

Birg, Laura

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External reference pricing and the choice of country baskets and pricing rules

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**EXTERNAL REFERENCE PRICING AND
THE CHOICE OF COUNTRY
BASKETS AND PRICING RULES**

Laura Birg

GEORG-AUGUST-UNIVERSITÄT GÖTTINGEN

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External Reference Pricing and the Choice of Country Baskets and Pricing Rules

Laura Birg *

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Abstract

This paper models different external reference pricing schemes – a price cap based on the drug price in one or two countries and on the minimum or average drug price– in a three-country framework. It studies the choice of external reference pricing schemes in one country as well as its effect on welfare in the other countries, the manufacturer’s export decision, and the incentives for the other countries to also adopt an external reference pricing scheme. Depending on market size in the country adopting external reference pricing and market size difference of the other two countries, welfare is highest under the minimum price-rule or under the average price-rule. External reference pricing increases the drug price and decreases welfare in the other countries. If the market size in the country adopting an external reference pricing scheme is sufficiently large, the manufacturer does not export to the other countries. There is the incentive for the other countries also adopt external reference pricing.

JEL classification: F12, I11, I18

Keywords: external reference pricing

1 Introduction

This paper studies the design of external reference pricing schemes, i.e. the choice of reference countries and pricing rules in a three-country framework.

The increase in public health expenditure has induced a number of government interventions. Consequently, pharmaceutical markets are characterized by a variety of regulatory instruments that are partly overlapping and impede each other (see Espin

*Department of Economics, University of Göttingen, Platz der Göttinger Sieben 3, 37073 Göttingen, Germany, laura.birg@wiwi.uni-goettingen.de.

& Rovira, 2007 for an overview of regulatory interventions in the European Union). In general, pharmaceutical regulation follows two approaches: On the supply side, regulatory instruments such as price caps or maximum wholesale margins are intended to restrict monopoly pricing and reduce prices of covered products and services. On the demand side, instruments like reference prices or copayments aim at increasing price sensitivity and reducing reimbursement by the insurer. A commonly applied supply side instrument is external reference pricing, where the price cap for a drug is based on prices for the same product in other countries (Espin & Rovira, 2007). All European Union member states except the United Kingdom and Sweden apply external reference pricing¹, mainly for publicly reimbursed medicines (Toumi et al., 2013). External reference pricing schemes vary in the number of countries referred to and pricing rule. Historically, reference countries have been chosen according to economic comparability and/or geographic proximity, but over the last years, a trend towards larger country baskets has evolved (Toumi et al., 2013). Whereas Luxembourg refers to the price in one country and Croatia, Estonia, and Portugal refer to the price in three countries, Hungary and Poland set a price cap based on the price in 31 countries (Toumi et al., 2013). The reference price is mainly calculated as the average price in the reference countries, e.g. in Austria, Belgium, Cyprus, Denmark, Iceland, Ireland, Portugal, Switzerland, and the Netherlands (Toumi et al., 2013). Alternatively, some countries such as Bulgaria, Hungary, Italy, Romania, and Spain, use the lowest price in all the reference countries (Toumi et al., 2013).

External reference pricing makes pricing decisions for different countries interdependent and may result in a (downward) price convergence (Toumi et al., 2013). Stargardt & Schreyögg (2006) analyze the impact of a price change in Germany on pharmaceutical prices in other countries under external reference pricing. They find that, if the respective drug is sold in all referenced countries, a 1 Euro-price reduction in Germany will reduce maximum reimbursement prices from €0.15 in Austria to €0.36 in Italy, with the method applied to calculate the external reference price determining the impact. Price spillovers may induce firms to delay or even limit supply to low-price countries in order to (temporarily) retain high prices in other countries (Richter, 2008). Danzon, Wang & Wang (2005) who analyze launches of new drugs in 25 countries between 1994 and 1998, find that parallel exporting countries have fewer launches and longer launch delays. Moreover, Danzon & Epstein (2008), Verniers, Stremersch & Croux (2011), Costa-Font, McGuire & Varol (2014) suggest that stricter regulation and/or interdependence between

¹ Also non-European countries such as Australia, Canada, Japan, South Korea, Mexico, New-Zealand, and Turkey apply external reference pricing (Toumi et al., 2013).

countries lead to greater launch delays. Houy & Jelovac (2015) study timing decisions of pharmaceutical firms when launching a drug under external reference pricing. They find no incentive to delay the launch, when the countries only refer to the prices of a subset of all countries in a transitive way and in any period. Persson & Jönsson (2015) argue that applying external reference pricing is attractive, but costly, as it induces manufacturers to limit or delay launches and reduces the opportunities for price discrimination among countries.

Garcia Mariñoso, Jelovac & Olivella (2011) and Ackermann (2010) analyze the incentives for countries to adopt external reference pricing. Using a two-country framework, where the home country can either negotiate prices independently or adopt external reference pricing, while the foreign country negotiates the drug price with a pharmaceutical firm, Garcia Mariñoso, Jelovac & Olivella (2011) find that the home country prefers external reference pricing if copayments are relatively high. Using a two-country framework where countries differ in market size, Ackermann (2010) shows that a country prefers external reference pricing if its regulatory agency has considerably less bargaining power compared to the other country.

Against this background, this paper models different external reference pricing schemes – a price cap based on the drug price in one or two countries and on the minimum or average drug price – in a three-country framework. It studies the choice of external reference pricing schemes in one country as well as its effect on welfare in the other countries, the manufacturer’s export decision, and the incentives for the other countries to also adopt an external reference pricing scheme. Depending on market size in the country adopting external reference pricing and market size difference of the other two countries, welfare is highest under the minimum price-rule or under the average price-rule. External reference pricing increases the drug price and decreases welfare in the other countries. If the market size in the country adopting an external reference pricing scheme is sufficiently large, the manufacturer does not export to the other countries. There is the incentive for the other countries also adopt an external reference pricing scheme.

The rest of the paper is organized as follows. In the next section, the model is presented. Section 3 studies the regulatory scenarios. Section 4 analyzes the choice of regulatory schemes in one country, section 5 studies its effect on welfare in the other countries. Section 6 analyzes the choice of external reference pricing schemes on the manufacturer’s export decision. Section 7 studies incentives for the other countries to also adopt an external reference pricing scheme. Section 8 concludes.

2 The Model

Consider an innovative firm selling a drug in three countries, $j = A, B, C$. The firm is located in a fourth country.

Each consumer demands either one or zero units of the drug. The utility derived from no drug consumption is zero. A consumer i in country j who buys one unit of drug obtains a net utility of

$$U(\theta_{ij}, c_j) = \theta_{ij} - c_j, \quad (1)$$

where θ_{ij} is a preference parameter and c_j country-specific drug copayment. Assume that the parameter θ is uniformly distributed over the interval $[0, \mu_j]$ in country $j = A, B, C$, where $\mu_A, \mu_B \geq \mu_c = 1$. This is, countries differ in size. The parameter θ can be interpreted as willingness to pay, for instance due to differences in the severity of the condition, prescription practices or insurance coverage (see e.g. Brekke, Holmas & Straume, 2011) or it can be interpreted as income. In country j , health insurance reimburses a fraction of the drug price, the remaining fraction γ_j is paid by the patient. This is, the drug copayment is $c_j = \gamma_j p_j$.

Assume the following timing: In stage 1, the government in country A chooses the design of the external reference pricing scheme to maximize welfare. In stage 2, the firm sets prices.

3 Regulatory Scenarios

3.1 Free Price Setting

Consider first the case without regulation, when the manufacturer can set country-specific prices. The manufacturer sets country-specific prices p_j to maximize its profit in country j

$$\pi_j = \frac{\mu_j - \gamma_j p_j}{\mu_j} p_j. \quad (2)$$

The equilibrium price p_j in country j is

$$p_j = \frac{\mu_j}{2\gamma_j} \quad (3)$$

The manufacturer's profit from selling in country j is

$$\pi_j = \frac{\mu_j}{4\gamma_j}. \quad (4)$$

3.2 External Reference Pricing

Consider now the case that country A adopts external reference pricing.

3.2.1 One Reference Country

Consider first that country A sets a price cap based on the price in one country. Two cases are possible, the price cap can be based on the drug price in country B or on the drug price in country C. The choice between the two reference countries is considered exogenous at this point.

If the price cap is based on the price in country B, the manufacturer sets the price $p_B^{A=B}$ with $p_B^{A=B} = p_A^{A=B}$ to maximize its joint profit from countries A and B and the price p_C to maximize the profit from country C

$$\begin{aligned}\pi_A^{A=B} + \pi_B^{A=B} &= \left(\frac{(\mu_A - \gamma_A p_B^{A=B})}{\mu_A} + \frac{(\mu_B - \gamma_B p_B^{A=B})}{\mu_B} \right) p_B^{A=B}, \\ \pi_C^{A=B} &= (1 - \gamma_C p_C^{A=B}) p_C^{A=B}\end{aligned}\tag{5}$$

The equilibrium prices are

$$p_A^{A=B} = p_B^{A=B} = \frac{\mu_A \mu_B}{\gamma_B \mu_A + \gamma_A \mu_B}, \quad p_C^{A=B} = \frac{1}{2\gamma_C}\tag{6}$$

The manufacturer's profit is

$$\begin{aligned}\pi_A^{A=B} + \pi_B^{A=B} &= \frac{\mu_A \mu_B}{\gamma_A \mu_B + \mu_A \gamma_B}, \\ \pi_C^{A=B} &= \frac{1}{4\gamma_C}.\end{aligned}\tag{7}$$

If the price cap is based on the price in country C, the manufacturer sets the price $p_C^{A=C}$ with $p_C^{A=C} = p_A^{A=C}$ to maximize its joint profit from countries A and C and the price $p_B^{A=C}$ to maximize the profit from country B

$$\begin{aligned}\pi_A^{A=C} + \pi_C^{A=C} &= \left(\frac{(\mu_A - \gamma_A p_C^{A=C})}{\mu_A} + (1 - \gamma_C p_C^{A=C}) \right) p_C^{A=C}, \\ \pi_B^{A=C} &= \frac{(\mu_B - \gamma_B p_B^{A=C})}{\mu_B} p_B^{A=C}\end{aligned}\tag{8}$$

The equilibrium prices are

$$p_A^{A=C} = p_C^{A=C} = \frac{\mu_A}{\gamma_C \mu_A + \gamma_A}, \quad p_B^{A=C} = \frac{\mu_B}{2\gamma_B} \quad (9)$$

The manufacturer's profit is

$$\begin{aligned} \pi_A^{A=B} + \pi_C^{A=C} &= \frac{\mu_A}{\gamma_A + \mu_A \gamma_C}, \\ \pi_B^{A=C} &= \frac{\mu_B}{4\gamma_B}. \end{aligned} \quad (10)$$

3.2.2 Two Reference Countries, Minimum Price

Consider now that country A sets a price cap based on the minimum price in countries B and C.

If $\mu_B < \widehat{\mu}_B = \frac{\gamma_B}{\gamma_C}$, the price in country B is lower than in country C and the price cap is based on the drug price in country B. If $\mu_B > \widehat{\mu}_B = \frac{\gamma_B}{\gamma_C}$, the price in country C is lower than in country B and the price cap is based on the drug price in country C.

If $\mu_B < \widehat{\mu}_B$ and the price cap is based on the price in country B, the manufacturer sets the price p_B^{\min} with $p_B^{\min} = p_A^{\min}$ to maximize its joint profit from countries A and B and the price p_C^{\min} to maximize the profit from country C

$$\begin{aligned} \pi_A^{\min}|_{\mu_B < \widehat{\mu}_B} + \pi_B^{\min}|_{\mu_B < \widehat{\mu}_B} &= \left(\frac{(\mu_A - \gamma_A p_B^{\min})}{\mu_A} + \frac{(\mu_B - \gamma_B p_B^{\min})}{\mu_B} \right) p_B^{\min}, \\ \pi_C^{\min}|_{\mu_B < \widehat{\mu}_B} &= (1 - \gamma_C p_C) p_C \end{aligned} \quad (11)$$

The equilibrium prices are

$$\begin{aligned} p_A^{\min}|_{\mu_B < \widehat{\mu}_B} &= p_B^{\min}|_{\mu_B < \widehat{\mu}_B} = \frac{\mu_A \mu_B}{\gamma_B \mu_A + \gamma_A \mu_B}, \\ p_C^{\min}|_{\mu_B < \widehat{\mu}_B} &= \frac{1}{2\gamma_C} \end{aligned} \quad (12)$$

The manufacturer's profit is

$$\begin{aligned} \pi_A^{\min}|_{\mu_B < \widehat{\mu}_B} + \pi_B^{\min}|_{\mu_B < \widehat{\mu}_B} &= \frac{\mu_A \mu_B}{\gamma_A \mu_B + \mu_A \gamma_B}, \\ \pi_C^{\min}|_{\mu_B < \widehat{\mu}_B} &= \frac{1}{4\gamma_C}. \end{aligned} \quad (13)$$

For $\underline{\mu}_B^2 < \mu_B < \widehat{\mu}_B$ and $\widetilde{\mu}_A|_{\mu_B < \widehat{\mu}_B} < \mu_A < \widetilde{\mu}_A|_{\mu_B < \widehat{\mu}_B}^3$, the price ranking is intransitive: If the price cap is based on the drug price in country B, i.e. the price in B is the "minimum price", the drug price in country C is lower, but if the price cap is based on the drug price in country C, the drug price in country B is lower. Moreover, the resulting price is higher, if the price cap is based on the drug price in country C. Two assumptions for this intransitive price ranking are possible: i) The price cap is based on the drug price in country B. This is a reasonable outcome, if the government aims at the lowest price and accepts the violation of the minimum price-rule, if it anticipates this intransitive price ranking or if the minimum price-rule is based on ex-ante prices, i.e. prices before external reference pricing is implemented. ii) The price cap is based on the drug price in country C. This outcome can be expected if the government learns that the price in country C is lower, switches to basing the price cap on the price in country C, but does not switch back, either because it does not further observe prices in the market or because it learns about the intransitive price ranking. If there are multiple switches, either of these outcomes is possible. In what follows, both outcomes will be considered.

If $\mu_B > \widehat{\mu}_B$ and the price cap is based on the price in country C, the manufacturer sets the price p_C^{\min} with $p_C^{\min} = p_A^{\min}$ to maximize its joint profit from countries A and C and the price p_B^{\min} to maximize the profit from country B

$$\begin{aligned}\pi_A^{\min}|_{\mu_B > \widehat{\mu}_B} + \pi_C^{\min}|_{\mu_B > \widehat{\mu}_B} &= \left(\frac{(\mu_A - \gamma_A p_C^{A=C})}{\mu_A} + (1 - \gamma_C p_C^{\min}) \right) p_C^{\min}, \\ \pi_B^{\min}|_{\mu_B > \widehat{\mu}_B} &= \frac{(\mu_B - \gamma_B p_B)}{\mu_B} p_B\end{aligned}\quad (14)$$

The equilibrium prices are

$$\begin{aligned}p_A^{\min}|_{\mu_B > \widehat{\mu}_B} &= p_C^{\min}|_{\mu_B > \widehat{\mu}_B} = \frac{\mu_A}{\gamma_C \mu_A + \gamma_A}, \\ p_B^{\min}|_{\mu_B > \widehat{\mu}_B} &= \frac{\mu_B}{2\gamma_B}\end{aligned}\quad (15)$$

The manufacturer's profit is

$$\begin{aligned}\pi_A^{\min}|_{\mu_B > \widehat{\mu}_B} + \pi_C^{\min}|_{\mu_B > \widehat{\mu}_B} &= \frac{\mu_A}{\gamma_A + \mu_A \gamma_C}, \\ \pi_B^{\min}|_{\mu_B > \widehat{\mu}_B} &= \frac{\mu_B}{4\gamma_B}.\end{aligned}\quad (16)$$

² $\underline{\mu}_B = \frac{3\gamma_C}{5\gamma_B}$.

³ $\widetilde{\mu}_A|_{\mu_B < \widehat{\mu}_B} = \frac{\gamma_A \mu_B}{2\mu_B \gamma_C - \gamma_B}$, $\widetilde{\mu}_A|_{\mu_B < \widehat{\mu}_B} = \gamma_A \mu_B \frac{\gamma_B + \mu_B \gamma_C}{\gamma_B (5\mu_B \gamma_C - 3\gamma_B)}$.

For $\widehat{\mu}_B < \mu_B < \overline{\mu}_B^4$ and $\widetilde{\mu}_A|_{\mu_B > \widehat{\mu}_B} < \mu_A < \widetilde{\mu}_A|_{\mu_B > \widehat{\mu}_B}^5$ an intransitive price ranking occurs. If the price cap is based on the drug price in country C, i.e. the price in C is the "minimum price", the drug price in country B is lower, but if the price cap is based on the drug price in country B, the drug price in country C is lower. Similarly, two outcomes – price cap is based on the price in country C and the price cap is based on the price in country B – are reasonable and will be considered both in the following analysis.

3.2.3 Two Reference Countries, Average Price

Consider now that country A sets a price cap based on the average price in countries B and C. The manufacturer sets the prices p_B^{avg} and p_C^{avg} with $p_A^{avg} = \frac{1}{2}p_B^{avg} + \frac{1}{2}p_C^{avg}$ to maximize its joint profit from countries A, B, and C

$$\begin{aligned}
& \pi_A^{avg} + \pi_B^{avg} + \pi_C^{avg} \\
= & \frac{(\mu_A - \gamma_A p_A^{avg})}{\mu_A} p_A^{avg} \\
& + \frac{(\mu_B - \gamma_B p_B^{avg})}{\mu_B} p_B^{avg} \\
& + (1 - \gamma_C p_C^{avg}) p_C^{avg}.
\end{aligned} \tag{17}$$

Equilibrium prices are

$$\begin{aligned}
p_A^{avg} &= \frac{3\mu_A(\gamma_B + \mu_B\gamma_C)}{2(\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + 4\mu_A\gamma_B\gamma_C)} \\
p_B^{avg} &= \frac{3\mu_A\mu_B\gamma_C}{\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + 4\mu_A\gamma_B\gamma_C}, \\
p_C^{avg} &= \frac{3\mu_A\gamma_B}{\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + 4\mu_A\gamma_B\gamma_C}.
\end{aligned} \tag{18}$$

⁴ $\overline{\mu}_B = \frac{2\gamma_B}{\gamma_C}$.

⁵ $\widetilde{\mu}_A|_{\mu_B > \widehat{\mu}_B} = \frac{\gamma_A\mu_B}{2\gamma_B - \mu_B\gamma_C}$, $\widetilde{\mu}_A|_{\mu_B > \widehat{\mu}_B} = \gamma_A \frac{\gamma_B + \mu_B\gamma_C}{\gamma_C(5\gamma_B - 3\mu_B\gamma_C)}$.

The manufacturer's profit is

$$\begin{aligned}
\pi_A^{avg} + \pi_B^{avg} + \pi_C^{avg} &= \frac{3\mu_A(\gamma_B + \mu_B\gamma_C)(8\mu_A\gamma_B\gamma_C - \gamma_A\mu_B\gamma_C - \gamma_A\gamma_B)}{4(\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + 4\mu_A\gamma_B\gamma_C)^2}, \\
&+ \frac{3\mu_A\mu_B\gamma_C(\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + \mu_A\gamma_B\gamma_C)}{(\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + 4\mu_A\gamma_B\gamma_C)^2}, \\
&+ \frac{3\mu_A\gamma_B(\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + \mu_A\gamma_B\gamma_C)}{(\gamma_A\gamma_B + \gamma_A\mu_B\gamma_C + 4\mu_A\gamma_B\gamma_C)^2}. \tag{19}
\end{aligned}$$

4 Choice of Regulatory Schemes

Consider now the choice of the external reference pricing schemes, i.e. the choice of reference countries and pricing rules in a three-country framework. The government in country A chooses the regulatory scheme to maximize local welfare.

Welfare is given as

$$W_A = CS_A - E_A + \pi_A = \frac{(\mu_A^2 - \gamma_A^2 p_A^2)}{2\mu_A}$$

Local profits of the manufacturer are considered because it may result in tax revenues for the government and/or in jobs in country A. The same results would be obtained if profits were not considered at all.⁶ Welfare decreases in the price, so maximizing welfare is equivalent to minimizing the drug price.

If the government wants to minimize the drug price, referring to the drug price of one country only (either B or C) is not optimal, as it yields the same price as referring to the minimum price in countries B and C or yields a higher price. This is, in what follows the choice between free price setting, referring to two countries with a minimum price-rule, and referring to two countries with an average price-rule will be studied.

External reference pricing results in a lower drug price and higher welfare, if the market size in country A relative to the coinsurance rate is sufficiently large.⁷

For the choice between the external reference pricing schemes consider four cases.

⁶Then welfare is given as $W_A = CS_A - E_A = \frac{(\mu_A - p_A(2 - \gamma_A))(\mu_A - \gamma_A p_A)}{2\mu_A}$.

⁷In particular, for $\mu_B < \widehat{\mu}_B$ and the minimum price based on drug price in country B, the drug price under external reference pricing is lower than under free price setting if $p_A^{A=\min\{B,C\}} \leq p_A \iff \mu_A \geq \frac{\mu_A}{\gamma_B} \Big|_{\mu_B < \widehat{\mu}_B} = \frac{\gamma_A \mu_B}{\gamma_B}$. Similarly, for $\mu_B > \widehat{\mu}_B$ and the minimum price based on drug price in country C, the drug price under external reference pricing is lower than under free price setting if $p_A^{A=\min\{B,C\}} \leq p_A \iff \mu_A \geq \frac{\mu_A}{\gamma_C} \Big|_{\mu_B > \widehat{\mu}_B} = \frac{\gamma_A}{\gamma_C}$. If the price cap is based on average price, the drug price external reference pricing if $p_A^{A=avg\{B,C\}} \leq p_A \iff \mu_A \geq \frac{(\gamma_A \gamma_B + \gamma_A \mu_B \gamma_C)}{2\gamma_B \gamma_C}$.

First, if $\mu_B < \underline{\mu_B}$ ⁸ the minimum price-rule based on the drug price in country B yields the lowest drug price ($p_A^{\min} < p_A^{avg}$, $p_A^{\min} < p_A$). Second, if $\underline{\mu_B} < \mu_B < \widehat{\mu_B}$, for $\underline{\mu_A}|_{\mu_B < \widehat{\mu_B}}$ ⁹ $< \mu_A < \widehat{\mu_A}|_{\mu_B < \widehat{\mu_B}}$, the minimum price-rule based on the drug price in country B yields the lower drug price ($p_A^{\min} < p_A^{avg}$, $p_A^{\min} < p_A$), for $\widehat{\mu_A}|_{\mu_B < \widehat{\mu_B}} < \mu_A$, the average price-rule yields the lower drug price ($p_A^{avg} < p_A^{\min}$). If in case of the intransitive price ranking under the minimum price-rule the price cap is based on the drug price in country B, $\widehat{\mu_A}|_{\mu_B < \widehat{\mu_B}} = \widetilde{\mu_A}|_{\mu_B < \widehat{\mu_B}}$, if the price cap is based on the drug price in country C, $\widehat{\mu_A}|_{\mu_B < \widehat{\mu_B}} = \widetilde{\mu_A}|_{\mu_B < \widehat{\mu_B}}$.¹⁰ Third, if $\widehat{\mu_B} < \mu_B < \overline{\mu_B}$ ¹¹, for $\underline{\mu_A}|_{\mu_B > \widehat{\mu_B}}$ ¹² $< \mu_A < \widehat{\mu_A}|_{\mu_B > \widehat{\mu_B}}$, the minimum price-rule based on the drug price in country C yields the lower drug price ($p_A^{\min} < p_A^{avg}$, $p_A^{\min} < p_A$), for $\widehat{\mu_A}|_{\mu_B > \widehat{\mu_B}} < \mu_A$, the average price-rule yields the lower drug price ($p_A^{avg} < p_A^{\min}$). If in case of the intransitive price ranking under the minimum price-rule the price cap is based on the drug price in country C, $\widehat{\mu_A}|_{\mu_B > \widehat{\mu_B}} = \widetilde{\mu_A}|_{\mu_B > \widehat{\mu_B}}$, if the price cap is based on the drug price in country B, $\widehat{\mu_A}|_{\mu_B > \widehat{\mu_B}} = \widetilde{\mu_A}|_{\mu_B > \widehat{\mu_B}}$.¹³ Fourth, $\overline{\mu_B} < \mu_B$, the minimum price-rule based on the drug price in country C yields the lowest drug price ($p_A^{\min} < p_A^{avg}$, $p_A^{\min} < p_A$).

This is, for an intermediate market size in country A and a sufficiently small or large market in country B, the minimum price rule results in a lower drug price and higher welfare, for a sufficiently large market size in country A, the average price rule results in a lower drug price and higher welfare. Otherwise, the minimum price rule results in a lower drug price and higher welfare.

Proposition 1 summarizes the choice of regulatory schemes in country A:

Proposition 1 For i) $\mu_B < \underline{\mu_B}$, ii) $\underline{\mu_B} < \mu_B < \widehat{\mu_B}$ and $\underline{\mu_A}|_{\mu_B < \widehat{\mu_B}} < \mu_A < \widehat{\mu_A}|_{\mu_B < \widehat{\mu_B}}$, iii) $\widehat{\mu_B} < \mu_B < \overline{\mu_B}$ and $\underline{\mu_A}|_{\mu_B > \widehat{\mu_B}} < \mu_A < \widehat{\mu_A}|_{\mu_B > \widehat{\mu_B}}$ and iv) $\overline{\mu_B} < \mu_B$ welfare is highest under the minimum price-rule, for i) $\underline{\mu_B} < \mu_B < \widehat{\mu_B}$ and $\mu_A > \widehat{\mu_A}|_{\mu_B < \widehat{\mu_B}}$, ii) $\widehat{\mu_B} < \mu_B < \overline{\mu_B}$ and $\mu_A > \widehat{\mu_A}|_{\mu_B > \widehat{\mu_B}}$ welfare is highest under the average price-rule.

$$8 \underline{\mu_B} = \frac{3\gamma_C}{5\gamma_B}.$$

$$9 \underline{\mu_A}|_{\mu_B < \widehat{\mu_B}} = \frac{\gamma_A \mu_B}{\gamma_B}.$$

$$10 \widehat{\mu_A}|_{\mu_B < \widehat{\mu_B}} = \frac{\gamma_A \mu_B}{2\mu_B \gamma_C - \gamma_B}, \widetilde{\mu_A}|_{\mu_B < \widehat{\mu_B}} = \gamma_A \mu_B \frac{\gamma_B + \mu_B \gamma_C}{\gamma_B (5\mu_B \gamma_C - 3\gamma_B)}.$$

$$11 \overline{\mu_B} = \frac{2\gamma_B}{\gamma_C}.$$

$$12 \underline{\mu_A}|_{\mu_B > \widehat{\mu_B}} = \frac{\gamma_A}{\gamma_C}$$

$$13 \widehat{\mu_A}|_{\mu_B > \widehat{\mu_B}} = \frac{\gamma_A \mu_B}{2\gamma_B - \mu_B \gamma_C}, \widetilde{\mu_A}|_{\mu_B > \widehat{\mu_B}} = \gamma_A \frac{\gamma_B + \mu_B \gamma_C}{\gamma_C (5\gamma_B - 3\mu_B \gamma_C)}.$$

5 Effect on Welfare in Countries B and C

This section studies the effect of the choice of regulatory scheme in country A on the drug price and welfare in countries B and C. The effect of the regulatory scheme in country A on the drug price and welfare in countries B and C is similar, so consider the effect in country B in what follows. In principle, the same results hold for country C.

Welfare in country B is given as

$$W_B = CS_B - E_B + \pi_B = \frac{\mu_B^2 - \gamma_B^2 p_B^2}{2\mu_B}. \quad (20)$$

As welfare decreases in the price, lower drug prices increase welfare, while higher prices decrease welfare.

Under both the minimum price-rule and the average price-rule, the drug price in country B is higher than under free pricing ($p_B^{\min} > p_B$, $p_B^{avg} > p_B$). The drug price in country B is higher under the average price-rule than under the minimum price-rule, if $\mu_A < \widehat{\mu}_A$ ¹⁴, with $\widehat{\mu}_A < \widehat{\mu}_A|_{\mu_B < \widehat{\mu}_B}$ and $\widehat{\mu}_A < \widehat{\mu}_A|_{\mu_B > \widehat{\mu}_B}$. This is, $\mu_A < \widehat{\mu}_A$, country A chooses the minimum price-rule and in both countries A and B, drug prices are lower than under the average price-rule. For $\widehat{\mu}_A < \mu_A < \widehat{\mu}_A|_{\mu_B < \widehat{\mu}_B}$ and $\widehat{\mu}_A < \mu_A < \widehat{\mu}_A|_{\mu_B > \widehat{\mu}_B}$, country A chooses the minimum price-rule and in country A, the drug price is lower than under the average price-rule, while in country B the drug price is higher than it would be under the average price-rule. For $\mu_A > \widehat{\mu}_A|_{\mu_B < \widehat{\mu}_B}$ and $\mu_A > \widehat{\mu}_A|_{\mu_B > \widehat{\mu}_B}$, country A chooses the average price-rule and in both countries A and B, drug prices are lower than under the minimum price-rule.

Proposition 2 summarizes the effect of the choice of regulatory scheme in country A on welfare in country B:

Proposition 2 *If country A adopts the minimum price-rule or the average price-rule, welfare in country B is lower than under free pricing in country A.*

6 Endogenous Export Decision

Consider now that the firm may adjust its export decision to the choice of regulatory schemes in country A. In particular, it may refrain from exporting to one of the countries, if a low price may spill over to a high price country. The effect of the regulatory scheme

¹⁴ $\widehat{\mu}_A < \gamma_A \frac{2\mu_B\gamma_C - \gamma_B}{\gamma_B\gamma_C}$, $\widehat{\mu}_A < 0$ if $\mu_B > \frac{\gamma_B}{2\gamma_C}$.

in country A on the decision to export to country B or C is similar, so consider the effect in country B in the following.

For $\mu_B < \widehat{\mu}_B$ and $\left. \frac{\mu_A}{\mu_B} \right|_{\mu_B < \widehat{\mu}_B}^{15} < \mu_A < \widehat{\mu}_A|_{\mu_B \leq \widehat{\mu}_B}$, country A adopts the minimum price-rule and the drug price in country A is based on the drug price in country B. The firm decides to not to export to country B (with the minimum price based on the drug price in country C then), if $\pi_A^{\min}|_{\mu_B > \widehat{\mu}_B} + \pi_C^{\min}|_{\mu_B > \widehat{\mu}_B} > \pi_A^{\min}|_{\mu_B < \widehat{\mu}_B} + \pi_B^{\min}|_{\mu_B < \widehat{\mu}_B} + \pi_C^{\min}|_{\mu_B < \widehat{\mu}_B}$, which is the case if $\mu_A > \mu_A^*$ ¹⁶. This increases the drug price in country A and C. The firm decides to export neither to country B or C, if $\pi_A > \pi_A^{\min}|_{\mu_B > \widehat{\mu}_B} + \pi_C^{\min}|_{\mu_B > \widehat{\mu}_B}$, which is the case if $\mu_A > \mu_A^{**}$ ¹⁷. This increases the drug price in country A. For $\mu_A > \widehat{\mu}_A|_{\mu_B < \widehat{\mu}_B}$, country A adopts the average price-rule. The firm decides to not to export to country B and C, if $\pi_A > \pi_A^{avg} + \pi_B^{avg} + \pi_C^{avg}$, which is the case if $\mu_A > \mu_A^{***}$ ¹⁸. This increases the drug price in country A.

Proposition 3 summarizes the effect of the choice of regulatory scheme in country A on the export decision of the firm:

Proposition 3 *If country A adopts the minimum price-rule, the firm does not export to country B (countries B and C) if $\mu_A > \mu_A^*$ ($\mu_A > \mu_A^{**}$). If country A adopts the average price-rule, the firm does not export to countries B and C if $\mu_A > \mu_A^{***}$.*

7 Mutual Referencing

Consider now that not only country A, but all countries may adopt external reference pricing schemes. Consider symmetric regulatory scenarios, where countries adopt the same regulatory scheme.

7.1 One Reference Country

If countries set a price cap based on the price in one other country, two scenarios are possible.

¹⁵ $\left. \frac{\mu_A}{\mu_B} \right|_{\mu_B < \widehat{\mu}_B} = \frac{\gamma_A \mu_B}{\gamma_B}$.

¹⁶ $\mu_A^* = \frac{1}{2} \frac{\gamma_A (\gamma_B + \mu_B \gamma_C + \sqrt{(\gamma_B - \mu_B \gamma_C)(\gamma_B + 15\mu_B \gamma_C)})}{3\gamma_B \gamma_C - 4\mu_B \gamma_C^2}$, $\mu_A^* > 0$ if $3\gamma_B \gamma_C - 4\mu_B \gamma_C^2 > 0$. $\widetilde{\mu}_A|_{\mu_B \leq \widehat{\mu}_B} > \mu_A^*$ if $\mu_B > \frac{3}{4} \frac{\gamma_B}{\gamma_C} \vee \frac{1}{2} \frac{\gamma_B}{\gamma_C} < \mu_B < \widetilde{\mu}_B$, where $\widetilde{\mu}_B$ is the solution to $10\mu_B^2 \gamma_C^2 - \gamma_B^2 - 5\gamma_B \mu_B \gamma_C - \sqrt{\gamma_B^2 - 15\mu_B^2 \gamma_C^2 + 14\gamma_B \mu_B \gamma_C} (\gamma_B - 2\mu_B \gamma_C)$.

$\widetilde{\mu}_A|_{\mu_B \leq \widehat{\mu}_B} > \mu_A^*$ if $\mu_B > \frac{3}{4} \frac{\gamma_B}{\gamma_C} \vee \frac{3}{5} \frac{\gamma_B}{\gamma_C} < \mu_B < \widetilde{\mu}_B$, where $\widetilde{\mu}_B$ is the solution to $(\gamma_B + \mu_B \gamma_C) (-3\gamma_B^2 - \gamma_B \mu_B \gamma_C + 8\mu_B^2 \gamma_C^2) - \sqrt{(\gamma_B + 15\mu_B \gamma_C)(\gamma_B - \mu_B \gamma_C)} \gamma_B (3\gamma_B - 5\mu_B \gamma_C)$.

¹⁷ $\mu_A^{**} = \frac{3\gamma_A}{\gamma_C}$. $\widetilde{\mu}_A|_{\mu_B \leq \widehat{\mu}_B} > \mu_A^{**}$ if $\mu_B < \frac{\gamma_B}{2\gamma_C}$. $\widetilde{\mu}_A|_{\mu_B \leq \widehat{\mu}_B} > \mu_A^*$ if $\mu_B < \frac{1}{\gamma_C} (7\gamma_B - 2\sqrt{10}\gamma_B)$.

¹⁸ $\mu_A^{***} = 2\gamma_A \frac{\gamma_B + \mu_B \gamma_C}{\gamma_B \gamma_C}$.

i) Only one country sets a price cap based on the price in another country or two countries refer to each other. Then the manufacturer sets the same drug price in these two countries, while he can set the price in the third country freely. This case is similar to the one studied in section 3.2.1.

ii) Countries circularly refer to another country. Then the manufacturer sets the same drug price in all three countries.

In case ii), the firm sets a uniform price p for all three countries to maximize its profit

$$\pi = \left(\frac{(\mu_A - \gamma_A p)}{\mu_A} + \frac{(\mu_B - \gamma_B p)}{\mu_B} + (1 - \gamma_C p) \right) p. \quad (21)$$

The equilibrium price is

$$p = \frac{3\mu_A\mu_B}{2(\gamma_A\mu_B + \mu_A\gamma_B + \mu_A\mu_B\gamma_C)}. \quad (22)$$

The equilibrium profit is

$$\pi = \frac{9\mu_A\mu_B}{4(\gamma_A\mu_B + \mu_A\gamma_B + \mu_A\mu_B\gamma_C)} \quad (23)$$

In case i), if country A refers to the price in country B (or C), there is no incentive or disincentive for country B (or C) to refer back to the price in country A, as this has no effect on drug price in the respective country. But if country A refers to the price in country B, there is the incentive for country C to also refer to the price in country A or B, as it would result in a lower drug price in country C ($p < p_C$ for $\mu_A < \widehat{\mu}_A|_{\mu_B < \widehat{\mu}_B}$).

7.2 Two Reference Countries, Minimum Price

If countries set a price cap based on the minimum price in two other countries, three cases are possible.

i) Only one country adopts the minimum price-rule and refers to the drug prices in the two other countries. The manufacturer can set the price in the third country freely. This case is similar to the one studied in section 3.2.2., except that it refers to a different country.

ii) Two countries adopt the minimum price-rule and prices are in these countries are lower than in the third country. The manufacturer can set the price in the third country freely. This case is similar to the one studied in section 3.2.2.

iii) All countries adopt the minimum price-rule and the manufacturer sets the same drug price in all three countries. This is the case studied in section 7.1 ii).

If country A adopts the minimum price-rule and refers to the minimum price in country B or C, there is no incentive for the country with the lower price (B or C) to also adopt the minimum price-rule, as the outcome in case i) and ii) is the same. But for the third country, say country C, if $\mu_B < \widehat{\mu}_B$, there is the incentive to also adopt the minimum price-rule, as it would result in a lower drug price ($p < p_B$ for $\mu_A < \widehat{\mu}_A|_{\mu_B > \widehat{\mu}_B}$, $p < p_C$ for $\mu_A < \widehat{\mu}_A|_{\mu_B < \widehat{\mu}_B}$).

7.3 Two Reference Countries, Average Price

If countries set a price cap based on the average price in two other countries, three cases are possible.

- i) Only one country adopts the average price-rule. This case is similar to the one studied in section 3.2.3.
- ii) Two countries adopt the average price-rule. Then the manufacturer sets the same drug price in all three countries. This is the case studied in section 7.1 ii).
- iii) All countries adopt the average price-rule and the manufacturer sets the same drug price in all three countries. This is the case studied in section 7.1 ii).

If country A adopts the average price-rule, there is the incentive to also adopt the average price rule for the "larger" country with the higher drug price, as it would result in a lower drug price ($p < p_B^{avg}$ for $\mu_B > \widehat{\mu}_B$, $p < p_C^{avg}$ for $\mu_B < \widehat{\mu}_B$).

This is, independent of which regulatory scheme country A chooses, there is the incentive for the third country or the country with the higher price to also adopt an external reference pricing scheme.

Also, independent of which regulatory scheme country A chooses in the first place, the outcome is the same in all cases: uniform pricing for all three countries. This also implies that independent of which external reference pricing scheme the other countries choose, uniform pricing is the outcome. The incentive for other countries to also adopt an external reference pricing scheme holds for symmetric and asymmetric cases.

If country A adopts the minimum price-rule, a switch to uniform pricing (because country B or C also adopt an external reference pricing scheme) increases the drug price in country A ($p > p_A^{\min}|_{\mu_B < \widehat{\mu}_B}$, $p > p_A^{\min}|_{\mu_B > \widehat{\mu}_B}$). If country A adopts the average price-rule, a switch to uniform pricing decreases the drug price in country A ($p < p_A^{avg}$).

Proposition 4 summarizes the incentive for the other countries to also adopt an external reference pricing scheme:

Proposition 4 *If country A adopts an external reference pricing scheme, there is the incentive for the third country or country with the higher drug price to also adopt ex-*

ternal reference pricing. If all countries adopt an external reference pricing scheme, the manufacturer sets a uniform drug price for all three countries.

8 Conclusion

In this paper, I have modelled different external reference pricing schemes – a price cap based on the drug price in one or two countries and on the minimum or average drug price– in a three-country framework. It studies the choice of external reference pricing schemes in one country as well as its effect on welfare in the other countries, the manufacturer’s export decision, and the incentives for the other countries to also adopt an external reference pricing scheme. Depending on market size in the country adopting external reference pricing and market size difference of the other two countries, welfare is highest under the minimum price-rule or under the average price-rule. External reference pricing increases the drug price and decreases welfare in the other countries. This is, there is a negative impact of regulation in one country on welfare in the other countries. Country A reduces the drug price and increase welfare at the expense of other countries.

If the market size in the country adopting an external reference pricing scheme is sufficiently large, the manufacturer does not export to the other countries. This result is in line with the observation that external reference pricing might induce launch delays in or limited supply to other countries. In the case of the manufacturer not exporting to the other countries, external reference pricing has no effect on the drug price in country A, but has an effect on the welfare in the other countries, namely that the drug is not available there.

Under external reference pricing in country A, there is the incentive for the other countries also adopt an external reference pricing scheme. This is, there is regulatory convergence. Only if country A adopts the average price-rule, there is also price convergence, with the uniform drug price being lower than the drug price under the average price-rule in country A. If country A adopts the minimum price-rule, the switch of the other countries to external reference pricing decreases the drug price in the respective country, but increases the drug price in country A. This suggests that external reference pricing does not necessarily result in a downward price trend.

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