

Birg, Laura

Article — Published Version

The design of external reference pricing schemes and the choice of reference countries and pricing rules

Canadian Journal of Economics/Revue canadienne d'économique

Suggested Citation: Birg, Laura (2024) : The design of external reference pricing schemes and the choice of reference countries and pricing rules, Canadian Journal of Economics/Revue canadienne d'économique, ISSN 1540-5982, Vol. 57, Iss. 4, pp. 1182-1202, <https://doi.org/10.1111/caje.12744>

This Version is available at:

<https://hdl.handle.net/10419/313811>

Standard-Nutzungsbedingungen:

Die Dokumente auf EconStor dürfen zu eigenen wissenschaftlichen Zwecken und zum Privatgebrauch gespeichert und kopiert werden.

Sie dürfen die Dokumente nicht für öffentliche oder kommerzielle Zwecke vervielfältigen, öffentlich ausstellen, öffentlich zugänglich machen, vertreiben oder anderweitig nutzen.

Sofern die Verfasser die Dokumente unter Open-Content-Lizenzen (insbesondere CC-Lizenzen) zur Verfügung gestellt haben sollten, gelten abweichend von diesen Nutzungsbedingungen die in der dort genannten Lizenz gewährten Nutzungsrechte.

Terms of use:

Documents in EconStor may be saved and copied for your personal and scholarly purposes.


You are not to copy documents for public or commercial purposes, to exhibit the documents publicly, to make them publicly available on the internet, or to distribute or otherwise use the documents in public.

If the documents have been made available under an Open Content Licence (especially Creative Commons Licences), you may exercise further usage rights as specified in the indicated licence.



<http://creativecommons.org/licenses/by-nc/4.0/>

The design of external reference pricing schemes and the choice of reference countries and pricing rules

Laura Birg 

Ruhr-University Bochum

Abstract. External reference pricing imposes a price cap for drugs based on prices in other countries. I study the choice of reference countries and pricing rules in a three-country framework. If the manufacturer sells to all three countries, the minimum price rule yields the lowest drug price. If the referencing country is sufficiently large, the manufacturer may not export to reference countries under the minimum price rule. External reference pricing creates the incentive for the reference countries also to adopt external reference pricing. Thus, external reference pricing results in price convergence.

Résumé. La conception des structures de prix de référence externe et le choix des pays de référence et des règles d'établissement des prix. Un prix de référence externe impose un plafond tarifaire aux médicaments selon les prix fixés dans les autres pays. J'étudie le choix des pays de référence et des règles d'établissement des prix, dans un cadre à trois pays. Si le fabricant vend un médicament dans les trois pays, la règle du prix minimum produit le prix le plus faible pour le médicament. Si le pays de référence est suffisamment grand, le fabricant peut décider de ne pas exporter vers les autres pays de référence pour un prix moindre. Le prix de référence externe crée ainsi un incitatif pour les pays de référence afin qu'ils adoptent un prix de référence externe. Par conséquent, le prix de référence externe entraîne une convergence des prix.

JEL classification: L51, I11, I18, F12

1. Introduction

A WIDELY USED INSTRUMENT IN PHARMACEUTICAL price regulation is external reference pricing, which imposes a price cap for drugs based on their prices in other countries (Espin and Rovira 2007). That is, external reference pricing follows the idea that prices in different countries may be compared. It is an easily applicable regulatory instrument, which requires no (additional) information, e.g., on the therapeutic value of a drug. Under external reference pricing, countries do not regulate domestic pharmaceutical prices directly. They merely determine the price(s) on which the domestic price is to be based. The domestic price results from the supplier's pricing in the respective (referenced) markets. Thus, the price cap is effectively set by the supplier. But hereby the supplier can no longer set prices in different countries independently, but must consider a common pricing strategy.

In principle, a country can choose to refer to only reference country or to construct the reference price with reference to several countries. In the first case, the price in the reference country is the reference price. In the second case, information from several countries can

Corresponding author: Laura Birg, laura.birg@ruhr-uni-bochum.de

At the time of writing, the author was affiliated with the universities of Bremen and Bochum. No financial support was received for this paper, and the author declares no conflict of interest. Open Access funding enabled and organized by Projekt DEAL.

Canadian Journal of Economics / *Revue canadienne d'économie* 2024 57(4)
November 2024. / *Novembre 2024*.

24 / pp. 1182–1202 / DOI: 10.1111/caje.12744

© The Author(s). Canadian Journal of Economics/Revue canadienne d'économie published by Wiley Periodicals LLC on behalf of Canadian Economics Association.

This is an open access article under the terms of the [Creative Commons Attribution-NonCommercial](https://creativecommons.org/licenses/by-nc/4.0/) License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited and is not used for commercial purposes.

be used. However, this also requires an aggregation rule on how the prices in the reference countries are converted into the reference price. Two aggregation rules are considered in this paper: The minimum rule and the average price rule.

External reference pricing is applied in many countries around the globe, e.g., Australia, Canada, Japan, South Korea, Mexico, New Zealand and Turkey (Toumi et al. 2013, Schneider and Vogler 2019). Also, almost all European countries apply external reference pricing, with schemes varying in the number of reference countries and pricing rules. For instance, Portugal refers to prices in three other countries, while Italy uses 24 reference countries (Schneider and Vogler 2019).¹ In Austria, Belgium, the Netherlands and Portugal, the reference price is calculated as the average drug price in the reference countries, while Denmark and Spain use the lowest price in the reference countries (Schneider and Vogler 2019).

Given that many countries apply reference pricing, refer to different countries and apply different aggregation rules, two interdependencies are interesting to analyze: at the government level, the introduction of a reference price in one country leads to incentives for other countries to introduce reference prices as well. Another interdependence concerns the producer: the introduction of reference pricing systems changes the producer's incentive to supply countries.

My contribution is three-fold. First, I explore the design of external reference pricing schemes, especially the choice of reference countries and pricing rules, which has not been studied so far. In this part of the analysis, I assume that a country first determines which external reference pricing scheme it applies and then the firm sets the prices in all countries. Second, I contribute to the literature on the effect of external reference pricing on launch delays² by studying the choice of external reference pricing scheme under an endogenous export decision of the manufacturer. The manufacturer decides which countries to export to after the countries have decided on the external reference pricing schemes. The decision of a manufacturer not to sell to some countries may limit the effective set of reference countries and pricing rules. Third, I analyze the incentives for reference countries also to adopt simultaneously external reference pricing schemes. Since reference pricing makes drug prices interdependent, it may also make reference pricing regimes interdependent: one country applying external reference pricing may incentivize other countries to immediately follow.

I show that, given that the manufacturer sells to all three countries, the minimum price rule yields the lowest drug price in the referencing country. If the referencing country is sufficiently large, the manufacturer may decide not to export to reference countries under the minimum price rule. That is, under external reference pricing, direct launch delays may occur when a manufacturer does not export to a country with low prices due to strict regulation to avoid the spillover of low prices to high-price countries. But also the choice of a pricing rule in the referencing country may provoke indirect launch delays when a manufacturer does not export to a reference country under the minimum price rule in a referencing country because it results in stronger spillovers of prices and higher price concessions. In Europe, many countries apply the average price rule, for instance, Austria, Ireland, the Netherlands and Portugal. One potential explanation for this practice is that these countries—and

1 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).

2 As the model in this paper is static, only non-launches, not launch delays can be studied. However, because the two phenomena are closely related and, empirically, launch delays are the more relevant problem compared with actual non-launches, the term launch delay is used in the text.

the countries they reference to—are rather different in willingness to pay, and thus prices. Indirect launch delays could be possible under the minimum price rule.

Moreover, the paper shows that external reference pricing may create the incentive for the reference countries also to adopt external reference pricing. Thus, external reference pricing results in regulatory convergence and a uniform price among all countries, i.e., price convergence. The widespread use of external reference pricing in Europe seems to be in line with this incentive for other countries also to adopt external reference pricing. The empirical evidence for price convergence in the European Union, however, is mixed (Kyle 2019). Also, the manufacturer's decision not to export to potential reference countries may counteract regulatory and thus price convergence.

There is a rich literature on external reference pricing. Garcia Mariñoso et al. (2011) and Ackermann (2010) analyze incentives for countries to adopt external reference pricing in a two-country framework. A country prefers external reference pricing against individual price negotiations with a firm under high copayments (Garcia Mariñoso et al. 2011) or low bargaining power of its regulatory agency (Ackermann 2010).

By making pricing decisions for different countries interdependent, external reference pricing may result in a (downward) price convergence (Toumi et al. 2013). Stargardt and Schreyögg (2006) study the impact of a price change in Germany on pharmaceutical prices in other countries under external reference pricing. They show that a €1-price reduction in Germany reduces prices from €0.15 in Austria to €0.36 in Italy.

These price spillovers may induce firms to delay or even limit supply to low-price countries to (temporarily) retain high prices in other countries (Richter 2008). Danzon et al. (2005), who analyze launches of new drugs in 25 countries between 1994 and 1998, find that parallel exporting countries with relatively low drug prices have fewer launches and longer launch delays. Moreover, Danzon and Epstein (2012), Verniers et al. (2011) and Costa-Font et al. (2014) suggest that stricter regulation and/or interdependence between countries lead to greater launch delays. Also Cockburn et al. (2016) find that countries with stringent pharmaceutical price controls face a notable increase in the time it takes for new drugs to reach the market.

Houy and 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 and Jönsson (2016) argue that applying external reference pricing may be attractive but may also induce manufacturers to limit or delay launches and it reduces opportunities for price discrimination among countries. Maini and Pammolli (2017), who analyze the impact of external reference pricing on launch delays, document the presence of launch delays across Europe, especially in Eastern Europe. They show that removing external reference pricing would reduce delays in Eastern Europe by up to 14 months. Houy and Jelovac (2019) study the effect of drug approval procedures on launch decisions of pharmaceutical firms under external reference pricing, showing that a centralized drug approval procedure limits the number of countries in which a firm launches a drug.

This paper extends this line of research by showing that external reference pricing can induce launch delays, with the risk of delay varying according to the relative size of the referenced country. Thus, it is not only the level of price regulation within a country that can contribute to launch delays but also whether that country is used as a reference and the size of its market.

Parallel trade, the cross border resale of goods without the authorization of the manufacturer (Maskus 2000), can be considered a related instrument because it also generates price spillovers and may result in launch delays and price convergence (Kyle 2007). While parallel trade can be seen as a form of competition and is driven mostly by the pricing strategies of

pharmaceutical manufacturers, external reference pricing can be considered a form of regulation and is determined by regulatory choices of governments, e.g., the choice of reference countries and pricing rules. Brekke et al. (2015) show that the presence of parallel imports affects the effect of price regulation. Although parallel imports and external reference pricing are therefore related instruments and it can be assumed that they interact, this paper will abstract from parallel trade for reasons of analytical clarity.

The rest of the paper is organized as follows. Section 2 presents the model. Section 3 studies the regulatory scenarios. Section 4 analyzes the choice of regulatory schemes in one country, while section 5 analyzes the choice of an external reference pricing schemes on the manufacturer's export decision. Sections 6 and 7 study the effect of external reference pricing on drug prices in reference countries and thus the incentives for other countries to also adopt an external reference pricing scheme. Section 8 discusses dynamic efficiency and bargaining between the firm and governments. Section 9 concludes.

2. Model

Consider an innovative firm selling an on-patent drug in three countries, $j = A, B, C$. Assume that the drug manufacturer is located in a fourth country. The firm produces at constant marginal cost, which is normalized to zero. For the moment, the decision to supply these countries is exogenous. The decision to supply will be endogenized later in the paper. The fact that all three countries are supplied does not necessarily mean that the whole world is supplied. It is conceivable that there are other countries that are supplied and those that are not. For the purpose of the following analysis, it is only important that the decision to supply other countries is independent of the decision to supply countries j .

In all three countries, third-party payers cover drug costs partially. Consider that consumers pay a fraction γ_j , $\gamma_j \in (0, 1)$, of the drug price out-of-pocket (coinsurance). Thus, the drug copayment and the effective price for consumers is $c_j = \gamma_j p_j$. Third-party payers reimburse a fraction $(1 - \gamma_j) p_j$ of the drug price. Reimbursement and the role of third-party payers in financing the drug create an incentive for governments to decrease public cost.³

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 the drug obtains a net utility of

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

where θ_{ij} is a preference parameter, γ_j is the coinsurance rate and p_j is the drug price in country j .

Consumers differ in the preference parameter θ , which may be interpreted as willingness to pay. Heterogeneity among consumers may stem from differences in income or in the severity of the condition or prescription practices (see, e.g., Brekke et al. Straume 2011). Assume that the parameter θ is uniformly distributed over the interval $[0, \mu_j]$ in country j . The parameter μ_j can be interpreted as the maximum willingness to pay.⁴ The total mass of consumers in each country is one. Let $\beta_j = \frac{\gamma_j}{\mu_j}$ denote the coinsurance rate relative to the maximum willingness to pay for simplification. I will refer to β_j as the normalized

3 Also, welfare maximization or increasing consumer surplus may motivate regulating drug prices.

4 Following the interpretation of θ as income, a country with a high μ_j could be labelled as high-income country and a country with a low μ_j could be labelled as low-income country.

coinsurance rate. A higher β_j indicates, therefore, a higher coinsurance rate γ_j and/or a lower maximum willingness to pay μ_j .

Assume $\beta_A < \beta_B < \beta_C$ with $\mu_C = 1$, implying that, in absence of external reference pricing, country *A* is a high-price country, country *B* a medium-price country and country *C* a low-price country.

The marginal consumer in country *j* who is indifferent between buying the drug or not has a gross valuation $\hat{\theta}_j = \gamma_j p_j$. Hence, demand in country *j* is given as $q_j = 1 - \beta_j p_j$.

In this setup, there are two sources of differences between countries. First, countries differ in maximum willingness to pay. Second, countries differ in price elasticity of demand (due to differences in coinsurance rates). These differences are captured by differences in β_j . They generate differences in drug prices, providing the incentive for governments to implement price caps based on the price in another country (external reference pricing).

Consider the following timing in the basic model. In stage 1, the government in country *A* chooses the external reference pricing scheme anticipating the reaction of the firm. In stage 2, the manufacturer sets prices knowing the decision of the government in the first stage.

3. Choice of prices: Second-stage outcome

In this section, I study the manufacturer's pricing decision for a given regulatory setting. Based on this, the effect of the choice of an external reference pricing scheme will then be investigated in the following section. Conditions for equilibrium existence can be found in appendix A1.

3.1. Coinsurance

Consider first the case of coinsurance and no regulation. The manufacturer may price discriminate, i.e., set country-specific prices. An asterisk denotes variables under coinsurance.

The manufacturer sets country-specific prices p_j^* to maximize its profit:

$$\pi = \sum_{j \in A, B, C} (1 - \beta_j p_j^*) p_j^*. \quad (2)$$

The equilibrium price p_j in country *j* is

$$p_j^* = \frac{1}{2\beta_j}. \quad (3)$$

The price p_j in country *j* decreases in β_j , increases in the maximum willingness to pay μ_j and decreases in the coinsurance rate γ_j . Thus, price differences between countries are driven by differences in maximum willingness to pay μ_j and coinsurance rates γ_j .

The manufacturer's profit from selling in country *j* is

$$\pi_j^* = \frac{1}{4\beta_j}. \quad (4)$$

3.2. External reference pricing: Regulatory scenarios

Consider now the case where the government in country *A* adopts external reference pricing in the first stage. I study the following external reference pricing schemes. Note that if multiple countries are referenced, an aggregation rule is required.

- One reference country (*B*), denoted as *B*. This scheme imposes a price cap $P_A^B = p_B$.

- One reference country (C), denoted as C . This scheme imposes a price cap $P_A^C = p_C$.
- Two reference countries, denoted as $minj$. This scheme imposes a price cap $P_A^{min} = \min\{p_B, p_C\}$.
- Two reference countries, denoted as avg . This scheme imposes a price cap $P_A^{avg} = \frac{1}{2}p_B + \frac{1}{2}p_C$.

3.2.1. One reference country

Consider first that the government in country A sets a price cap based on the price in one country in the first stage. Assume that the other countries do not set price caps. Two cases are possible: the price cap may be based on (i) the drug price in country B (scheme B) or (ii) the drug price in country C (scheme C). The choice between the two reference countries is considered to be exogenous at this point.

Under scheme B , the manufacturer sets prices in the second stage to maximize profit given the price cap in country A based on the price in country B .

$$\begin{aligned}\pi^B &= (1 - \beta_A p_A^B) p_A^B + (1 - \beta_B p_B^B) p_B^B + (1 - \beta_C p_C^B) p_C^B \\ \text{s.t. } p_A^B &\leq P_A^B = p_B^B.\end{aligned}\quad (5)$$

Best response prices are

$$p_A^B = p_B^B = \frac{1}{\beta_A + \beta_B}, \quad p_C^B = \frac{1}{2\beta_C}. \quad (6)$$

The manufacturer's profit is

$$\pi^B = \frac{1}{\beta_A + \beta_B} + \frac{1}{4\beta_C}. \quad (7)$$

The imposed price cap P_A^B is binding, i.e., $p_A^B < p_A^*$ as $\beta_A < \beta_B$. The scheme B decreases the drug price in country A .

Under scheme C , the manufacturer sets prices to maximize

$$\begin{aligned}\pi^C &= (1 - \beta_A p_A^C) p_A^C + (1 - \beta_B p_B^C) p_B^C + (1 - \beta_C p_C^C) p_C^C \\ \text{s.t. } p_A^C &= P_A^C \leq p_C^C.\end{aligned}\quad (8)$$

Best response prices are

$$p_A^C = p_C^C = \frac{1}{\beta_A + \beta_C}, \quad p_B^C = \frac{1}{2\beta_B}. \quad (9)$$

The manufacturer's profit is

$$\pi^C = \frac{1}{\beta_A + \beta_C} + \frac{1}{4\beta_B}. \quad (10)$$

The imposed price cap P_A^C is binding, i.e., $p_A^C < p_A^*$ as $\beta_A < \beta_C$.

3.2.2. Two reference countries, minimum price

Consider now that the government in country A sets a price cap based on the lower of the prices in countries B and C in the first stage. For instance, Denmark and Spain use the minimum price rule (Toumi et al. 2013).

The manufacturer sets prices in the second stage to maximize

$$\begin{aligned}\pi^{minj} &= (1 - \beta_A p_A^{minj}) p_A^{minj} + (1 - \beta_B p_B^{minj}) p_B^{minj} + (1 - \beta_C p_C^{minj}) p_C^{minj} \\ \text{s.t. } p_A^{minj} &\leq P_A^{min} = \min\{p_B^{minj}, p_C^{minj}\}.\end{aligned}\quad (11)$$

In principle, two cases can be distinguished: (i) in case *minC*, the price cap in country *A* is based on the price in country *C*, constraining price-setting in countries *A* and *C*, while in country *B*, price-setting is unconstrained; (ii) in case *minBC*, the price-setting in all three countries is constrained and the manufacturer sets a uniform price.

In case *minC*, best response prices are

$$p_A^{minC} = p_C^{minC} = \frac{1}{\beta_A + \beta_C}, p_B^{minC} = \frac{1}{2\beta_B}. \quad (12)$$

The manufacturer's profit is

$$\pi^{minC} = \frac{1}{\beta_A + \beta_C} + \frac{1}{4\beta_B}. \quad (13)$$

The imposed price cap P_A^{minC} is binding, i.e., $p_A^{minC} \leq p_A^*$ because $\beta_A \leq \widehat{\beta_{AminC}} = \beta_C$.

Note that the case *minC* yields the same price equilibrium as rule *C* because, in both cases, the price cap in country *A* is based on the price in country *C*, while price-setting is free in country *B*. Throughout the paper, the cases *C* and *minC* are labelled accordingly to indicate the choice of reference countries and pricing rule.⁵

In case *minBC*, the uniform best response price is

$$p_A^{minBC} = p_B^{minBC} = p_C^{minBC} = \frac{3}{2(\beta_A + \beta_B + \beta_C)}. \quad (14)$$

The manufacturer's profit is

$$\pi^{minBC} = \frac{9}{4(\beta_A + \beta_B + \beta_C)}. \quad (15)$$

The imposed price cap P_A^{minBC} is binding, i.e., $p_A^{minBC} < p_A^*$ because $\beta_A < \frac{\beta_B + \beta_C}{2}$.

Which of the cases occurs, *minC* or *minBC*, depends on the deviations from the profit-maximizing price under coinsurance in country *A* and the reference country or countries. When setting prices under the minimum price rule, the manufacturer balances the loss in profit from a lower price in country *A* against the loss in profit from a higher price in the reference country or countries. Because the change in profit due to a deviation $\pm\lambda$ from the profit-maximizing price under coinsurance increases exponentially in λ ,⁶ it is not optimal to adjust the price in only one country and to not change the price in the other country. Instead, the manufacturer minimizes losses in profits across countries by reducing the price in country *A* and increasing it in the reference country or countries, imposing a constraint on price-setting in both or all countries. Thus, the adoption of the minimum price rule in country *A* does not change the drug price in only country *A* but also in at least one of the other countries.

Because the change in profit from price changes depends on β_j —the maximum willingness to pay and the coinsurance rate in the respective country—and the manufacturer balances losses in profit across all markets, price changes in all countries affected depend on β_j in all countries.

5 Note that it is useful to distinguish between rule *C* and *minC* because the choice of *minj* may also result in case *minBC*. Also, the choice of *minj* may have different implications than the choice of rule *C* if more than one country adopts external reference pricing; see section 5.

6 The change in profit due to a price change $\Delta p = p^* - (p^* - \lambda)$ is $\Delta\pi = \pi_j(p^*) - \pi_j(p^* - \lambda) = -\beta_j\lambda^2$.

If countries B and C are rather different in β_j , so are the profit-maximizing prices under coinsurance. Then the price cap in country A is based on the lower of both prices (price in country C), and the manufacturer may set the price without constraints in the third country (country B). That is, the equilibrium outcome is $\min C$: the price cap is based on the price in country C and the price in country B is the same as under coinsurance.

If countries B and C are rather similar in β_j , two cases can be distinguished. (i) If β_A is rather high relative to β_B and β_C , i.e., all three countries are similar in terms of β_j , the deviations from the profit-maximizing price under coinsurance in the reference country are small and they do not affect the price in the third country. Then, the manufacturer may set the price without constraints in country B , and the price cap in country A is based on the price in country C . The equilibrium outcome is $\min C$. (ii) If β_A is rather low relative to β_B and β_C , the deviations from the profit-maximizing price under coinsurance (and no external reference pricing) in country A and the reference country are rather large. In this case, the manufacturer decreases the price in country A and increases the price in the reference country to a rather great extent (as indicated by the difference between β_A on the one hand and β_B and β_C on the other hand). This also affects the price in the third country because the rather large increase in the price in the reference country changes the price ranking between the two potential reference countries.⁷ So if β_A is rather low relative to β_B and β_C , the minimum rule constrains the manufacturer in all three countries. The equilibrium outcome is scheme $\min BC$.

To summarize, depending on differences in β_j , two cases are possible under the minimum price rule. (i) For $\beta_A \geq \widehat{\beta}_{A p_B^{\min C} = p_C^{\min C}}$, the equilibrium outcome is $\min C$. (ii) For $\beta_A \leq \widehat{\beta}_{A p_B^{\min C} = p_C^{\min C}}$, the equilibrium outcome is $\min BC$.

The two cases are shown in figure 1. The equilibrium outcomes under the minimum price rule are depicted as a function of maximum willingness to pay in countries A and B . Note that the area left to the dashed line, where $\mu_A < \mu_B$, is ruled out by assumption. The figure illustrates the case of identical coinsurance rates in all three countries.

Two areas can be distinguished. (i) $\min C$: For a sufficiently large maximum willingness to pay in country B , the drug price in country C is lower than in country B , and the equilibrium outcome is $\min C$. (ii) $\min BC$: For an intermediate maximum willingness to pay in country B (similar to the maximum willingness to pay in country C), the equilibrium outcome is $\min BC$ with a uniform price.

3.2.3. Two reference countries, average price

Consider now that the government in country A sets a price cap based on the average price in countries B and C (scheme *avg*).

In Austria, Belgium, the Netherlands and Portugal, for example, the average price rule is applied (Toumi et al. 2013).

7 A failure to adjust the price in the third country would create an inconsistent price ranking, with country A setting a price cap based on the price in one country, while the price in the third country is lower. This violation of the minimum price rule could induce the government in A to set a price cap based on the lower price in the third country, either triggering multiple adjustment decisions of the manufacturer's price-setting and the government in A choosing the reference country based on the lowest price or resulting in the manufacturer not adjusting its pricing decision at the cost of not setting profit-maximizing prices.

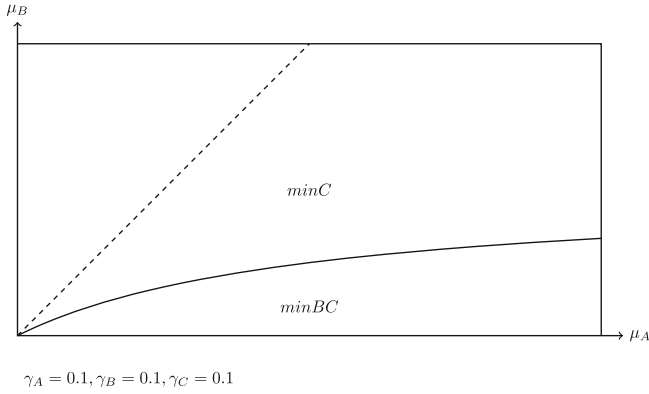


FIGURE 1 Equilibrium outcomes under the minimum price rule

The manufacturer sets prices to maximize

$$\begin{aligned} \pi^{avg} &= (1 - \beta_A p_A^{avg}) p_A^{avg} + (1 - \beta_B p_B^{avg}) p_B^{avg} + (1 - \beta_C p_C^{avg}) p_C^{avg} \\ \text{s.t. } p_A^{avg} &\leq P_A^{avg} = \frac{1}{2} p_B^{avg} + \frac{1}{2} p_C^{avg}. \end{aligned} \quad (16)$$

Equilibrium prices are

$$\begin{aligned} p_A^{avg} &= \frac{3(\beta_B + \beta_C)}{2(\beta_A \beta_B + \beta_A \beta_C + 4\beta_B \beta_C)}, \\ p_B^{avg} &= \frac{3\beta_C}{(\beta_A \beta_B + \beta_A \beta_C + 4\beta_B \beta_C)}, \\ p_C^{avg} &= \frac{3\beta_B}{(\beta_A \beta_B + \beta_A \beta_C + 4\beta_B \beta_C)}. \end{aligned} \quad (17)$$

The manufacturer's profit is

$$\pi^{avg} = \frac{9(\beta_B + \beta_C)}{4(\beta_A \beta_B + \beta_A \beta_C + 4\beta_B \beta_C)}. \quad (18)$$

The imposed price cap P_A^{avg} is binding, i.e., $p_A^{avg} < p_A^*$ because $\beta_A < \widehat{\beta}_{A^{avg}} = \frac{2\beta_B \beta_C}{\beta_B + \beta_C}$.

4. Choice of regulatory scheme: First-stage outcome

In this section, I study the choice of the external reference pricing scheme by the government in country A in the first stage. The manufacturer sets prices in the second stage as analyzed in the previous section. Drug price comparisons can be found in appendix A1.

Welfare in country A is given as consumer surplus (CS_A) less third-party payer expenditure (E_A):⁸

⁸ Throughout this paper, profit generated in country j is not included in the definition of welfare of country j . Results do not change, however, if local profits were considered in country j (e.g., due to jobs or tax revenue) because welfare defined as local profits plus consumer surplus less third-party payer expenditure also decreases in the drug price.

$$\begin{aligned}
 W_A &= \underbrace{\int_{\gamma_A p_A}^{\mu_A} \left(\frac{1}{\mu_A} \theta - \beta_A p_A \right) d\theta}_{CS_A} - \underbrace{(1 - \beta_A p_A) p_A (1 - \gamma_A)}_{E_A} \\
 &= \frac{\mu_A}{2} + \beta_A p_A^2 \left(1 - \frac{1}{2} \gamma_A \right) - p_A (1 - \gamma_A + \beta_A \mu_A). \quad (19)
 \end{aligned}$$

Welfare decreases in the drug price.⁹ This implies minimizing the drug price is equivalent to maximizing welfare.

A price increase decreases welfare because consumer surplus decreases, while third-party payer expenditure increases: consumer surplus decreases because an increase in the drug price increases copayments ($\gamma_A p_A$) and reduces demand. A higher drug price increases reimbursement per consumer ($(1 - \gamma_A) p_A$), increasing third-party payer expenditure, whereas the reduction in demand decreases third-party payer expenditure. The effect of higher reimbursement dominates the effect of lower demand, and overall, third-party payer expenditure increases in the drug price.¹⁰

External reference pricing lowers the drug price compared to coinsurance if β_A is sufficiently low, i.e., the maximum willingness to pay is sufficiently high and/or the coinsurance rate is sufficiently low, and the price cap imposed by external reference pricing is binding.

Choosing only one reference country, i.e., scheme *B* or *C*, is not optimal because the government in country *A* foregoes using the information on a potentially lower price and accordingly the possibility of choosing a lower price cap. Scheme *B* bases the price cap in country *A* on the higher of the two drug prices in the potential reference countries, countries *B* and *C*. Scheme *C* yields the same drug price as scheme *minC*, but for the parameter set where the minimum rule generates a uniform price across all three countries, scheme *C* would yield a higher drug price than the minimum price rule. The minimum price rule allows the regulator to exert a stronger restriction on the manufacturer's price-setting and to enforce a uniform price.

Consider in the following that the government in country *A* chooses two reference countries. If countries *B* and *C* are sufficiently different in β_j , the minimum price rule generates a lower price than the average price rule. The minimum price rule does not use the information on the higher price in country *B*, whereas the average price rule necessarily uses the information on prices in both reference countries. Moreover, the link between prices in country *A* and the country with the lower price is stronger under the minimum price rule: whereas under the average price rule, price changes in the reference countries are transmitted to country *A* by only 50% each; the minimum price rule enforces a direct one-to-one link between prices in the reference country and the referencing country *A*. Also, if all three countries are rather similar, the minimum price rule yields a lower price because the manufacturer makes higher price concessions in the reference country and country *A* to be able to set the price without being constrained in the third country. The average price rule, on the

9 Welfare decreases in the drug price: $\frac{\partial W_A}{\partial p_A} = -(1 - \beta_A p_A (2 - \gamma_A)) < 0$ as long as $p_A < p_A^*$.

10 The higher the coinsurance rate, i.e., the higher the fraction consumers pay of the drug price, the higher the increase in copayments for a given increase of the drug price and the stronger the reduction in demand. At the same time, a higher coinsurance rate dampens the effect of a higher reimbursement for the third-party payer. That is, under a higher coinsurance rate, a price increase decreases consumer surplus to a larger extent than it increases third-party payer expenditure.

contrary, imposes restrictions on the manufacturer's price-setting in all three countries.¹¹ If β_A is rather low relative to β_B and β_C , both the minimum price rule and the average price rule impose restrictions on the manufacturer's price-setting in all three countries. In this case, the minimum price rule yields a lower price because it enforces a direct one-to-one link between prices in all countries.

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

PROPOSITION 1. *The government in country A chooses two reference countries and the minimum price rule to minimize the drug price.*

5. Endogenous export decision

Consider now that the manufacturer may respond to the choice of an external reference pricing scheme in country A by changing its export decision in the second stage when it sets prices. In particular, it may refrain from exporting to one of the countries, if a low price from this country may "spill over" to a high-price country. Consider in the following that country A applies the minimum price rule because it generates the lowest drug price. Export decisions under all external reference pricing schemes can be found in appendix A3.

If the government in country A applies the minimum price rule, $\min C$ is the equilibrium outcome.¹² The manufacturer may avoid a low price in country A by not exporting to country C (with the price cap being based on the price in country B instead). The manufacturer does not export to country C if the profit from selling in only country A and B under the scheme B is higher than the profit from selling in all three countries under the scheme $\min C$, i.e., $\pi_A^B + \pi_B^B - \pi^{\min C} \geq 0$, which is the case if $\beta_A \leq \widetilde{\beta}_{A\min C, B}$ and $\beta_B \leq \widetilde{\beta}_{B\min C, B}$.

If $\min BC$ is the equilibrium outcome¹³ under the minimum price rule, the manufacturer does not export to country B if $\pi_A^C + \pi_C^C - \pi^{\min BC} \geq 0$, which is the case if $\beta_A \leq \widetilde{\beta}_{A\min BC, C}$ and $\beta_B \geq \widetilde{\beta}_{B\min BC, C}$. It does not export to country C if $\pi_A^B + \pi_B^B - \pi^{\min BC} \geq 0$, which is the case if $\beta_A \leq \widetilde{\beta}_{A\min BC, B}$ and $\beta_B \leq \widetilde{\beta}_{B\min BC, B}$. And it exports to neither country if $\pi_A^* - \pi^{\min BC} \geq 0$ if $\beta_A \leq \widetilde{\beta}_{A\min BC, A^*}$. The manufacturer may decide not to export to a country if the loss in profit in country A from reducing the price is higher than the loss in profit from not selling to this country and accepting a price constraint in the third country. Because the loss in profit from deviations from the optimal price decreases in β_j , the manufacturer decides not to export if β_A is rather small. This implies that the minimum price rule may not be feasible for all combinations of β_j .

Figure 2 depicts equilibrium outcomes under the minimum price rule for different willingness to pay in countries A and B and identical coinsurance rates in all three countries when the export decision is endogenous. Note that the area to the left of the dashed line, where $\mu_A < \mu_B$, is ruled out by assumption. If the willingness to pay in countries A and B is large, the firm refrains from supplying country C under the minimum price rule so that the resulting price rule is scheme B instead. In that case, the government in A either chooses

11 The minimum price rule allows the manufacturer to set the same price as under coinsurance in the third country because, under this rule, only the lowest price spills over to the referencing country. Under the average price rule, prices in all countries spill over to the referencing country, imposing a constraint on price-setting in all three countries.

12 $\min C$ is the equilibrium outcome if $\beta_A \geq \widehat{\beta}_{A p_B^{\min C} = p_C^{\min C}}$.

13 $\min BC$ is the equilibrium outcome if $\beta_A \leq \widehat{\beta}_{A p_B^{\min C} = p_C^{\min C}}$.

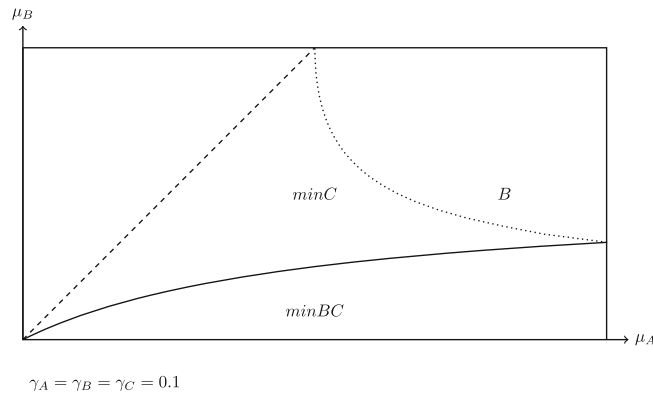


FIGURE 2 Minimum price rule and endogenous export decision

scheme B directly (anticipating the export decision of the firm) or it realizes ex post that only country B remains as a possible reference country.

Proposition 2 summarizes the effect of the minimum price rule on the export decision by the manufacturer.

PROPOSITION 2. *If country A adopts the minimum price rule, the manufacturer does not export to country C if $\beta_A \leq \widetilde{\beta}_{AminC,B}$.*

The results of this model can be interpreted as suggesting that launch delays are possible depending on the external reference pricing scheme. The model used in this paper is static, which means that it can be used only to study non-launches, not launch delays. However, because the two phenomena are closely related and launch delays are more common than actual non-launches, the term “launch delay” is used in the text. Permanent non-launches are obviously costly, and companies may find it difficult to defend them publicly. A more detailed analysis of a company’s launch strategy, including the timing of the launch and the duration of any delay, would require a different model. This model would be less suitable for comparing the effects of different pricing schemes due to its more complex structure.

6. Effect on drug prices in reference countries

In this section, I study the effect of external reference pricing in country A on drug prices and welfare in countries B and C . Price comparisons can be found in online appendix A.4.

Welfare in countries B and C is given as

$$\begin{aligned} W_B &= CS_B - E_B = \frac{\mu_B}{2} + \beta_B p_B^2 \left(1 - \frac{1}{2}\gamma_B\right) - p_B(1 - \gamma_B + \beta_B \mu_B), \\ W_C &= CS_C - E_C = \frac{1}{2} + \beta_C p_C^2 \left(1 - \frac{1}{2}\gamma_C\right) - p_C(1 - \gamma_C + \beta_C). \end{aligned} \quad (20)$$

In both countries, welfare decreases in the drug price.

Consider that country A implements the minimum price rule to minimize the drug price in the first stage. The manufacturer may decide whether to export and sets prices in the second stage. In the case $minC$, the drug price in country C is higher than under coinsurance in country A , while the drug price in country B is not affected, i.e., $p_C^{minC} > p_C^*$, $p_B^{minC} = p_B^*$. Also, under $minBC$, drug prices in countries B and C are higher than under coinsurance if

β_A is sufficiently low ($p_B^{minBC} - p_B^* > 0$ if $\beta_A \leq \widehat{\beta_A}_{p_B^{minC}=p_C^{minC}}$, $p_C^{minBC} - p_C^* > 0$ if $\beta_A \geq \widehat{\beta_A}_{p_B^{minB}=p_C^{minB}}$).

Also, if country A applies the average price rule, e.g., because of an endogenous export decision, drug prices in countries B and C are higher than under coinsurance ($p_B^{avg} - p_B^* > 0$, $p_C^{avg} - p_C^* > 0$). As a result, these countries may also have an incentive to introduce external reference pricing. This is examined in the following section.

Proposition 3 summarizes the effect of the choice of the regulatory scheme in country A on drug prices in countries B and C :

PROPOSITION 3. *If country A adopts the minimum price rule or the average price rule, drug prices in countries B and C are higher than under no external reference pricing in country A .*

7. Mutual referencing

So far, the paper has analyzed the decision of country A to adopt an external reference pricing scheme, assuming that the other countries apply coinsurance only. The analysis has revealed that there are strong incentives in country A to implement an external reference pricing scheme. This section examines whether the other countries have an incentive to adopt an external reference pricing scheme as well, given that A uses one, and whether this changes anything for A 's decision to implement an external reference pricing scheme. This allows to show whether there is a global pricing equilibrium. In this section, consider that countries simultaneously decide upon introducing an external reference pricing scheme. Consider also that the firm sets prices in all countries simultaneously after the governments have made their decisions about the external reference pricing schemes and that governments know prices in all relevant countries.

Consider now that also countries B and C may also simultaneously adopt external reference pricing schemes after country A has decided to implement an external reference pricing scheme. In countries B and C , the increase in drug prices under external reference pricing in country A may create the incentive to apply also an external reference pricing scheme. Equilibrium prices can be found in online appendix A.5.

7.1. Choice of second country

Consider first the choice of a second country to adopt an external reference pricing scheme given that external reference pricing is applied in country A (it will be analyzed in a later subsection whether this is a consistent strategy of country A). Without loss of generality, consider first the choice of country B in what follows. For all combinations of choices of countries A and B , the manufacturer's profit and equilibrium prices can be found in online appendix A.5. Superscripts denote choices in countries A and B , respectively.

7.1.1. One reference country

Consider first that country A chooses the scheme B . If country B does not adopt external reference pricing given the choice of country A , equilibrium prices are $p_A^B = p_B^B = \frac{1}{\beta_A + \beta_B}$, $p_C^B = \frac{1}{2\beta_C}$.

If country B chooses the scheme A , the choice of country B does not affect equilibrium prices. If country B chooses the scheme *minj*, the manufacturer sets a uniform price. If country B chooses the scheme C or the scheme *avg*, the manufacturer sets a uniform price $p = \frac{3}{2(\beta_A + \beta_B + \beta_C)}$. Compared with the price p_B^B , uniform pricing decreases the drug price in

country B ($p - p_B^{B,(\cdot)} < 0$). That is, the best response for country B is to choose any external reference pricing scheme except for A .

Consider now that country A chooses the scheme C . If country B does not adopt external reference pricing, equilibrium prices are $p_A^C = p_C^C = \frac{1}{\beta_A + \beta_C}$, $p_B^C = \frac{1}{2\beta_B}$.

Irrespective of which scheme country B chooses, the manufacturer sets a uniform price p . In country B , uniform pricing yields a lower drug price than the price p_B^C ($p - p_B^* \leq 0$ if $\beta_A \geq \widehat{\beta_A}_{p_B^{minC}=p_C^{minC}}$). That is, the best response for country B is to choose any external reference pricing scheme to induce uniform pricing.

7.1.2. Two reference countries, minimum price

If country A chooses the scheme $minj$ and country B does not adopt external reference pricing, equilibrium prices are $p_A^{minC} = p_C^{minC} = \frac{1}{\beta_A + \beta_C}$, $p_B^{minC} = \frac{1}{2\beta_B}$ if $\beta_A \geq \widehat{\beta_A}_{p_B^{minC}=p_C^{minC}}$, and $p_A^{minBC} = p_B^{minBC} = p_C^{minBC} = \frac{3}{2(\beta_A + \beta_B + \beta_C)}$ if $\beta_A \leq \widehat{\beta_A}_{p_B^{minC}=p_C^{minC}}$.

If country B chooses A or $minj$, the manufacturer sets a uniform price. If country B chooses scheme C or avg , the manufacturer sets a uniform price. Because in country B the price under the scheme $minC$ is higher than the uniform price, the best response for country B is to choose scheme C or avg to induce a uniform price. If $\beta_A \leq \widehat{\beta_A}_{p_B^{minC}=p_C^{minC}}$, the manufacturer sets a uniform price anyway, irrespective of the choice by country B .

7.1.3. Two reference countries, average price

If country A chooses the scheme avg and country B does not adopt external reference pricing, equilibrium prices are $p_A^{avg} = \frac{3(\beta_B + \beta_C)}{2(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)}$, $p_B^{avg} = \frac{3\beta_C}{(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)}$,

$$p_C^{avg} = \frac{3\beta_B}{(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)}.$$

Irrespective of which scheme country B chooses, the manufacturer sets a uniform price. In country B , the uniform price is lower than the price under avg ($p - p_B^{avg} < 0$ because $\beta_B < \beta_C$). That is, the best response for country B is to choose any external reference pricing scheme to induce uniform pricing.

7.1.4. Best response of country A

In country A , the uniform price is higher than the price under $minC$ ($p_A - p_A^{minC} \geq 0$ if $\beta_A \geq \widehat{\beta_A}_{p_B^{minC}=p_C^{minC}}$) but the uniform price is lower than the price under avg ($p - p_A^{avg} \leq 0$). The best response of country A given the choice of country B is to choose any external reference pricing scheme.

Country A would prefer the pricing scheme $minC$ (i.e., country B applies coinsurance only) over a uniform price, but country B prefers a uniform price over the price under the pricing scheme C or $minC$. This implies that the pricing scheme C or $minC$ is not an equilibrium outcome.

Country A prefers uniform pricing over the pricing scheme avg , and country B does so also if $\beta_B \leq \widehat{\beta_B}_{p_B=p_C}$. This implies that the pricing scheme avg is also not an equilibrium outcome. The equilibrium outcome is uniform pricing.

7.2. Choice of third country

Consider now the choice of the third country to adopt an external reference pricing scheme given that external reference pricing is applied in the other two countries.

From section 7.1, the choice of external reference pricing by two countries yields uniform pricing. The choice of country C for or against an external reference pricing scheme has no effect on equilibrium prices.

There is no incentive for the country with the lower price (country B if the implemented scheme is B) to adopt an external reference pricing scheme.¹⁴ But there is an incentive for the third country (country C if the implemented scheme is B) or the country with the higher price (country B (C) if the implemented scheme is C or $\min C$ (B)) also to adopt an external reference pricing scheme. This adoption does not change the incentives for the other countries to apply external reference pricing. In these cases, the outcome is a uniform price, implying price convergence across all countries.

Proposition 4 summarizes the incentive for the other countries also to adopt an external reference pricing scheme under any external reference pricing scheme in country A .

PROPOSITION 4. *There is no incentive for the country with the lower price to adopt an external reference pricing scheme, but there is an incentive for the third country or country with the higher drug price also to adopt external reference pricing. If all countries adopt an external reference pricing scheme, the manufacturer sets a uniform drug price for all three countries.*

If country A applies any external reference scheme, the incentive for the third country or country with the higher drug price also to adopt external reference pricing results in a uniform price in all three countries.

Compared with the scenario with coinsurance, a uniform price increases welfare in country A if β_A is sufficiently low, i.e., $\Delta W_A = W_A^* - W_A^p \geq 0$ if $\beta_A \leq \widehat{\beta}_{A\Delta W_A}$. In this case, the uniform price is lower than the price under coinsurance and no external reference pricing, increasing consumer surplus and decreasing third-party payer expenditure. In country B , the uniform price increases welfare if β_A is sufficiently high or β_B is sufficiently low, i.e., $\Delta W_B = W_B^p - W_B^* \geq 0$ if $\beta_A \geq \widehat{\beta}_{A\Delta W_B} \vee \beta_B \leq \widehat{\beta}_{B\Delta W_B}$. In both cases, the uniform price is lower than the price under coinsurance. A high β_A decreases the uniform price, and a low β_B increases the price under coinsurance by more than the uniform price. Similarly, in country C , the uniform price increases welfare if β_A is sufficiently high or β_C is sufficiently low, i.e., $\Delta W_C = W_C^p - W_C^* > 0$ if $\beta_A \geq \widehat{\beta}_{A\Delta W_C} \vee \beta_C \leq \widehat{\beta}_{C\Delta W_C}$. A high β_A decreases the uniform price, and a low β_C increases the price under coinsurance by more than the uniform price. For all three countries, these effects offset each other and global welfare increases, i.e., $W^p - W^* > 0$.

Proposition 5 summarizes the welfare effect of uniform pricing.

PROPOSITION 5. *If one country applies an external reference price scheme, the country not referenced at or the country with the higher drug price has an incentive to also adopt an external reference price scheme. If other countries also apply external reference pricing and a uniform price is the outcome, global welfare increases.*

Under uniform pricing, the manufacturer may also decide to not export to one of the countries. If the manufacturer does not export to country B , prices in country A and country C are the same (scheme C). The manufacturer can avoid a lower uniform price at the cost of foregoing profits from not selling in country B . The manufacturer does not export to country B if the profit from selling only in countries A and C under the scheme C is higher than the profit from selling at a uniform price in all three countries, i.e., $\pi_A^C + \pi_C^C - \pi \geq 0$ if $\beta_A \leq \widehat{\beta}_{A p, C} \wedge \beta_B \geq \widehat{\beta}_{B p, C}$; see online appendix A.5. If the manufacturer decided not to export to country C as well, this would be equivalent to the corresponding case in appendix A3.1.

14 The choices of country B for an external reference pricing scheme that are best responses do not affect equilibrium prices.

Similarly, if the manufacturer does not export to country C , prices in country A and country B are the same (scheme B). The manufacturer does not export to country C if the profit from selling only in countries A and B under the scheme B is higher than the profit from selling at a uniform price in all three countries, i.e., $\pi_A^B + \pi_B^B - \pi \geq 0$ if $\beta_A \leq \widetilde{\beta}_{Ap,B} \wedge \beta_B \leq \widetilde{\beta}_{Bp,B}$.

That is, the manufacturer's decision to not export to potential reference countries may be a major obstacle for regulatory convergence and thus price convergence. If countries take the threat of a non-launch of the drug into account when deciding whether to adopt external reference pricing, they may refrain from strict regulation or the application of external reference pricing.

8. Discussion

8.1. Firm's profit and dynamic efficiency

The analysis of the welfare effects of external reference pricing has so far been based on two assumptions. First, the firm's profits are not part of welfare in the countries under consideration (the firm is located in another country). Second, the analysis is static. Incentives on innovation behaviour and future availability of drugs are not considered.

Compared with the case of coinsurance only, all reference pricing schemes lower firm's profit. Thus, if the firm's profit is a component of social welfare, social welfare in the case of external reference pricing is lower than assumed here.

Pharmaceuticals are typically developed as a result of a lengthy and expensive process of research and development. Profits are an incentive for companies to take on the costs and risks of development. Lower (expected) profits due to external reference pricing could result in the firm having less incentive to invest in research and development. This reduces the availability of new drugs in all countries. Small countries might have the incentive to use the cost-reducing effects of external reference pricing under the assumption that they have only a small (negligible) effect on the firm's profits. If this is true for a sufficiently large number of countries, it could have the effect of slowing down innovative behaviour.

In contrast, large countries may have an incentive to consider this effect. Price reductions are then not the only objective in the social welfare function. They would aim for lower price reductions than assumed in this paper. However, the qualitative effects of external reference pricing, particularly the linkage of prices in several countries, would remain.

8.2. Price bargaining

The paper assumes that the firm sets prices in all countries without negotiating with the government. Here, the external reference pricing schemes constitute restrictions on the firm's profit maximization. From the perspective of country A , negotiations and an external reference pricing scheme are substitutes. An external reference pricing scheme can be introduced by the government without negotiations.

Unlike an external reference pricing scheme, negotiations do not necessarily result in spillovers to other countries. If negotiations take place in a country that is referenced on by another country and the firm's export decision is exogenous, negotiations may dampen the price-increasing effect of being referenced on. In the referenced country, the magnitude of the effect of the reference price is thus smaller, but the direction of the effect remains the same.

In the referencing country, the price-dampening effect of the reference price amplifies. If the firm's export decision is endogenous, lower prices as a result of negotiations in the reference country may prevent the firm from exporting to the referenced country. This tends

to dampen the effect of the external reference pricing scheme in the referencing country. This also increases the effect of the external reference pricing scheme on the export decision. Overall, bargaining in the referenced country acts such as lowering the market size in that country.

9. Conclusion

In this paper, I have studied the design of external reference pricing schemes, in particular, the choice of reference countries and pricing rules, in a three-country framework.

Given that the manufacturer sells to all three countries, the minimum price rule yields the lowest drug price. If the referencing country is sufficiently large, the manufacturer may not export to reference countries under the minimum price rule.

The fact that external reference pricing is so widespread cannot be explained solely by its price-reducing effect. Rather, this paper shows that the use of external reference pricing is “contagious,” i.e., it is accompanied by spillovers. Once one country uses external reference pricing, other countries have an incentive to use it as well. In the referencing countries, external reference pricing lowers drug prices and increases welfare. At the same time, it increases drug prices in the reference countries, creating the incentive for other countries also to adopt external reference pricing. Thus, external reference pricing results in regulatory convergence and a uniform price among all countries, i.e., price convergence. The widespread use of external reference pricing in Europe seems to be in line with this incentive for using external reference pricing. However, the manufacturer’s decision not to export to potential reference countries may counteract regulatory and thus price convergence.

However, in Europe, many countries apply the average price rule rather than the minimum price rule, for instance, Austria, Ireland, the Netherlands and Portugal (Schneider and Vogler 2019). The average price rule results in higher prices than the minimum price rule.

By deciding to export, the manufacturer can influence the way that reference pricing is applied and prevent price convergence. If the referencing country applies the minimum price rule, the referenced country runs the risk of not being supplied. This risk is lower under the average price rule. Under incomplete information, this could be advantageous not only for the referenced country. The referencing country also has the opportunity to use information from as many countries as possible. Therefore, the average rules allow for the possibility to use the information on prices in reference countries, which would not be possible under a non-launch. Another reason could be lobbying of pharmaceutical manufacturers. Also, the manufacturer may prevent the use of external reference pricing and price comparisons by strategic modifications of products such as different dosage forms for different countries (Kyle 2011).

Appendix

A1. External reference pricing: Regulatory scenarios

A1.1. External reference pricing scheme B

Binding price cap P_A^B : The price cap P_A^B is binding as β_A is sufficiently low

$$(p_A^B - p_A^* = -\frac{\beta_B - \beta_A}{2\beta_A(\beta_A + \beta_B)} < 0 \text{ if } \beta_A < \beta_B).$$

A1.2. External reference pricing scheme C

Binding price cap P_A^C : The price cap P_A^C is binding as β_A is sufficiently low ($p_A^C - p_A^* = -\frac{\beta_C - \beta_A}{2\beta_A(\beta_A + \beta_C)} < 0$ as $\beta_A < \beta_C$).

A1.3. External reference pricing scheme minj

Binding price cap P_A^{minC} : The price cap P_A^{minC} is binding as β_A is sufficiently low

$$(p_A^{minC} - p_A^* = -\frac{\beta_C - \beta_A}{2\beta_A(\beta_A + \beta_C)}) \leq 0 \text{ if } \beta_A < \beta_C).$$

Binding price cap P_A^{minBC} : The price cap P_A^{minBC} is binding as β_A is sufficiently low

$$(p_A^{minBC} - p_A^* = -\frac{\beta_B + \beta_C - 2\beta_A}{2\beta_A(\beta_A + \beta_B + \beta_C)}) < 0 \text{ if } \beta_A < \frac{\beta_B + \beta_C}{2}.$$

As β_B is sufficiently low, the threshold for P_A^{minBC} to be binding is lower than the threshold for P_A^{minC} to be binding ($\widehat{\beta}_{AminBC} - \widehat{\beta}_{AminC} = -\frac{1}{2}(\beta_C - \beta_B) < 0$ if $\beta_B < \widehat{\beta}_{B_{p_B=p_C}} = \beta_C$).

Consistent scheme *minC*: Under the scheme *minC*, the price cap in country A, i.e., the price in country C p_C^{minC} is lower than the price in country B if β_A is sufficiently high ($p_C^{minC} - p_B^{minC} = -\frac{\beta_A + \beta_C - 2\beta_B}{2\beta_B(\beta_A + \beta_C)} \leq 0$, if $\beta_A > \beta_{Ap_B^{minC}=p_C^{minC}} = 2\beta_B - \beta_C$, with $\widehat{\beta}_{Ap_B^{minC}=p_C^{minC}} - \widehat{\beta}_{AminC} = -2(\beta_C - \beta_B) < 0$, if $\beta_B < \widehat{\beta}_{B_{p_B=p_C}}$).

A1.4. External reference pricing scheme avg

Binding price cap P_A^{avg} : The price cap P_A^{avg} is binding as β_A is sufficiently low

$$(p_A^{avg} - p_A^* = -\frac{2\beta_B\beta_C - \beta_A\beta_B - \beta_A\beta_C}{\beta_A(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)}) < 0 \text{ if } \beta_A < \widehat{\beta}_{Aavg} = \frac{2\beta_B\beta_C}{\beta_B + \beta_C}.$$

A2. Choice of regulatory scheme

Minimum price rule vs. average price rule, *minC*: the price is lower under the scheme *minC* than under the scheme *avg* if β_A is sufficiently high ($p_A^{avg} - p_A^{minC} = \frac{3\beta_C^2 + \beta_A\beta_B + \beta_A\beta_C - 5\beta_B\beta_C}{2(\beta_A + \beta_C)(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)} \geq 0$ if $\beta_A \geq \widehat{\beta}_{Ap_A^{avg}=p_A^{minC}} = \frac{\beta_C(5\beta_B - 3\beta_C)}{\beta_B + \beta_C}$, $\widehat{\beta}_{Ap_A^{avg}=p_A^{minC}} - \widehat{\beta}_{Ap_B^{minC}=p_C^{minC}} = \frac{\beta_C(10\beta_B^2 - 11\beta_B\beta_C + 3\beta_C^2)}{2(\beta_B - \beta_C)^2} \leq 0$ if $\beta_B > \overline{\beta}_B = \frac{3\beta_C}{5} \vee \beta_B > \overline{\beta}_B = \frac{\beta_C}{2}$).

Minimum price rule vs. average price rule, *minBC*: The price is lower under the scheme *minBC* than under the scheme *avg* ($p_A^{avg} - p_A^{minBC} = -\frac{3(\beta_B - \beta_C)^2}{2(\beta_A + \beta_B + \beta_C)(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)} < 0$).

A3. Endogenous export decision**A3.1. One reference country**

Scheme B vs. no exports to country B and coinsurance in countries A and C: Under the scheme B, the profit from selling only in countries A and C (under coinsurance) is higher than the profit from selling in all three countries (under the scheme B) if β_A is sufficiently low ($\pi_A^* + \pi_C^* - \pi^B = \frac{(\beta_A - 3\beta_B)}{4\beta_B(\beta_A + \beta_B)} \geq 0$, if $\beta_A \leq \beta_{AB,A^*C^*} = \frac{\beta_B}{3}$).

Scheme B vs. no exports to country B and scheme C: Under the scheme B, the profit from selling only in countries A and C (under the scheme C) is higher than the profit from selling in all three countries (under the scheme B) if β_A is sufficiently low and β_B is sufficiently high ($\pi_A^C + \pi_C^C - \pi^B = \frac{3\beta_B\beta_C - \beta_A^2 - \beta_A\beta_C - \beta_B\beta_A - 4\beta_C^2}{4\beta_C(\beta_A + \beta_B)(\beta_A + \beta_C)} \geq 0$ if $\beta_A \leq \widetilde{\beta}_{AB,C} = \frac{2\beta_C(3\beta_B - 4\beta_C)}{\beta_B + \beta_C + \sqrt{(\beta_B - \beta_C)(\beta_B + 15\beta_C)}} \wedge \beta_B \geq \widetilde{\beta}_{BB,C} = \frac{4\beta_C}{3}$).

Scheme B vs. no exports to countries B and C: Under the scheme B, the profit from selling only in country A (under coinsurance) is higher than the profit from selling in all three countries (under the scheme B) if β_A is sufficiently low ($\pi_A^* - \pi^B = \frac{\beta_B\beta_C - \beta_A\beta_B - 3\beta_A\beta_C - \beta_A^2}{4\beta_A\beta_C(\beta_A + \beta_B)} \geq 0$ if $\beta_A \leq \widetilde{\beta}_{AB,A^*} = \frac{2\beta_B\beta_C}{\beta_B + 3\beta_C + \sqrt{(\beta_B + \beta_C)(\beta_B + 9\beta_C)}}$).

Scheme C vs. no exports to country C and coinsurance in countries A and B: Under the scheme C, the profit from selling only in countries A and B (under coinsurance) is higher

than the profit from selling in all three countries (under the scheme C) if β_A is sufficiently low ($\pi_A^* + \pi_B^* - \pi^C = \frac{(\beta_C - 3\beta_A)}{4\beta_A(\beta_A + \beta_C)} \geq 0$ if $\beta_A \leq \bar{\beta}_{AC,A^*B^*} = \frac{\beta_C}{3}$).

Scheme C vs. no exports to countries C and scheme B : Under the scheme C , the profit from selling only in countries A and C (under the scheme B) is higher than the profit from selling in all three countries (under the scheme C) if β_A is sufficiently low and β_B is sufficiently low ($\pi_A^B + \pi_B^B - \pi^C = \frac{3\beta_C\beta_B - \beta_A^2 - \beta_A\beta_B - \beta_C\beta_A - 4\beta_B^2}{4\beta_B(\beta_A + \beta_B)(\beta_A + \beta_C)} \geq 0$ if $\beta_A \leq \bar{\beta}_{AC,B} = \frac{2\beta_B(3\beta_C - 4\beta_B)}{\beta_B + \beta_C + \sqrt{(\beta_C - \beta_B)(15\beta_B + \beta_C)}} \wedge \beta_B \leq \bar{\beta}_{BC,B} = \frac{3\beta_C}{4}$).

Scheme C vs. no exports to countries B and C : Under the scheme C , the profit from selling only in country A (under coinsurance) is higher than the profit from selling in all three countries (under the scheme C) if β_A is sufficiently low ($\pi_A^* - \pi^C = \frac{\beta_B\beta_C - 3\beta_A\beta_B - \beta_A\beta_C - \beta_A^2}{4\beta_A\beta_B(\beta_A + \beta_C)} \geq 0$ if $\beta_A \leq \bar{\beta}_{AC,A^*} = \frac{2\beta_B\beta_C}{3\beta_B + \beta_C + \sqrt{(\beta_B + \beta_C)(9\beta_B + \beta_C)}}$).

A3.2. Two reference countries, minimum rule

Scheme $minC$ vs. no exports to country C and scheme B : Under the scheme $minC$, the profit from selling only in countries A and B (under the scheme B) is higher than the profit from selling in all three countries (under the scheme $minC$) if β_A is sufficiently low and β_B is sufficiently low ($\pi_A^B + \pi_B^B - \pi^{minC} = \frac{3\beta_C\beta_B - \beta_A^2 - \beta_A\beta_B - \beta_C\beta_A - 4\beta_B^2}{4\beta_B(\beta_A + \beta_B)(\beta_A + \beta_C)} \geq 0$ if

$$\beta_A \leq \bar{\beta}_{AminC,B} = \frac{2\beta_B(3\beta_C - 4\beta_B)}{(\beta_B + \beta_C + \sqrt{(\beta_C - \beta_B)(15\beta_B + \beta_C)})} \wedge \beta_B \leq \bar{\beta}_{BminC,B} = \frac{3\beta_C}{4}.$$

Scheme $minC$ vs. no exports to countries B and C : Under the scheme $minC$, the profit from selling only in country A (under coinsurance) is higher than the profit from selling in all three countries (under the scheme $minC$) if β_A is sufficiently low ($\pi_A^* - \pi^{minC} = \frac{\beta_B\beta_C - 3\beta_A\beta_B - \beta_A\beta_C - \beta_A^2}{4\beta_A\beta_B(\beta_A + \beta_C)} \geq 0$ if $\beta_A \leq \bar{\beta}_{AminC,A^*} = \frac{2\beta_B\beta_C}{3\beta_B + \beta_C + \sqrt{(\beta_B + \beta_C)(9\beta_B + \beta_C)}}$).

Scheme $minBC$ vs. no exports to country B and scheme C : Under the scheme $minBC$, the profit from selling only in countries A and C (under the scheme C) is higher than the profit from selling in all three countries (under the scheme $minBC$) if β_A is sufficiently low and β_B is sufficiently high ($\pi_A^C + \pi_C^C - \pi^{minBC} = \frac{4\beta_B - 5\beta_A - 5\beta_C}{4(\beta_A + \beta_C)(\beta_A + \beta_B + \beta_C)} \geq 0$ if $\beta_A \leq \bar{\beta}_{AminBC,C} = \frac{4\beta_B - 5\beta_C}{5} \wedge \beta_B \geq \bar{\beta}_{BminBC,C} = \frac{5\beta_C}{4}$).

Scheme $minBC$ vs. no exports to country C and scheme B : Under the scheme $minBC$, the profit from selling only in countries A and B (under the scheme B) is higher than the profit from selling in all three countries (under the scheme $minBC$) if β_A is sufficiently low and β_B is sufficiently low

$$(\pi_A^B + \pi_B^B - \pi^{minBC} = \frac{4\beta_C - 5\beta_B - 5\beta_A}{4(\beta_A + \beta_B)(\beta_A + \beta_B + \beta_C)} \geq 0 \text{ if } \beta_A \leq \bar{\beta}_{AminBC,B} = \frac{4\beta_C - 5\beta_B}{5} \wedge \beta_B \leq \bar{\beta}_{BminBC,B} = \frac{4\beta_C}{5}).$$

Scheme $minBC$ vs. no exports to countries B and C : Under the scheme $minBC$, the profit from selling only in country A (under coinsurance) is higher than the profit from selling in all three countries (under the scheme $minBC$) if β_A is sufficiently low ($\pi_A^* - \pi^{minBC} = \frac{\beta_B + \beta_C - 8\beta_A}{4\beta_A(\beta_A + \beta_B + \beta_C)} \leq 0$ if $\beta_A \leq \bar{\beta}_{AminBC,A^*} = \frac{\beta_B + \beta_C}{8}$).

A3.3. Two reference countries, average rule

Scheme avg vs. no exports to country B and coinsurance in countries A and C : Under the scheme avg , the profit from selling only in countries A and C (under coinsurance) is higher than the profit from selling in all three countries (under the scheme avg) if

β_A is sufficiently low ($\pi_A^* + \pi_C^* - \pi^{avg} = \frac{(\beta_A^2\beta_C + \beta_B\beta_A^2 - 4\beta_C(\beta_A\beta_B + 2\beta_A\beta_C - \beta_B\beta_C))}{4\beta_A\beta_C(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)} \geq 0$, if $\beta_A \leq \widetilde{\beta}_{A_{avg}, A^*C^*} = \frac{2\beta_B\beta_C}{\sqrt{\beta_C(3\beta_B + 4\beta_C) + \beta_B + 2\beta_C}}$).

Scheme *avg* vs. no exports to country *C* and coinsurance in countries *A* and *B*: Under the scheme *avg*, the profit from selling only in countries *A* and *B* (under coinsurance) is higher than the profit from selling in all three countries (under the scheme *avg*) if β_A is sufficiently low ($\pi_A^* + \pi_B^* - \pi^{avg} = \frac{\beta_A^2\beta_B + \beta_C\beta_A^2 - 4\beta_B(2\beta_A\beta_B + \beta_A\beta_C - \beta_B\beta_C)}{4\beta_A\beta_B(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)} \geq 0$, if $\beta_A \leq \widetilde{\beta}_{A_{avg}, A^*B^*} = \frac{2\beta_B\beta_C}{\sqrt{\beta_B(4\beta_B + 3\beta_C) + 2\beta_B + \beta_C}}$).

Scheme *avg* vs. no exports to country *B* and scheme *C*: Under the scheme *avg*, the profit from selling only in countries *A* and *C* (under the scheme *C*) is higher than the profit from selling in all three countries (under the scheme *avg*) if β_A is sufficiently low and β_B is sufficiently high ($\pi_A^C + \pi_C^C - \pi^{avg} = \frac{7\beta_B\beta_C - 5\beta_A\beta_B - 5\beta_A\beta_C - 9\beta_C^2}{4(\beta_A + \beta_C)(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)} \geq 0$ if $\beta_A \leq \widetilde{\beta}_{A_{avg}, C} = \frac{\beta_C(7\beta_B - 9\beta_C)}{5(\beta_B + \beta_C)} \wedge \beta_B \geq \widetilde{\beta}_{B_{avg}, C} = \frac{9\beta_C}{7}$).

Scheme *avg* vs. no exports to country *C* and scheme *B*: Under the scheme *avg*, the profit from selling only in countries *A* and *B* (under the scheme *B*) is higher than the profit from selling in all three countries (under the scheme *avg*) if β_A is sufficiently low and β_B is sufficiently low ($\pi_A^B + \pi_B^B - \pi^{avg} = \frac{7\beta_B\beta_C - 5\beta_A\beta_B - 5\beta_A\beta_C - 9\beta_B^2}{4(\beta_A + \beta_B)(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)} \geq 0$ if $\beta_A \leq \widetilde{\beta}_{A_{avg}, B} = \frac{\beta_B(7\beta_C - 9\beta_B)}{5(\beta_C + \beta_B)} \wedge \beta_B \leq \widetilde{\beta}_{B_{avg}, B} = \frac{7\beta_C}{9}$).

Scheme *avg* vs. no exports to countries *B* and *C*: Under the scheme *avg*, the profit from selling only in country *A* (under coinsurance) is higher than the profit from selling in all three countries (under the scheme *avg*) if β_A is sufficiently low ($\pi_A^* - \pi^{avg} = \frac{\beta_B\beta_C - 2\beta_A\beta_C - 2\beta_A\beta_B}{\beta_A(\beta_A\beta_B + \beta_A\beta_C + 4\beta_B\beta_C)} \geq 0$ if $\beta_A \leq \widetilde{\beta}_{A_{avg}, A^*} = \frac{\beta_B\beta_C}{2(\beta_B + \beta_C)}$).

Supporting information

Supplementary material accompanies this article.

References

- Ackermann, P. (2010) "External price benchmarking vs. price negotiation for pharmaceuticals," University of Bern Department of Economics working paper no. 10-04
- Brekke, K.R., T. H. Holmås, and O. R. Straume (2011) "Reference pricing, competition, and pharmaceutical expenditures: Theory and evidence from a natural experiment," *Journal of Public Economics* 95(7–8), 624–38
- (2015) "Price regulation and parallel imports of pharmaceuticals," *Journal of Public Economics* 129, 92–105
- Cockburn, I.M., J. O. Lanjouw, and M. Schankerman (2016) "Patents and the global diffusion of new drugs," *American Economic Review* 106(1), 136–64
- Costa-Font, J., A. McGuire, and N. Varol (2014) "Price regulation and relative delays in generic drug adoption," *Journal of Health Economics* 38, 1–9
- Danzon, P.M., and A. J. Epstein (2012) "Effects of regulation on drug launch and pricing in interdependent markets." In K. Bolin and R. Kaestner, eds, *The Economics of Medical Technology (Advances in Health Economics and Health Services Research)*, vol. 23, pp. 35–71. Leeds, UK: Emerald Group Publishing Limited
- Danzon, P.M., Y. R. Wang, and L. Wang (2005) "The impact of price regulation on the launch delay of new drugs: Evidence from twenty-five major markets in the 1990s," *Health Economics* 14(3), 269–92
- Espin, J., and J. Rovira (2007) "Analysis of differences and commonalities in pricing and reimbursement systems in Europe," study funded by DG Enterprise and Industry of the European Commission: Final Report

- Garcia Mariñoso, B., I. Jelovac, and P. Olivella (2011) "External referencing and pharmaceutical price negotiation," *Health Economics* 20, 737–56
- Houy, N., and I. Jelovac (2015) "Drug launch timing and international reference pricing," *Health Economics* 24, 978–89
- (2019) "Comparing approval procedures for new drugs," *World Economy* 42(5), 1598–619
- Kyle, M. (2011) "Strategic responses to parallel trade," *B.E. Journal of Economic Analysis & Policy* 11(2), 1–34
- Kyle, M.K. (2007) "Pharmaceutical price controls and entry strategies," *Review of Economics and Statistics* 89(1), 88–99
- (2019) "The single market in pharmaceuticals," *Review of Industrial Organization* 55(1), 111–35
- Maini, L., and F. Pammolli (2017) "Reference pricing as a deterrent to entry: Evidence from the European pharmaceutical market," Harvard working paper
- Maskus, K.E. (2000) "Parallel imports," *World Economy* 23, 1269–84
- Persson, U., and B. Jönsson (2016) "The end of the international reference pricing system?," *Applied Health Economics and Health Policy* 14(1), 1–8
- Richter, A. (2008) "Assessing the impact of global price interdependencies," *Pharmacoeconomics* 26, 649–59
- Schneider, P., and S. Vogler (2019) "Practice of external price referencing." In S. Vogler, ed., *Medicine Price Surveys, Analyses and Comparisons*, pp. 345–68. London, UK, and Washington: Academic Press
- Stargardt, T., and J. Schreyögg (2006) "Impact of cross-reference pricing on pharmaceutical prices," *Applied Health Economics and Health Policy* 5, 235–47
- Toumi, M., C. Rémuzat, A.-L. Vataire, and D. Urbinati (2013) "External reference pricing of medicinal products: Simulation-based considerations for cross-country coordination," *European Commission report*. Available at www.redaccionmedica.com/contenido/images/erp_reimbursement_medicinal_products_en-1.pdf
- Verniers, I., S. Stremersch, and C. Croux (2011) "The global entry of new pharmaceuticals: A joint investigation of launch window and price," *International Journal of Research in Marketing* 28, 295–308