Parallel Imports of Hospital Pharmaceuticals: An empirical analysis of price effects from parallel imports and the design of procurement procedures in the Danish hospital sector

by

Gisela Hostenkamp,

Christian Kronborg

and

Jacob Nielsen Arendt

Parallel Imports of Hospital Pharmaceuticals: An empirical analysis of price effects from parallel imports and the design of procurement procedures in the Danish hospital sector

Gisela Hostenkamp[a]   Christian Kronborg[b]   Jacob Nielsen Arendt[c]

---

[a] COHERE, Department of Business and Economics, University of Southern Denmark, e-mail: gih@sam.sdu.dk.

[b] COHERE, Department of Business and Economics, University of Southern Denmark, e-mail: cka@sam.sdu.dk.

[c] Danish Institute of Governmental Research, e-mail: jna@akf.dk.

Parallel Imports of Hospital Pharmaceuticals: An empirical analysis of price effects from parallel imports and the design of procurement procedures in the Danish hospital sector

JEL classification:

I11, K23, L12, D44

Abstract

We analyse pharmaceutical imports in the Danish hospital sector. In this market medicines are publicly tendered using first-price sealed-bid procurement auctions. We analyse whether parallel imports have an effect on pharmaceutical prices and whether the way tenders were organised matters for the competitive effect of parallel imports on prices.

Our theoretical analysis shows that the design of the procurement rules affects both market structure and pharmaceutical prices. Parallel imports may induce price competition for patented medicines if tenders are organised in a first-price sealed–bid format. In addition splitting a national supply contract into several regional tenders increases parallel importers' incentives to enter the market, but decrease original producers' incentives to engage in price competition so that their net effect on pharmaceutical prices needs to be established empirically.

We exploit a unique panel dataset containing contract prices of hospital medicines in Denmark between 2005 and 2009 to empirically analyse the effect of parallel imports on pharmaceutical prices and the role of the procurement rules for attracting parallel imports. Controlling for unobservable product characteristics using fixed effect estimation, parallel imports appear to have decreased pharmaceutical prices, but their effect on prices is smaller in regional tenders. Our results also support the conjecture that regional tenders increase parallel importers' propensity to participate in the bidding process.

Our results imply that the design of the procurement rules affect parallel importers' propensity to participate in the bidding process and that centralising pharmaceutical procurement may not always lead to lower prices than decentralised regional procurement.

Keywords:

Parallel Imports, Hospital Pharmaceuticals, Procurement Auctions, Denmark

1. Introduction

Governments in high price countries, such as Denmark, encourage parallel imports to limit pharmaceutical expenditures on patented medicines. Parallel trade, although legal in the EU, is a disputed pharmaceutical policy issue because the overall welfare effects can be positive as well as negative [1-6]. However, a necessary condition for welfare effects to be positive is that parallel trade leads to price competition in the destination countries. It is therefore also an empirical question whether parallel trade increases total welfare.

So far the empirical evidence concerning the price effects of parallel import in the destination countries has concentrated on the pharmaceutical retail sector and is inconclusive. While Ganslandt, Maskus [2] found that parallel imports reduced prices for imported products in the primary pharmaceutical sector in Sweden after joining the European Union, Linnosmaa et al. [7] found no price reducing effects from parallel imports in Finland. Another recent study investigated whether parallel trade leads to price convergence among European countries finding that prices are primarily affected by regulation and competition in the distribution chain, and that prices converge upwards rather than downwards [8].

The present paper contributes to this literature on several dimensions. First, the paper presents the first analysis of parallel imports in the hospital sector. Parallel imports were previously found to have made much less inroads into the hospital sector than in the pharmaceutical retail sector [9]. This is a puzzle since a large share of pharmaceutical expenditures in the hospital sector is spent on patented medicines. Consequently, there is a high savings potential for public health insurances. Moreover, many European countries use tenders to procure hospital medicines such that the actual contract price can deviate considerably from the official price, increasing the incentives for original producers to engage in price competition. This institutional setup is very different from the one found in the primary pharmaceutical sector, hence warrants a different theoretical framework. The current study investigates the role of the procurement procedures for parallel importers' incentives to participate in the bidding process and their subsequent effect on price competition by accommodating auction theory to the given setup. To test our hypotheses empirically we use panel data on real contract prices and information on submitted bids from the Danish hospital sector. The analysis of the impact of tender type on parallel import decisions benefits from a quasi-experimental study design arising from the introduction of regional tenders midway through the observations period. The analysis of price effects from parallel import is conducted using panel data analysis that account for unobservable time-invariant differences between products and potential endogeneity of parallel imports.

The rest of the paper is organised as follows: section 2 outlines the legal requirements for parallel imports and the procurement process. Section 3 presents theory on parallel imports in a market setting of incomplete information and derives theoretical hypotheses to be tested empirically. Section 4 describes the data and the estimation strategy. Section 5 presents the results while section 6 discusses results and concludes.

2. Background

2.1 Legal Requirements for Parallel Import

In the European Union, the parallel import of pharmaceuticals is regulated by EC Treaty Articles 28 and 30 and the European Commission's communication on parallel imports of medicinal products [10]. The principle of *regional exhaustion* of intellectual property rights provides the legal basis for the importation of patented medicines from one EU-member state to another without the consent of the patent holder [11]. After the first sale in a European member state, the patent holder no longer has the right to control the resale of its product within the European Union [4].

To operate legally, parallel importers require a license and a marketing authorisation for each product that is issued by the importing country. The original product needs to be marketed in both the exporting and importing country, and the parallel importer is required to notify the patent holder before a repackaged product is put on the market [12,13]. Thus, parallel imports are identical to locally sourced original products except that they may have different packaging.

However, importation from countries outside of the European Union is illegal, and special transitional provisions apply for parallel imports from new member states that joined the EU in 2004 [2,14]. Thus most parallel imports in the Danish market presumably come from southern European countries such as Spain, Portugal, Italy and Greece. While original producers are generally limited in their ability to increase prices in these countries due to the wide use of price cap regulations they may be able to limit general supply to potential exporting countries as to curb arbitrage possibilities for parallel trade. The scope for parallel import therefore also depends on the possibility of the original producer to control its supply chain.

2.2 Procurement of hospital medicine

In Denmark pharmaceutical pricing is generally free. Yet, to contain pharmaceutical expenditures in the Danish government has centralised the procurement of all medicines for the use in public hospitals in a single procurement agency, called AMGROS. All products with a total expected turnover exceeding 500000 DKK (ca. 67000 €) are purchased through public tenders following the EU

directive for public procurement. Tendering is the public procurement of a clearly defined product or set of products through a competitive bidding process. In Denmark calls for tender for pharmaceuticals are organised in the first-price sealed-bid format in which the supplier who submitted the lowest bid or overall economically most advantageous offer is awarded the contract and receives his bid.

The calls for tender specify the desired pharmaceutical according to active substances, form and strength, such that only suppliers of bioequivalent products can bid on a specific contract. Competition for patented medicines, therefore, depends on the potential to attract parallel importers. Non-contracted medicines have to be bought at the official pharmacy purchasing price (PPP). After the closing date all bids are evaluated and the winning supplier is privately informed, however, all bids including the winning bid remain confidential. Thus, there are no direct price adjustments that link the prices of other European countries to the Danish contract price, for example through a European reference price system, which could restrain original producers from lowering their prices.

Tenders can be categorised along three dimensions: first, AMGROS distinguishes between exclusive contracts (Type A) and parallel contracts (Type B). Type B contracts are used in treatment areas where it is difficult to shift patients to a new product, e.g., for patient safety reasons. Furthermore, contracts are either awarded based on price only (Type 1) or include additional award criteria (Type 2). Typically, calls for tender are made for national contracts that cover all public hospitals in Denmark and extend over one to two years. However, since 2007 AMGROS has also experimented with regional tenders in an attempt to attract more suppliers. Although, during our observation time most tenders were exclusive, national tenders without additional award criteria.

Exclusive national tenders generally imply that at any point in time, only one company wins the right to supply the entire market for a particular medicine since most hospital medicines do not have significant sales in the primary healthcare sector. Hence, in contrast to the primary pharmaceutical sector parallel importers and original producers often cannot coexist in the same product market simultaneously in the hospital sector.

3. Theory

Procurement environments are characterised by incomplete information about the value that suppliers place on a contract. In the following, we therefore analyse the price effect of parallel imports and the role of procurement rules in the destination country in a static incomplete informational setting.

Ganslandt, Maskus [2] showed that under complete information original producers always have an incentive to undercut the parallel importers' price if the entire market in the destination country could

be served through parallel imports; and thus parallel imports cannot exist in equilibrium unless parallel importers pre-commit to a quantity restriction. In contrast to the full information setting, parallel imports can exist in equilibrium if pharmaceuticals are procured using FPSB tenders. Thus it is sufficient to show that - even with exclusive national tenders - a unique equilibrium can exist in which parallel importers have a non-zero probability of earning positive profits. We show under which conditions this result holds and how alternative procurement rules affect suppliers' incentives for price setting.

We demonstrate that parallel imports can exist in equilibrium using the results of Kaplan, Zamir [15] assuming there is one originator and one parallel importer that compete for the right to supply a given contract and who draw their costs from different non-overlapping uniform distributions.[1] We denote the originator's distribution of costs as F_1, with $F_1(\underline{c_1}) = 0$ and $F_1(\overline{c_1}) = 1$ and a strictly positive uniform density f_1 on $[\underline{c_1}, \overline{c1}]$, such that $0 \leq \underline{c_1} < \overline{c_1} \leq P_f$, where P_f is the price in the exporting country. Similarly, the parallel importers' cost distribution is denoted as F_2, with $F_2(\underline{c_2}) = 0$ and $F_2(\overline{c_2}) = 1$ with a strictly positive uniform density f_2 on $[\underline{c_2}, \overline{c_2}]$, such that the order of costs is common knowledge $P_f \leq \underline{c_2} \leq \overline{c_2} \leq P_m$, where P_m is the price a originator can charge as a monopolist. This cost structure reflects a simple two country model in which the price in the destination country is unregulated and therefore at its monopoly level P_m, but regulated at $\overline{P}_f$ in the exporting country. However, the original producer still voluntarily chooses to serve the exporting country implying that his costs are below $\overline{P}_f$. Although the order of costs is common knowledge, the exact realisations of these costs are only known to the suppliers individually. Therefore our procurement environment can be analysed in the independent private values framework.

Assuming that pharmaceutical suppliers are profit maximisers and that spillovers to the pharmaceutical retail sector are negligible, no supplier would submit a bid below his own costs, because this would entail a negative payoff. Furthermore we assume that no bids above P_m are accepted and parallel importers that entered but have no chance of winning bid their own cost. Although the costs of the original producer and the parallel importer are drawn from non-overlapping distributions, the range of suppliers' bids for which they both have a positive probability of winning must be the same $\underline{b_1} = \underline{b_2}$ and $\overline{b_1} = \overline{b_2}$ so that no supplier may benefit from deviating from the equilibrium strategy [17]. Thus a necessary condition for parallel imports to be able to exist in equilibrium is that the upper bound for the equilibrium bid must be above the minimal costs of the parallel importer $\overline{b} > \underline{c_2}$. For the uniform distribution this is the case whenever $\overline{b} = \frac{\overline{c_2} + \overline{c_1}}{2} > \underline{c_2}$.[2] This

---

[1] A unique equilibrium also exists for the general n-bidder case see Lebrun [16].
[2] This follows from the parallel importer's profit maximisation problem and the condition that originator's profit from bidding above $\underline{c_2}$ must be at least as high as bidding $\underline{c_2}$, which guarantees winning.

example illustrates that the price reducing effect from parallel import could be substantial in a tendering market, because a parallel importer would need to bid at least half the difference between P_f and P_m in order to successfully enter the market.

The equilibrium can be found by solving the first order conditions of the suppliers' profit maximisation problems subject to the condition that $[\underline{b}, \overline{b}]$. See the appendix for the derivation of the inverse equilibrium bid functions for the case when suppliers' costs are uniformly distributed and sufficiently close together. Kaplan, Zamir [15] prove that these equilibrium bidding strategies are continuous and unique. Thus in equilibrium parallel importers may have a non zero probability to earn positive profits and the original manufacturer does not benefit from always bidding $\underline{c_2}$. Figure 2 illustrates the mapping of cost functions into bidding functions for the case when $\underline{c_1} = 0$; $\overline{c_1} = \underline{c_2} = 3$ and $\overline{c_2} = 5$. Parallel importers can thus participate in a first price sealed bid procurement auction if their ex-ante expected profits exceed any entry and bid preparation costs [18].

Instead, if the parallel importers' and original manufacturer's costs are too far apart such that $\overline{c_1} \leq 2\underline{c_2} - \overline{c_2}$ then parallel imports have no possibility to enter the market, because the original producer would always have an incentive to underbid any parallel importer. The same would be the case if procurement was organised in the English auction format. In this auction format, the price is consecutively lowered until only one supplier remains. The originator would be able to observe the presence of the parallel importer and could wait until the parallel importer, knowing that he has higher costs, has dropped out. Thus, the originator would always win the contract. Since a rational parallel importer would realise this, he would not participate in the tender if he has even the slightest bid preparation costs, and the price in the destination country would remain at P_m. As a consequence the revenue equivalence theorem is violated if suppliers' order of costs is common knowledge and the first-price procurement auction generates lower expected procurement costs [19]. However, the potential to obtain lower prices through parallel imports is based on the possibility that the contract will be allocated inefficiently, meaning to the supplier that does not have the lowest cost to accomplish the contract.

Regional tenders

Although original producers are often limited in their possibilities to increase prices in exporting countries, one legal possibility to respond to parallel import is to limit general supply to exporting countries. Parallel importers may thus face supply restrictions in the exporting countries and may not be capable of supplying the entire destination country. In such a situation the procurer could benefit from splitting a national contract into several smaller regional tender lots to attract additional suppliers to bid on a contract.

However, the overall effect of regional tenders on prices may be ambiguous, since regional tenders may induce suppliers to bid less aggressively, which increases the expected profits for parallel importers [20]. Parallel importers could thus have an incentive to pretend to face supply restrictions in exporting countries and commit to a quantity restriction, in a similar vein as in the full information setting analysed by Ganslandt, Maskus [2]. Procurement costs are thus minimised when the division into lots maximises the possibility that the original producer will try to outbid any parallel importers. Grimm et al. [21] suggest that the number of lots should be smaller than the expected number of suppliers but should not exclude potential suppliers that are subject to supply restrictions.

The above discussion shows that parallel imports can exist in equilibrium, even with exclusive national tenders, and that parallel imports can induce price competition for patented medicines. Regional tenders can increase parallel importers profit opportunities and therefore increase their propensity to participate in a call for tender. However, they may induce originators to bid less aggressively and thus their overall effect on pharmaceutical prices is a priori ambiguous. Thus in our empirical analysis we test whether i) parallel imports have a negative effect on prices ii) regional tenders attract more parallel importers and iii) regional tenders that attract parallel imports subsequently reduce pharmaceutical prices.

4. Empirical Analysis

We undertake an empirical analysis of the impact of procurement procedures on parallel imports and their subsequent effect on pharmaceutical prices in the Danish market for hospital medicines. This analysis is based on sales data for the years 2005 through 2009, which enables us to use panel data analyses to identify determinants of parallel imports and price developments of medicines that face competition from parallel imports compared to other patented medicines. We first compare the average price development for parallel imported products to the price development for products that are not subject to competition from parallel trade. Second, we estimate an econometric model of the impact of parallel trade on prices, and identify factors that determine the entry of parallel importers into the Danish hospital market.

4.1 Data

The data for this study were provided by the Danish public procurement agency for hospital medicines, which administers all sales to the hospital sector. These data include information on annual turnover, tender type, contract prices and suppliers at a product level for all medicines sold in the hospital sector in Denmark between 2005 and 2009. Pharmaceutical expenditures in the hospital sector in Denmark grew from 337 million € in 2005 to 705 million € in 2009. During this time,

parallel imports represented between 3.5% and 5% of total sales in the hospital sector, which is considerably lower than in the pharmaceutical retail sector.

For the purpose of the present analysis we concentrate on the 100 top-selling substances in the hospital sector in terms of turnover and excluded all medicines for which generic alternatives were available.[3] Since parallel importers have higher costs than generic companies, they tend to leave the market as soon as generics enter. Additionally, we excluded two substances because they had significant sales in the primary sector. We perform our analysis at the level of a product market, which is defined to contain all medicines that are bioequivalent to one another, thus they contain the same active substance in the same form and concentration. The final dataset includes 347 products distributed over 89 substances, representing approx. 78% of the Danish market for hospital medicines in terms of sales value in 2009.

4.1.1 Definition of price and parallel import variables

Since price levels varied considerably between products, we used relative prices as our main outcome variable, denoted $RelPrice_{it}$, which is the ratio between the price for product i in year t and the price in the previous year. The price in year t is defined as the volume weighted average price per DDD for a specific product. This variable captures the change in price of a product from one year to the next. In addition, we defined a variable $RelPrice2_{it}$ by dividing the price in period t by the price in the first year of our observation period, which captures the price development over the entire observation period.

We defined a dummy variable PI_t for the presence of parallel imports, which is equal to 1 if at least one parallel importer had positive sales for product i in year t or had submitted a positive bid but lost. To capture long term effects of parallel imports, we additionally defined a dummy variable PI_long equal to 1 if the product experienced competition from a parallel importer at time t or any previous year during our observation period.

4.1.2 Descriptive analysis of prices and parallel imports

The development in relative prices for products that faced competition from parallel imports at some point during the observation period versus products that never faced competition from parallel imports are shown in Table 1. The average price increase was significantly higher for products that faced parallel imports when compared to other patented medicines.[4] Prices for products that faced competition from parallel imports increased on average by 11.8%, whereas prices for products not subject to parallel trade decreased on average by 1.6%. However, for many products parallel imports

---

[3] Restriction to top-selling substances should not affect analyses of prices.
[4] Whether the price trends differed between the two groups was tested using a t-test with equal variance.

were not active from the beginning of the observation period, so that price increases could have preceded the entry of parallel imports. During the end of the observation period price changes between the two groups did not differ significantly.

Table 1 about here

Table 2 provides an overview of the distribution of the variables that were used in the analysis. The table shows that only 5.6% of all products faced competition from parallel imports in any specific year.

Table 2 about here

A number of additional facts are worth mentioning but are not shown due to space limitations. During the observation period, a total of 10 parallel importers had a license to import pharmaceuticals into the Danish market, but parallel importers varied greatly in size. The largest parallel importer in 2005 had only 2% market share in 2009 and the largest parallel importer in 2009, accounting for 56% of parallel import sales, did not even exist in 2005. There were 47 products that faced competition from parallel imports at least at one point between 2005 and 2009. However, exit and re-entry is common: only six products faced competition from parallel imports during the entire observation period, and in 30% of the products parallel importers were only active during the last two years. This pattern is quite different from the patterns observed in the primary pharmaceutical sector in previous studies. 40% of the products in which parallel importers entered were tendered through regional contracts, whereas 11% were tendered using parallel contracts (type B) and in 8% tenders with additional award criteria were used (type 2).

4.2 Methods

The goal of the study was to explore whether the tendering procedures (regional as opposed to national tenders in particular) have an impact on parallel importers participation in the tenders, whether parallel importers have a lasting effect on prices and whether the way tenders were organised matters for the competitive effect of parallel imports on prices.
To answer the first question we investigated the factors that were associated with parallel importers participation in the tendering process. For this purpose we estimated a probit model regressing presence of parallel imports on a set of dummy variables representing the tendering procedure and a number of explanatory variables, that were previously shown to be associated with presence of parallel imports or the number of competitors in a pharmaceutical market in general in previous studies[2,22,23]. We include the natural logarithm of the previous year's turnover for product i, denoted ln(MKSZ), to control for market size, the time since market authorisation in years, denoted AGE, and the share of sales to the hospital sector denoted HShare. Tender type is controlled for by

three dummy variables, which are equal to one for tender $TypeB$ (parallel contracts); tender $Type2$ (additional award criteria); regional tenders ReT, respectively.

$$\Pr(\text{PI}_{it} = 1) = \Phi(\alpha_0 + \beta_1 AGE + \beta_2 \ln(MKSZ) + \beta_3 ReT + \beta_4 Type2 + \beta_5 TypeB + \beta_6 HShare)$$

Here, Φ is the cumulative distribution function of the standard normal distribution. To obtain insights into the role of AGE and MKSZ that are likely to be important for parallel importer's decision to enter a market, we estimate a population averages model. However, this model cannot account for a correlation between product specific effects and the regressors and is therefore not useful for causal statements about the role of tender types on parallel importers decision to enter a market.

To answer the questions of causal effects of tender type on parallel import and of subsequent effects of parallel import on relative prices, we estimate a system of two equations, one parallel import equation and one price equation using fixed effects to identify any causal effects. The parallel import equation uses the same set of explanatory variables as the probit model mentioned above:

$$\text{PI}_{it} = \alpha_i + \beta_1 AGE + \beta_2 \ln(MKSZ) + \beta_3 ReT + \beta_4 Type2 + \beta_5 TypeB + \beta_6 HShare + \varepsilon_{it}$$

$$\frac{P_{it}}{P_{it-1}} = \gamma_i + \delta_1 PI + \delta_2 ReT * PI + \delta_3 ReT + \delta_4 Type2 + \delta_5 TypeB + \delta_6 HShare + v_{it}$$

Note that the price equation allows for differential effects of parallel import on prices in markets where procurement was conducted using regional and national tenders through the inclusion of an interaction effect between parallel import and regional tender type, thus allowing us to answer the third question. The FE specification implies that the intercepts can vary across products, but that the slopes are the same for all products assuming that the price flexibility across products to be homogeneous. This specification renders consistent estimates and controls for endogeneity of parallel import if all unobserved factors that affect either parallel importers selection of medicines or price changes are time invariant.[5] The fixed effects estimation can be applied to each regression separately if contract prices are truly confidential implying that parallel importers have no possibility to select products based on past realised prices or that their expectation of prices is time invariant.

Since regional tenders were first introduced in 2007 and we observe PI for later treated and controls both before and after the introduction of the regional tenders, we can take advantage of the quasi-experimental nature of our study design to identify whether regional tenders increase parallel importers participation in the bidding process. Thus the first question can be answered by examining the coefficient for ReT in the FE PI equation, and a causal interpretation of the estimate of this coefficient does not only hinge upon the assumptions rendering fixed effect specifications valid, but also draws its validity from the quasi-experimental design.

---

[5] A time invariant factor could for example be whether the medicine is a biological or chemical medicine.

An obvious difficulty in determining whether parallel imports have an impact on pharmaceutical prices is that parallel importers' entry decision might directly depend on expected prices that could be time varying and unobservable to us; accordingly FE would generate biased and inconsistent estimates in the price equation. To account for general endogeneity occurring through a correlation between the time-varying error terms of the parallel import and the price equation, we use instrumental variables (IV) estimation, where both presence of parallel imports and the interaction effect between parallel imports and regional tenders are estimated using AGE and MKSZ as instruments.[6] We estimate the fixed effects model presented above using the user written two stage least squares estimator with fixed effects in both stages denoted xtivreg2 command in STATA [24] that allows for the estimation of robust standard errors in the presence of heteroscedasticity. This might be the more realistic situation if parallel importers learn the previous period's winning bid. We replicate the analysis with *PI_long* instead of *PI* to take any lagged reactions of the original producer in subsequent periods into account.

5. Results

Based on the Probit estimates for the PI equation, table 3 column I shows that large markets, regional tenders and higher product age are more likely to attract parallel imports, whereas type B tenders and a high share of hospital sales are negatively associated with parallel imports. Since regional tenders were first introduced in 2007 we can take advantage of the quasi-experimental structure of the data to estimate the effect of the introduction of regional tenders on presence of parallel imports. The fixed effects estimates for the PI equation in column II show that regional tenders increased parallel importers participation in the tenders, however, most of the other variables seem to vary little across time periods.[7]

Column III and IV in Table 3 presents our fixed effect estimates for the price equation. These estimations can inform about the effect of parallel imports on prices and whether effect differs for regional tenders if all other relevant unobserved factors are time-invariant. Contrary to the overall observed trend seen in Table 1, the model shows that accounting for product specific effects, prices on average decreased in markets with parallel imports. Column III shows the estimates of the effect of parallel imports in period t on price changes in the same year, whereas Column IV presents the estimates of the effect of parallel imports on prices in all subsequent years. The estimated coefficients

---

[6] Traditionally prices of patented products remain constant for long periods of time until competitors enter the market.

[7] We tested the fixed effects specification against a random effects specification using a Hausman test, which clearly favours the fixed effects specification; therefore we continue our analysis using fixed effects. We also estimated models where MKSZ*ReT and AGE*ReT are used as additional instruments, but this only increases imprecision.

for *PI* point in the expected direction, indicating that the effect is to reduce prices by about 11%. However, the effect of parallel imports on price reductions is only about 4% in markets where regional tenders were used. A similar picture emerges for the effect of parallel imports in the longer run although the effect of parallel importers on prices is generally larger, which points towards some lagged price reactions of original producers.

Table 3 about here

Column V and VI present the FE 2SLS results that control for general time varying endogeneity. Unfortunately our instruments do not pass the Kleinbergen-Paap test for weak instruments since yearly changes in market size and product age are only weakly correlated with PI presence in the Danish hospital market. The coefficient estimates of the 2SLS regression can therefore not be interpreted. In an alternative specification we tested alternative measures for market size such as the turnover valued in official prices and time dummies instead of age as instruments. However, this did not improve the precision of our estimates.[8] It is worth stressing that if parallel importers select products that are expected to increase in price, the fixed effects are upwardly biased, i.e. the true effects are even more negative, but in the absence of better instruments we cannot investigate the size of the effect of parallel imports on relative prices with more precision, nor can we test for endogeneity of PI due to time varying factors.

6. Discussion

To the authors' knowledge, this is the first study on parallel imports in the hospital sector. The current study contributes to understanding the processes that drive parallel imports and the role that pharmaceutical procurement policies play for parallel importers participation in the tenders and their effect on pharmaceutical prices.

Our study has four main results: First, regional tenders increase parallel importers' participation in the bidding process for pharmaceutical supply contracts. Second, parallel imports have led to price competition in the Danish hospital sector. Third, a substantial part of the price reducing effect of parallel imports seems to come from a lagged reaction of the original producer and implies that there is an indirect price effect of parallel import that is effective in the long run. Fourth, the effect of parallel imports on prices is smaller for regional tenders implying that the design of the procurement rules affect the competitive effect of parallel imports on pharmaceutical prices in the hospital sector.

While our data provide a unique opportunity to study parallel imports in the hospital sector, our analysis is limited by the fact that we only had few actual observations of parallel imports. Although

---

[8] Results are available from the corresponding author upon request.

this fact principally supports our theoretical arguments, that exclusive national tenders limit parallel importers' ability to enter the market, it also provides some limitations with respect to our empirical analyses. Since there are few observations of markets in which parallel importers entered, propensity score matching that makes weaker assumptions about the functional form of the relationship between parallel imports and prices does not appear to be an option here. While the validity of the instruments can be discussed in any instrumental variable approach, we believe that by focussing on patented medicines, the assumptions capture the underlying processes in this market quite well.

Note that whereas market size and product age were fairly highly correlated with presence of parallel imports in the population averages probit model, our instruments did not have any explanatory power in the fixed effects specifications. Thus the within transformation performed by FE that eliminates the levels out of the variables had removed much of their explanatory power, which may imply that market age varies very little over time and that a general time trend cannot explain presence of parallel imports in the Danish market. Considering that most exporting countries are likely to be found among the Euro zone countries and that the Danish kroner is pegged to the Euro, varying exchange rates may not have a big impact on parallel imports neither. Thus most determinants of parallel import are probably time invariant and our FE estimates of the effect of parallel import on prices may not be seriously biased. After all, our fixed effects estimates are of a similar magnitude as the price effects previously found in the primary sector in Sweden using instrumental variables estimation [2].

Our analysis has shown that splitting national supply contracts into smaller regional lots increases parallel importers' participation in the tendering process. In this respect our results are in line with results from Kjerstad [22] who found that centralised procurement of hospital devices attracts fewer bidders than decentralised purchasing. This implies that centralising pharmaceutical procurement does not always provide the most competitive prices, because it may limit business opportunities for parallel importers and small suppliers. While parallel importers' effect on pharmaceutical prices was smaller in regional tenders they still decreased prices compared to national tenders in which parallel importers could not enter. Parallel importers may, therefore, have a strategic incentive to pretend that they cannot serve the entire market.

 Further research in this area could focus on the determinants of parallel imports in the hospital sector in an international context. Such research could also investigate to what extent centralised procurement of hospital medicines affects parallel importers' possibilities to source medicines in exporting countries. While the number of distribution channels is generally more limited in the hospital sector, than in the primary pharmaceutical sector, the low share of parallel imports in the market for hospital medicines may also result from the widespread use of tendering procedures in the

hospital sector. Many EU countries use tenders to procure hospital medicines, thus tendering could exacerbate original manufacturers' possibilities to control their supply chain [25,26].

Aside from difficulties in sourcing sufficient amounts of medicine for parallel import in potential exporting countries, it must also be considered whether pharmaceutical procurement agencies *should* focus on parallel imports to achieve savings in pharmaceutical expenditures. Parallel importers can only enter the market if the supply contracts are awarded inefficiently. This inefficient allocation induces a welfare loss, because it is not the supplier with the lowest costs that wins the contract. This welfare loss has to be considered against any potential gains in consumer surplus through lower prices and increased access to pharmaceuticals.

References

1. Danzon, P.M.: The economics of parallel trade. Pharmacoeconomics **13**(3), 293-304 (1998).
2. Ganslandt, M., Maskus, K.E.: Parallel imports and the pricing of pharmaceutical products: evidence from the European Union. Journal of Health Economics **23**(5), 1035-1057 (2004). doi:10.1016/j.jhealeco.2004.03.005
3. Jelovac, I., Bordoy, C.: Pricing and welfare implications of parallel imports in the pharmaceutical industry. International journal of health care finance and economics **5**(1), 5-21 (2005).
4. Kanavos, P., Costa-Font, J.: Pharmaceutical parallel trade in Europe: stakeholder and competition effects. Economic Policy **20**(44), 751-798 (2005).
5. Malueg, D.A., Schwartz, M.: Parallel imports, demand dispersion, and international price discrimination. Journal of International Economics **37**(3-4), 167-195 (1994).
6. Szymanski, S., Valletti, T.: Parallel trade, price discrimination, investment and price caps. Economic Policy(44), 705-750 (2005).
7. Linnosmaa, I., Karhunen, T., Vohlonen, I.: Parallel importation of pharmaceuticals in Finland: effects on markets and expenditures. Pharmaceutical Development and Regulation **1**(1), 67-74 (2003).
8. Kanavos, P., Vandoros, S.: Competition in prescription drug markets: is parallel trade the answer? Managerial and Decision Economics (2010).
9. Hostenkamp, G.: The market for hospital medicines in Denmark. Nordic Journal of Health Economics **1**(1), 61 - 77 (2011).
10. CEC: Communication from the Commission - Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted. In: COM(2003)839. (2003)
11. Directive 2008/95/EC: Article 7 Directive 2008/95/EC of the European parliament and of the council of 22 October 2008 to approximate the laws of the Member States relating to trade marks. Official Journal of the European Union **L 299/25** (2008).
12. Armengod, H., Baudenbacher, L.M.: The Repackaging of Pharmaceutical Products and Parallel Trade in the EU. Regulatory Affairs Pharma, 783 - 786 (2009).
13. Danish Medicines Agency, Ministry of Health and Prevention: Guidelines on parallel import of medicinal products No. 44 of 14 th July 2008. In. (2008)
14. Kyle, M.: Strategic Responses to Parallel Trade. The B.E. Journal of Economic Analysis & Policy **11**(2) (2011). doi:10.2202/1935-1682.2629
15. Kaplan, T.R., Zamir, S.: Asymmetric first-price auctions with uniform distributions: analytic solutions to the general case. Economic Theory, 1-34 (2010).
16. Lebrun, B.: Uniqueness of the equilibrium in first-price auctions. Games and Economic Behavior **55**(1), 131-151 (2006). doi:10.1016/j.geb.2005.01.006
17. Krishna, V.: Auction Theory, vol. 2nd. Elsevier Inc., (2010)

18. Li, T., Zheng, X.: Entry and Competition Effects in First Price Auctions: Theory and Evidence from Procurement Auctions. Review of Economic Studies **76**(4), 1397-1429 (2009).
19. Vickrey, W.: Counterspeculation, auctions, and competitive sealed tenders. The Journal of finance **16**(1), 8-37 (1961).
20. Milgrom, P.: Putting auction theory to work. Cambridge Univ Pr, (2004)
21. Grimm, V., Pacini, R., Spagnolo, G., Zanza, M.: Division into lots and competition in procurement. In: Handbook of procurement. pp. 168-192. (2006)
22. Kjerstad, E.: Auctions vs negotiations: a study of price differentials. Health Economics **14**(12), 1239-1251 (2005).
23. Scott Morton, F.M.: Barriers to entry, brand advertising, and generic entry in the US pharmaceutical industry. International Journal of Industrial Organization **18**(7), 1085-1104 (2000). doi:10.1016/s0167-7187(98)00057-5
24. Schaffer, M.E.: xtivreg2: Stata module to perform extended IV/2SLS, GMM and AC/HAC, LIML and k-class regression for panel data models. Statistical Software Components (2010).
25. Towse, A.: The pros and cons of a single 'Euro-price' for drugs. Pharmacoeconomics **13**(3), 271-276 (1998).
26. Vogler, S., Habl, C., Leopold, C., Mazag, J., Morak, S., Zimmermann, N.: PHIS Hospital Pharma Report 2010. In. (2010)

Tables:

Table 1: Comparison of relative price changes by presence of competition from parallel imports in any period between 2005 and 2009

		2005 – 2009		2008 - 2009	
	Obs.	Mean	St. Dev.	Mean	St. Dev.
Products not facing PI	263	0.984	(0.018)	1.001	(0.030)
Products facing PI	45	1.118	(0.057)	0.991	(0.021)

Table 2: Descriptive statistics of variables used in the empirical analysis

Variable	Mean	Std. Dev.	Min	Max	Obs.
Price	1219.8	3778.6	.62	47983	1594
P_t/P_{t-1}	1.0036	0.792	0.070	19.918	1594
P_t/P_0	1.0046	0.191	0.097	21.231	1594
PI_t	0.0559	0.229	0	1	1869
PI_long	0.0826	0.275	0	1	1869
ReT	0.1953	0.394	0	1	1869
Tender Type B	0.2746	0.443	0	1	1850
Tender Type 2	0.1367	0.343	0	1	1850
HShare	91.165	20.84	50.06	100	1594
Ln(MKSZ)	14.477	2.206	4.573	19.34	1598
Age	13.859	9.164	0	52	1869

Table 3: Regression results

	PI equations		Price equations		IV-2SLS Price equations	
	I	II	III	IV	V	VI
	PI_t	PI_t	PI_t	PI-long	PI_t	PI_long
	Probit	FE	FE	FE	FE	FE
	MEM	Coeff.	Coeff.	Coeff.	Coeff.	Coeff.
	(p>|z|)	(p>|z|)	(p>|t|)	(p>|t|)	(p>|z|)	(p>|z|)
PI			-.1137	-.1956	-1.929	-.3078
			(.002)***	(.004)***	(.497)	(.330)
ReT*PI			.0701	.0652	1.207	-.0411
			(.046)**	(.043)**	(.203)	(.584)
ReT	. 0288	. 0338	.0005	-.0004	.0956	.0341
	(.021)**	(.043)**	(.970)	(.974)	(.458)	(.115)
Type B	-.0223	.0180	-.0062	.0108	.0035	-.0113
	(.061)*	(.312)	(.543)	(.552)	(.945)	(.447)
Type 2	-.0139	-.0211	. 0090	-.0029	.0245	.0021
	(.374)	(.346)	(.619)	(.064)*	(.696)	(.906)
HShare	-.0004	-.0113	-.0034	-.0033	-.0018	-.0034
	(.054)*	(.254)	(.006)***	(.073)*	(.627)	(.035)
Age	. 0013	.0033				
	(.079)*	(.498)				
Ln(MKSZ)	. 01713	.0026				
	(.000)***	(.740)				
Constant	-3.202	.1043	1.011	1.259		
	(.000)***	(.362)	(.000)***	(.000)**		
Nr. Obs	1543	1543	1543	1543	1522	1522
Nr. Groups	347	346	346	346	326	326

Notes: The probit model is a population averaged model and the reported effects refer to marginal effects evaluated at the mean of the regressors (MEM).

Figures:

Fig. 1: Bidding if cost distributions are sufficiently close or too far apart

$$\overline{c1} = \underline{c2}$$

$$0 = \underline{c1}$$

$$\overline{c2}$$

$$\underline{b} = \frac{\underline{c1} * \underline{c2} - \left(\frac{\overline{c1} + \overline{c2}}{2}\right)^2}{(\underline{c1} - \overline{c1}) + (\underline{c2} - \overline{c2})} \qquad \overline{b} = \frac{\overline{c1} + \overline{c2}}{2}$$

$$0 = \underline{c1}$$

$$\overline{c1} \neq \underline{c2}$$
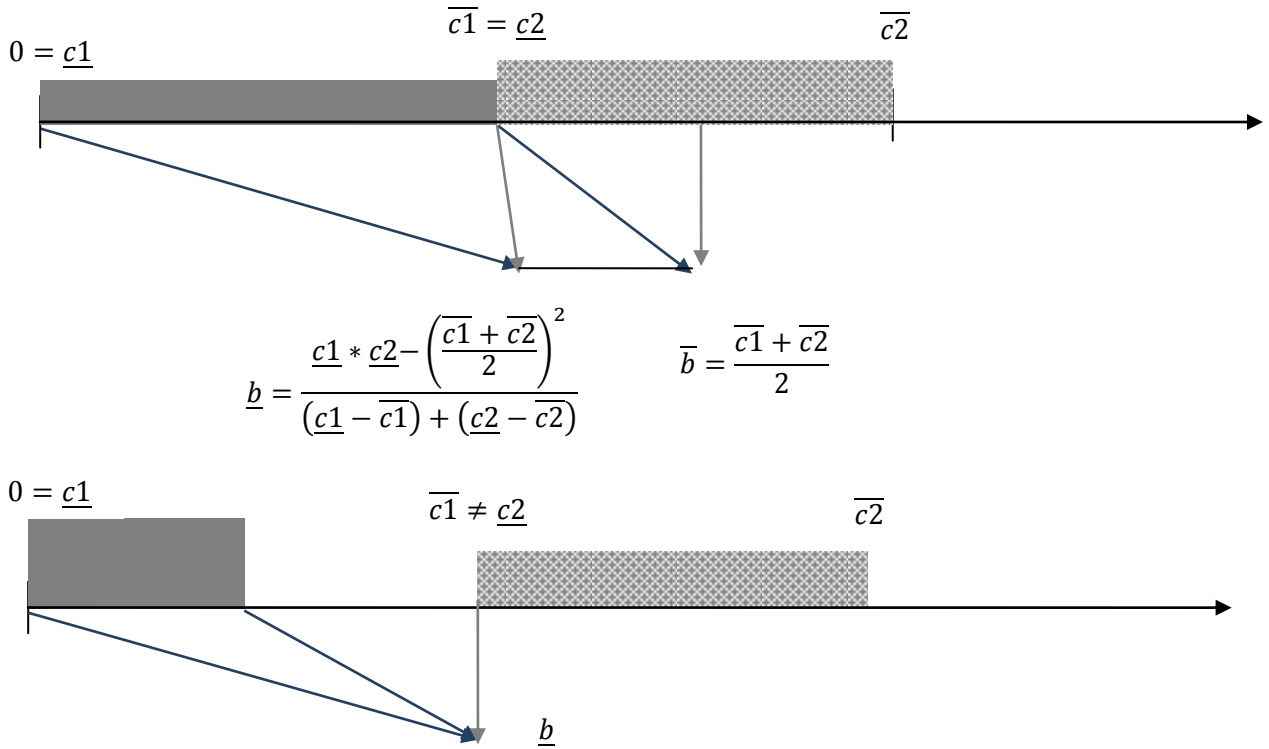
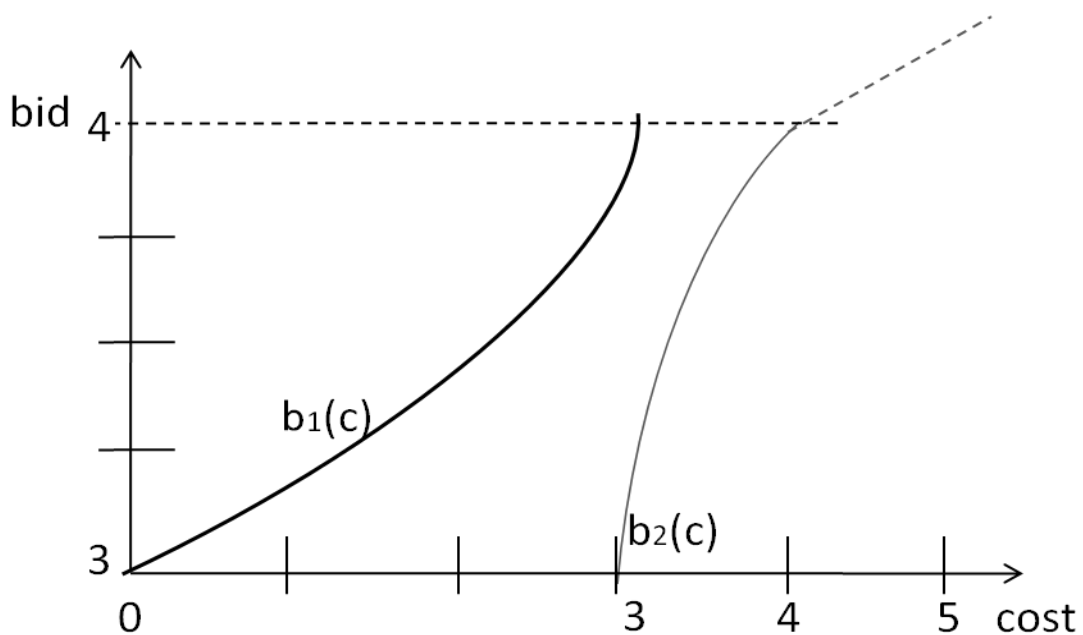$$\overline{c2}$$

$$\underline{b}$$

Fig. 2: Pure strategy equilibrium bidding strategies when originator's costs are uniformly distributed over [0; 3] and parallel importer's costs are distributed over [3; 5]

17

APPENDIX:

A1: DERIVING THE EQUILIBRIUM BID FUNCTIONS IF COMPETITORS' COSTS ARE UNIFORMLY DISTRIBUTED OVER DIFFERENT SUPPORTS.

The equilibrium bid functions can be identified by solving the first-order conditions of the profit maximisation problems, subject to the condition that the boundaries of the bidding functions must be the same for all bidders $[\underline{b} - \overline{b}]$. The profit function of the parallel importer can be characterised as follows:

$$\pi_2 = \max_b \ (b - c_2) \, Prob(2 \ wins|b)$$

where $(b - c_2)$ is the profit of the parallel importer if he wins and $Prob(2 \ wins|b)$ is the probability that he wins given his bid b. Denote by $b_i(c)$ the bid function, which is the equilibrium solution to the joint maximisation problem, and the inverse of the bid functions by $c_i(b)$ with support $[\underline{b}_i - \overline{b}_i]$. $G_i(b)$ denotes the distribution function of equilibrium bids, thus $1 - G_1(b)$ is the probability that the originator will bid more than b and the parallel importer wins the contract. Hence

$$\pi_2 = \max_b \ (b - c_2) \, (1 - G_1(b)),$$

With $(1 - G_1(b)) = \left(\frac{c_1(b) - \overline{c_1}}{\underline{c_1} - \overline{c_1}} \right)$ the parallel importer's profit function can be written as:

$$\pi_2 = \max_b \ (b - c_2) \left(\frac{c_1(b) - \overline{c_1}}{\underline{c_1} - \overline{c_1}} \right),$$

Similarly, if there is one potential parallel importer the originator's profit function can be written as:

$$\pi_1 = \max_b \ (b - c_1) \left(\frac{c_2(b) - \overline{c_2}}{\underline{c_2} - \overline{c_2}} \right),$$

In addition, the inverse bid functions must satisfy the boundary conditions such that no bidder has an incentive to deviate from his bid in equilibrium.

$B1$: $c_2(\overline{b}) = \min\{\overline{c_2}, \overline{b}\} = \overline{b}$; thus, if the parallel importer has higher costs than $\overline{b}$, his probability of winning is zero.

$B2$: $c_1(\overline{b}) = \min\{\overline{c_1}, \overline{b}\} = \overline{c_1}$

If both bidders draw their lowest possible costs, they would bid at least $\underline{b}$, thus

$B3$: $c_2(\underline{b}) = \underline{c_2}$ and $c_1(\underline{b}) = \underline{c_1}$[9]

In absence of a binding maximum below $\overline{c_2}$ the upper bound for the bid function $\overline{b}$ can be derived from the originator's maximization problem and the boundary conditions.

---

[9] See Kaplan and Zamir (2010) for proof of the boundary conditions in the analogue problem for a selling auction.

The parallel importer bids weakly above his cost $c_2(b) \geq b$, while the originator with costs $c_1(\overline{b})$ must not benefit from deviating from bidding $\overline{b}$. Hence from the parallel importer's profit function and the boundary condition $B1$: $c_2(\overline{b}) = \overline{b}$ follows,

$$(\overline{b} - \overline{c}_2)(\overline{b} - c_1(\overline{b})) \geq (c_2(b) - \overline{c}_2)(b - c_1(\overline{b})) \geq (b - \overline{c}_2)(b - c_1(\overline{b}))$$

Then the b for which $(\overline{b} - \overline{c}_2)(\overline{b} - c_1(\overline{b}))$ achieves its maximum is at $\overline{b} = \frac{\overline{c}_2 + c_1(\overline{b})}{2}$, and from substituting $c_1(\overline{b}) = \overline{c}_1$ follows:

$$\overline{b} = \frac{\overline{c}_2 + \overline{c}_1}{2} \qquad (1)$$

from (1) also follows that $\overline{c}_1 = 2\overline{b} - \overline{c}_2$, thus if $\overline{b} = \underline{c}_2$ then $\overline{b} = \underline{b}$ thus for all $\overline{c}_1 \leq 2\underline{c}_2 - \overline{c}_2$ the originator will always have an incentive to underbid the parallel importer. Differentiating the profit functions of the parallel importer and the originator with respect to b yields:

$$\frac{\partial \pi_2}{\partial b} = (b - c_2(b))c_1'(b) + c_1(b) - \overline{c}_1 = 0 \qquad (2)$$

$$\frac{\partial \pi_1}{\partial b} = (b - c_1(b))c_2'(b) + c_2(b) - \overline{c}_2 = 0 \qquad (2)$$

Adding the two FOC provides:

$$c_2'(b)b + c_2(b) + c_1'(b)b + c_1(b) - \overline{c}_2 - \overline{c}_1 = c_1'(b)c_2(b) + c_2'(b)c_1(b)$$

Then, rearranging creates the following:

$$[(c_2(b) + c_1(b))b]' - (\overline{c}_2 + \overline{c}_1) = c_1'(b)c_2(b) + c_2'(b)c_1(b)$$

Thus, by integrating, we have:

$$b(c_2(b) + c_1(b)) - (\overline{c}_2 + \overline{c}_1)b + k = c_2(b) * c_1(b) \qquad (3)$$

where k is the constant of integration.

The lower bound of the bid function can be found by substituting boundary condition $B1$ into (3).

$$\overline{b}(c_2(\overline{b}) + \overline{b}) - (\overline{c}_2 + \overline{c}_1)\overline{b} + k = c_2(\overline{b})\overline{b}$$

which simplifies to:

$$k = (\overline{c}_2 + \overline{c}_1)\overline{b} - \overline{b}^2$$

Substituting (1) into the above equation, we have (4)

$$k = \left(\frac{\overline{c}_1 + \overline{c}_2}{2}\right)^2 \qquad (4)$$

Using $B3$ and (2) we have,

$$\underline{b}(\underline{c_2} + \underline{c_1}) - (\overline{c}_2 + \overline{c}_1)\underline{b} + k = \underline{c_2} * \underline{c_1}$$

which can be rearranged to (5).

$$\underline{b} = \frac{\underline{c_1} * \underline{c_2} - k}{(\underline{c_1} - \overline{c}_1) + (\underline{c_2} - \overline{c}_2)} \qquad (5)$$

Equation (2) can be used to find $c_2(b)$ as a function of $c_1(b)$ as follows:

$$bc_1(b) - (\overline{c}_2 + \overline{c}_1)b + k = c_2(b) * c_1(b) - bc_2(b)$$

$$\frac{bc_1(b) - (\overline{c}_2 + \overline{c}_1)b + k}{c_1(b) - b} = c_2(b) \qquad (6)$$

We can rewrite equation (2) as:

$$\left(b - \frac{bc_1(b) - (\overline{c}_2 + \overline{c}_1)b + k}{c_1(b) - b}\right) c_1'(b) = -c_1(b) + \overline{c}_1$$

Or

$$(b^2 + (\overline{c}_2 + \overline{c}_1)b + k)c_1'(b) = (-c_1(b) + \overline{c}_1) * (c_1(b) - b) \quad (7)$$

Equation (4) and (7) together with the boundary condition $B3: c_2(\underline{b}) = \underline{c_2}$ are used to find the solution for $c_2(b)$, which then can be used together with equation (4) and (6) to find $c_1(b)$. Thus the inverse equilibrium bid function for the parallel importer is:

$$c_2(b) = \overline{c}_2 - \frac{(\overline{c}_1 - \overline{c}_2)^2}{(\overline{c}_1 + \overline{c}_2 - 2b)k_1 e^{\frac{\overline{c}_1 - \overline{c}_2}{\overline{c}_1 + \overline{c}_2 - 2b}} + 4(\overline{c}_1 - b)}$$

$$k_1 = \frac{\frac{(\overline{c}_1 - \overline{c}_2)^2}{\underline{c_2} - \overline{c}_2} + 4(\underline{b} - \overline{c}_1)}{-2(\overline{b} - \underline{b})} e^{\frac{\overline{c}_1 - \overline{c}_2}{2(\overline{b} - \underline{b})}}$$

The originator's inverse bid function $c_1(b)$ can be obtained from $c_2(b)$ by interchanging the subscripts 1 and 2. Although the differential equation is derived from the first-order conditions, any solution to it also satisfies the second-order conditions and hence is an equilibrium bid function [15]. Parallel importers can thus participate in a first price sealed bid procurement auction if their ex-ante expected profits exceed any entry and bid preparation costs [18], which can be written as:

$$E[\pi_2] = (b - c_2)\left(\frac{c_1(b) - \overline{c}_1}{\underline{c_1} - \overline{c}_1}\right)\left(\frac{c_2 - \overline{b}}{\underline{c_2} - \overline{c}_2}\right) - k \geq 0$$

Where $\left(\frac{c_2 - \overline{b}}{\underline{c_2} - \overline{c}_2}\right)$ is the probability that c_2 is smaller than $\overline{b}$.