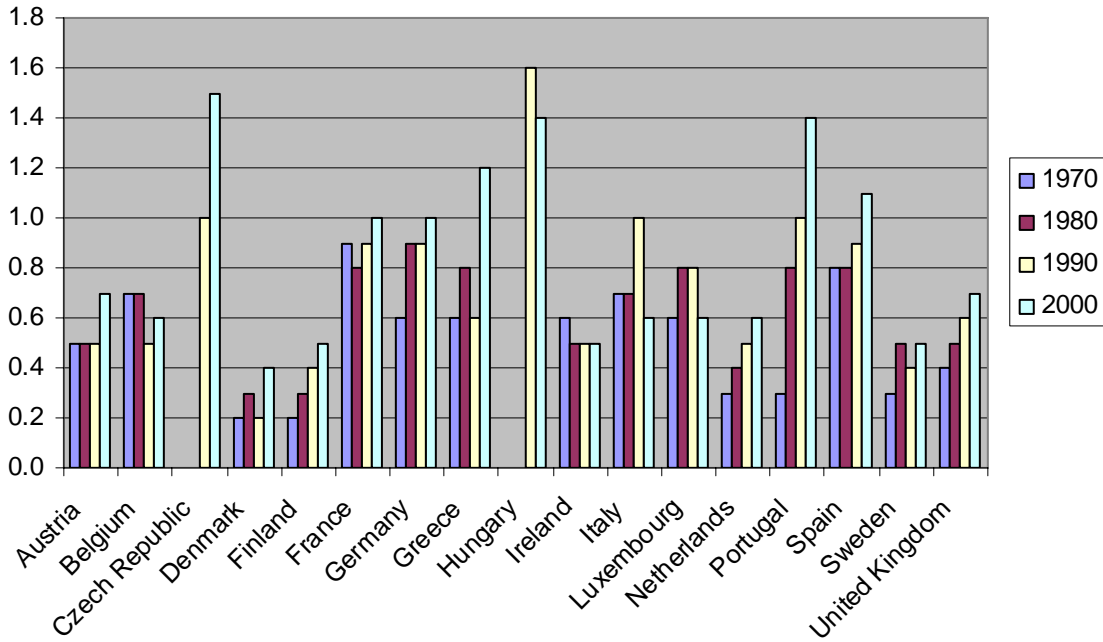
In 1998 the European Commission issued a communication, on the single market for pharmaceuticals, reviewing the principal policy options for pharmaceutical markets, price controls, profit controls and contractual policies.

The single currency (the euro) increased price transparency facilitating comparisons across countries.

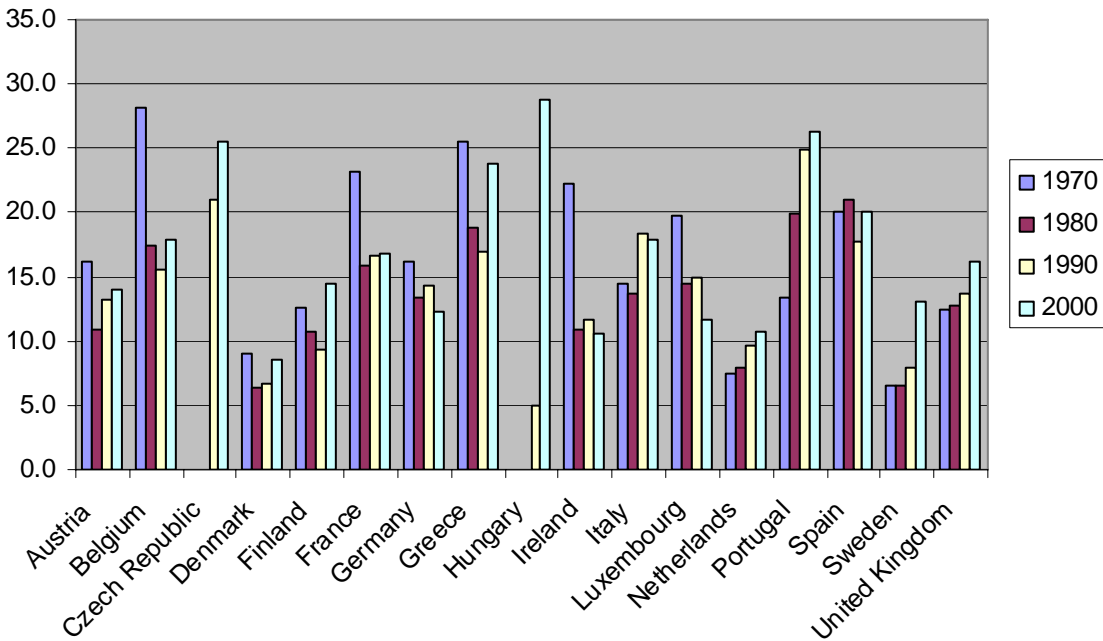
The consumption of pharmaceuticals depends on income levels and national health policies. Within the total health expenditure, pharmaceuticals represent an important share.



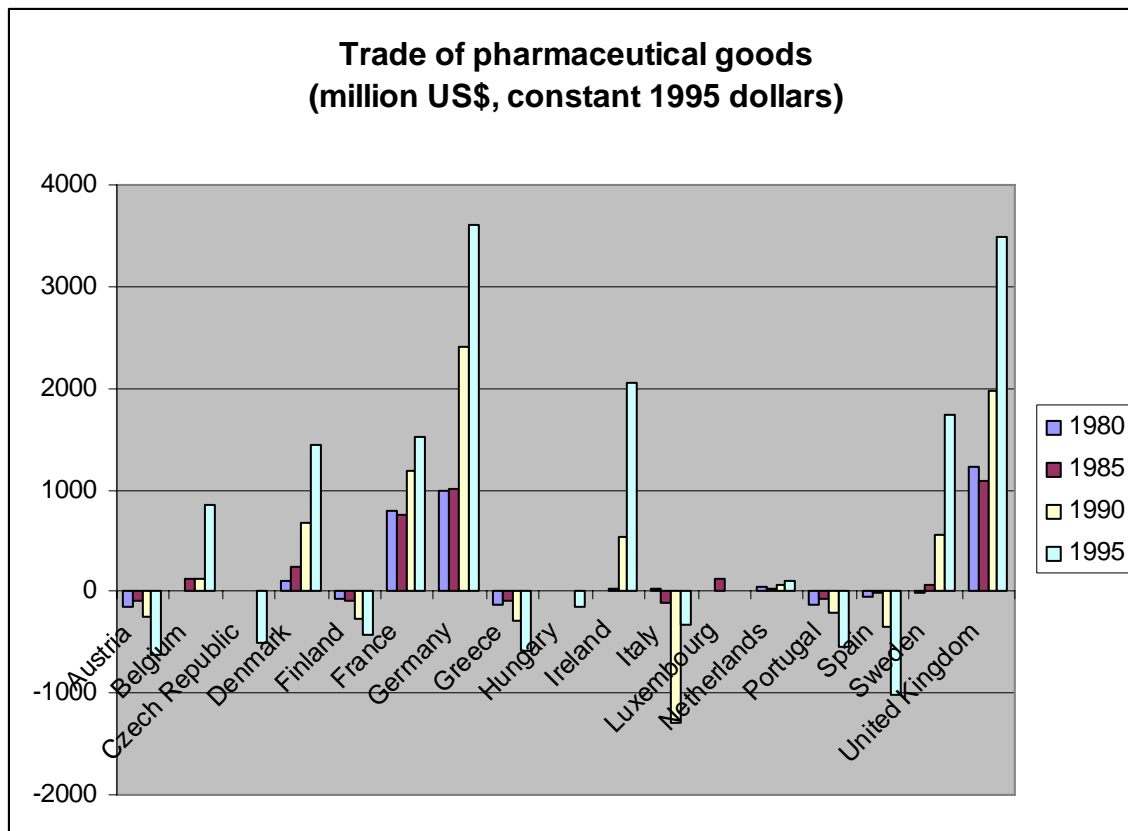
**Public expenditure on pharmaceutical goods as a percentage of GDP**



**Total expenditure on pharmaceutical goods as a percentage of total health expenditure**



The trade balance of pharmaceutical products seems to be linked to the international competitiveness of the pharmaceutical industry of a country. Germany, France and United Kingdom have strong exporting industries. Belgium, Sweden, Denmark and Ireland have significant surpluses. Italy, Finland and the former Eastern European countries are net importers.



Individual countries regulated demand and supply in order to achieve their goals (high level of health care, without distorting too much the industrial policy).

In order to influence the demand, public health authorities made reimbursement lists (based on some test) with the drugs eligible for reimbursement. In general patients would have to pay a co-payment. Co-payment levels can be: proportionally to the final price (used in Belgium, Denmark, France, Greece, Hungary, Ireland, Luxemburg, The Netherlands, Portugal, Spain and Sweden), with a fixed charge per prescription (Austria, Germany and United Kingdom) or with an annual deductible. Finland and Italy have a mixed system.

In order to regulate the supply side of the pharmaceutical market, authorities have implemented profit control and price fixing.

There are different criteria (which can be mixed) to fix prices for drugs: the therapeutic value of the drug (Belgium, Czech Republic, Finland, France, Hungary, Spain and Sweden), reference to existing products (Belgium, Czech Republic, Finland, France, Hungary, Spain and Sweden) and the contribution of the pharmaceuticals to the economy (Belgium, Hungary, Spain and United Kingdom).

Profit controls (controlling costs while allowing a certain profit margin) are used in United Kingdom, Spain and the Czech Republic.

In the European Union the following countries have (in general) price levels above the European average for brand-name pharmaceuticals: UK, Germany, Sweden, Denmark and The Netherlands.

Pharmaceutical companies are searching for alternative ways of restricting parallel imports. Such an example is Bayer's legal victory on the Adalat case in 2004 when a pharmaceutical company found a way to restrict parallel imports without infringing European Union law. The European Court of Justice, declared that the imposition of a supply quota system (under which Bayer unilaterally limited supplies to wholesalers) did not constitute an "agreement" to restrict parallel imports and could not be prohibited.

In 2007, Bulgaria and Romania will join the EU. These countries have price levels below the European average for pharmaceutical products. It would be interesting to see the effect of this enlargement (or the previous one when other eight countries joined the EU) to parallel trade in brand-name pharmaceuticals.

The current situation of the common pharmaceutical market does not satisfy the European Commission. In this respect a new High Level Pharmaceutical Forum was set up in 2006 in order to enhance competitiveness in the pharmaceutical industry while sustaining high public health standards. The Forum consists of relevant ministers from the EU, members of the European Parliament, senior industry representatives and other stakeholders. It meets once a year to review progress and give a political mandate for further work.

The Vice-President of the European Commission, Gunter Verheugen, described the purpose of the new Forum as follows: "Our objective is to examine the benefits of giving industry more flexibility in establishing prices without sacrificing any capacity of member states to protect their health care budgets. In addition, this reflection should look at the speed of access to the market, lifting of pricing controls for medicines that fall outside the state sector, parallel trade and the impact of the Transparency Directive. Given the importance and sensitive nature of this issue, it is clear that we will not be able to make quick progress. - But that is no reason not to start."

#### **4. The model**

The model presented below is the one introduced by Ganslandt and Maskus (2006), with one exception. Now patients only pay a fraction of the price of drugs, representing the co-payment. The other fraction is paid by the government. This will affect public expenditure and the welfare.

There is a drug manufacturer (M) that sells its product in two countries (A and B) through independent wholesalers. The demand in country A is  $Q_A = 1 - P_A$  and in country B is  $Q_B = S(1 - bP)$ , where S is the relative population of market B (population in area A is normalized to 1) and b is the co-payment (in country A is normalized to 1). The marginal cost of production and the marginal cost of distribution is zero.

The manufacturer offers to wholesalers a contract of the form  $(w_i, T_i)$ , where  $w_i$  is the wholesale price at which the wholesaler purchases the product and  $T_i$  is a franchise fee. Perfect information will allow the manufacturer to extract the entire profits from wholesalers. The manufacturer is not

allowed to restrict the supply of drugs towards the customers. The wholesaler in Country A can only sell drugs in his country. The manufacturer cannot prevent the wholesaler in country B from selling drugs in country A. Wholesalers will compete in a Cournot fashion for market A. The wholesale prices charged by the manufacturer must be non-negative prices.

The manufacturer establishes a single, independent, representative for each market. He chooses the wholesale prices such that profits are maximized:

$$\Pi = p_A(q_A^* + q_B^*) - tq_B^* + p_Bq_B$$

Where  $q_A^*$  is the quantity sold by wholesaler A on market A, and  $q_B^*$  is the quantity sold by wholesaler B on market A, and  $q_B$  is the quantity sold by wholesaler B on market B;  $t$  stands for trade costs (for example: transportation costs or re-packing expenditure).

The franchise fees will be the profits generated by wholesalers.

Wholesalers will choose the quantities that will maximize their profits:

$$\pi_A = (P_A - w_A) q_A^*$$

$$\pi_B = (P_A - w_A) q_B - t q_B^*$$

We solve this problem backwards: first we find the optimal quantities for wholesalers and then optimal wholesale prices.

For certain values of  $t$ , the optimal wholesale price for manufacturer A will be negative. This contradicts the assumption of non-negative price, so the optimal wholesale price will zero under these circumstances.

There are three optimal choices regarding each endogenous variable, corresponding to different intensities of trade costs. For a low cost, sets optimal (positive) prices for both wholesalers. An intermediate level of trade cost will result in a zero price in country A, but parallel imports will still occur. High trade costs will deter parallel imports (when the difference between the price paid by patients and the trade cost is smaller than the wholesale price for market B) . Further increase in trade costs will result in market segmentation.

The upper bound that delimits low trade cost from intermediate costs is found when the optimal choice of wholesale price in market A is zero.

$$t = \frac{Sb}{4 + 5Sb}$$

The upper bound that delimits intermediate trade cost from high costs is found when the difference between the price paid by patients and the trade cost is equal to the wholesale price for market B and parallel imports come to an end.

$$\underline{t} = \frac{3}{2} \left( \frac{Sb}{4 + 3Sb} \right)$$

## Results:

Variable	Low trade costs	Intermediate trade costs	High trade costs
Prices	$P_A = \frac{1}{2} - \frac{1}{2}t$ $P_B = \frac{1}{2b} - \frac{1}{Sb}t$	$P_A = \frac{1}{3} + \frac{2}{3} \left( \frac{1+4t}{4+9Sb} \right) + \frac{t}{3}$ $P_B = \frac{1}{2b} + \left( \frac{1+4t}{4+9Sb} \right)$	$P_A = \frac{1}{2}$ $P_B = \frac{1}{2b} + \frac{1}{4} - \frac{t}{2}$
Profits	$\Pi = \frac{Sb + 5Sbt^2 - 2tSb + 4t^2 + S^2}{4Sb}$	$\Pi = \frac{8Sb^2 + 20Sb^2t^2 - 8tSb^2 + 9S^2b + 16bt^2}{4b(4+9Sb)}$	$\Pi = \frac{4b + 4S - Sb^2 + 4tSb^2 - 4Sb^2t^2}{16b}$
Consumer Surplus	$CS = \frac{1}{2} \left( \frac{1}{2} + \frac{1}{2}t \right)^2 + \frac{S}{2b} \left( \frac{1}{2} - \frac{t}{s} \right)^2$	$CS = \frac{1}{2} \left[ \frac{2}{3} - \frac{2}{3} \left( \frac{1+4t}{4+9Sb} \right) + \frac{t}{3} \right]^2 + \frac{S}{2b} \left[ \frac{1}{2} - b \left( \frac{1+4t}{4+9Sb} \right) \right]^2$	$CS = \frac{1}{8} + \frac{S}{2b} \left( \frac{1}{2} - \frac{b}{4} + \frac{tb}{2} \right)^2$
Public expenses	$PE_B = (1-b)S \left( \frac{1}{2} - \frac{t}{5} \right) \left( \frac{1}{2b} + \frac{t}{Sb} \right)$	$PE_B = (1-b)S \left[ \frac{1}{2} - b \left( \frac{1+4t}{4+9Sb} \right) \right] \left( \frac{1}{2b} + \frac{1+4t}{4+9Sb} \right)$	$PE_B = (1-b)S \left( \frac{1}{2} - \frac{b}{4} + \frac{bt}{2} \right) \left( \frac{1}{2b} + \frac{1}{4} - \frac{t}{2} \right)$

Ganslandt and Maskus (2006) looked at how an increase in trade costs will affect retail prices in the two countries. They found that for low trade cost price will have the tendency to converge while intermediate or high prices will result in price divergence.

An important feature of the European pharmaceutical market is that each country implements its own health policy which will affect prices, profits, consumer welfare and public expenditure. Would prices have the same dynamic as presented by Ganslandt and Maskus if member countries have very different health policies? What would happen if they would move towards a common health policy?

In the first case, for a low trade cost:

$$P_A - P_B = \frac{1}{2} - \frac{1}{2}t - \left( \frac{1}{2b} - \frac{1}{Sb}t \right)$$

$$\frac{\partial P_A - P_B}{\partial b} = \frac{1}{2b^2} + \frac{1}{Sb^4} > 0$$

In this range an increase in co-payment in country B will result in price divergence between the two countries. It seems counter-intuitive that as countries become more similar (in country A the patients bear the whole price of pharmaceuticals), the prices faced by them will move apart. Consumers in country B will now face a higher price (because they are not subsidized anymore) and will demand a lower quantity of pharmaceuticals.

For an intermediate trade cost:

$$P_A - P_B = \frac{1}{3} - \frac{2}{3} \left( \frac{1+4t}{4+9SB} \right) + \frac{t}{3} - \frac{1}{2b} - \frac{1+4t}{4+9Sb}$$

$$\frac{\partial P_A - P_B}{\partial b} = \frac{1}{2b^2} + \frac{(1+4t)}{3} \frac{1}{(4+9Sb)^2} > 0$$

For intermediate costs, we observe the same behavior for prices relative to changes in the co-payment level in country B.

For a high trade cost:

$$P_A - P_B = \frac{1}{2} - \frac{1}{2b} - \frac{1}{4} + \frac{t}{2}$$

$$\frac{\partial P_A - P_B}{\partial b} = \frac{1}{2b^2} > 0$$

It seems that different trade costs do not affect the relationship between the prices faced by patients in country A and B and differences in co-payment levels.

## 6. Conclusions

The pharmaceutical market is a highly regulated market, both on the demand side and on the supply side. This paper aimed to acknowledge the importance of this specificity when it comes to discussing future health policy. For example, when considering a common health policy (enforceable to all member countries), the European Union might face a decrease in welfare relative to the current situation when each country decides what is best for them. A divergence in prices might result in important share of market going un-served.

Future work on this paper will take into consideration other important characteristics of this market: an intensive R&D sector which needs to be protected (to foster future investment) and supply side regulation (like price caps).

Pharmaceutical firms proved to be able to restrict parallel imports without infringing European Union law. This was the case when Bayer imposed a supply quota system to their distributors. Modeling such behavior will enhance the model presented in this paper.

The benefits of parallel imports go towards the consumers who pay lower prices rather than those who face a price increase. The welfare loss related to them is not negligible. On the supply side, intellectual property laws exist to encourage investments which in turn will generate quality pharmaceutical products and better health outcomes.

An empirical study regarding the efficiency of price regulation or demand regulation would have a significant policy value. Pharmaceutical policies represent a great diversity in achieving the same goals. Coordinating those policies between countries might be beneficial to everybody.

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OECD SOCIAL EXPENDITURE DATABASE

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