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Article — Published Version

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Canadian Journal of Economics/Revue canadienne d'économie

Provided in Cooperation with:

John Wiley & Sons

Suggested Citation: Birg, Laura (2023) : Pharmaceutical regulation under market integration through parallel trade, Canadian Journal of Economics/Revue canadienne d'économie, ISSN 1540-5982, Wiley, Hoboken, NJ, Vol. 56, Iss. 4, pp. 1322-1346, <https://doi.org/10.1111/caje.12647>

This Version is available at:

<https://hdl.handle.net/10419/288246>

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Pharmaceutical regulation under market integration through parallel trade

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Abstract. In this paper, I study the effect of parallel trade (cross-border resale of goods without the authorization of the manufacturer) on pharmaceutical regulation. Governments may restrict prices directly (price caps) or limit third-party payer reimbursement for the drug (reimbursement limits). I find that parallel trade may relax regulation in the source country of parallel imports under both instruments and intensify regulation in the destination country under a reimbursement limit. I also find that parallel trade may change regulatory preferences: under no parallel trade, both the source and destination country set price caps, and under parallel trade, the source country sets a price cap but the destination country sets a reimbursement limit, thereby enforcing a higher price cap in the South. This implies that drug prices are higher under parallel trade in both source and destination countries.

Résumé. *Réglementation pharmaceutique dans le cadre de l'intégration du marché par le commerce parallèle.* Dans cet article, j'étudie l'effet du commerce parallèle (revente transfrontalière de biens sans l'autorisation du fabricant) sur la réglementation pharmaceutique. Les gouvernements peuvent restreindre les prix directement (plafonnement des prix) ou limiter le remboursement du médicament par les tiers payeurs (limite de remboursement). Je constate que le commerce parallèle peut assouplir la réglementation dans le pays d'origine des importations parallèles avec les deux instruments et intensifier la réglementation dans le pays de destination avec une limite de remboursement. Je constate également que le commerce parallèle peut modifier les préférences réglementaires : en l'absence de commerce parallèle, le pays d'origine et le pays de destination fixent tous deux des plafonds de prix. Dans le cadre du commerce parallèle, le pays d'origine fixe un plafond de prix, mais le pays de destination fixe une limite de remboursement, imposant ainsi un plafond de prix plus élevé en aval. Cela signifie que les prix des médicaments sont plus élevés dans le cadre du commerce parallèle, tant dans le pays d'origine que dans le pays de destination.

JEL classification: F12, I11, I18

1. Introduction

IN THIS PAPER, I study the effect of parallel trade on pharmaceutical regulation in a North–South framework. Parallel trade refers to the cross-border resale of goods without the authorization of the manufacturer (Maskus 2000). This type of arbitrage is a response to international price differences (Kyle 2010). While the literature on the effect of parallel trade on pharmaceutical regulation has focused on the effect of price caps in source countries of parallel imports, this paper extends the analysis to the effects on regulation in both the destination and the source country and to two potential regulatory instruments, price caps and reimbursement limits. This set-up allows differentiating between the effect of parallel

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Open Access funding enabled and organized by Projekt DEAL.

Canadian Journal of Economics / *Revue canadienne d'économie* 2023 56(4)
November 2023. / *Novembre 2023*.

23 / pp. 1322–1346 / DOI: 10.1111/caje.12647

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trade on regulation in export-oriented destination countries and the effect of parallel trade on regulation in import-oriented source countries. Moreover, the analysis of two regulatory instruments allows studying the choice of instruments under parallel trade.

One major source of international drug price differences are regulatory differences, both in the level of regulation and the type of regulatory instruments applied. Commonly applied regulatory instruments are price caps and (internal) reference prices. Price caps aim at restricting monopoly pricing and limit prices (of covered drugs) directly by establishing price ceilings.¹ (Internal) reference prices are intended to increase price sensitivity by limiting reimbursement by third-party payers. Typically, reimbursement limits are set for a group of substitutable drugs. Substitutability may be defined with respect to the active ingredient, therapeutic category or therapeutic function (Lopez-Casanovas and Puig-Junoy 2000). Under (internal) reference pricing, price setting is free but the limitation of third-party payer reimbursement implies that patients have to pay the difference between the drug price and the reimbursement limit.

By creating differences in drug prices, regulatory differences² drive the direction and volume of parallel trade. At the same time, parallel trade limits firms' ability to set different prices in different countries. In destination countries of parallel imports, parallel trade may reduce drug prices by providing lower-priced substitutes and enhancing competition in pharmaceutical markets. Empirical evidence on the price-decreasing effect of parallel trade in destination countries is ambiguous. While some studies (Kanavos et al. 2004, Kyle et al. 2008) find no evidence for price competition generated by parallel trade or for stronger price competition than in countries without parallel trade, other studies (West and Mahon 2003, Ganslandt and Maskus 2004, Granlund and Köksal-Ayhan 2016, Duso et al. 2014, Granlund and Köksal-Ayhan 2015, Granlund 2022) find that parallel trade may generate competitive pressure on drug prices.

Price interdependencies under parallel trade may create incentives for firms to delay or avoid launches in low-price countries, i.e., potential source countries of parallel imports. This allows firms to (temporarily) retain high prices in other countries (see Danzon et al. 2005, Kyle 2007).³ For instance, there is an average launch delay of 10 months in the EU 15, ranging from 3.5 months in Germany to 18.9 months in Belgium (Heuer et al. 2007). This suggests that pharmaceutical firms' export decisions are shaped by parallel trade and regulatory decisions (Bennato and Valletti 2014).

Because firms may delay (or even limit) supply to low-price countries, governments in source countries of parallel imports may refrain from strict regulation if they take into account their impact on firms' decisions to export to their country (Pecorino 2002, Königbauer 2004, Grossman and Lai 2008, Bennato and Valletti 2014). Pecorino (2002) shows that under parallel trade, a pharmaceutical manufacturer will make fewer concessions in drug price bargaining in a potential source country of parallel imports. Königbauer (2004) argues that parallel imports may discipline national regulators in the European Union

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- 1 Price caps may be based on prices of the same drug in other countries or prices of therapeutic alternatives.
 - 2 Beside regulation via price caps and reimbursement examined in this paper, other regulation can also foster competition by parallel imports; see, for example, Birg (2023) for an analysis of the effect of regulation on the wholesale level on competition by parallel imports.
 - 3 Danzon et al. (2005), Danzon and Epstein (2012) and Kyle (2011) suggest that stricter regulation and/or parallel trade may result in greater launch delays. Also, approval procedures for new drugs and approval times may contribute to non-launches (Houy and Jelovac 2019).

because the manufacturer's threat of not supplying countries with low drug prices prevents free-riding on the pharmaceutical firms' R&D investment by setting low prices. Similarly, Grossman and Lai (2008) show that the pace of innovation may be faster under parallel trade because of the change in regulatory choices. Bennato and Valletti (2014) find that a withdrawal from price regulation in a source country of parallel imports may increase R&D investment.

By changing regulatory decisions in destination and/or source country of parallel imports, parallel trade may result in regulatory convergence or regulatory divergence. In the former case, parallel trade may also erode price differences between countries, in particular, if price differences are driven by regulatory differences. In this sense, market integration through parallel trade may replace policy harmonization. Given that virtually no harmonization instrument is in place in the European Union or in other regions where parallel trade of pharmaceuticals takes place, such as Canada and the US, parallel trade may be particularly important.

The effect of parallel trade on regulation is linked to the policy issue of access to pharmaceuticals. Parallel trade may affect access in the source country of parallel imports if manufacturers decide to limit or avoid selling in low-price countries. Moreover, through its impact on regulatory decisions, parallel trade may also affect access: If governments change regulatory decisions in response to parallel trade, this also changes drug prices and, with it, access to the drug.

I find that in the source country (hereafter, South), parallel trade may relax regulation under both regulatory instruments. The manufacturer's threat of not exporting to the South may increase the price cap or the reimbursement limit under certain conditions.⁴ In the destination country (North), parallel trade may intensify regulation under a reimbursement limit and has no effect on the strictness of regulation under a price cap. Under a price cap, the government in the North prefers a price cap of zero, maximizing consumer surplus and minimizing third-party payer expenditure. Under a reimbursement limit, the government in the North prefers a high level of reimbursement because a potential decrease in the reimbursement limit would decrease both consumer surplus and third-party payer expenditure.

Under no parallel trade, both the North and the South prefer price caps over reimbursement limits. Welfare in both countries decreases in the drug price. Price caps allow governments to set a drug price of zero, while reimbursement limits result in higher drug prices. Under parallel trade, the North applies a reimbursement limit but the South sets a price cap. Choosing a reimbursement limit allows the North to enforce a lower level of regulation and thus also a higher price in the South. This is, a reimbursement limit in the North allows enforcing a higher drug price in the South than under price caps. As under no parallel trade, the South prefers a price cap to the reimbursement limit because it allows attaining a lower drug price. This is, under endogenous health policy, parallel trade results in a lower level of regulation and higher drug prices. Compared with the equilibrium without parallel trade in which both countries set price caps of zero, drug prices under parallel trade are higher. This worsens access in both the source and destination country.

To study the effect of parallel trade on regulation, I use a stylized model in which, under parallel trade, the firm sets a uniform price in both countries (as in Pecorino 2002,

⁴ Under a price cap, parallel trade relaxes regulation unless the North also sets a price cap. Under a reimbursement limit, parallel trade relaxes regulation if countries are sufficiently different in demand.

Valletti 2006, Roy and Saggi 2012, Bennato and Valletti 2014). Thus, there are no parallel importers and no differentiated products in the destination country of parallel imports in my model. Parallel trade generates a lower price in the North and a higher price in the South.

If parallel traders were active but products from the original distribution channel and the parallel imports were homogeneous goods for consumers, parallel trade would also lead to a lower price in the North and a higher price in the South.

If some consumers associated a lower quality with the parallel import because of differences in appearance and packaging (Maskus 2000) or manufacturers tried to restrict parallel trade by differentiating products across countries (Kyle 2011), only a part of the market in the North would be affected by parallel trade and the firm could set a different (and higher) price for the part of the market that was isolated from parallel trade. For the part of the market that was subject to competition from parallel trade, the price would be lower. Results from a model with parallel trades and differentiated products would be qualitatively similar to results from my model but weaker.

The paper is organized as follows. The next section provides a brief overview of parallel trade and pharmaceutical regulation in the European Union as well as in Canada and the US. Section 3 introduces the model. Section 4 studies the effect of regulation on the export decision. Section 5 analyzes the effect of parallel trade on the level of regulation for a given instrument. Section 6 studies the effect of parallel trade on the choice of regulatory instruments. Section 7 presents discussions of the model. Section 8 concludes.

2. Background: Parallel trade and pharmaceutical regulation

Under the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement), countries are allowed to choose the regional exhaustion of patent rights. This choice determines whether a patent holder is able to prevent parallel trade (Kyle 2011). For pharmaceutical parallel imports, additional provisions may apply (Canada Institute Staff 2019).

2.1. European Union

In the European Union, parallel trade is allowed within the single market. A firm cannot prevent parallel imports from other European Union member states (Méndez 2018). Parallel trade is a common phenomenon, especially for pharmaceuticals, for which price differences may reach up to 300% (Kanavos and Costa-Font 2005).

Pharmaceutical price differences may stem from differences in pharmaceutical regulation. Almost all member states of the European Union use or have used price caps and/or reference prices (see Espin and Rovira 2007 or Carone et al. 2012 for an overview of regulatory interventions in the European Union). According to 168 TFEU, health policy is in the national competence of member states. The Price Transparency Directive (Directive 89/195/EC), which provides rules for the control of pharmaceutical prices, is the only existing harmonization measure in the field of pharmaceutical price regulation and reimbursement.

Typical source countries of parallel imports are low-price countries with strict price regulation, for example, Greece, Italy, Portugal and Spain. In contrast, destination countries are high-price countries with relatively free price setting, for example, Denmark, Germany, the Netherlands and Sweden (Kanavos and Costa-Font 2005). In 2018, pharmaceutical parallel trade had a volume of €5.4 billion (European Federation of Pharmaceutical Industries and Associations 2020). In the destination countries, the share of parallel imports in pharmacy market sales ranged between 8.2% in the Netherlands, 8.5% in Germany, 12.9% in Sweden and 25.5% in Denmark in 2018 (European Federation of Pharmaceutical Industries and Associations 2020).

2.2. Canada and the United States of America

In Canada, the regional exploitation of patent rights is not regulated by law. The existing case law can be interpreted so that *de facto* national exploitation for patent rights is applied (Grigoriadis 2016, Calboli 2022). In the US, parallel trade is allowed in principle by judicial precedents. However, pharmaceutical imports from Canada to the US were allowed only through cross-border retail purchases or internet commerce (Canada Institute Staff 2019). Only recently, some states allowed pharmaceutical parallel imports from Canada at the wholesale level.

Canada applies price caps for patent-protected drugs (Houston and Attaran 2019). Drug reimbursement in Canada is not regulated on a national level. The Canadian provinces decide on the provision of drug benefits. Usually, a mixture of private and public coverage exists (Wyatt 2017). In the US, price caps for patent-protected drugs are not applied in general. Drug expenses are partly reimbursed by private or public insurance programs. The extent to which expenses are reimbursed depends on several patient-specific factors (Berndt and Newhouse 2010, Desai et al. 2022).

Drug prices in Canada are similar to drug prices in countries such as Germany, Switzerland and the United Kingdom. Drug prices in the US are, on average, three to four times higher than in Canada (Danzon 2018, Labban 2021). Given the substantial price differences and the opening for pharmaceutical imports in the US, an increase in parallel imports from Canada to the US is expected (Canada Institute Staff 2019, Houston and Attaran 2019, Roubein and Seipel 2018). Because the US market for pharmaceuticals is about 10 times larger than the Canadian market, there are Canadian concerns regarding the security of supply and maintaining relatively low drug prices (Canada Institute Staff 2019, Houston and Attaran 2019, Shepherd 2010, Shepherd 2018).

3. The model

Consider two countries $j = N, S$, North and South, which differ in demand in two respects: maximum willingness to pay and price elasticity. An innovative firm, which sells an on-patent drug, is located in the North. The firm may decide not to sell to the South. In both countries, welfare-maximizing governments may restrict prices directly via price caps or limit third-party payer reimbursement for the drug via reimbursement limits.

3.1. The firm

In the North, an innovative firm F is located, which sells an on-patent drug. The firm always sells in the North (if the price is non-negative), but the firm may decide whether or not to sell in the South on the basis of the price in the South and the potential impact on the price in the North under parallel trade. Patent protection provides the firm with a monopoly in both countries. The firm produces at constant marginal cost, which is normalized to zero.

Therefore, two pricing regimes are possible depending on the (non-) occurrence of parallel trade: (i) If parallel trade does not take place, the firm may price discriminate between the North and the South and set country-specific drug prices p_j ; (ii) if parallel trade takes place, the firm sets a uniform price p_{NS} . Therefore, parallel trade (as costless arbitrage) enforces a uniform drug price in both countries (as in Pecorino 2002, Valletti 2006, Roy and Saggi 2012, Bennato and Valletti 2014).

Under parallel trade, the firm may avoid selling at a uniform price in both countries by not exporting to the South. Then the firm foregoes sales in the South but may set a country-specific price in the North. This is, under parallel trade the firm faces the trade-off between selling at a uniform price in both countries or selling at a country-specific price in the North and foregoing sales in the South.

3.2. The consumers

In both countries, there is a unit mass of consumers differing in willingness to pay for the drug. Each consumer demands either one or zero units of the drug. This implies that the market is not covered and changes in drug prices result in quantity changes. 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 the gross valuation and c_j the country-specific drug co-payment. The (preference) parameter θ can be interpreted as willingness to pay.

Assume that θ is uniformly distributed over the interval $[0, \mu_j]$ in country $j = N, S$, with $\mu_N = \mu \geq \mu_S = 1$. The parameter μ_j can be interpreted as the maximum willingness to pay. In the following, μ will be referred to as demand parameter.

The marginal consumer in country j who is indifferent between buying the drug or not has a gross valuation $\theta_{ij}^* = c_j$. Hence, demand in country N is given as $q_N = \frac{1}{\mu}(\mu - c_N)$ and demand in country S is given as $q_S = 1 - c_S$.

3.3. The governments

In both countries, third-party payers (health insurance, health insurance programs or social insurance, etc.) partially cover drug costs. The co-payment is price-dependent: Consider that consumers pay a fraction γ_j , $\gamma_j \in (0, 1)$, out of pocket (co-insurance).⁵ Under co-insurance, the drug co-payment (and thus, the relevant price for consumers) is $c_j = \gamma_j p_j$, the third-party payer expenditure is $(1 - \gamma_j) p_j$.

In both countries, governments may restrict prices directly via price caps or limit third-party payer reimbursement for the drug via reimbursement limits. Under price caps, governments restrict drug prices to maximum prices P_j . Under reimbursement limits, governments restrict reimbursement by third-party payers to reimbursement limits r_j . Firms are free to set prices, but third-party payers reimburse the drug according to the reimbursement limit, which changes the consumer co-payment to $c_j^R = \gamma_j r_j + p_j - r_j$ and reimbursement to $(1 - \gamma_j) r_j$.

Governments maximize domestic welfare, which is defined as the (unweighted) sum of consumer surplus and the firm's profit net of third-party payer reimbursement in the North and consumer surplus net of third-party payer reimbursement in the South:

$$\begin{aligned} W_N &= CS_N + \pi - E_N, \\ W_S &= CS_S - E_S. \end{aligned} \quad (2)$$

Consumer surplus in country j is given as $CS_j = \frac{1}{\mu_j} \int_{\theta_{ij}^*}^{\mu_j} (\theta_{ij} - c_j) d\theta$, the firm's profit is given as $\pi = q_N p_N + q_S p_S$, third-party payer reimbursement in country j is defined as $E_j = (1 - \gamma_j) p_j q_j$ under no regulation and price caps⁶ and $E_j = (1 - \gamma_j) r_j q_j$ under reimbursement limits.⁷

5 Typically, co-insurance rates are not subject to frequent changes. Co-insurance rates are set to balance the protection from risks of financial losses due to sickness and (prevention of) moral hazard in utilizing health care products and services. In Germany, for example, the co-insurance rate has not been changed since 2004.

6 Under no regulation and price caps, the third-party payer reimburses the drug on the basis of the drug price.

7 Under reimbursement limits, the third-party payer reimburses the drug on the basis of the reimbursement limit.

3.4. Structure of the model

In this setup, there are two differences between countries. First, countries N and S differ in demand and price elasticity (because of differences in maximum willingness to pay and co-insurance rates). Differences in μ_j and/or γ_j generate differences in drug prices and trigger parallel trade. Second, because the North is export-oriented while the South is import-oriented, accordingly, welfare, government objectives and regulatory decisions differ between countries.

As for timing, consider that governments commit to a regulatory instrument (i.e., price caps or reimbursement limits) and then define price caps and/or reimbursement limits anticipating the firm's decision whether to export to the South or not. Therefore, consider the following timing:

- In stage 1, governments in the North and the South commit to a regulatory instrument, i.e., price caps or reimbursement limits.
- In stage 2, governments set price caps or reimbursement limits.
- In stage 3, the firm decides whether or not to sell to the South.
- The firm sets prices in stage 4. Under price caps, this stage does not apply.

Note that, without regulation, the game begins at stage 3.

3.5. Main assumptions

In this subsection, I discuss the main assumptions of the model.

Under parallel trade, the firm sets a uniform price, therefore, there are no parallel importers and no differentiated products in the destination country of parallel imports. If parallel traders were active but products from the original distribution channel and parallel imports were homogeneous goods for consumers, parallel trade would also result in a lower price in the North and a higher price in the South. If some consumers associated a lower quality with the parallel import or manufacturers tried to restrict parallel trade by differentiating products across countries, only a part of the market in the North would be affected by parallel trade. Therefore, results from a model with parallel trade and differentiated products would be qualitatively similar to results from my model but weaker.

The firm cannot block arbitrage from parallel imports by vertical price fixing. In addition, it is not able to limit the quantity exported to the South to domestic use. Both of these practices are not offhandedly allowed under competition law in many countries (Kyle 2011). However, quantity restrictions on exports could be a relevant phenomenon in the future for the European single market (Dubois and Sæthre 2020). In this paper, I abstract from the possibility that the firm supplies differentiated products to different markets to hamper parallel trade (Kyle 2011).

Consumer behaviour is based on a stylized utility function. Heterogeneity among consumers in the preference parameter θ may stem from, for instance, differences in the severity of the condition, prescription practices or insurance coverage (see, e.g., Brekke et al. 2011). This kind of stylized utility function is well established in the literature on pharmaceutical markets (see, e.g., Brekke et al. 2011, Brekke et al. 2015). This type of utility function allows for heterogeneous consumers, quantity effects and different market sizes.

In principle, the decision on the admissibility of parallel trade is also a decision by the government. However, this paper does not endogenize this stage. In the European Union, an individual member state cannot decide on the admissibility of parallel imports from other member states. This can be done only by the EU. In addition, a source country does not have a say in whether parallel imports are allowed in the destination country. Treating the

question of the permissibility of parallel trade as exogenous allows me to focus on the effect of parallel trade on the intensity of regulation and the choice of regulatory instruments.

The model assumes that the government sets the reimbursement limit autonomously, i.e., independently of prices in other countries or for therapeutic substitutes. Frequently, governments set reimbursement limits in such a way that they are based on prices in other countries or on prices for therapeutic substitutes. This would lead to feedback effects in the present model framework: Price reductions due to a reimbursement limit would further lower the limit. Qualitatively, however, the results would remain unchanged.

4. The effect of parallel trade on the export decision

In this section, the effect of parallel trade on the firm's export decision is analyzed in a scenario without regulation to illustrate how the export decision is the basis for the firm's threat of non-supply.

Equilibrium prices, quantities and the firm's profit can be found in online appendix A.1. The superscript x denotes variables under no parallel trade.

PROPOSITION 1. *(i) Parallel trade occurs if: (a) demand in the North is sufficiently high, $\mu > \widetilde{\mu}^x = \frac{\gamma_N}{\gamma_S}$, and/or if the co-insurance rate in the North is sufficiently low relative to that in the South, $\gamma_N < \widetilde{\gamma}_N^x = \mu\gamma_S$, and (b) the drug is sold to the South in the first place. (ii) Parallel trade increases welfare in the North if demand is sufficiently low, i.e., $W_N > W_N^x$ if $\mu < \widetilde{\mu}_{W_N}^x$. Parallel trade increases welfare in the South if demand in the North is sufficiently high, i.e., $W_S > W_S^x$, if $\mu > \widetilde{\mu}_{W_S}^x$.*

The following subsections explain this proposition.

4.1. No parallel trade

When parallel trade is not allowed, the firm can price-discriminate. The firm maximizes

$$\pi_{N,S}^x = q_N(p_N^x)p_N^x + q_S(p_S^x)p_S^x. \quad (3)$$

The firm price sets country-specific prices $p_N^x = \frac{\mu}{2\gamma_N}$ and $p_S^x = \frac{1}{2\gamma_S}$.

Equilibrium drug prices decrease in co-insurance rates γ_j . Also, the drug price in the North increases in the maximum willingness to pay μ .

Differences in drug prices stem from differences in co-insurance rates or differences in demand. In particular, the price in the North is higher than the price in the South, if demand in the North is sufficiently high, $\mu > \widetilde{\mu}^x = \frac{\gamma_N}{\gamma_S}$, and/or if the co-insurance rate (and accordingly price elasticity) in the North is sufficiently low relative to that in the South, $\gamma_N < \widetilde{\gamma}_N^x = \mu\gamma_S$.⁸ This implies that both differences in demand and differences in co-insurance rates may be drivers of parallel trade.⁹ Parallel trade is profitable if $p_N^x > p_S^x$. In what follows, assume $\gamma_N < \widetilde{\gamma}_N^x = \mu\gamma_S$, i.e., parallel trade takes place.

8 If demand in both countries is identical ($\mu = 1$), $p_N^x > p_S^x$ if $\gamma_N < \gamma_S$. If co-insurance rates in both countries are identical ($\gamma_N = \gamma_S = \gamma$), $p_N^x > p_S^x$ if $\mu > 1$.

9 Jelovac and Bordoy (2005) study the welfare consequences of parallel trade if parallel trade is driven by differences in co-insurance rates ("health systems") or differences in willingness to pay ("health needs"). They show that when countries differ in health systems, parallel trade decreases welfare; when countries differ in health needs, parallel trade increases welfare. Note that Jelovac and Bordoy (2005) consider these differences between countries separately.

4.2. Parallel trade

If parallel trade is allowed, the possibility to price discriminate is undermined and the firm sells at a uniform price p_{NS} in both countries. The firm's profit is

$$\pi_{N,S} = (q_N(p_{NS}) + q_S(p_{NS})) p_{NS}, \quad (4)$$

which is maximized for the price $p_{NS} = \frac{\mu}{\gamma_N + \mu\gamma_S}$.

Parallel trade decreases the price in the North and increases the price in the South ($p_N^x > p_{NS} > p_S^x$).¹⁰ Higher demand μ aggravates the price changes generated by parallel trade ($\frac{\partial(p_{NS}-p_N)}{\partial\mu} > 0$, $\frac{\partial(p_{NS}-p_S)}{\partial\mu} > 0$).

Under parallel trade, the firm may decide not to sell to the South to avoid selling at a uniform price. The firm sells to both countries if $\Delta = \pi_{N,S} - \pi_N^x \geq 0$, i.e., the profit from selling at a uniform price p_{NS} to both countries is at least as high as the profit from selling at a country-specific price p_N^x only to the North. The firm trades off accepting a lower price in the North and selling in both countries and setting a country-specific price for the North and foregoing sales in the South.

Parallel trade occurs only within a limited range of parameters. Two conditions have to be met. The first condition is that a sufficiently high price difference between N and S makes parallel trade profitable. The second condition is that the drug has to be sold to the South in the first place. This is, by not supplying the South, the firm can deter parallel trade.

4.3. Welfare

Welfare in the North is given as $W_N^x = CS_N^x + \pi - E_N^x$ and welfare in the South is given as $W_S^x = CS_S^x - E_S^x$. Note that because of uniform pricing under parallel trade, parallel imports do not occur. Therefore, consumers in the North do not face the choice between different kinds of drugs (originally distributed and parallel imports) and do not obtain different consumer surpluses depending on drug choice.

In the North, parallel trade decreases the drug price. The lower drug price increases consumer surplus and decreases third-party payer expenditure. The firm's profit decreases because parallel trade generates distortions from the profit-maximizing prices in both countries, i.e., both the profit from sales to the North and the profit from sales to the South are lower under parallel trade. If demand in the North is sufficiently low and prices in both countries under no parallel trade are rather similar, the latter effect is less strong. Therefore, parallel trade increases welfare in the North if demand is sufficiently low, i.e., $W_N > W_N^x$ if $\mu < \widehat{\mu_{W_N}}$.

In the South, parallel trade increases the drug price. The higher drug price decreases consumer surplus but decreases third-party payer expenditure (the quantity effect is stronger than the price effect). Higher demand in the North increases the uniform price under parallel trade, and the latter effect is stronger. Thus, parallel trade increases welfare in the South if demand in the North is sufficiently high, i.e., $W_S > W_S^x$, if $\mu > \widehat{\mu_{W_S}}$. Note that parallel trade increases welfare in both countries if co-payments in the South are sufficiently low relative to co-payments in the North.

5. Choice of regulation level: Second-stage outcome

In this section, I study the effect of parallel trade on the level of regulation for a given regulatory instrument. The regulatory instrument is treated as exogenous in this section

¹⁰ This also implies that the quantity in the North increases, while the quantity in the South decreases.

but will be endogenized in section 6. I denote no regulation by the superscript \emptyset , a price cap by the superscript P , a reimbursement limit by the superscript R and policy choice by $\Psi = \{\emptyset, P, R\}$. Superscripts Ψ_N, Ψ_S denote equilibrium policy choices in the North and South. There are two symmetric equilibria (PP, RR) and two asymmetric equilibria (PR, RP). In addition, there are two equilibria, in which only the South limits prices or reimbursement ($\emptyset R, \emptyset P$). In what follows, I will discuss the symmetric equilibria as well as the equilibria in which only the South regulates first, followed by the asymmetric equilibria.

Under no parallel trade, policy choices in both countries are independent, under parallel trade, policy choices are linked via the uniform drug price.

5.1. Price caps in both countries (PP) or in the South only ($\emptyset P$)

Consider first a scenario in which both governments set price caps or only the government in the South sets a price cap.

Price caps define maximum prices that can be charged. In what follows, consider binding price caps in both countries, i.e. $P_N^{x,(\cdot)} < p_N^x$, $P_S^{x,(\cdot)} < p_S^x$ under no parallel trade and $P_N^{(\cdot)} < p_{NS}$, $P_S^{(\cdot)} < p_{NS}$ under parallel trade. Price caps and welfare can be found in online appendix A.2.

Parallel trade may create spillovers in the regulatory decision: Under price caps, the price cap in the South becomes the global price cap if it is lower than the price or even the price cap in the North. While under no parallel trade, the domestic government in the North is in charge of the setting the price cap, under parallel trade, the pricing decision may be shifted to the government in the South. This depends on which government sets the lower price cap.

Moreover, parallel trade may distort regulatory decisions. In the North, the government may not be able to set a high price cap, if the price or price cap in the South is lower. In the South, the government cannot set a very low price cap if the firm's decision to export is endogenous. The firm's threat not to supply the South under parallel trade may force the government to set a higher price cap.

5.1.1. No parallel trade ($x, \emptyset P, x, PP$)

LEMMA 1. *Without parallel trade, under price caps, both North and South prefer a high level of regulation, i.e., price caps of zero.*

Consider first that parallel trade is not allowed. Because drug prices and policy choices are independent, the equilibria in which only the government in the South ($x, \emptyset P$) sets a price cap $P_S^{x, \emptyset P}$ and in which both governments in the North and in the South set price caps $P_N^{x, P}$, $P_S^{x, P}$ (x, PP) are discussed jointly.

The firm's profit is given as

$$\pi_{N,S}^{x,(\cdot)P} = \begin{cases} q_N \left(p_N^{x, \emptyset P} \right) p_N^{x, \emptyset P} + q_S \left(P_S^{x, \emptyset P} \right) P_S^{x, \emptyset P} & \text{for } \emptyset P \\ q_N \left(P_N^{x, PP} \right) P_N^{x, PP} + q_S \left(P_S^{x, PP} \right) P_S^{x, PP} & \text{for } PP. \end{cases} \quad (5)$$

For equilibrium $\emptyset P$, the firm may set the drug price freely in the North, while in the South the government sets a price cap $P_S^{x, \emptyset P}$. The firm sets the drug price $p_N^{x, \emptyset P} = \frac{\mu}{2\gamma_N}$ in the North. In the South, welfare decreases in the price cap, because a lower drug price increases consumer surplus and decreases third-party payer expenditure. The government in the South sets $P_S^{x, \emptyset P*} = 0$.

For equilibrium PP , governments in the North and the South set price caps $P_N^{x, PP}$, $P_S^{x, PP}$. In both countries, welfare decreases in the price cap. In the North, a lower price cap increases demand, increasing consumer surplus and decreasing third-party payer expenditure. At the same time, lower price caps in both countries decrease the firm's profit. The

former effect dominates the latter and welfare decreases in the drug price. In the South, welfare decreases in the price cap.

The government in the North sets $P_N^{x,PP*} = 0$, the government in the South sets $P_S^{x,PP*} = 0$. Price caps of zero imply that neither consumers nor health insurance have to pay for the drug and the market is covered.

5.1.2. Parallel trade

PROPOSITION 2. (i) *If only the government in the South sets a price cap, parallel trade results in a higher price cap.* (ii) *If governments in both the North and South set price caps, parallel trade has no effect on price caps in both countries.*

The following subsections explain this proposition.

Price cap in the South ($\emptyset P$)

Consider that parallel trade is allowed and only the South sets a price cap P_S^P . The firm's profit is given as

$$\pi_{N,S}^{\emptyset P} = (q_N (P_S^{\emptyset P}) + q_S (P_S^{\emptyset P})) P_S^{\emptyset P}. \quad (6)$$

In this case, the price in the North is neither determined by the firm nor the government in the North but is given by the price cap in the South: The government in the South sets the global price.

Under parallel trade, the firm may avoid selling at the price cap set by the government in the South by not exporting to the South. The firm exports to the South under parallel trade if the profit from selling at the price cap P_S^P in both markets is at least as high as selling at the (free) price p_N^x in the North only, i.e., $\Delta^{\emptyset P} = \pi_{N,S}^{\emptyset P} - \pi_N^x \geq 0$. A (strict) price cap aggravates the trade-off associated with the export decision: The lower the price cap, the higher the difference in profits for the firm's two strategies and the less likely it is that the firm sells to the South. Note that for a price cap of zero (because it is under no parallel trade), the firm abstains from exporting to the South. Only if $P_S^{\emptyset P} > \widehat{P_S^{\emptyset P}}$, i.e., the price cap is sufficiently high, the firm sells to the South.

Welfare in the South decreases in the price cap $P_S^{\emptyset P}$ because a lower price cap increases consumer surplus and decreases third-party payer expenditure. The government in the South maximizes W_S^P subject to $\Delta^{\emptyset P} = \pi_{N,S}^{\emptyset P} - \pi_N^{x,(.)} \geq 0$, i.e., the firm selling to the South. The government in the South would prefer a price cap of zero. But given that the firm does not export to the South at a very low price cap, the government in South sets $P_S^{\emptyset P*} \geq 0$, which is the lowest price cap compatible with the firm selling in the South. Thus, parallel trade relaxes regulation by preventing the government in the South from setting a very low price cap.

These results suggest, in line with empirical evidence, that strict regulation increases the threat of the firm not supplying the South under parallel trade (Danzon and Epstein 2012, Verniers et al. 2011, Costa-Font et al. 2014). Source countries face a trade-off under parallel trade: accept high prices and benefit from (safe) drug supply or regulate prices and face the risk of not being supplied. The endogenous export decision of the firm stemming from the trade-off described above results in a credible threat generated by price spillovers under parallel trade. As a result, source countries of parallel imports may abstain from very strict regulation under parallel trade (Bennato and Valletti 2014, Grossman and Lai 2008). This may also explain the observation of Kanavos and Costa-Font (2005) that source countries of parallel import such as France, Italy and Portugal have changed to less strict regulation.

Price caps in the North and South (PP)

Consider that parallel trade is allowed and both countries set price caps. In this case, the lower price cap becomes the global price cap. This is, de facto, only one government decides on the price cap in both countries. Parallel trade constrains regulatory decisions in the sense that the price cap has to be not only lower than the firm's price but also lower than the price cap in the other country to be binding.

The firm's profit is given as

$$\pi_{N,S}^{PP} = \begin{cases} q_N^{PP} (P_N^{PP}) P_N^{PP} + q_S^{PP} (P_S^{PP}) P_S^{PP} & \text{if } P_N^{PP} \leq P_S^{PP} \\ (q_N^{PP} (P_S^{PP}) + q_S^{PP} (P_S^{PP})) P_S^{PP} & \text{if } P_N^{PP} > P_S^{PP}. \end{cases} \quad (7)$$

If $P_N^{PP} \leq P_S^{PP}$, the price cap in the North is P_N^{PP} , the price cap in the South is P_S^{PP} . In this case, the higher price cap does not spill over to the North. If $P_N^{PP} > P_S^{PP}$, the price cap in the South is the global price cap. In the former case, if $P_N^{PP} \leq P_S^{PP}$, $\Delta^{PP} \Big|_{P^{PP}=P_N^{PP}} = \pi_{N,S}^{PT,P} - \pi_N^{P,(.)} > 0$, i.e., the firm sells to the South at any price cap P_S^{PP} , because selling in the South does not imply accepting a lower price for sales in the North. Also, in this case, the government in the North sets a lower price than the government in the South and parallel trade does not take place so that a potentially lower price from the South cannot spill over to the North. In the latter case, if $P_N^{PP} > P_S^{PP}$, the price cap in the South is the global price cap. The firm sells in the South, if the profit from selling at the price cap P_S^{PP} in both markets is at least as high as the profit from selling at the (free) price p_N^x in the North only, i.e., $\Delta^{PP} \Big|_{P^{PP}=P_S^{PP}} = \pi_{N,S}^{PP} - \pi_N^{x,PP} \geq 0$, that is, if $P_S^{PP} \geq \widehat{P_{S,\Delta^{PP}}^{PP}}$, i.e., the price cap is sufficiently high.

As before, welfare in both countries decreases in the price cap. Lower price caps increase consumer surplus, decrease third-party payer expenditure and decrease the firm's profit, increasing welfare in both countries. Governments set price caps $P_N^{PP*} = 0$, $P_S^{PP*} = 0$. Under these equilibrium price caps, the firm sells to the South because sales to the South do not come at the cost of accepting a lower price for sales in the North. The price cap in the North if the firm decided not to export to the South would be $P_N^{x,PP*} = 0$, this is, it would be the same.

To sum up, the effect of parallel trade on regulation depends on whether only the South sets price caps or both countries do. If only the South sets a price cap, parallel trade relaxes regulation. If both countries apply price caps, parallel trade does not affect regulatory decisions. Then the preference of the North for a low price cap deprives the firm of its threat of non-supply and enables the South to also set a low price cap. The firm can make use of the threat of non-supply only if it has the option of selling at a higher price in the North. The possibility of parallel trade to prevent a high level of regulation in source countries is thus contingent on the regulatory decision in the North.

5.2. Reimbursement limits in both countries (RR) or in the South only ($\emptyset R$)

Consider now a scenario in which both governments set reimbursement limits or only the government in the South sets a reimbursement limit. This implies that governments do not regulate prices directly but regulate third-party payer reimbursement. The regulation of reimbursement separates the consumer's co-payment from the amount financed by the third-party payer and from the price received by the firm. Governments restrict reimbursement to $r_j \leq p_j^R$ in country j . The firm is free in setting prices. Reimbursement limits change the consumer co-payment in country j to $c_j^R = \gamma_j r_j + p_j^R - r_j$ and reimbursement

to $(1 - \gamma_j)r_j$. Consider binding reimbursement limits, i.e., $r_N \leq \tilde{r}_N$, so that $p_N^{R(\cdot)} - r_N \geq 0$ and $r_S < \tilde{r}_S$ so that $p_S^{(\cdot)R} - r_S \geq 0$. Reimbursement limits and welfare can be found in online appendix A.2.

5.2.1. No parallel trade $(x, \emptyset R, x, RR)$

LEMMA 2. *Without parallel trade, under reimbursement limits, the North prefers a low level of regulation, i.e., reimbursement of the drug price, and the South prefers a high level of regulation, i.e., a reimbursement limit of zero.*

When parallel trade is not allowed, drug prices and policy choices are independent, the equilibria in which only the government in the South $(x, \emptyset R)$ sets reimbursement limit $r_S^{x,R}$ and in which both governments in the North and the South set reimbursement limits $r_N^{x,R}$, $r_S^{x,R}$ (x, RR) are discussed jointly. The firm's profit is given as

$$\pi_{N,S}^{x,(\cdot)R} = \begin{cases} q_N \left(p_N^{x,\emptyset R} \right) p_N^{x,\emptyset R} + q_S \left(p_S^{x,\emptyset R} \right) p_S^{x,\emptyset R} & \text{for } \emptyset R \\ q_N \left(p_N^{x,RR} \right) p_N^{x,RR} + q_S \left(p_S^{x,RR} \right) p_S^{x,RR} & \text{for } RR. \end{cases} \quad (8)$$

In equilibrium $\emptyset R$, the firm sets drug prices $p_N^{x,\emptyset R} = \frac{\mu}{2\gamma_N}$ and $p_S^{x,\emptyset R} = \frac{1+r_S^{x,\emptyset R}(1-\gamma_S)}{2}$.¹¹ The drug price in the South increases in the reimbursement limit. Welfare in the South decreases in the reimbursement limit. A (potential) decrease in the reimbursement limit increases the consumer co-payment for a given drug price and decreases the quantity demanded, decreasing consumer surplus and decreasing third-party payer expenditure. The overall effect of a (potential) decrease in the reimbursement limit on welfare is positive. The government in the South sets $r_S^{x,\emptyset R*} = 0$. Patients pay the full price of the drug out of pocket. The government in the South removes insurance coverage by limiting reimbursement.

In equilibrium RR , the firm sets drug prices $p_N^{x,RR} = \frac{\mu+r_N(1-\gamma_N)}{2}$ and $p_S^{x,RR} = \frac{1+r_S(1-\gamma_S)}{2}$.¹² In the North, welfare increases in the reimbursement limit. A (potential) decrease in the reimbursement limit increases the consumer co-payment for a given drug price¹³ and decreases the quantity demanded. This decreases consumer surplus and the firm's profit and decreases third-party payer expenditure, with an overall negative effect on welfare. Therefore, the government sets the highest possible binding reimbursement limit, $r_N^{x,RR*} = \widetilde{r_N^{x,RR}}$. Because $p_N^{x,RR} \left(\widetilde{r_N^{x,RR}} \right) = \widetilde{r_N^{x,\emptyset RR}}$, there is no additional co-payment for patients. This implies that the government in N chooses not to limit the reimbursement but reimburses the full drug price.

In the South, welfare decreases in the reimbursement limit. The government in the South sets $r_S^{x,RR*} = 0$. The government in the South de facto removes insurance coverage.

This shows that without parallel trade, regulatory preferences differ among the two countries, with the North preferring a very low level of regulation, while the South prefers a very high level of regulation.

11 A binding reimbursement limit implies $r_S \leq \widetilde{r_S^{x,\emptyset R}} = \frac{1}{\gamma_S+1}$.

12 Binding reimbursement limits imply $r_N \leq \widetilde{r_N^{x,RR}} = \frac{\mu}{\gamma_N+1}$ and $r_S \leq \widetilde{r_S^{x,RR}} = \frac{1}{\gamma_S+1}$.

13 The drug price increases in the reimbursement limit. A decrease in the reimbursement limit decreases the drug price, but the decrease in the drug price does not fully compensate the decrease in the reimbursement limit and the consumer co-payment increases.

5.2.2. Parallel trade

PROPOSITION 3. (i) If only the government in the South sets a reimbursement limit, parallel trade does not affect the reimbursement limit if $\mu < \widetilde{\mu^R}$ and increases the reimbursement limit if $\mu \geq \widetilde{\mu^R}$. (ii) If both governments in the North and the South set reimbursement limits, parallel trade decreases the reimbursement limit in the North and (a) does not affect the reimbursement limit in the South if $\mu < \widetilde{\mu^{RR}}$ and (b) increases the reimbursement limit in the South if $\mu \geq \widetilde{\mu^{RR}}$.

The following subsections explain this proposition.

Reimbursement limit in the South ($\varnothing R$)

Consider now that parallel trade is allowed and only the South sets a reimbursement limit $r_S^{\varnothing R}$. The firm sells at a uniform price p_{NS}^R in both countries. The firm's profit is

$$\pi_{N,S}^{\varnothing R} = (q_N (p_{NS}^{\varnothing R}) + q_S (p_{NS}^{\varnothing R})) p_{N,S}^{\varnothing R}. \quad (9)$$

The firm sets the uniform price $p_{NS}^{\varnothing R} = \frac{\mu(2+r_S^{\varnothing R}(1-\gamma_S))}{2(\gamma_N+\mu)}$.¹⁴ The drug price increases in the reimbursement limit in the South. The firm exports to the South under parallel trade if the profit from selling to both countries at a uniform price is at least as high as the profit from selling to only the North at the country-specific price (and not selling to the South), i.e., $\Delta^{\varnothing R} = \pi_{N,S}^{\varnothing R} - \pi_N^{x,\varnothing R} \geq 0$.

The government in the South maximizes $W_S^{\varnothing R}$ subject to $\Delta^{\varnothing R} \geq 0$, i.e., the firm exporting to the South. Depending on demand in the North, two cases are possible: For $\mu < \widetilde{\mu^R}$, the government sets a reimbursement limit of $r_S^{\varnothing R*} \big|_{\mu < \widetilde{\mu^R}} = 0$; for $\mu > \widetilde{\mu^R}$, the government sets a reimbursement limit of $r_S^{\varnothing R*} \big|_{\mu > \widetilde{\mu^R}} \geq 0$.

Parallel trade does not affect the level of regulation in the South if demand in the North is sufficiently low. In this case, the difference between the uniform price under parallel trade (and regulation in the South) and the price that the firm would charge in the North if it decided not to sell to the South is rather small, so that the benefit of additional sales to the South set off the cost of accepting a lower uniform price under parallel trade. A high level of regulation and the corresponding decrease in the uniform price then have a rather small effect on the firm's export decision.

Parallel trade relaxes regulation, i.e., it increases the reimbursement amount, if demand in the North is sufficiently high. In this case, the price the firm would charge in the North if it did not export to the South and the uniform price under parallel trade are rather different. If a high level of regulation lowers the price in the South and with it the uniform price under parallel trade even more, the firm would not export to the South. In this case, similar to the case of price caps, parallel trade prevents the government in the South from setting a very low reimbursement limit.

Also under reimbursement limits, parallel trade has the potential to relax regulation but only if sufficiently high differences in demand and/or co-insurance rates between countries put exports to the South at risk. If countries are sufficiently similar, parallel trade does not relax regulation under reimbursement limits. The firm's threat of not selling to the South may not help to achieve a higher reimbursement level if small differences in demand do not provide the firm with a profitable outside option when not selling in the South.

14 A binding reimbursement limit implies $r_S \leq \widetilde{r_S^R} = \frac{2\mu}{2\gamma_N + \mu(1+\gamma_S)}$.

Compared with price caps, the potential of parallel trade to prevent a high level of regulation under reimbursement limits is lower. Price caps enforce maximum prices set by the government. Free pricing under reimbursement limits implies that the firm may avoid a very low drug price even for a high level of regulation, but the firm loses the threat of non-supply at the same time.

Reimbursement limits in the North and South (RR)

Consider now that parallel trade is allowed and both governments set reimbursement limits r_N^{RR} and r_S^{RR} . The firm's profit is

$$\pi_{N,S}^{RR} = (q_N (p_{N,S}^{RR}) + q_S^{RR} (p_{N,S}^{RR})) p_{N,S}^{RR}. \tag{10}$$

The firm sets the uniform price $p_{N,S}^{RR} = \frac{2\mu + \mu r_S^{RR}(1-\gamma_S) + r_N^{RR}(1-\gamma_N)}{2(\mu+1)}$.¹⁵ The drug price increases in both reimbursement limits. The firm exports to the South under parallel trade if the profit from selling to both countries at a uniform price is at least as high as the profit from selling to only the North at a country-specific price (and not selling to the South), i.e., $\Delta^{RR} = \pi_{N,S}^{RR} - \pi_N^{RR} \geq 0$. If demand in the North is sufficiently low ($\mu \leq \widehat{\mu_{\Delta^{RR}}}$), the firm sells to the South.

The government in the North maximizes W_N^{RR} , the government in the South maximizes W_S^{RR} subject to $\Delta^{RR} \geq 0$, i.e., the firm exporting to the South. There is strategic interaction of reimbursement limits via the uniform price under parallel trade. Optimal (unconstrained) reimbursement limits are strategic complements. An increase in the reimbursement limit in the South increases the drug price, which in turn, ceteris paribus, increases the co-payment and reduces the quantity demanded in the North. The increase of the co-payment and decrease in quantity reduces consumer surplus and third-party payer expenditure. The firm's profit decreases as well. An increase of the reimbursement limit in the North then reduces the co-payment and increases the quantity demanded, countervailing the effect on consumer surplus, third-party payer expenditure and the firm's profit. Similarly, an increase in the reimbursement limit in the North increases the co-payment and reduces the quantity demanded in the South, decreasing consumer surplus and third-party payer expenditure. If the government in the North then raises the reimbursement limit, the reduction of the co-payment and increase in the quantity demanded increase consumer surplus and third-party payer expenditure.

Depending on demand in the North, two cases are possible. First, if countries are sufficiently similar ($\mu < \widehat{\mu^{RR}}$), countries set (unconstrained) reimbursement limits to maximize welfare. The government in the South sets a reimbursement limit of zero ($r_S^{RR*}|_{\mu < \widehat{\mu^{RR}}} = 0$) (as under no parallel trade). The government in the North sets a reimbursement limit ($r_N^{RR*}|_{\mu < \widehat{\mu^{RR}}} > 0$) that is lower than under no parallel trade. The lower drug price under parallel trade decreases the co-payment and increases demand for the drug, ceteris paribus, which increases consumer surplus and increases third-party payer expenditure.¹⁶ Then the government in the North reduces the reimbursement limit to countervail this effect, reducing third-party payer expenditure. Second, if countries differ in market size sufficiently ($\mu \geq \widehat{\mu^{RR}}$), the government in the South sets a positive reimbursement limit ($r_S^{RR*}|_{\mu \geq \widehat{\mu^{RR}}} > 0$),

15 Reimbursement limits are binding for $r_N \leq \widehat{r_N^{RR}} = \frac{\mu(2+r_S^{RR}(1-\gamma_S))}{\gamma_N+2\mu+1}$ and $r_S^{RR} < \widehat{r_S^{RR}} = \frac{2\mu+r_N^{RR}(1-\gamma_N)}{\mu+\gamma_S+2}$.

16 Note that there is no price effect for third-party payer expenditure because the reimbursement limit r_N is the basis for reimbursement per unit purchased.

which is compatible with the firm exporting to the South. The North sets a lower reimbursement limit than under no parallel trade ($r_N^{RR*}|_{\mu \geq \widetilde{\mu_{RR}}} > 0$) for the same reason as described above.

To sum up, if governments set reimbursement limits, parallel trade results in regulatory convergence. If demand in the North is sufficiently small, parallel trade decreases the reimbursement limit in the North and has no effect on the reimbursement limit in the South. If demand in the North is sufficiently large ($\mu > \widetilde{\mu_{RR}}$), parallel trade decreases the reimbursement limit in the North and increases the reimbursement limit in the South. In both cases, parallel trade generates regulatory convergence.

This is, there may be no need for explicit harmonization of regulatory decisions but market integration through parallel trade may align regulatory decisions under reimbursement limits.

While under both price caps and reimbursement limits, parallel trade may relax regulation, market outcomes under the two instruments differ: Under reimbursement limits, relaxed regulation implies higher reimbursement limits and lower co-payments (i.e., a shift of the financing burden from the patient to the insurer); whereas under price caps, relaxed regulation results in higher price caps, that is, higher co-payments and higher reimbursement (i.e., an increase in the transfer from patient and insurer to the firm).

5.3. “Asymmetric” equilibria

In this subsection, the effect of parallel trade on regulation is explored for asymmetric regulatory decisions in both countries, i.e., one country applies a price cap and the other country applies a reimbursement limit.

PROPOSITION 4. *If the government in the North sets a price cap and the government in the South sets a reimbursement limit, parallel trade does not affect the level of regulation in either country. (ii) If the government in the North sets a reimbursement limit and the government in the South sets a price cap, parallel trade decreases the reimbursement limit in the North and increases the price cap in the South.*

The following subsections explain this proposition.

5.3.1. No parallel trade, price cap in the North, reimbursement limit in the South (x, PR)

Consider first that parallel trade is not allowed and the government in the North sets a price $P_N^{x,PR}$ and the government in the South sets a reimbursement limit $r_S^{x,PR}$. The firm's profit is given as

$$\pi_{N,S}^{x,PR} = q_N \left(P_N^{x,PR} \right) P_N^{x,PR} + q_S \left(p_S^{x,PR} \right) p_S^{x,PR}. \quad (11)$$

Under no parallel trade, pricing and regulatory decisions are independent. Therefore, the price for the North is the same as in the equilibrium $\emptyset P$ or PP and the price for the South is the same as in the equilibrium $\emptyset R$ or RR . In the North, the government sets $P_N^{x,PR*} = 0$. In the South, the firm sets the drug price $p_S^{x,PR} = \frac{1+r_S(1-\gamma_S)}{2}$ ¹⁷ and the government in the South sets $r_S^{x,PR*} = 0$.

5.3.2. Parallel trade and price cap in the North, reimbursement limit in the South (PR)

Consider now that parallel trade is allowed and the government in the North sets a price cap P_N^{PR} and the government in the South sets a reimbursement limit r_S^{PR} . The firm's profit is given as

¹⁷ Binding reimbursement limits imply $r_S \leq \tilde{r}_S = \frac{1}{\gamma_S+1}$.

$$\pi_{N,S}^{PR} = q_N (P_N^{PR}) P_N^{PR} + q_S (p_S^{PR}) p_S^{PR}. \quad (12)$$

The price cap in the North is P_N^{PR} , the (freely set) drug price in the South is p_S^{PR} . In this case, a binding price cap in the North is lower than the drug price in the South and parallel trade does not occur. If $P_N^{PR} > p_S^{PR}$, the price cap in the North would not be binding and the drug price in the South is the global price.

In the South, the firm sets the drug price $p_S^{PR} = \frac{1+r_S^{PR}(1-\gamma_S)}{2}$. The firm always sells to the South, i.e., $\Delta^{PR} = \pi_{N,S}^{PR} - \pi_N^{xP} > 0$. Selling in the South does not imply that the firm accepts a lower price for sales also in the North because parallel trade does not take place. In the North, welfare decreases in the price cap, and therefore, the government sets a price cap of $P_N^{PR*} = 0$. In the South, welfare decreases in the reimbursement limit, and thus, the government sets $r_S^{PR,P*} = 0$. Parallel trade does not affect regulatory decisions in both countries.

5.3.3. No parallel trade, reimbursement limit in the North, price cap in the South (RP)

Consider that parallel trade is not allowed, the government in the North sets a reimbursement limit $r_N^{x,RP}$ and the government in the South sets a price cap $P_S^{x,RP}$. The firm's profit is given as

$$\pi_{N,S}^{x,RP} = q_N (p_N^{x,RP}) P_N^{x,RP} + q_S (P_S^{x,RP}) P_S^{x,RP}. \quad (13)$$

Under no parallel trade, pricing and regulatory decisions are independent. Therefore, the price for the North is the same as in the equilibrium $\emptyset R$ or RR ; the price for the South is the same as in the equilibrium $\emptyset P$ or PP . In the North, the firm sets the drug price $p_N^{x,RP} = \frac{\mu + r_N^{x,RP}(1-\gamma_N)}{2}$ ¹⁸ and the government sets $r_N^{x,RP*} = \tilde{r}_N$. In the South, the government sets the price cap $P_S^{x,RP*} = 0$.

5.3.4. Parallel trade and reimbursement limit in the North, price cap in the South (RP)

Consider that parallel trade is allowed and the government in the North sets a reimbursement limit r_N^{RP} and the government in the South sets a price cap P_S^{RP} . The firm's profit is given as

$$\pi_{N,S}^{PR} = q_N (P_S^{RP}) P_S^{RP} + q_S (P_S^{RP}) P_S^{RP}. \quad (14)$$

The price cap in the South is the global price cap. This implies that the drug price in the North is P_S^{RP} .¹⁹ The firm sells to the South if the profit from selling to both countries at a uniform price is at least as high as the profit from selling to only the North at the drug price p_N^{RP} (and not selling to the South), i.e., $\Delta^{RP} = \pi_{N,S}^{RP} - \pi_N^{xP} \geq 0$. In the North, welfare increases in the reimbursement limit. Therefore, the government sets the highest possible binding reimbursement limit, $r_N^{x,RP*} = \widetilde{r_N^{x,\emptyset RP}}$. The government in the South maximizes W_S^{RP} subject to $\Delta^{RP} = \pi_{N,S}^{RP} - \pi_N^{xP} \geq 0$, i.e., the firm selling to the South. Given that the government in the South would prefer a price cap of zero but the firm would not export to the South at a very low price cap, the government in South sets $P_S^{RP*} > 0$, which is the lowest price cap compatible with the firm selling in the South. As in the equilibrium $\emptyset P$, parallel trade prevents the government in the South from setting a very low price cap.

18 Binding reimbursement limits imply $r_N \leq \widetilde{r}_N = \frac{\mu}{\gamma_N + 1}$.

19 A binding reimbursement limit implies $r_N \leq \widetilde{r_N^{RP}} = P_S^{RP}$.

TABLE 1

Equilibrium regulatory choices

North, South \emptyset P	R	
\emptyset	No parallel trade: South: Price cap = 0 Parallel trade: South: Price cap > 0	No parallel trade: South: Reimbursement limit > 0 Parallel trade, market size in the North small: South: Reimbursement limit = 0 Parallel trade, market size in the North large: South: Reimbursement limit \geq 0
P	No parallel trade: North: Price cap = 0; South: Price cap = 0 Parallel trade: North: Price cap = 0; South: Price cap = 0	No parallel trade: North: Price cap = 0; South: Price cap = 0 Parallel trade: North: Price cap = 0; South: Price cap = 0
R	No parallel trade: North: Reimbursement limit > 0; South: Price cap = 0 Parallel trade: North: Reimbursement limit > 0; South: Price cap > 0	No parallel trade: North: Reimbursement limit > 0; South: Reimbursement limit = 0 Parallel trade, market size in the North small: North reimbursement limit > 0; South: Reimbursement limit = 0 Parallel trade, market size in the North large: North: Reimbursement limit > 0; South: Reimbursement limit > 0

5.4. Summary

Table 1 summarizes all regulatory choices under no parallel trade and parallel trade.

I can now characterize the complete effect of parallel trade on regulation for price caps and reimbursement limits: Under price caps, parallel trade has no effect on the level of regulation in the North and it decreases the level of regulation in the South if either the North does not regulate or if the North sets a reimbursement limit. If the North also sets a price cap, parallel trade does not affect the level of regulation in the South because the North's preference for a low price cap allows the South to also set a low price cap without the risk of the firm not selling to the South. Under reimbursement limits, parallel trade increases the level of regulation in the North to counteract the effect of a lower drug price on expenditure and to further decrease the drug price to increase welfare. Parallel trade decreases the level of regulation in the South if countries are sufficiently different in terms of demand and if the North does not set a price cap. Parallel trade does not affect the level of regulation in the South if countries are sufficiently similar in terms of demand or if the North sets a price cap. The firm's threat of not selling to the South may not achieve a lower level of regulation if small differences in demand or the North's preference for a low price cap do not provide the firm with a profitable outside alternative when selling only in the North.

6. Choice of regulatory instrument: First-stage outcome

Consider now the choice of regulatory instruments in both countries.

PROPOSITION 5. *In the South, a price cap maximizes welfare under no parallel trade as well as under parallel trade. In the North, under no parallel trade, a price cap maximizes welfare. Under parallel trade, given that the South chooses a price cap, a reimbursement limit maximizes welfare in the North.*

The following subsections explain this proposition.

6.1. No parallel trade

Under no parallel trade, the choice of the regulatory instrument in both countries is independent. The choice of the regulatory instrument in the South affects welfare in the North via the firm's profit, but there is no strategic effect of the North's choice of policy instrument on policy choice in the South or vice versa. In the South, welfare is the same, irrespective of the instrument chosen by the North.

Both countries prefer price caps over reimbursement limits. In both countries, welfare decreases in the drug price. Price caps allow governments to set a drug price of zero, whereas reimbursement limits with the free pricing always generate a higher drug price. In addition, under price caps, governments may increase consumer surplus and decrease third-party payer expenditure at the same time. Under reimbursement limits, however, there is a trade-off between increasing consumer surplus and decreasing expenditure: A decrease in the reimbursement limit increases the co-payment, thus decreasing third-party payer expenditure but also decreasing consumer surplus.

6.2. Parallel trade

Under parallel trade, the choices of the regulatory instrument are linked via the price. If the South sets a price cap, the (lower) price cap translates directly to the drug price in the North. If the South sets a reimbursement limit, the uniform price under parallel trade increases in the reimbursement limit in the South.

The North chooses a price cap if the South sets a reimbursement limit and the North chooses a reimbursement limit if the South sets a price cap. If the South sets a reimbursement limit, the North chooses a price cap because it generates a lower drug price and thus higher welfare in the North. Compared with the equilibrium in which both countries choose reimbursement limits, welfare in the North is higher because the drug price is lower, consumer surplus is higher and third-party payer expenditure is lower. If the South sets a price cap, the North sets a reimbursement limit to enforce a higher price cap in the South. The North accepts a higher drug price and thus lower consumer surplus and higher third-party payer reimbursement at the benefit of boosting the firm's profit. Compared with the equilibrium in which both countries choose price caps, welfare in the North is higher because the firm's profit is higher because of the higher drug price in the South, although consumer surplus is lower and third-party payer expenditure is higher.

The South always prefers price caps over reimbursement limits, irrespective of the policy choice in the North. Welfare decreases in the drug price and price caps allow the government in the South to achieve a lower drug price compared with a reimbursement limit.

In the resulting equilibrium, the North sets a reimbursement limit, while the South sets a price cap. In this equilibrium, the South sets a price cap (higher than zero) that is compatible with the firm exporting to the South. This price cap also applies in the North, where the government sets a reimbursement limit equal to the price cap.

Parallel trade diversifies regulation in the sense that it results in different instruments being applied in the two countries. Compared with the equilibrium under no parallel trade where both countries set price caps of zero, parallel trade relaxes regulation. This suggests that the potential of parallel trade to relax regulation also holds under endogenous health policy choice.

7. Discussion

7.1. Country differences

The countries North and South differ in two respects. Demand in the North is higher than in the South and the firm's profits are considered only in the social welfare function of the North. The demand assumption drives the magnitude of the effects. The profit assumption is crucial for the effect of parallel trade on the level of regulation and the choice of regulatory instrument.

In the main part of the paper, both countries differ in their preference regarding the level of regulation and the choice of the regulatory instrument. If the firm were a multinational enterprise located in a third country or if the government in the North did not consider the firm's profit, regulatory preferences in the North would change.

Under price caps, the preference for the level of regulation would not change. Under reimbursement limits, the North would set a reimbursement limit of zero, just like the South. This is, under both instruments, price caps and reimbursement limits, the North would prefer strict regulation.

However, the consequences are different for both instruments. When the North applies a price cap of zero, the drug price is zero and the quantity increases. Consumer surplus increases and third-party expenditure decreases. By contrast, when the North applies a reimbursement limit of zero, co-payments increase and the quantity decreases. Consumer surplus and third-party expenditure decrease.

Under endogenous regulatory instrument choice, the North would then choose a price cap (of zero), and parallel trade would not affect the choice of regulatory instruments in both countries.

If the government in the North considered only a part of the profits in the social welfare function, for example, local profits of a multinational firm, results would be qualitatively the same as in the main part of the paper.

The profit assumption in the paper could also reflect the fact that the government in the North takes into account that the firm must be able to fund innovative activities and should have the ability to develop new drugs while the government in the South behaves myopically (or free rides on innovation efforts).

Differences in demand drive the magnitude of the effect of parallel trade. The price difference, and, therefore, the threat of non-supply, increase in μ . A higher demand difference aggravates the effect of a threat of non-supply on regulatory decisions.

7.2. Governments objectives

Governments might give more weight to minimizing third-party payer expenditure than to maximizing welfare. In this case, the South would have a similar preference for strict regulation under both instruments because a low price cap and a low reimbursement limit decrease third-party payer expenditure. The North, however, would prefer a low price cap but would also choose a low reimbursement limit if minimizing third-party payer expenditure was more important. In this case, the effect of parallel trade on regulation under reimbursement limits would be similar than the effect under price caps, a preference for a high level of regulation in the North would eliminate the firm's threat of non-supply to the South. This allows the South to pursue strict regulation without risking the non-supply of the drug.

Without parallel trade, both governments would prefer strict price caps. This could raise the question of why governments are then interested in parallel trade at all. The model suggests that under certain conditions, parallel trade results in welfare gains. In the European Union, however, parallel trade is based on articles 34 and 35 of the Treaty on

the Functioning of the European Union (TFEU) and the related decisions of the Court of Justice of the European Union. From the perspective of an individual member state, it is not open for disposition.

The model is static. Both governments take drug development as a given. In particular, they do not consider the impact of regulation on drug development. Because new drug development is a long-term process, this could be explained by the myopia of governments. Of course, it is possible that governments also consider the long-term dynamic effects (see, e.g., Grossman and Lai 2008). This factor weakens the preference for low prices in both countries. Failure to adequately address innovation incentives in regulation can result in innovation not being pursued or pursued slowly. It can also change the nature of innovation, with fewer expensive genuine innovations and more low-cost, me-too innovations being developed. To incentivize innovation, governments would have to allow higher firm profits (at the expense of current consumer surplus and/or third-party expenditure). Dynamic incentives would require governments to balance the interests of current patients and third-party payers against those of future patients. This would require an intertemporal model. The trade-off between short- and long-term effects is beyond the model and is left for future research.

7.3. Cooperative governments

Governments might also cooperate in choosing the level of regulation or setting regulatory instruments. Under price caps, both countries choose a price cap of zero, but a higher price cap in the South would increase welfare in the North (via the firm's profit). Under cooperation (and a potential side payment) the South could potentially be motivated to increase its price cap, thereby reducing consumer surplus and increasing third-party payer expenditure, while welfare in the North would increase because of an increase in the firm's profit. Under reimbursement limits, cooperation would relax regulation in both countries. This would increase the drug price and reduce the quantity demanded, thereby reducing consumer surplus, reducing third-party payer expenditure and increasing the firm's profit.

7.4. Direction and volume of parallel imports

The model assumes that pricing interdependence under parallel trade induces the manufacturer to set a uniform price under parallel trade. This assumption can also be found in Pecorino (2002), Valletti (2006), Roy and Saggi (2012) and Bennato and Valletti (2014). Empirical evidence on whether parallel trade erodes price differences, however, is ambiguous. Competition from parallel trade may affect only a part of the market in the North, for example, because some consumers associate a lower quality with the parallel import because of differences in appearance and packaging (Maskus 2000) or because manufacturers try to restrict parallel trade by differentiating products across countries (Kyle 2011). In this case, only a part of the market in the North would be affected by parallel trade and the firm could set a different (and higher) price for the part of the market that is isolated from parallel trade. Results from the model would qualitatively be similar but weaker. For example, for a significant difference in demand between the North and the South, it would be optimal for the firm to sell to the North only and not export to the South in order to retain a high price in the North and to avoid the spillover of the lower price in the South to part of the market in the North.

The model considers only parallel trade from the South to the North. If the drug price in the North is lower than the drug price in the South, parallel trade could transmit the lower price in the North to the South. Two cases can be distinguished: If both countries set price caps, both prices are zero, so parallel trade has no effect. If the North sets a price cap and the South applies a reimbursement limit, parallel trade has no effect on the price in the

North but results in a lower price in the South. The main results of this paper hold in this case.

If the firm does not export to the South, parallel trade from the North to the South could make the drug available in the South. However, this undermines the firm's decision not to export to the South if the price in the South is too low. This mechanism weakens the threat of the drug being unavailable in the South and allows the government in the South to set higher prices. However, parallel imports typically take place if a locally sourced version of a drug is available.

8. Conclusion

In this paper, I have studied the effect of parallel trade on pharmaceutical regulation in a North–South framework. An innovative firm located in the North can sell its drug only in the North or in both countries. Governments may set price caps or may limit reimbursement for the drug.

Parallel trade may relax regulation in the source country under both regulatory instruments: Under price caps, it decreases the level of regulation only if the destination country does not set a price cap. Under reimbursement limits, it does so only if both countries are sufficiently different with respect to demand and if the destination country does not set a price cap. The manufacturer's threat of not supplying the source country of parallel imports requires a profitable alternative, i.e., the loss in profit from not selling in the source country has to be compensated by selling at a higher price in the destination country.

Parallel trade may intensify regulation in the destination country but only under reimbursement limits. Under price caps, the destination country prefers a high level of regulation, i.e., a price cap of zero, because it increases consumer surplus and decreases third-party payer expenditure. Under reimbursement limits, the destination country prefers a low level of regulation, i.e., reimbursement of the full drug price, because a decrease in the reimbursement limit would decrease third-party payer expenditure but also consumer surplus.²⁰ In response to the increase in third-party payer expenditure because of the lower drug price under parallel trade, the government in the destination country decreases the reimbursement limit. By relaxing regulation in the source country and/or intensifying regulation in the destination country, parallel trade results in regulatory convergence. This implies that, for given regulatory instruments, parallel trade may be a substitute for policy harmonization in some cases, for example, if both countries set reimbursement limits, but not in other cases, for example, if both countries set price caps. Whether parallel trade may replace policy harmonization depends on whether the firm has a profitable outside option when not selling in the South, i.e., the regulatory choice in the destination country or on differences in demand between countries.

Parallel trade may change regulatory preferences: Under no parallel trade, both the North and the South prefer price caps over reimbursement limits. Welfare in both countries decreases in the drug price. Price caps allow governments to set a drug price of zero, while free pricing under reimbursement limits yields a higher drug price. Under parallel trade, the South sets a price cap because it allows attaining a lower drug price. The North applies a reimbursement limit because it allows the North to enforce a higher price cap in the South. The North accepts a higher drug price and thus lower consumer surplus and higher third-party payer reimbursement at the benefit of boosting the firm's profit. The reimbursement limit in the North allows enforcing a higher drug price in the South than under price

20 Under both instruments, a high level of regulation decreases the firm's profit.

caps. This result complements the result in the previous literature on the effect of parallel trade on regulation, namely that governments in source countries may refrain from strict regulation if they take into account the impact of regulatory decisions on the firm's decision to supply the respective country. For endogenous health policy choice, both source and destination countries of parallel imports choose less strict regulation with higher drug prices. This result also implies that the ability of parallel trade to replace policy harmonization is not dependent on differences in demand between countries. Moreover, this effect seems not to be brought about by the firm's profit maximization but is also in the interest of the welfare-maximizing government in the destination country.

Under endogenous health policy choice, parallel trade results in a lower level of regulation and higher drug prices. Compared with the equilibrium without parallel trade in which both countries set price caps of zero, drug prices under parallel trade are higher. This also worsens access in both the source and destination country.

The firm's decision not to sell to the South and thus both the effect of parallel trade on the level regulation in the South and the effect of parallel trade on the choice of regulatory instrument in the North are driven by the decrease of the firm's profit. The lower profit of the firm may also induce a dynamic consequence if lower profits translate to less investment in innovation. This is left for further research.

ACKNOWLEDGEMENT

Open Access funding enabled and organized by Projekt DEAL.

Supporting information

Supplementary material accompanies this article.

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