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External Price Benchmarking vs. Price Negotiation for Pharmaceuticals

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DISCUSSION PAPERS

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Abstract

External price benchmarking imposes a price cap for pharmaceuticals based on prices of identical products in other countries. Suppose that a regulatory agency can either directly negotiate drug prices with pharmaceutical manufacturers or implement a benchmarking regime based on foreign prices. Using a model where two countries differ only in their market size, we show that a country prefers benchmarking if its agency has considerably less bargaining power compared to the agency in the other country. Assuming that bargaining power is positively correlated to country size, we find that only small countries might have an incentive to engage in external price benchmarking. This incentive shrinks if population size grows.

Keywords: Pharmaceuticals, price negotiation, administered prices, external reference pricing.

JEL-Classification: L65, I18

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1 Introduction

Nearly all countries in the industrialized world regulate the market for pharmaceutical products. There is a widespread agreement that an unregulated market would not lead to a socially desirable outcome: neither in terms of safety nor in the access to life-saving drugs.

The pharmaceutical market differs from other markets in some important respects. Most high-potency drugs are available only by prescription: that is, the consumer of a prescription drug and the consumption decision-maker—the prescribing physician—are not the same person. Moreover, the range of drugs is so vast and complex that few physicians can fully inform themselves about all the available alternatives. Most governments, therefore, recognize that information failures require regulation in terms of drug safety and therapeutical efficacy. Many go further by reimbursing prescription drug outlays on the grounds that the access to life-enhancing drugs should not depend on the ability to pay. This, however, means that patients are often not only removed from product decision-making, but also from paying the full price associated with their drug consumption.

The combination of physician decision-making, imperfect information, and third-party reimbursement makes drug demand stronger and less price-elastic than it might otherwise be, conferring considerable market power upon the sellers of well-accepted drugs (Scherer, 1993). This has led many countries to regulate prices and to control for over-prescription and inappropriate use of pharmaceutical products. In spite of the wide variety of existing regulatory regimes, we can broadly distinguish two types of drug price regulation.²

• External price benchmarking, according to which the price of a drug at market entry is based on the price of the same drug in a group of reference countries, and

¹To give an example: by the end of 2008 a total of 16'247 pharmaceutical products—counting different pharmaceutical forms, dosages, and pack sizes—has been registered in Switzerland. Data from Interpharma (2009).

²Danzon (1997a) provides an excellent overview of various regulatory mechanisms in the pharmaceutical industry. Cross-national impacts of pharmaceutical price regulation is analyzed in a recent OECD report (2008). For a more detailed discussion of the pharmaceutical market in Switzerland, see Paris and Docteur (2007).

• Direct price negotiations, according to which the price of a drug at market entry is the outcome of a bargaining process between the manufacturer and a regulatory agency.

External price benchmarking is the most widely used technique to regulate pharmaceutical prices in European countries (OECD, 2008). In essence, this technique consists of a price cap for a new drug, based on the price for the same drug in a basket of reference countries.³ The basic procedure can be summarized as follows. Upon the launch of a drug in a country, the manufacturer submits a price proposal to the authorizing agency. The agency then compares the proposed price with the retail price of the same drug in reference countries. The drug is not approved if the proposed price exceeds the average price in the reference countries by more than a certain amount.

Of course, external price benchmarking does not provide a strong basis for price regulation in first- or early-launch countries. Hence, in these countries the drug price must be determined in a negotiation process with the pharmaceutical manufacturer. Such negotiations are characterized by the difficult task of assessing the degree of differentiation and the level of substitutability between a new drug and already authorized drugs in the same area of therapeutic practice.

In this paper we analyze the incentives for a country to engage in external price benchmarking as opposed to direct price negotiations. Using a gametheoretical model where two countries differ only in their market size, we show that small countries are more likely to engage in external price benchmarking than big countries. This result can be explained by the fact that a small country has less resources to finance its regulatory agency than a big country. Due to a positive correlation between budget size and negotiating skills, the agency in the small country is assumed to have comparatively little bargaining power; however, the implementation of an external benchmarking policy allows a free ride on the superior negotiating skills in the big country.

³In general, reference countries are selected according to either economic and/or geographic proximity. For instance, Switzerland benchmarks its price for reimbursed drugs against prices in Austria, Denmark, France, Germany, Italy, the Netherlands, and the United Kingdom; cf. OECD (2008).

We find that not only small countries may profit from external price benchmarking, but also pharmaceutical firms. One of the reasons for this result is the fact that the implementation of a benchmarking policy in one country results in a change of the bargaining problem in the other country, which then becomes the country of reference. The idea is that the profits accrued in the first country become part of the "bargaining pie;" this reinforces the implicit negotiation power of the firm when negotiating the drug price in the reference country since the disagreement payoff of the firm is higher when two countries rather than one are concerned by the negotiation.

A Brief Overview of the Model. We consider a simple model with two countries. A pharmaceutical firm produces a prescription drug that can be sold in both countries. The countries are at the same level of development, but of different size: this means that, except for a scaling factor, the demand functions are identical. Obviously, the firm would like to charge the same monopoly price in both countries,⁴ but in order to be authorized for sale the drug's price has to be approved by regulatory agencies. In doing so, the agencies may be bound to a policy of either external price benchmarking (EPB) or direct price negotiations (DPN). In each country the regulation policy is defined beforehand by the national legislator.

The sequence of actions is a follows. First, in both countries, the legislator defines the regulatory policy for his agency. Second, the manufacturer decides on the optimal timing to launch the drug in the two countries. Third, the drug launch occurs and price negotiations take place when necessary. A negotiation process is modeled as a Nash bargaining game between the firm and an agency. We assume that the agency in the big country has more bargaining power compared to the agency in the small country: hence, if both countries negotiate independently with the firm, then the drug is cheaper in the big country.

We first show that total profits are higher under external price benchmarking than under independent price negotiations. This suggests that, whenever possible, the firm will decide on a product launch strategy that

⁴Note that the size of a country has only a level effect on the maximization problem of the monopolists; thus, the monopoly price is identical in both countries.

enables an EPB policy to be applied. In particular, the firm wants the big country to regulate its drug price based on the negotiated price in the small country. However, such a move is not part of the equilibrium path since EPB is a weakly dominated strategy for the big country.

While the big country never implements an EPB policy, the small country will do so in equilibrium if its agency has considerably less bargaining power than its counterpart in the big country. If this is the case, then the equilibrium path has the following structure. At the outset of the game, the legislator in the big country decides on a DPN policy while the legislator in the small country decides on an EPB policy. The firm then decides to launch the drug first in the big country, followed by introduction in the small country. As a result, the drug price for both countries is determined through a Nash bargaining game between the firm and the agency in the big country.

Related Literature. The economic literature on pharmaceutical price regulation is mainly empirical, focusing on measuring cross-national price differences and explaining them by the regulatory environment.⁵ Danzon and Chao (2000) find that countries with strict price regulation—like France, Italy, and Japan—have lower prices than the less regulated markets of the United States and the United Kingdom. However, Berndt (2000) provides a number of caveats about their interpretation of their data.

In a more recent paper, Kyle (2007) examines the impact of price regulation on the extent and the timing of drug launch. She finds two results: first, drugs developed by firms headquartered in countries that regulate prices reach fewer markets than products that originate in countries without price control; second, companies delay launch into price-controlled markets, and are less likely to introduce their products in additional markets after entering a country with low prices.⁶ Kyle's findings are in line with our theoretical predictions. We find that in equilibrium a pharmaceutical firm will launch a

⁵The literature is extensively surveyed by Lopez-Casasnovas and Puig-Junoy (2000) and Danzon (2000). However, as Lopez-Casasnovas and Puig-Junoy complain, the bulk of the literature is mainly descriptive and only few studies examine the effects of external price benchmarking in the grounds of some sort of theoretical model.

⁶Other papers with similar conclusions are Danzon, Wang, and Wang (2005) and Danzon and Furukawa (2008).

new drug first in a big country that is not engaged in external price benchmarking, followed by introduction in a small country that does regulate prices based on foreign prices.

Despite a substantial empirical literature, there are few theoretical papers on pharmaceutical price regulation. Notable exception are the papers by Danzon (1997b), Wright (2004), and Mariñoso, Jelovac, and Olivella (2008). The last one is specifically relevant for our purpose. Mariñoso et al. use a model where two countries differ only in their population size and the reimbursement level for prescription drugs. They show that a country has an incentive to engage in external price benchmarking if its reimbursement level is higher as compared to that in the other country. This preference dwindles as the size of the country engaging in benchmarking increases.

Our setup is related to Mariñoso et al. (2008), but the driving force to engage in external benchmarking is the difference in bargaining power, rather than the difference in reimbursement levels. Moreover, we explicitly model the decision whether or not to engage in external price benchmarking.

This paper is also connected to the literature on parallel trade and reimports of pharmaceutical products.⁷ The closest paper to our contribution is Pecorino (2002), who studies the potential effect of drug reimports from Canada to the United States. Usually, prescription drugs are much cheaper in Canada due to the single payer system which allows the Canadian government to exercise monopsony power in setting prices. Using a stylized model of the North American drug market, Pecorino shows that, surprisingly, the presence of parallel imports results in higher profits for pharmaceutical firms. We show in our model that the presence of external price benchmarking has a similar effect. The present model can be interpreted as a generalized version of Pecorino's: the structure becomes the same if we restrict the bargaining power of one country to zero. Hence, our model corroborates the statement made by Danzon (1997b) that pharmaceutical price regulation based on foreign prices is equivalent to a system of 100% parallel trade.

The remainder of the paper is organized as follows. The next section introduces the general model. In section 3 we derive the equilibrium price

 $^{^{7}}$ For a primer on the economics of reimportation of prescription drugs see Berndt (2007).

for different regulation policies. We then solve the model in the sections 4 and 5. Section 6 concludes. Computational details are relegated to the Appendix.

2 The Model

Our model is based on a game between a pharmaceutical firm and the health authorities in a big country (A) and a small country (B). Henceforth, we will refer to this players as the firm and the agencies. In approving a drug the agencies may either be bound to a policy of external price benchmarking (EPB) or a policy of direct price negotiations (DPN). These policies are defined beforehand by two additional players; these players are referred to as the legislators.

The firm produces a prescription drug that is patent protected in both countries. The development process of the drug is not explicitly modeled, but presumably the firm has borne large sunk costs of research and development in bringing the drug to market. The marginal costs of production are normalized to zero.

Assume that the two countries are at a similar level of development, so that up to a scaling parameter k < 1 demand is the same in both countries. We say that the big country has size 1 while the small country has size k. To derive explicit results, we restrict the analysis to linear demand. Aggregated demand in country A and B are defined as follows:

$$Q(P_A) = 1 - P_A$$
 and $k Q(P_B) = k(1 - P_B)$. (1)

The firm aims at maximizing its profits from sales in both countries, with

$$\Pi(P_A) = (1 - P_A)P_A \text{ and } k \Pi(P_B) = k(1 - P_B)P_B$$
 (2)

being the profits in country A and B, respectively. Agencies and legislators are assumed to care only about the surplus of domestic consumers.⁸ Therefore, they strive to maximize the net consumer surplus in country A and B,

⁸This implies that a country's objective function does not include the profits of the firm. We believe this assumption to be appropriate, especially for countries with no pharmaceutical industry.

given by

$$CS(P_A) = \frac{(1 - P_A)^2}{2}$$
 and $k \, CS(P_B) = \frac{k(1 - P_B)^2}{2}$. (3)

Although the firm enjoys patent protection in both countries, it cannot act as a monopolist. To obtain market approval in country i = A, B, the firm must prove that its product is safe and efficacious for the intended use; in addition, the drug price must be authorized by the local agency. As mentioned above, the agency may either be bound to an EPB or a DPN policy.

Under an EPB policy, the agency takes the negotiated price in the other country as price cap; thus, the drug price in the reference country becomes the domestic price as well. However, if the drug has not yet been approved by the other agency—or if the approval was rejected—then the agency can still negotiate with the pharmaceutical firm directly. In contrast, under a DPN policy, the agency always negotiate independently with the firm.

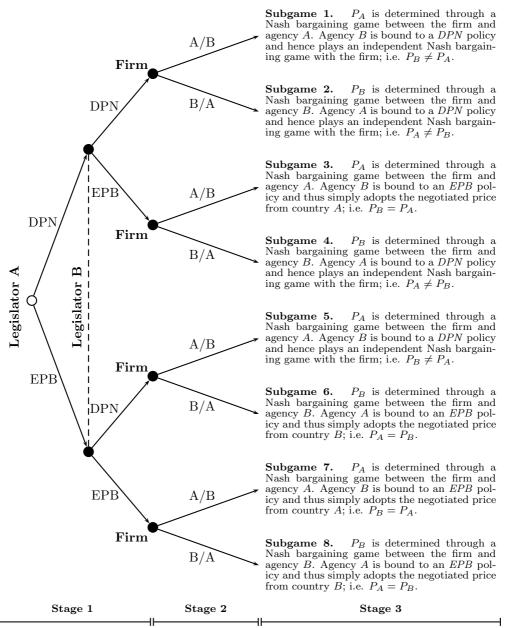
We model the negotiation process as a Nash bargaining game between the firm and an agency. The scenario is one of threats: that is, the negotiating agency can credibly threaten not to authorize the drug if negotiations fail. The agencies have different bargaining power, denoted by $\alpha \in (0,1)$ and $\beta \in (0,\alpha)$, where country A has the more powerful agency because $\alpha > \beta$. The bargaining power of the firm is $1-\alpha$ in negotiations with agency A, and $1-\beta$ in negotiations with agency B.

Timing. We study the three-stage game illustrated by Figure 1. In the first stage, the legislators of both countries simultaneously decide on the price approval policy for their country: they can implement an EPB policy or a DPN policy. These policies are observed by the pharmaceutical firm, who in the second stage of the game defines the product launch strategy for the third stage: that is, it decides whether to launch the drug first in the big country, followed by introduction in the the small country (strategy "A/B"), or vice versa (strategy "B/A"). In stage three, the drug is launched

⁹This assumption can be sustained by the fact that a big country has more resources to finance its authorities than a small country.

¹⁰To keep the analysis tractable, we abstract from the possibility of a simultaneous product launch. However, this simplification is not crucial because a simultaneous product

Figure 1: Game structure



The legislators of both countries simultaneously decide on the price approval policy for their agency.

The firm defines the product launch strategy for the next stage.

The drug is launched according to the predefined strategy. The agencies approve the drug's price by applying their respective policy.

according to the predefined strategy and price negotiations take place when necessary.

Henceforth, we will refer to the country in which the drug is launched first as *first-launch country* and to the country in which the drug is launched second as *second-launch country*.

Note that the drug price in the first-launch country is always determined through a Nash bargaining game: this price becomes the price for the second-launch country as well, if the second-launch country is bound to an EPB policy (and provided that negotiations in the first-launch country were successful); otherwise, however, the agency in the second-launch country will play an independent Nash bargaining game with the firm as well.

We assume that all players are risk neutral and that none of them discounts the future. Therefore, the firm's expected payoff at the beginning of the game is just the sum of the expected profits in both countries, i.e. $\Pi_{Total} = \Pi(P_A) + k \Pi(P_B)$. The expected payoff of the legislator and the agency in country A is $CS(P_A)$, and similarly, the expected payoff of the legislator and the agency in country B is $k CS(P_B)$. We restrict the analysis to pure strategy equilibria.

3 Third-stage Nash Bargaining Games

We solve the game by backward induction, starting with the price approval process in stage three. The outcome of this process depends on both the product launch strategy defined by the firm in stage two and, more crucially, on the regulatory policies defined by the legislators in stage one. As can be seen from Figure 1, the model has eight third-stage subgames, numbered 1 to 8. These subgames can be classified into two groups: subgames in which the agency of the second-launch country is bound to a DPN policy, and subgames in which the agency of the second-launch country is bound to an EPB policy.

Note that each subgame in the first group consists of two independent Nash bargaining games. Since the outcomes of these Nash games do not depend on whether A or B is the first launch country, the subgames in

launch would be a weakly dominated strategy.

the first group are payoff equivalent. Conversely, a subgame in the second group does only consist of a Nash game with the agency in the first-launch country. Hence, in this group of subgames the equilibrium payoffs do depend on whether A or B is the first launch country. In total, three different types of third-stage equilibrium payoffs are to be considered, each of which is the result of one of the following processes.

- Independent price negotiations: The prices in the two countries are determined through two independent Nash bargaining games; this is the case in subgames 1, 2, 4, and 5.
- The big country as benchmark for the small country: The price for both countries is determined through a Nash bargaining game between the firm and agency A; this is the case in subgames 3 and 7.
- The small country as benchmark for the big country: The price for both countries is determined through a Nash bargaining game between the firm and agency B; this is the case in subgames 6 and 8.

Independent price negotiations. We first derive the equilibrium payoffs for those subgames where (at least) the second launch country is bound to a DPN policy and thus both agencies play independent Nash bargaining games with the firm (subgames 1, 2, 4, and 5).

In both Nash games the negotiating agency aims to maximize the surplus for domestic consumers, while the firm aims to maximize its profits from sales to these consumers. In absence of an agreement, net consumer surplus and profits are both zero. Therefore, zero is the threat point for both, the negotiating agency and the pharmaceutical firm. The Nash bargained prices in country A and B are found from the solutions to the following

¹¹This assumes that the agency can prevent the consumers in its country from purchasing the drug in the other country in the event an agreement is not reached. We believe that this assumption is in accordance with reality, especially in countries that do not allow parallel imports of pharmaceutical products.

maximization problems.

$$\max_{P_A} \left[CS(P_A) \right]^{\alpha} \left[\Pi(P_A) \right]^{1-\alpha} = \max_{P_A} \left[\frac{(1-P_A)^2}{2} \right]^{\alpha} \left[(1-P_A)P_A \right]^{1-\alpha} \tag{4}$$

and

$$\max_{P_B} \left[k \, CS(P_B) \right]^{\beta} \left[k \, \Pi(P_B) \right]^{1-\beta} = \max_{P_B} \left[\frac{k(1-P_B)^2}{2} \right]^{\beta} \left[k(1-P_B)P_B \right]^{1-\beta}, \quad (5)$$

Note that country size is only a level effect in these maximization problems, and in consequence will not affect the final result. By solving (4) and (5) we obtain the first lemma.

Lemma 1. When both countries independently negotiate the drug price with the firm, then the price in the big and the small country is

$$P_A^* = \frac{1-\alpha}{2}$$
 and $P_B^* = \frac{1-\beta}{2}$.

Total profits for the pharmaceutical firm are

$$\Pi_{Total}^* = \Pi(P_A^*) + k \, \Pi(P_B^*) = \frac{1 - \alpha^2}{4} + \frac{k(1 - \beta^2)}{4},$$

and the net consumer surplus in the big and the small country is

$$CS_A^* = \frac{(1+\alpha)^2}{8}$$
 and $CS_B^* = \frac{k(1+\beta)^2}{8}$, respectively.

Remark. Since $\alpha > \beta$, we find that the negotiated price in country A is lower than the negotiated price in country B, i.e. $P_A^* < P_B^*$. This implies that the per capita surplus in the big country exceeds the per capita surplus in the small country. Expecting this result, the legislator in the small country may therefore have an incentive to implement an EPB policy.

The big country as benchmark for the small country. Next we focus on subgames where the negotiated price in the big country becomes the price in the small country as well (subgames 3 and 7).

Provided that B is bound to an EBP policy and A is the first-launch country, the price for both countries is determined through a Nash bargaining game between the firm and agency A. Since in this Nash game, price concessions are much more costly—compared to the independent price negotiations case—we should expect the firm to drive a harder bargain with agency A. As a result, the negotiated price will be higher and the net consumer surplus in country A will be lower.

The firm's surplus from reaching an agreement with agency A is given by $(1+k)\Pi(P_A) - k\Pi(P_B^*)$. In this expression the first term reflects the profits from sales in both markets (given that B takes the negotiated price as price cap) and the second term reflects the firm's threat point of only selling in market B. The Nash bargained price is the solution to the following problem:

$$\max_{P_A} \left[CS(P_A) \right]^{\alpha} \left[(1+k)\Pi(P_A) - k\Pi(P_B^*) \right]^{1-\alpha}$$

$$= \max_{P_A} \left[\frac{(1-P_A)^2}{2} \right]^{\alpha} \left[(1+k)(1-P_A)P_A - \frac{k(1-\beta^2)}{4} \right]^{1-\alpha}$$
(6)

Note that problem (6) is identical to problem (4), except that the term $k \Pi(P_B^*)$ is implicit in problem (4). Under independent price negotiations, the expected profits from sales in country B are always $k \Pi(P_B^*)$, whether or not the firm reaches an agreement with agency A. Accordingly, the term $k \Pi(P_B^*)$ can be netted out of problem (4). If, however, the negotiated price in country A is the price cap for country B, then the profits from sales in country B depend upon the Nash bargaining game in country A. As a result, $k \Pi(P_B^*)$ cannot be netted out of the expression in problem (6). Lemma 2 summarizes the outcome.

Lemma 2. When the small country is bound to an EPB policy and the big country is the first-launch country, then the drug price in both countries is

$$P^{\stackrel{AB}{\to}} = \frac{3 - \alpha - X}{4}, \quad where \quad X = \sqrt{(1 + \alpha)^2 - \frac{4\alpha k(1 - \beta^2)}{k + 1}}.$$

Total profits for the pharmaceutical firm are

$$\Pi_{Total}^{AB} = \frac{(1+k)(3-\alpha-X)(1+\alpha+X)}{16}$$

and the net consumer surplus in the big and the small country is

$$CS_A^{\stackrel{AB}{\rightarrow}} = \frac{(1+\alpha+X)^2}{32}$$
 and $CS_B^{\stackrel{AB}{\rightarrow}} = \frac{k(1+\alpha+X)^2}{32}$, respectively.

Remark. Straight forward comparison reveals that $P \stackrel{AB}{\rightarrow} > P_A^*$. This confirms our conjecture that the net consumer surplus in the big country decreases due to an EPB policy in the small country. The reason for this result is the general rule that the introduction of an EPB policy in the second-launch country increases the threat point for the firm in the Nash game with the first agency: the firm's outside option is no longer zero; instead, it is determined by the expected profits from sales in the second-launch country.

Obviously, the small country is better off under an EPB policy, compared to independent price negotiations, if $CS^{\stackrel{AB}{\rightarrow}} \geq CS_B^*$. Straight forward calculations (given in the Appendix), reveal that this inequality is satisfied iff $\beta < \alpha/(1 + k(1 - \alpha))$.

The small country as benchmark for the big country. Finally, we are left with the case where the negotiated price in the small country becomes the price for the big country as well (subgames 6 and 8).

Provided that A is bound to an EBP policy and B is the first-launch country, the price for both countries is determined by the solution to

$$\max_{P_B} \left[k \, CS(P_B) \right]^{\beta} \left[(1+k)\Pi(P_B) - \Pi(P_A^*) \right]^{1-\beta}$$

$$= \max_{P_B} \left[\frac{k(1-P_B)^2}{2} \right]^{\beta} \left[(1+k)(1-P_B)P_B - \frac{(1-\alpha^2)}{4} \right]^{1-\beta}. \tag{7}$$

By solving (7) we obtain the next lemma.

Lemma 3. When the big country is bound to an EPB policy and the small country is the first-launch country, then the drug price in both countries is

$$P^{\stackrel{BA}{\to}} = \frac{3 - \beta - Y}{4}, \quad where \quad Y = \sqrt{(1 + \beta)^2 - \frac{4\beta(1 - \alpha^2)}{k + 1}}.$$

Total profits for the pharmaceutical firm are

$$\Pi_{Total}^{BA} = \frac{(1+k)(3-\beta-Y)(1+\beta+Y)}{16}$$

and the net consumer surplus in the big and the small country is

$$CS_A^{BA} = \frac{(1+\beta+Y)^2}{32}$$
 and $CS_B^{BA} = \frac{k(1+\beta+Y)^2}{32}$, respectively.

Remark. Price comparisons show that $P^{\stackrel{BA}{\rightarrow}} > P_B^* > P_A^*$. From this we can conclude that all consumers are worse off, compared to the case of independent price negotiations, when the price for both countries is negotiated by the agency in the small country. This is not an astonishing result as the small country has the less powerful agency.

Lemmas 1 to 3 fully characterize the outcome for all third stage subgames. Table 1 summarizes the equilibrium payoffs.

Table 1: Subgame equilibrium payoffs for different strategy combinations

	"A/B"	"B/A"
Country A: "DPN" Country B: "DPN"	$(CS_A^*, CS_B^*, \Pi_{Total}^*)$ Subgame 3.1	$\left(CS_A^*, CS_B^*, \Pi_{Total}^*\right)$ Subgame 3.2
Country A: "DPN" Country B: "EPB"	$ (CS_A^{\stackrel{AB}{\rightarrow}}, CS_B^{\stackrel{AB}{\rightarrow}}, \Pi_{Total}^{\stackrel{AB}{\rightarrow}}) $ $Subgame \ 3.3 $	$\left(CS_A^*, CS_B^*, \Pi_{Total}^*\right)$ Subgame 3.4
Country A: "EPB" Country B: "DPN"	$(CS_A^*, CS_B^*, \Pi_{Total}^*)$ Subgame 3.5	$ (CS_{A}^{\stackrel{BA}{\rightarrow}}, CS_{B}^{\stackrel{BA}{\rightarrow}}, \Pi_{Total}^{\stackrel{BA}{\rightarrow}}) $ $Subgame \ 3.6 $
Country A: "EPB" Country B: "EPB"	$ (CS_A^{\stackrel{AB}{\rightarrow}}, CS_B^{\stackrel{AB}{\rightarrow}}, \Pi_{Total}^{\stackrel{AB}{\rightarrow}}) $ $Subgame \ 3.7 $	$ (CS_A^{\stackrel{BA}{\rightarrow}}, CS_B^{\stackrel{BA}{\rightarrow}}, \Pi_{Total}^{\stackrel{BA}{\rightarrow}}) $ $Subgame \ 3.8 $

The payoffs for the different combinations of price approval policies and product launch strategies are defined in Lemmas 1, 2, and 3.

4 Product Launch Strategies

We now focus on the second stage where the pharmaceutical firm chooses its product launch strategy. Observing the price approval policies in the two countries, the firm has to decide whether to launch the drug first in the big country, followed by introduction in the the small country, or vice versa.

Calculations given in the Appendix reveal that the firms's total profits are highest when the big country is bound to an EPB policy and thus takes the negotiated price from the small country as price cap. Conversely, total profits are lowest if both countries carry independent price negotiations with the firm. That is, the firm's expected profits from the subgames in stage three are ordered as follows:

$$\Pi_{Total}^{\stackrel{BA}{\rightarrow}} > \Pi_{Total}^{\stackrel{AB}{\rightarrow}} > \Pi_{Total}^{*}.$$
 (8)

This payoff ordering implies that, whenever possible, the firm should decide on a product launch strategy that leads to a price cap: in particular, the firm should launch the drug first in the small country, followed by introduction in the big country, when the big country is bound to an EPB policy. Lemma 4 further characterizes the optimal strategy.

Lemma 4. The firm has the following subgame-perfect strategy profile for stage two: "B/A" if agency A is bound to an EPB policy, and "A/B" otherwise.

Remark. It is not very surprising that profits are highest when the weak agency B negotiates the price for both countries. However, it is less obvious that profits are lowest under independent price negotiations. The reason is that implementing an EPB policy in the small country reinforces the bargaining position of the firm in the Nash game with the big country. As a result, profits rise on sales in the big country, but they probably fall on sales in the small country. Nevertheless, in the case of linear demand, the first effect always outweighs the second and, thus, total profits increase under external benchmarking.

5 Price Approval Policies

In this section, we analyze the first-stage game where the legislators of both countries simultaneously define the price approval policy for their country.

It is straightforward to show that the implementation of an EPB policy is a weakly dominated strategy for legislator A. We show in the Appendix that the three possible payoffs for country A are ordered as follows:

$$CS_A^* > CS_A^{AB} > CS_A^{AB} > CS_A^{BA}$$
.

From this payoff ordering follows that the big country is better off under independent price negotiations than under any form of external price benchmarking: in fact, domestic consumers are worst off if agency A is committed to accept the negotiated drug price from country B. Obviously, legislator A can prevent this outcome by deciding on a DPN policy. This suggests the following lemma.

Lemma 5. In the first stage, the legislator of the big country A always decides on a DPN policy.

As to the payoffs for the small country B, we show in the Appendix that

where $\widehat{\beta} = \frac{\alpha}{1+k(1-\alpha)}$. This allows the following statement. Provided that agency B has considerably less bargaining power than agency A, it is preferable for the small country to rely on an EPB policy; however, if the difference in bargaining power is small, then it is beneficial to implement a DPN policy. The optimal strategy for legislator B is summarized in the next lemma.

Lemma 6. Let $\widehat{\beta} := \frac{\alpha}{1+k(1-\alpha)}$. In the first stage, the legislator of the small country B implements an EPB policy if $\beta < \widehat{\beta}$ and a DPN policy otherwise.

Remark. The cutoff $\widehat{\beta}$ is decreasing in k. This means that, ceteris paribus, the small country is less likely to implement an EPB policy when its population grows. The reason for this result is the fact that under independent

price negotiations an increase in k leads to an increase in the firm's profits accrued in the small country. Since these profits represent the firm's outside option in the bargaining problem (6), the negotiated price under external benchmarking increases as well. Therefore, under an EPB policy the per capita surplus in country B decreases as the population grows.

The equilibrium outcome of the model follows from Lemmas 1 to 6. Propositions 1 and 2 summarize the results.

Proposition 1. Provided that the small country has considerably less bargaining power than the big country, i.e., $0 < \beta < \widehat{\beta}$, the equilibrium path of the model is as follows:

- 1. Legislator A implements a DPN policy and legislator B implements an EPB policy.
- 2. The firm decides to launch the drug first in the big country A, followed by introduction in the small country B.
- 3. First, the drug price for the big market is determined through a Nash bargaining game between the firm and agency A and agency B then adopts this price as cap for the small market; i.e. $P_A = P_B = P^{AB}$.

Proposition 2. Provided that the small country has only slightly less bargaining power than the big country, i.e., $\hat{\beta} < \beta < \alpha$, the equilibrium path of the model is as follows:

- 1. Both legislators implement a DPN policy.
- 2. The firm decides to launch the drug first in the big country A, followed by introduction in the small country B.
- 3. First, the drug price for the big market is determined through a Nash bargaining game between the firm and agency A; then, the drug price for the small market is determined through a Nash bargaining game between the firm and agency B; i.e. $P_A = P_A^*$ and $P_B = P_B^*$.

Remark. Note that our results also hold for k=1 This implies that, provided that one country has considerably less bargaining power than the other, external price benchmarking may also occur if countries are similar in size. However, in this case, the difference in bargaining power should be explained by other factors, such as the degree of centralization of health care financing or the importance of the pharmaceutical industry to the national economy. On the one hand, countries with more centralized health care systems, such as the United Kingdom, should be expected to be more likely to exercise monopsony power in the pharmaceutical market than other countries. On the other hand, countries headquartering major pharmaceutical companies, such as Switzerland, seem to be less tough in drug price negotiations due to a constant lobbying from the industry.

6 Conclusion

The present model characterizes external price benchmarking as an effective policy to regulate pharmaceutical prices. Our analysis demonstrates that a country may adopt such a policy to free ride on superior negotiating skills of other countries. Since a big country has more resources to finance a regulatory agency than a small country, we assume that a big country also has more bargaining power in price negotiations with a pharmaceutical firm. Using a model where two countries only differ in their market size, we show that the smaller country engages in external price benchmarking if its regulatory agency has considerably less bargaining power than the agency in the big country. This preference dwindles when the population in the small country grows. We find that the big country never engages in external price benchmarking; indeed, any form of benchmarking harms the big country.

Our model removes the presumption that pharmaceutical profits will automatically fall if prices are regulated with an external benchmarking policy. The implementation of such a policy in the small country causes the firm to drive a harder bargain in negotiations with the agency of the big country. As a result, profits rise on sales in the big country. However, profits fall on sales in the small country because the small country has only an incentive to engage in external price benchmarking if the new price is lower than the in-

dependently negotiated price. We find that in the case of linear demand, the first effect dominates the second and total profits always rise. Why, in light of this result, do pharmaceutical firms oppose to external price benchmarking policies? There are a couple of issues that should be addressed in future research. First, pharmaceutical firms are active in many different countries and in some of these countries there are incentives to engage in price discrimination. External price benchmarking destroys the ability of these firms to engage in price discrimination. Second, our results crucially depend on the linear demand assumption. There might be other demand specifications for which profits would not rise under external price benchmarking.

However, in summary we can conclude that external price benchmarking is an effective policy for small countries to regulate pharmaceutical prices. This theoretical result is in line with the finding of a recent OECD report (2008), stating that Germany and the United Kingdom do not engage in external price benchmarking, but are often first- or early-launch countries. Together with France, these are also the three countries most commonly referenced by other European countries.

Appendix

Comparison of profits. According to Lemmas 1, 2, and 3 the firm has the following possible payoffs:

$$\Pi_{Total}^* = \frac{1 - \alpha^2}{4} + \frac{k(1 - \beta^2)}{4}, \tag{9}$$

$$\Pi_{Total}^{AB} = \frac{(1+k)(3-\alpha-X)(1+\alpha+X)}{16}, \quad \text{and} \quad (10)$$

$$\Pi_{Total}^{BA} = \frac{(1+k)(3-\beta-Y)(1+\beta+Y)}{16}, \tag{11}$$

where
$$X = \sqrt{(1+\alpha)^2 - \frac{4\alpha k(1-\beta^2)}{k+1}}$$
 and $Y = \sqrt{(1+\beta)^2 - \frac{4\beta(1-\alpha^2)}{k+1}}$.

For the comparison it is useful to memorize that

$$1 - \alpha < X < 1 + \alpha$$
, $1 - \beta < Y < 1 + \beta$ and $Y < X$.

This results follow directly from the facts that $0 < \beta < \alpha < 1$ and 0 < k < 1 by assumption.

Now subtract (10) from (11) and simplify to find that $\Pi^{BA}_{Total} - \Pi^{AB}_{Total}$ has the same sign as $(X - Y + \alpha - \beta)(X - (1 - \alpha) + Y - (1 - \beta)) > 0$.

Similarly, subtract (9) from (10) and simplify to find that $\Pi_{Total}^{AB} - \Pi_{Total}^*$ has the same sign as $\alpha^2 + 2\alpha\beta^2 + \beta^2 + k(\beta^2 - \beta^4) > 0$.

As a result we obtain the following ordering of total profits:

$$\Pi_{Total}^{\stackrel{BA}{\rightarrow}} > \Pi_{Total}^{\stackrel{AB}{\rightarrow}} > \Pi_{Total}^*. \tag{12}$$

Comparison of the consumer surplus in the big country. According to Lemmas 1, 2, and 3, possible payoffs to country A are

$$CS_A^* = \frac{(1+\alpha)^2}{8},$$
 (13)

$$CS_A^{\stackrel{AB}{\rightarrow}} = \frac{(1+\alpha+X)^2}{32}, \quad \text{and} \quad (14)$$

$$CS_A^{\stackrel{BA}{\rightarrow}} = \frac{(1+\beta+Y)^2}{32}.$$
 (15)

First, subtract (14) from (13) and simplify to find that the sign of $CS_A^* - CS_A^{AB}$ is the same as the sign of $1 + \alpha - X > 0$.

Second, subtract (15) from (14) and simplify to see that $CS_A^{AB} - CS_A^{BA}$ has the same sign as $X - Y + \alpha - \beta > 0$.

As a result we obtain the following ordering of the net consumer surplus in the big country A:

$$CS_A^* > CS_A^{AB} > CS_A^{BA} > CS_A^{BA}.$$
 (16)

Comparison of the consumer surplus in the small country. According to Lemmas 1, 2, and 3, possible payoffs to country B are

$$CS_B^* = \frac{k(1+\beta)^2}{8},$$
 (17)

$$CS_B^{\stackrel{AB}{\rightarrow}} = \frac{k(1+\alpha+X)^2}{32}, \quad \text{and} \quad (18)$$

$$CS_B^{BA} = \frac{k(1+\beta+Y)^2}{32}.$$
 (19)

First, subtract (19) from (17) and simplify to find that the sign of $CS_B^* - CS_B^{BA}$ is the same as the sign of $1 + \beta - Y > 0$.

Second, subtract (19) from (18) and simplify to see that $CS_B^{AB} - CS_B^{BA}$ has the same sign as $X - Y + \alpha - \beta > 0$.

Third, subtract (17) from (18) and simplify to find that $CS_B^{\stackrel{AB}{\rightarrow}} - CS_B^*$ has the same sign as $\alpha - \beta (1 + k(1 - \alpha))$, which is positive if $\beta < \frac{\alpha}{1 + k(1 - \alpha)}$.

As a result we obtain the following ordering of the net consumer surplus in the small country B:

$$CS_{B}^{AB} > CS_{B}^{*} > CS_{B}^{*} > CS_{B}^{BA} \quad \text{if} \quad 0 < \beta < \frac{\alpha}{1+k(1-\alpha)},$$

$$CS_{B}^{AB} = CS_{B}^{*} > CS_{B}^{BA} \quad \text{if} \quad \beta = \frac{\alpha}{1+k(1-\alpha)},$$

$$CS_{B}^{*} > CS_{B}^{AB} > CS_{B}^{BA} \quad \text{if} \quad \frac{\alpha}{1+k(1-\alpha)} < \beta < \alpha.$$

$$(20)$$

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